

Response to Comments Received on the January 5, 1999 Proposed Rule (64 FR 688) to Lower the EPCRA Section 313 Reporting Thresholds for Persistent, Bioaccumulative Toxic (PBT) Chemicals and to Add Certain PBT Chemicals to the EPCRA Section 313 List of Toxic Chemicals and Response to Comments Received on the May 7, 1997 Proposed Rule (62 FR 24887) to Add a Category of Dioxin and Dioxin-like Compounds to the EPCRA Section 313 List of Toxic Chemicals. Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Washington, DC (1999).

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U.S. Environmental Protection Agency
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Response to Comments Received on the January 5, 1999 Proposed Rule (64 FR 688) to Lower the EPCRA Section 313 Reporting Thresholds for Persistent, Bioaccumulative Toxic (PBT) Chemicals and to Add Certain PBT Chemicals to the EPCRA Section 313 List of Toxic Chemicals

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Introduction

Part 1 contains and responses to the summaries of the comments submitted to the Agency on the proposed rule (64 FR 688, January 5, 1999) to add certain chemicals to the list of EPCRA section 313 toxic chemicals and to lower reporting thresholds for certain chemicals that meet the EPCRA section 313 criteria for persistence and bioaccumulation. The full copies of the comments are found in the public docket established for this rulemaking (Number OPPTS-400132). In addition to this document, readers are advised to refer to the preambles of both the proposed and final rules as well as other support material in the docket.

The Agency reviewed comments concerning the listing of specific chemicals on the EPCRA section 313 list of toxic chemicals, the EPCRA section 313 persistence and bioaccumulative criteria, the lowering of the reporting thresholds for certain persistent bioaccumulative toxic (PBT) chemicals, and general issues pertaining to groups of chemicals discussed in the proposed rule. EPA has grouped together similar comments and responses into categories. In addition to comments specific to the proposed rule, sections of this document address comments on general and/or policy issues. A section addressing comments on economic issues raised on the proposal is also included.

Many of the issues and comments received on this proposed rule were similar to or the same as those received on EPA's proposal to add certain dioxin and dioxin-like compounds to the EPCRA section 313 list (62 FR 24887, May 7, 1997) (Docket Number OPPTS-400111). The January 5, 1999 proposed rule also modified certain aspects of the May 7, 1997 proposed rule, most notably the Agency withdrew its proposal to move 11 co-planar PCBs from their current listing to the dioxin and dioxin-like compounds category. Part 2 of this document contains comments and responses to the May 7, 1997 proposed rule. Therefore, in cases where an issue has already been addressed in Part 2, the reader is referred back to Part 2 for the response and/or additional information. Thus, any reference to Part 2 means comment responses for the May 7, 1997 proposed rule.

EPA received over 35,000 comments on the January 5, 1999 proposed rule. At the end of this part, there is a list of the people, organizations, companies, etc., that commented on the January 5, 1999 and the May 7, 1997 proposed rules. The commenters are identified by name and comment number (i.e, C-#####). Throughout this document the commenters are usually identified by comment number rather than by name.

1.0 COMMENTS RELATED TO GENERAL POLICY ISSUES

1.a. Whether reporting will provide meaningful data to the public

Commenter Number: Duquesne Light (C1168); EPRI (C-1419); Edison Electric Institute; Class of '85 Regulatory Group (C1425); Indianapolis Power and Light Company (C1861)

Comment: Several commenters contend that lowering the reporting thresholds for PBT chemicals will not provide meaningful information for the public because the reporting thresholds were not determined using a risk-based analysis. They also contend that this information will not be meaningful because EPA has not demonstrated that PBT chemicals pose a significant risk to human health or the environment.

Response: EPA believes that the commenters' concept of what constitutes meaningful TRI data is inconsistent with Congress' concept. Congress stated in EPCRA section 313(h) that:

The release forms required under this section are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available... to inform persons about releases of toxic chemicals to the environment; to assist government agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes.

Neither EPCRA section 313(h) nor its legislative history directs EPA to limit the collection of information on releases to those releases that, from the federal government perspective, pose significant local human and environmental exposure and human health and environmental risks. It is important to note, however, that all chemicals in this rule meet the listing criteria as set forth by Congress in EPCRA section 313 (d)(2).

Federal and local perspectives on what may be an acceptable risk are likely to be very different. In passing EPCRA, Congress determined that it is for the public to take the information reported on the use and releases and other waste management of toxic chemicals, and to determine whether these releases result in potential risks that the community determines warrant further action given other factors, such as economic and environmental conditions, or particularly vulnerable human or ecological populations. Congress did not intend the federal government to assess all potential local factors prior to determining whether certain types of information should be made public, or prior to determining whether a different threshold should be established for one or more toxic chemicals.

Further, EPCRA section 313 does not require the collection of quantitative risk data nor does the statute require that risk data be disseminated to the public. Rather TRI data provide communities with information on releases and other waste management. TRI data cannot solely, in themselves, provide information on quantitative risks to individual communities. A determination of the potential risk that a chemical release may pose is dependent upon a number of things, including the toxicity of the chemical, the physical-chemical properties of the chemical, the specific media to which the chemical is released, and site-specific information that will determine the estimated exposures. The important factors, therefore, in conducting a risk analysis may vary significantly between localities. While TRI data are not in themselves measures of risk, they are an important input that local communities can use along with the factors described above to determine potential risks to themselves, their children, their communities and their environment that may result from releases of toxic chemicals.

Finally, EPA believes that the commenters' wish to limit the focus of the TRI is not only inconsistent with the intent of Congress but also with how the TRI data have been used. TRI data have been used in many ways by a variety of users, including government, university researchers, public interest groups, industry, and the public. In addition to its use as inputs to exposure and risk assessments, the TRI data have been used as factors in investment determinations, in housing decisions, in assessing how facilities/states/industries are managing waste, and as a screening tool in social, economic, and scientific analyses. Given the variety of uses of the TRI data, EPA disagrees that the additional release and waste management information on PBTs will not be useful because they are not ultimately derived from risk assessments.

Commenter Number: Minnesota Office of Environmental Assistance (MOEA) (C802) General Electric (C1421) SCANA Corporation (SCE&G) (C1418); Class of '85 Regulatory Group (C1425); Utility Air Group (C1427); Chrome Coalition (C1431); SSINA (C1431a); Association of International Automobile Manufacturers (AIAM) (C-1434); Southeast Environmental Task Force (C1581); Indianapolis Power and Light Company (C1861); Cement Kiln Recycling Coalition (C1866); American Petroleum

Comment: Some commenters contend that rather than provide the public with useful information, the data EPA will collect on PBT chemicals at the lower thresholds have the potential to mislead the public and divert attention from actual risks from larger releases. They contend that by setting the thresholds relatively low the Agency will lead the general public to assume that PBT chemicals pose some level of danger and risk when, in fact, this is not the case. This will raise unfounded fear concerning these chemicals. Some commenters contend that these chemicals would be considered to present a higher risk than other EPCRA section 313 chemicals. Another commenter believes that the public is lacking the necessary information to determine if PBT chemicals are present in their communities at levels that pose a risk. They believe that by lowering the reporting thresholds EPA will capture significant amount of releases.

Response: The commenters do not provide information to support their contention that the PBT chemicals that are part of this rulemaking do not “pose some level of risk and danger.” While EPA believes that, as a part of this rulemaking, it need not and should not make a finding that the PBT chemicals pose a risk to human health and the environment, the Agency does note that a number of PBT chemicals in today’s rulemaking are the subject of international agreements to ban or severely restrict their use and release because their characteristics of persistence in the environment, accumulation in biological organisms and toxicity make them priority pollutants that present significant environmental risks to humans and ecosystems (see Refs. 1-4). EPA believes that some of the commenters underestimate the ability of the public to use and understand the TRI data. EPA does not believe that the data on PBT chemicals will mislead the public and divert their attention from actual risks. Rather, these data will provide them with a more complete picture of releases in their community. This will allow them to more accurately characterize their potential risk from exposure to these toxic chemicals. For example, if a community were to assess its potential exposure and risk from mercury and mercury compounds it would underestimate the potential risk because releases of mercury and mercury compounds from coal and oil burning electric utilities and industrial boilers are currently not reported to TRI because these facilities do not exceed the current section 313 thresholds for mercury and mercury compounds. Therefore, communities have insufficient information about the potential risks of PBTs such as mercury and mercury compounds because they currently have incomplete information. As noted by one commenter involved in the Chicago Cumulative Risk Initiative, which will produce a system for evaluating the cumulative risk of toxic emissions from all permitted sources in their area, if some of the PBT chemical releases are omitted from TRI, the cumulative risk that is found will not accurately represent the actual risk to the impacted community.

Further, considering only larger releases will not provide a community with an accurate picture of its potential risks. For example, some communities may have a number of facilities that release relatively small quantities. Considering the releases from all these facilities may indicate that there is a significant risk to human health and/or the environment. Looking at the releases individually and in isolation may mislead the community because the assessment may indicate that none of these facilities individually presents a risk, while the community is exposed to releases from all of the facilities, and considered in aggregate they do pose a risk to the community. As a another example, consider a community with a number of facilities that release a PBT chemical. One large facility releases relatively large quantities of the PBT chemical and a few smaller facilities release relatively small quantities of the PBT chemical. By considering only releases from the larger facility the community may determine that there is a potential risk but may also underestimate the magnitude of the potential risk by not considering the releases from the smaller facilities. The additional information that this rule will make available to the community may result in different and more sound risk management decisions by the community.

Finally, EPA agrees that PBT chemicals do have the potential to provide a greater risk than other toxic chemicals, **all other things being equal**. The characteristics of persistence in the environment, accumulation in biological organisms, in addition to their toxicity make them priority pollutants that may present significant environmental risks to humans and ecosystems.

References

1. United Nations Economic Commission for Europe, Convention on Long-Range Transboundary Air Pollution (UNECE-LRTAP). 1998. Draft composite negotiating text for a protocol on persistent organic pollutants. UNECE, EB.AIR/1998/2, 31 March 1998.
2. North American Free Trade Agreement-Commission for Environmental Cooperation (NAFTA-CEC). 1997. Process for identifying candidate substance for regional action under the sound management of chemicals initiative. Report to the North American working group on the sound management of chemicals by the task force on criteria. CEC, Montreal, Quebec, Canada. Draft, July 1997.

3. The Great Lakes Binational Toxics Strategy: Canada-United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes basin. 1997. Level I and Level II targeted persistent toxic substances. Great Lakes National Program Office (GLNPO), Chicago, IL. 7 April 1997.

4. International Joint Commission (IJC). 1993. A strategy for the virtual elimination of persistent toxic substances. Vol. 1, report of the Virtual Elimination Task Force to the IJC. Windsor, Ontario, Canada, 72 pp.

Commenter Number: General Electric (C1421); Chrome Coalition (C1431); Specialty Steel Industry of North America (C1431a); Chlorobenzene Producers Association (C1433); National Petrochemical & Refiners Association (NPRA) C1836; American Petroleum Institute (1865)

Comment: Reporting at lower thresholds will require estimation and will likely be overly conservative as companies attempt to determine whether low levels of PBTs are present in raw materials, even as impurities, and whether they are released in any amount. Measurement of such low levels is impractical and likely to result in the generation of inaccurate information, which will diminish the reliability of the TRI data base. Some commenters contend that companies will have little choice but to report on chemicals that are present at best, in *de minimis* quantities, or not present at all. Industry has no reasonable, reliable means to determine the presence of certain PBT chemicals at such small quantities. The sole recourse for many companies that manufacture and/or otherwise use chemicals that may contain a listed PBT substance is to report whether or not the company has evidence that it uses or manufactures the particular chemical above threshold amounts.

Response: EPA disagrees that facilities will be required to conduct additional measurements to determine the concentrations or quantities of PBT chemicals manufactured, processed or otherwise used, or released or otherwise managed as waste. Compliance with EPCRA section 313 does not require that a facility conduct additional monitoring or sampling EPCRA section 313(g)(2) states:

In order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released in the environment beyond the monitoring and measurement required under other provisions of law or regulation.

Therefore, this rule does not require that facilities conduct new measurements to determine the concentrations of PBT chemicals.

Further, as to the commenters' contention that they will be required to report on quantities that are "present, at best, in *de minimis* quantities," it is not clear whether the commenter really means "*de minimis*" quantities or "*de minimis*" concentrations. The latter relates to the EPCRA section 313 regulatory *de minimis* exemption. However, this exemption is not an across the board exemption for small quantities or small concentrations. In certain circumstances, under the *de minimis* exemption, facilities may exempt small concentrations of toxic chemicals. In other circumstances, however, the *de minimis* exemption cannot be taken. If the exemption is unavailable, the facility must determine how much they manufacture, process, otherwise use, release, and otherwise manage as waste of even small concentrations of section 313 listed toxic chemicals. The guidance that applies to the reporting of low concentrations of toxic chemicals under the current section 313 program that are not subject to the *de minimis* exemption will also apply to the reporting of PBT chemicals. Specifically, both the proposed and final rules implementing the EPCRA section 313 reporting requirements (52 FR 2115-2116, 53 FR 4510-4511) and the annual Toxic Chemical Release Inventory Reporting Forms and Instructions (for example see EPA 745-K-96-001) provide guidance for the reporting of the components of mixtures, given the following scenarios: (1) The concentration range is known, (2) only the upper bound concentration is known, (3) only the lowerbound concentration is known, and (4) when no concentration information is known. Although, for EPCRA section 313 reporting purposes, a waste is not considered a mixture, the guidance for making threshold determinations on the components of mixtures can be applied to wastes.

EPA disagrees that this rulemaking need result in facilities that manufacture and/or otherwise use chemicals that may possibly contain listed PBT chemicals, but at a concentration impossible to determine, to file a report regardless of whether a facility has evidence that it has exceeded the applicable thresholds. As EPA articulated in both the proposed and final rules

implementing the EPCRA section 313 reporting requirements (52 FR 2115-2116, 53 FR 4510-4511) and the annual Toxic Chemical Release Inventory Reporting Forms and Instructions (see for example EPA 745-K-96-001), if a facility has no information on the concentration of a toxic chemical in a mixture or a waste, or has no information that the facility can use to calculate the concentration, then the facility is not required to report for the chemical. Nor should a facility report information that it knows is incorrect. Incorrect information will mislead the public. Submitting false information would be in conflict with Part I, Section 3 of the Form R, in which the owner, operator, or management official must certify that the values in the Form R are accurate based on reasonable estimates. Reporting incorrect information, in addition to being contrary to the requirements of EPCRA section 313, would also violate other provisions of federal law (see, e.g., 18 U.S.C. 1001).

Finally, EPA disagrees that the information on chemicals present in small concentrations and/or small quantities is inherently more difficult to determine and more inaccurate than information on larger quantities. Facilities may have more precise data on chemicals that are present in low concentrations in raw materials than it has chemicals that are present in raw materials at higher concentrations. For example, an MSDS for "Xylenes" lists the following constituents: m-Xylene - 40-65%, o-Xylene - 15-20%, p-Xylene - 0-20%, Ethyl benzene - 15-25%. The US Geological Survey Coal Quality Data Base (Ref. 1) lists mercury as being present in Missouri bituminous coal at a concentration of 1.5 parts per million. Clearly even though mercury is present in bituminous coal at a much lower concentration than m-Xylene in the xylene mixture, the information on the mercury is more precise than the information on the m-xylene, and not more difficult to determine.

Reference

1. U.S. Geological Survey. U.S. Coal Quality Database. At <http://energy.er.usgs.gov/coalqual.htm>. Downloaded September 17, 1999.

Commenter Number: Association of International Automobile Manufacturers (AIAM) (C-1434)

Comment: One commenter contends that a problem with lowering the thresholds for PBT chemicals is that the reports by each facility for these chemicals will likely remain unchanged from year to year. Thus, it will not be possible to identify improvements or failings at any particular facility or identify the facilities with the worst problems.

Response: EPA disagrees that it is likely that releases will remain unchanged from year to year. An analysis of TRI data conducted by the National Environmental Trust (Ref. 1) shows that of the 62,419 facility/chemical combinations reported for both 1996 and 1997, 24,889 (39%) showed a change in releases of 20% or more between 1996 and 1997. EPA has no information nor has the commenter provided any information that would lead the Agency to conclude that there would be significantly fewer changes for the PBT chemicals.

Reference

1. National Environmental Trust. Comments on the Proposed Rule to Lower TRI Reporting Thresholds for Lead and Lead Compounds. (September 9, 1999).

Commenter Number: American Petroleum Institute (C1865)

Comment: One commenter contends that the lower thresholds in combination with elimination of the *de minimis* exemption and the other proposed changes, would result in a requirement to report releases below non-detect levels in some cases. Thus, some of the release data would be unreliable. In addition, the analytical result may be a false positive, in which case the analyte chemical is reported but was never really present.

Response: Facilities should use their best readily available information. If a facility has a reasonable basis to conclude that a toxic chemical is present in a mixture or in a waste, but at a concentration level that is below the detection limit, then the facility should use the detection limit as the upper level of the range. The fact that the concentration is below the detect level, however, would not necessarily exempt the facility from reporting. If the facility has information (e.g, process information) that indicates that the toxic chemical would not be present in the mixture or the waste then the facility would not report for the chemical. One false positive for the year, that is inconsistent with process information should not be a basis for reporting on a chemical that is not present. This approach is consistent with EPA's current guidance on how to interpret the non-detection of listed toxic

chemicals. See Q&As 472 & 497, 1998 EPCRA Section 313 Questions and Answers (EPA 745-B-98-004).

Further, although the commenter implies otherwise, the *de minimis* exemption is not a small concentration or small quantity exemption. It only applies in certain circumstances. There are currently chemicals present in low concentrations in process and waste streams that must be tracked and reported. For example, because the *de minimis* exemption does not apply to toxic chemicals coincidentally manufactured, chemicals that are coincidentally manufactured in concentrations below the *de minimis* levels must be accounted for and reported.

1.b. Whether the program should be risk-based

Commenter Number: C-1168, C-1419, C-1421, C-1423, C-1425, C-1428, C-1440, C-1448, C-1452, C-1812, C-1458, C-1820, C-1844, C-1851, C-1860, C-1861

Comment: One of the most significant issues raised by commenters relates to the Agency's lack of consideration of quantitative risk in modifying the section 313(f) reporting thresholds. Specifically, a number of commenters believe that EPA should use quantitative risk as a criterion in determining whether to lower the reporting thresholds and in choosing a particular reporting threshold for each PBT chemical. The commenters contend that EPA should conduct risk assessments and make a formal determination that at a particular threshold releases of the PBT chemical pose a risk before lowering the reporting threshold. While the majority of commenters who commented on the issue believe that EPA should make a risk determination before modifying the threshold, the rationale for their conclusions varied. Some commenters state that a risk determination is required by EPCRA because the intent of EPCRA is to provide information to the public of potential risks posed by the presence of toxic chemicals released to the environment in their communities. Some commenters state that in addition to addressing the substantial majority test, EPCRA section 313(f)(2) requires EPA to use the degree of risk that releases will pose to communities as a determinant in choosing new thresholds. Other commenters state that consideration of risk is a required component of any action under EPCRA section 313. In support of this position, one of the commenters cites two D.C. Circuit Court decisions. Other commenters contended that it would be good public policy to choose a threshold based on risks. Some commenters contend that EPA should lower the reporting thresholds only for those chemicals that present the highest risks to the public. One commenter, however, believes that the Agency should not consider the degree of risk in making a determination to lower the reporting thresholds for PBTs because the consideration of risk in past actions taken by EPA under other environmental statutes have not resulted in a decrease of human health or environmental risks due to PBTs. The commenter states that the increasing number of fish advisories and the lingering and, in some cases, increasing levels of PBTs in the environment and in fish, wildlife, and human tissue demonstrates the magnitude of the failure of the "risk management strategy."

Response: EPA disagrees with the commenters' assertion that evidence of risk is required prior to lowering the threshold for any EPCRA section 313 chemical. Section 313(f)(2) addresses revisions to the reporting thresholds. It does not require EPA to establish prior to the lowering of reporting thresholds that releases at a particular threshold will result in specific quantitative risks. That section expressly provides that the Administrator may establish a threshold amount for a toxic chemical different from the 25,000 pound threshold for manufacturing and processing activities and the 10,000 pound threshold for otherwise use activities. The only requirement for revising the reporting threshold for a toxic chemical is that the revised threshold must obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to reporting. By lowering the threshold for PBT chemicals, EPA meets this requirement because under the lower threshold, a substantial majority of releases currently being reported will continue to be reported.

EPA believes that the commenters attribute a purpose to EPCRA that is inconsistent with that clearly intended by Congress. Specifically, Congress stated in EPCRA section 313(h) that

The release forms required under this section are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available,...to inform persons about releases of toxic chemicals to the environment; to assist government agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes. 42 U.S.C. section 11023(h).

Neither EPCRA section 313(h) nor its legislative history directs EPA to limit the collection of information on releases to those releases that from the federal government perspective pose significant local human and environmental exposure and human

health and environmental risks.

Federal and local perspectives on what may be an acceptable risk are likely to be very different. The roles of local government and the federal government differ significantly in terms of ensuring environmental quality. In passing EPCRA, Congress determined that it is for the public to take the information reported on the use and releases and other waste management of toxic chemicals, and to determine whether these releases result in potential risks that the community determines warrant further action given other factors, such as economic and environmental conditions, or particularly vulnerable human or ecological populations. Congress did not intend the federal government to consider these local factors prior to determining whether certain information should be made public, or prior to determining whether a different threshold should be established for one or more toxic chemicals.

The intent of EPCRA section 313 is to move the determination of what risks are acceptable from EPA to the communities in which the releases occur. This basic local empowerment is a cornerstone of the right-to-know program. EPCRA section 313 establishes an information collection and dissemination program. The burden it imposes is significantly less than the burden imposed by a statute which controls the manufacture, use, and/or disposal of a chemical. EPCRA section 313 requires that a facility use the readily available data to prepare each chemical-specific TRI report. The statute does not require that the facility conduct monitoring or emissions measurements to determine these quantities. A facility must only estimate, to the best of its ability, the quantitative information it reports. This is in contrast to other environmental statutes that may require a facility to monitor releases, change its manufacturing process, install specific waste treatment technology, or dispose of wastes in a certain manner. As such, the Agency believes that as a matter of policy the standard that must be met to require information submission under EPCRA section 313 is less than that to regulate a chemical under a statute such as the Clean Air Act.

Further, contrary to assertions by some commenters, EPCRA section 313 does not require the collection of quantitative risk data nor does the statute require that risk data be disseminated to the public. Rather TRI data provide communities with information on releases and other waste management. TRI data cannot solely, in themselves, provide information on quantitative risks to individual communities. A determination of the potential risk that a chemical release may pose is dependent upon a number of things, including the toxicity of the chemical, the physical-chemical properties of the chemical, the specific media to which the chemical is released, and site specific information that will determine the estimated exposures. While TRI data are not in themselves measures of risk, they are an important input that local communities can use along with the factors described above to determine potential risks to themselves, their children, their communities and their environment that may result from releases of toxic chemicals.

EPA's decision to lower the reporting threshold for PBTs is rationally related to the EPCRA section 313 goals of informing communities, assisting research and data gathering, and aiding the development of regulations and guidelines. Because PBT chemicals persist in the environment for a significant period of time and bioaccumulate in animal tissues, PBTs have the potential to be pervasive in the environment, in the food chain, and often in humans. In short, for PBT chemicals, releases and other waste management activities for relatively small amounts of PBTs may be of concern. Accordingly, pursuant to the intended purposes of EPCRA, even relatively small releases and other waste management activities for PBTs need to be reported in order to inform communities, assist those engaged in research and data gathering, and to aid the development of regulations and guidelines. Lowered reporting thresholds for PBTs are needed to obtain reporting on these relatively small releases and other waste management activities for PBTs. Consequently, EPA believes that including consideration of the quantitative risk in establishing the thresholds would be poor public policy that would be inconsistent with the overall principles of EPCRA.

Finally, the reference by one of the commenters to two D.C. Circuit Court decisions is misplaced. In support of its position that EPA must undertake a risk assessment of any toxic chemical it is considering for lower reporting thresholds, the commenter cites American Petroleum Institute v. Costle, 665 F.2d 1176, 1187 (D.C. Cir, 1981), *cert. denied*, 455 U.S. 1034 (1982), and Milwaukee Metropolitan Sewerage District v. EPA, 40 F.3d 392 (D.C. Cir. 1994). Neither case cited by the commenter addresses EPCRA. In Milwaukee Metropolitan Sewerage the court reviewed standards adopted by EPA in a Clean Water Act regulation. In American Petroleum Institute the court reviewed the primary and secondary national ambient air quality standards for ozone promulgated by EPA under the Clean Air Act. Both the Clean Air Act and the Clean Water Act have no bearing on EPCRA section 313. Unlike these cases cited by the commenter, consideration of risk is not a requirement of section 313(f)(2) for modifying the reporting thresholds for EPCRA section 313 listed chemicals, and, in fact, the consideration of risk is generally not required for any rulemaking under section 313. Troy Corporation v. EPA, 120 F.3d 277 (D.C. Cir. 1997).

Comment: Some commenters contend that EPCRA requires that EPA consider the risks that a chemical may pose when making determinations to add a chemical to the EPCRA section 313 list of toxic chemicals. In support of this position, one of the commenter cites two D.C. Circuit Court decisions.

Response: As discussed in detail in the final rule adding 286 chemicals to EPCRA section 313 (59 FR 61432, November 30, 1994) EPA disagrees with commenters that the Agency must include a risk assessment component to EPCRA section 313 determinations. While the Agency believes that there are limited circumstances where it may be appropriate to consider risk in making listing determinations, e.g., acute human health effects, EPA does not believe that the intent of EPCRA, the EPCRA section 313 toxicity criteria, or the legislative history support the contention that risk assessment is a required component of all EPCRA section 313 listing determinations.

The EPCRA section 313 toxicity criteria require that exposure and risk factors be considered only when determining if the toxic chemical should be listed on EPCRA section 313 based on its acute human health effects. The statute mandates that EPA consider whether "a chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries." EPA has, and will continue to look at exposures reasonably likely to exist beyond facility site boundaries when making a listing determination pursuant to EPCRA section 313(d)(2)(A). However, EPA notes that none of the toxic chemicals added in today's action were added pursuant to paragraph A of that section.

The statute is silent on the issue of exposure considerations for the section 313(d)(2)(B) and (C) criteria. The language of section 313 does not prohibit EPA from considering exposure factors when making a finding under either section 313(d)(2)(B) or section 313(d)(2)(C). However, the language of sections 313(d)(2)(B) and (C) does not require the type of exposure assessment and/or risk assessment argued by the commenters. EPA believes that it has the discretion under both section 313(d)(2)(B) and section 313(d)(2)(C) to consider, where appropriate, those exposure factors that may call into question the validity of listing of any specific chemical on EPCRA section 313.

EPA believes that its position regarding the limited use of risk in listing decisions is consistent with the purpose and legislative history of EPCRA section 313, as illustrated in the following passage from the Conference report:

The Administrator, in determining to list a chemical under any of the above criteria, may, but is not required to, conduct new studies or risk assessments or perform site-specific analyses to establish actual ambient concentrations or to document adverse effects at any particular location. (H. Rep. 99-962, 99th Cong., 2nd Sess., p. 295 (Oct. 3, 1986)).

This passage indicates that Congress did not intend to require EPA to conduct new studies, such as exposure studies, or to perform risk assessments. Therefore, Congress did not consider these activities to be mandatory components of all section 313 decisions. EPA believes that this statement combined with the plain language of the statutory criteria clearly indicate that Congress intended that the decision of whether and how to consider exposure under EPCRA section 313(d)(2)(B) and (C) should be left to the Agency's discretion. EPA has carefully considered when and how to use exposure to fully implement the right-to-know provisions of EPCRA. The Agency believes that exposure should be considered only in very limited circumstances when adding a chemical to EPCRA section 313(d)(2)(B) or (C). The Agency's interpretation of the section 313(d)(2) and (d)(3) criteria for modifying the section 313 list of toxic chemicals is discussed in the final rule adding 286 chemicals to EPCRA section 313 (59 FR 61440-2, November 30, 1994). The addition of chemicals pursuant to EPCRA section 313(d)(2)(B) and (C) in today's rulemaking is consistent with this interpretation.

The intent of EPCRA section 313 is to move the determination of which risks are acceptable from EPA to the communities in which the releases occur. This basic, local empowerment is a cornerstone of the right-to-know program. EPCRA section 313 establishes an information collection and dissemination program. It provides the public with information that can be used with other site-specific factors to determine if releases into their communities result in risks that the community determines warrant further action given other factors, such as economic and environmental conditions, or particularly vulnerable human or ecological populations. It also provides information to researchers and governments that may be used, for example, to assess regional, national and international concerns related to chemical releases.

In addition, the reference by one of the commenters to two D.C. Circuit Court decisions is misplaced. In support of its

position that EPA must undertake a risk assessment of any toxic chemical it is considering for lower reporting thresholds, the commenter cites American Petroleum Institute v. Costle, 665 F.2d 1176, 1187 (D.C. Cir, 1981), *cert. denied*, 455 U.S. 1034 (1982), and Milwaukee Metropolitan Sewerage District v. EPA, 40 F.3d 392 (D.C. Cir. 1994). Neither case cited by the commenter addresses EPCRA. In Milwaukee Metropolitan Sewerage the court reviewed standards adopted by EPA in a Clean Water Act regulation. In American Petroleum Institute the court reviewed the primary and secondary national ambient air quality standards for ozone promulgated by EPA under the Clean Air Act. Both the Clean Air Act and the Clean Water Act have no bearing on EPCRA section 313. Unlike these cases cited by the commenter, consideration of risk is not a requirement of section 313(f)(2) for modifying the reporting thresholds for EPCRA section 313 listed chemicals, and, in fact, the consideration of risk is generally not required for any rulemaking under section 313. Troy Corporation v. EPA, 120 F.3d 277 (D.C. Cir. 1997).

Commenter Number: C-1421, C-1428

Comment: In proposing to change TRI reporting thresholds, EPA has not addressed any of the factors it mentioned when it originally promulgated TRI regulations. In the February 16, 1988 final TRI rule, EPA stated:

EPA may consider a number of factors for threshold modification including exposure factors such as population density, the distance of population from covered facilities, and the types of releases. Threshold modifications could also take into account the relative potency of the chemical of class of chemicals and effects of concern. (53 FR 4508).

In this statement, EPA correctly mentions factors that relate to risk (i.e., exposure and relative toxicity). The current proposal to change TRI reporting thresholds fails to address these factors.

Response: As is clearly evident in the quote from the February 16, 1988 final rule, EPA stated that these were things that it “may consider” or that could be taken into account. These statements do not require that the possible factors mentioned above be a basis for any change in the reporting thresholds nor do they preclude the consideration of factors such as the persistence and/or bioaccumulation of toxic chemicals in modifying the reporting thresholds. This statement does not bind the Agency. It merely provided examples of things that the Agency may consider.

As explained in previous responses, EPA does not believe that it would be good public policy to consider factors related to quantitative risk with respect to establishing thresholds for PBTs. Given the degree of persistence and bioaccumulation that these toxic chemicals exhibit, EPA believes that the value of this information to local communities outweighs the policy consideration presented in favor of the consideration of risk factors in establishing alternate thresholds. Any other decision would be inconsistent with the legislative intent underlying EPCRA section 313.

Finally, EPA notes that this decision is consistent in the approach adopted in modifying the thresholds to establish a one million pound manufacture, process, or otherwise use threshold for facilities that have 500 pounds or less of production-related waste (59 FR 61488). Any decision to include risk considerations in establishing modified thresholds under section 313(f)(2) would compel the Agency to re-examine the thresholds established for facilities with less than 500 pounds of production-related waste.

Commenter Number: C-1423, C-1860, C-1865

Comment: Some commenters state that EPA’s rulemaking is not scientifically sound. These commenters believe that the rulemaking could be scientifically sound only if the Agency’s choice of new thresholds were based on risk assessments.

Response: EPA believes that the commenters confuse science with policy. To support their contention that the rulemaking is scientifically unsound none of the commenters point to the scientific portions of today’s action, i.e., 1) the hazard assessments conducted that support the determinations that the chemicals proposed for addition to EPCRA section 313 meet the EPCRA section 313 toxicity criteria, 2) EPA’s assessment of the persistence and bioaccumulation for each chemical or category of chemicals, 3) the standards for acceptability of persistence and bioaccumulation data, and 4) the scientific aspects of the choice of persistence and bioaccumulation criteria. Rather these commenters contend that the rulemaking is not scientifically sound because EPA has not based its threshold determinations on risk assessments.

The use of a risk assessment in itself is not “good science” or “bad science.” A risk assessment may be a component of a regulatory determination or may be conducted outside of the regulatory sphere to assess the estimated risks that a specific population may face. But it is not by definition a component of every scientific assessment, nor every regulatory decision that is

based on a scientific assessment. Its presence or absence, in itself, will not determine in all situations whether an assessment or decision is based on “good” or “bad” science. For example, in determining the degree to which a chemical will persist in soils, an assessor will analyze the data available for the chemical, i.e., both the field and laboratory studies, and will determine any limitations in the studies, e.g., losses from the test medium by nondestructive processes such as volatilization. Based on these data the assessor will characterize the persistence of the chemical. The assessment will not include a risk assessment because this assessment would have no bearing on persistence nor provide information about the persistence of the chemical. Whether the assessment of the persistence of the chemical is based on “good” science or “bad” science will depend on both the quality of the data on the persistence of the chemical and how well the assessor analyzed the data. Thus, conducting a risk assessment will add no value to the assessment of the persistence of a chemical.

Whether a risk assessment is an appropriate component of a regulatory decision is dependent upon statutory requirements and policy considerations. For example, the listing of toxic chemicals pursuant to EPCRA section 313(d)(2)(B) is generally based on a hazard assessment rather than a risk assessment. When EPA makes a listing determination pursuant to EPCRA section 313(d)(2)(B) the statute directs EPA to determine whether the candidate for listing is “known to cause or can reasonably be anticipated to cause in humans” one or more types of chronic toxicity, e.g., cancer. The statute does not direct EPA to make the finding that the toxic chemical causes the toxic effect, e.g., cancer, and that there is the risk for that toxic effect. Therefore, basing the regulatory decision on a risk assessment would be inconsistent with EPA’s interpretation of the statutory criteria. In this case whether EPA has based its decision on “good” science or “bad” science is dependent upon the data underlying the hazard assessment and how well the hazard assessment was conducted, not on whether or not a risk assessment was conducted.

EPA does not believe that, in general, decisions under EPCRA section 313 should be based on risk, nor is EPA required to base its determinations to modify the reporting thresholds on risk. Section 313(f)(2) addresses revisions to the reporting thresholds. It does not require EPA to establish prior to the lowering of reporting thresholds that releases at a particular threshold will result in specific quantitative risks. That section expressly provides that the Administrator may establish a threshold amount for a toxic chemical different from the 25,000 pound threshold for manufacturing and processing activities and the 10,000 pound threshold for otherwise use activities. The only requirement for revising the reporting threshold for a toxic chemical is that the revised threshold must obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to reporting. As discussed elsewhere in this document, EPA’s thresholds satisfy this standard.

Commenter Number: C-1423, C-1168, C-1440, C-1861, C-1865

Comment: Several commenters contend that a chemical’s degree of persistence and bioaccumulation are unrelated to the chemical’s exposure potential. They disagree that persistence and bioaccumulation are necessarily indicators of exposure or exposure potential. As an example the commenter states that many of the compounds EPA is targeting are highly lipophilic, non-water-soluble compounds, and the greatest potential for bioaccumulative effects is through uptake from the water column. EPA should evaluate how these compounds partition in the environment. Those that are not bioavailable have limited exposure potential, and therefore limited risk. Thus the commenter believes that EPA must consider exposure in conjunction with persistence and bioaccumulation.

Response: EPA disagrees with the commenters. All other things being equal, the chemical with a higher degree of persistence and bioaccumulation will have a greater exposure potential than the chemical with a lower degree of persistence and bioaccumulation. For example, all other things being equal, a chemical that has a half-life in water of 4 months will have a higher exposure potential to aquatic organisms than a chemical with a half-life in water of 1 month. Fifty percent of the first chemical will remain in the water after 4 months while only 12.5 % of the second chemical will remain in the water after 4 months. Aquatic organisms will be exposed to 4 times more of the first chemical than the second chemical. Clearly the chemical with the greater persistence has the higher exposure potential.

EPA does not believe that the commenter’s example supports his contention that persistence and bioaccumulation are unrelated to exposure potential. As EPA understands the commenter’s example, chemicals that have the greatest bioaccumulation potential will not be bioavailable in water because they are highly lipophilic and non-water soluble. Thus, because they are not bioavailable in water, they cannot bioaccumulate in aquatic organisms. A well-studied example that clearly contradicts the commenter’s claim is the bioaccumulation of polychlorinated biphenyls (PCBs) in the Great Lakes. PCBs have bioaccumulation factors (BAFs) as high as 141,000,000 (Table 1, 64 FR 707-8) and very, very low water solubility. PCBs have been found throughout the Great Lakes in sediments, water, and aquatic organisms. Multimedia analyses indicate

that the majority (80-90%) of human exposure to chlorinated organic compounds, such as PCBs comes from the food pathway, a lesser amount (5-10%) from air, and minute amounts (less than 1%) from water. Most of the data available on human exposure to toxic substances in the Great Lakes come from the analyses of contaminant levels in drinking water and sport fish. The consumption of contaminated sport fish and wildlife can significantly increase human exposure to the Great Lakes critical pollutants. The sport fish are exposed to PCBs by consumption of sediments and in water, from which they bioaccumulate the PCBs. (Ref. 1).

Reference

1. USEPA/ATSDR. The Effects of Great Lakes Contaminants on Human Health: Report to Congress (1986) Internet at: www.epa.gov/glnpo/health/atsdr.htm.

Commenter Number: C-446, C-1860

Comment: Some commenters contend that chemicals that meet the EPCRA section 313 persistence and bioaccumulation criteria should be considered only as a screening list of chemicals. They contend that because these chemicals are only a screening list of chemicals, the screening cannot be used as a basis for risk management. They believe that the chemicals on this screening list should undergo a risk assessment. If the risk assessment indicates that a chemical presents a risk to human health or the environment then the Agency may lower the reporting threshold for these chemicals.

Response: EPA disagrees that the toxic chemicals that meet the EPCRA section 313 criteria for persistence and bioaccumulation are by definition a “screening list” of chemicals for risk assessment and risk management under EPCRA section 313. The commenters do not explain why these chemicals should be considered to be a screening list of chemicals other than their belief that regulatory determinations under EPCRA section 313 should be risk- based. As discussed in detail elsewhere in this document, EPCRA does not require that the Agency make risk determinations to modify the EPCRA section 313(f)(1) reporting thresholds, nor is it the intent of EPCRA to limit or even to focus the collection of information on releases to those releases that from the federal government perspective pose significant local human and environmental exposure and human health and environmental risks.

1.c. Identification of PBT chemicals for this rulemaking

Use of the Waste Minimization Prioritization Tool (WMPT)

Commenter List: C-1406, C-1429, C-1436, C-1815, C-1841, C-1850, and C-1863.

Comments: Commenters stated that it was inappropriate for EPA to use the Waste Minimization Prioritization Tool (WMPT) to help generate the initial list of PBT chemicals for this rulemaking and that EPA should reassess the emphasis it is placing on the WMPT to support this rulemaking. Commenters stated that WMPT has serious flaws that make it unsuitable as a tool even for screening chemicals. Commenters stated that the version of WMPT that EPA used was a draft beta version and that the Agency received significant comments concerning changes that need to be made to this tool and that the new version, which is supposed to address these comments, has not been rereleased for review and comment by the public. Commenters stated that WMPT should receive a rigorous and thorough peer review by the EPA Science Advisory Board and/or another qualified and objective institution as recommended by the Agency's Guidelines for Peer Review. Commenters stated that the Agency specifically stated that WMPT was not intended to be used for purposes other than developing the RCRA waste minimization list. Commenter stated that the use of the beta version of WMPT by EPA, even for initial screening, implies that the tool is valid and that it is attendant upon EPA to correct the belief that the beta version is acceptable for general use so that it is not misused. Commenter stated that WMPT has serious flaws that make it inappropriate for use as a primary method of identifying substances that warrant priority attention, and potentially, regulatory measures. Commenter stated that to the extent that the WMPT remains part of the screening process, EPA needs to ensure that the WMPT will use the most accurate and up-to-date data available. Commenter stated that neither the WMPT nor any similar tool that does not reflect actual assessments of how a

substance is used, the extent and nature of exposure, and other aspects of a true risk assessment, should be the primary determinant that a substance warrants designation as a priority PBT.

Commenter stated that despite EPA's claim that the WMPT "is not part of this rulemaking," the Beta version of the WMPT was placed in the docket, which the commenter contends indicates that the results of the tool were being relied upon to support decisions in the TRI program. The commenter states that many questions arise from such a use of WMPT; for example, 1) Is EPA evaluating re-registered pesticides using the WMPT, or is it relying on the much more robust data sets available under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) programs?; 2) where data in addition to that included in the WMPT is available, is EPA considering that data?; and 3) how is data of insufficient quality being identified and excluded?

Commenter stated that EPA has an important stewardship responsibility for the WMPT and for its management of data on which the Agency will rely for regulatory decisions and in the case of such a highly visible program as the TRI, EPA should give a high priority to information stewardship. Commenter states that these responsibilities include: 1) Making the tool(s) used to support an Agency decision or rulemaking available for public review; 2) clearly explaining what it is and how it works; 3) assisting customers – within the Agency and in the public – to use the tool(s) appropriately; 4) recalling defective or outmoded versions of the tool(s); and 5) assuring that, at a minimum, the various Agency offices, the Regions, and the states use only the most current version of the tool(s).

Commenter states that the preamble to the proposed rule states that "The screening process described here is not part of this rulemaking . . .", yet, the draft WMPT is a part of the docket for this proposed rule. Commenter contends that when an outdated, flawed WMPT is used as a screen for identifying PBTs, the screening process itself is flawed and the public should be given the opportunity to comment on that very issue. Commenter states that the fact that EPA used a draft, unrevised version of WMPT indicates that the screening process itself may have been flawed.

Commenter stated that EPA's Office of Pollution Prevention and Toxics like the agency's Office of Solid Waste, would prefer to keep the WMPT separate from public comments on any later rulemakings or draft regulatory notices, yet, both the January 5 proposed rule and the November 9 Draft RCRA PBT Notice rest on a fatally flawed tool - the WMPT. Commenter states that at least for metals, the WMPT requires a serious reexamination since it overlooks metals' bioavailability, transformation, fate and transport. Commenter states that WMPT is not a tool that is suited for screening or ranking metals.

Response: EPA disagrees with the comments concerning EPA's use of WMPT to develop potential candidates for inclusion in the proposed rule to lower EPCRA section 313 reporting thresholds for certain PBT chemicals. It is clear from the content of these comments that the commenters misunderstood the role WMPT played in this rulemaking. The commenters are attempting to make a strong link between the WMPT and the determination EPA made concerning the PBT status of certain chemicals under EPCRA section 313 but this link does not exist. In the proposal, EPA provided a clear explanation of the extent to which the Agency relied on WMPT in this rulemaking.

"EPA developed a preliminary list of chemicals for consideration in this rulemaking by reviewing the chemicals on the Great Lakes Binational Toxics Strategy, Level 1 list and chemicals that had received high scores for persistence and bioaccumulation from EPA's Office of Solid Waste's Waste Minimization Prioritization Tool (WMPT). EPA dropped from further consideration in this rulemaking certain pesticide chemicals included on the Level 1 list, for which assessments were not yet complete. The screening process described here is not part of this rulemaking, but was merely a process designed to identify candidate chemicals for further consideration in this rulemaking. It was not used to select chemicals for addition or to determine for which chemicals a lower threshold would be warranted. The process was intended to allow the Agency to establish internal priorities and to focus its limited resources in this initial rulemaking on those toxic chemicals that would result in significant environmental and public information benefits. The fact that a chemical was not included, either as a result of EPA's screening processes, or as a result of one of the assessments conducted during the rulemaking, does not mean that EPA has finally concluded that the chemical does not persist or bioaccumulate, or that the chemical does not warrant any further consideration under EPCRA section 313."

The only role the WMPT had in this rulemaking was that the chemicals that had high scores in the beta version of WMPT (scores of 17 and 18) were included on a list of “potential” candidates for further consideration for inclusion in this rulemaking. The results of the WMPT scoring did not determine whether a chemical would be classified as a PBT in the proposed rule. Each chemical was individually assessed prior to determining that it met the PBT criteria laid out in the proposed rule. The support documents for bioaccumulation, persistence, and chemical hazard (for those chemicals being added to the EPCRA section 313 list) provide the support for the determination that these chemicals met the PBT criteria in the proposed rule (references 47, 66, and 2 respectively as cited in the proposed rule). WMPT played no role in the Agency’s determination as to whether a chemical met the PBT criteria discussed in the proposed rule. Nor has the Agency relied on WMPT with respect to any determinations in the final rule.

The fact that the results of WMPT were not the basis for determining whether a chemical met the PBT criteria is supported by the fact that not all of the chemicals with high scores from the beta version of WMPT were included in the proposed rule. In fact, EPA dropped three chemicals because the analysis of the available data indicated that they would not meet the PBT criteria laid out in the proposed rule: hexachlorocyclopentadiene, hexachlorophene, and pentachlorophenol.

The commenters that stated that placing the beta version of WMPT in the docket for this rulemaking means that the results of the tool were being relied upon to support decisions in the TRI program are mistaken. The mere fact that the beta version of WMPT was placed in the docket for the proposed rule does not mean that the results of WMPT were the basis for determining that a chemical is a PBT under EPCRA section 313 or that the Agency’s screening activities were part of the rulemaking. As a matter of good public policy, EPA tries generally make copies of any material discussed or cited in a proposed rule available for the public to review, including items that were not part of the rulemaking and that played little or no role in the determinations made in the proposed rule. The beta version of WMPT was placed in the docket for informational purposes only, not as direct support that any of the chemicals in the rule were PBTs.

The comments concerning how WMPT should be improved, peer reviewed, etc, are not relevant to this rulemaking since WMPT was not used as a basis for any determinations made in this rulemaking. Commenters that suggested that WMPT was so “flawed” that the screening process was also flawed are mistaken. If WMPT were so “flawed” that it was not even good for screening chemicals then the results of EPA’s independent review of the data for the chemicals that had high scores in the beta version of WMPT would have resulted in many of the chemicals being dropped from consideration, but this was not the case.

No matter how “flawed” the beta version of WMPT may or may not have been its use in the context of this proposed rule was of such a limited scope that its use here was appropriate. Given the very limited use of WMPT results, to simply provide a list of “potential” PBT chemicals for review, the Agency does not believe that it was inappropriate or premature to use the WMPT results for this purpose.

List of All Chemicals Reviewed and Use of Separate Hazard Assessments

Commenter List: C-1407

Comment: Commenter stated that EPA did not provide a list of all of the chemicals considered in this rulemaking and that a list of chemicals that EPA decided not to add to the EPCRA section 313 list would provide useful information to the public. Commenter stated that information on chemicals which had been determined not to present certain hazards or be considered PBT chemicals is as important a part of Right-to-Know as information on chemicals that do meet the criteria. Commenter states that they do not understand why EPA conducted a hazard assessment on each chemical proposed for addition to the EPCRA section 313 list separately and independently from the review to determine the chemical’s persistence and bioaccumulative potential. Commenter states that it would seem that, if a chemical met the criteria set forth for a PBT chemical, it would concurrently meet the criteria for EPCRA sections 313(d)(2)(B) and (C). Commenter states that EPA should provide further discussion in the final rule to clarify the justification for separate hazard assessments.

Response: The commenter appears to have misunderstood the process EPA followed in this rulemaking. EPA did not review

every chemical in commerce, or even on the EPCRA section 313 list, and determine whether it met the PBT criteria. As EPA explained in the proposed rule:

“[t]he fact that a chemical was not included, either as a result of EPA’s screening processes, or as a result of one of the assessments conducted during the rulemaking, does not mean that EPA has finally concluded that the chemical does not persist or bioaccumulate, or that the chemical does not warrant any further consideration under EPCRA section 313.”

Thus the fact that a chemical did not appear in the proposed rule does not reflect a determination that the chemical is not a PBT or that it might not warrant listing under EPCRA section 313. This simply reflects the fact that EPA did not consider the chemical further, as in the case of certain pesticides, or that the data available at the time of the review was not sufficient for further action. Since there may be additional information available that EPA did not consider or since such information may become available in the future it is not possible to make a final absolute determination that a chemical, that EPA reviewed but did not include in the proposed rule, will never be considered a PBT.

However, EPA did explain the screening process by which it identified candidate chemicals and prioritized the chemicals considered for inclusion in this rulemaking.

“EPA developed a preliminary list of chemicals for consideration in this rulemaking by reviewing the chemicals on the Great Lakes Binational Toxics Strategy, Level 1 list and chemicals that had received high scores for persistence and bioaccumulation from EPA’s Office of Solid Waste’s Waste Minimization Prioritization Tool (WMPT). EPA dropped from further consideration in this rulemaking certain pesticide chemicals included on the Level 1 list, for which assessments were not yet complete.”

Both the Binational Level 1 list and the WMPT list were placed in the docket for this rulemaking so the complete list of chemicals EPA considered was available to those interested in this information.

Regarding the issue of separate hazard assessments for chemicals being added to EPCRA section 313, the statutory criteria does not allow for the listing of a chemical based solely on the fact that it might be persistent or bioaccumulative, rather the criteria focus on whether a chemical potentially poses a hazard. For EPCRA section 313 the hazard assessments determine if a chemical potentially poses a hazard; if a chemical does not potentially pose a hazard then its persistence or bioaccumulation potential will not support listing the chemical on EPCRA section 313. Thus, a determination that a chemical met the persistence or bioaccumulation criteria would not automatically determine that the chemical met the listing criteria of EPCRA section 313(d)(2)(B) or (C). Therefore, it was appropriate for EPA to conduct a separate hazard assessment to support the addition of certain chemicals to the EPCRA section 313 list.

Reliance on Number of Comments Received and Use of Animal Data

Commenter List: C-1423

Comment: The commenter states that the technical review undertaken by EPA to determine whether some TRI chemicals persist and bioaccumulate to the extent they should be subject to lower thresholds under EPCRA section 313 appears to be based on insufficient or faulty criteria, assumptions and methodologies. As an example that commenter states that EPA’s decision to propose the lower thresholds for dioxins and dioxin-like compounds appears to be based in part on the fact that a majority of commenters supported lower thresholds for these substances in comments submitted on EPA’s 1997 proposal to add dioxins to the TRI list of chemicals. The commenter states that the mere number of public supporters for a particular action under EPCRA 313 is not an appropriate criterion by which EPA should decide to lower the thresholds or make any other changes to the EPCRA 313 requirements.

The commenter also states that in Section IV.C. of the preamble to the proposed rule, EPA references toxicological studies on non-human species to justify the selection of certain chemicals for the lowered thresholds. The commenter states that no attempt is made to demonstrate equivalent impacts on humans and that such extrapolations are inconclusive at best. The commenter states that reliance only on subjects such as newborn or preweanling mice raises substantial questions about the applicability of these results to humans.

Response: EPA disagrees with these comments. The mere number of commenters in support of the lowering of thresholds for dioxin and dioxin-like compounds is not the basis for EPA's determination that thresholds should be lowered for these chemicals. The basis for lowering the reporting thresholds is the potential for these toxic compounds to persist in the environment and bioaccumulate in organisms and the fact that, as a result, the public has an interest in even relatively small releases and other waste management quantities for PBT chemicals. However, it is important for EPA to consider the comments that it receives on a proposed action just as EPA is considering and responding to the comments provided by this commenter. EPA's statements in the proposed rule regarding what commenters had said about lowering thresholds were provided so that those reading the proposed rule would know that EPA had already received comments that were generally supportive of the actions being proposed.

The commenter is incorrect in the statement that "EPA references toxicological studies on non-human species to justify the selection of certain chemicals for the lowered thresholds." EPA did not cite this data to lower the thresholds; this data is cited in support of the addition of these chemicals to the EPCRA section 313 list of toxic chemicals. The selection of lower thresholds was based on the potential of these chemicals to persist in the environment and bioaccumulate in organisms and on the correspondingly higher public interest in even relatively small amounts of release and other waste management quantities for PBT chemicals. Regarding the comment on the use of animal studies to assess the potential hazard to humans, this is a well established, scientifically valid method of determining whether a chemical can reasonably be anticipated to cause adverse effects in humans. While it would be best to have data from human studies, and in some cases human data is available, it is not practical or reasonable to conduct toxicity tests on humans. As the EPCRA section 313 statute states at the end of paragraph 313(d)(2):

"A determination under this paragraph shall be based on generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, available to the Administrator."

As to the specific example of using newborn or preweanling mice, this refers to the cancer studies conducted on these animals which again is a standard, scientifically valid method of assessing the potential of a chemical to cause cancer in humans.

Separate Toxicity Criteria for PBT Chemicals

Commenter List: C-1836

Comment: Commenter states that EPA should target specific compounds which are clearly persistent, bioaccumulative, and toxic and that in the proposed rule EPA does not include the degree of toxicity as a criteria for selection of PBT chemicals. The commenter believes that lowering thresholds based only on chemicals that are only persistent or bioaccumulative would be a flawed methodology and that the methodology must include all three criteria to justify the need to lower the threshold.

Response: EPA has targeted specific compounds that are persistent, bioaccumulative, and toxic. The criteria for the toxicity of PBT chemicals under EPCRA section 313 are the EPCRA section 313 listing criteria and EPA does not believe that it is appropriate to establish an additional toxicity criteria addressing the degree of toxicity for PBT chemicals under EPCRA section 313. While some PBT chemicals that have been identified by EPA and other groups are toxic at extremely low doses, even chemicals that are toxic at higher doses are of concern since the potential for exposure to amounts that are toxic is increased because of the persistence and bioaccumulation properties of these chemicals. In addition, although EPA is not proposing to do so at this time, there is no reason that EPCRA section 313 reporting thresholds could not be lowered for toxic chemicals that

are persistent or bioaccumulative.

Use of the Final Water Quality Guidance for the Great Lakes System

Commenter List: C-1841

Comments: The commenter stated that EPA should review the chemical assessments done in support of the Final Water Quality Guidance for the Great Lakes System (FWQGGLS). The commenter stated the more stringent methodology used in this guidance resulted in a list of chemicals that are not bioaccumulative chemicals of concern, and that some of those chemicals are proposed as PBT chemicals in EPA's proposal. Commenter stated that this means that EPA likely has data in a different program office that indicates some chemicals may have inappropriately been designated as PBT chemicals under this proposal.

This commenter also stated that EPA states in the proposed rule (64 FR 705) that "As with BCF values, EPA believes that it is appropriate, for section 313 purposes, to use a criterion of 1,000 for BAF values. . . Support for a BAF criterion of 1,000 also comes from the Final Water Quality Guidance for the Great Lakes System (60 FR 15366)." The commenter state that the final rule for the FWQGGLS states the following in regard to bioaccumulative chemicals of concern (BCCs):

"The final Guidance designates as BCCs only those chemicals with human health BAFs greater than 1000 that were derived from either a field-measured BAF or a predicted BAF based on a field-measured BSAF (for non-metals) or from a field -measured BAF or a laboratory-measured BCF (for metals). Field-measured BAFs and BSAFs, unlike BAFs based only on laboratory analyses or calculations, account for the effects of metabolism."

The commenter stated that it is clear from reading the FWQGGLS Guidance that a more strenuous methodology taking more factors into account was applied to a very large universe of chemicals, and the end result was a short list of actual BCCs and a long list of "pollutants that are not bioaccumulative chemicals of concern." The commenter stated that seven of the chemicals that are on the list of BCCs under the FWQGGLS Guidance are also on the TRI-proposed list of PBTs. The commenter state that these include: chlordane, mercury, PCBs, dioxin, hexachlorobenzene, octachlorostyrene, and pentachlorobenzene all of which EPA has designated in the proposed rule as "highly" PBT, with 10 pound reporting thresholds. The commenter also stated that nine other TRI-proposed PBT chemicals are not on the list of BCCs in the FWQGGLS Guidance, but rather are on the list of chemicals that are not BCCs. The commenter stated that several of these have been categorized as polycyclic aromatic compounds (PACs) in this proposal. The commenter stated that the nine non-BCCs are: aldrin, benzo(b)fluoranthene, benzo(g,h,i)perylene, heptachlor, methoxychlor, benzo(a)pyrene, benzo(k)fluoranthene, dibenz(a,h)anthracene, and indeno(1,2,3-cd)pyrene.

The commenter stated that EPA has proposed reporting thresholds for aldrin and methoxychlor at 100 pounds, and reporting thresholds for heptachlor, benzo(g,h,i)perylene and the members of the PAC category at 10 pounds, yet these particular chemicals have undergone a strenuous review as part of the Great Lakes project and have been deemed "not bioaccumulative chemicals of concern." The commenter requests that EPA review the work previously done by EPA in support of the FWQGGLS Guidance. Commenter states that if more in-depth studies were conducted to indicate that the properties of the chemicals are such that bioaccumulation is not a concern, then EPA should take those studies into account and not lower the reporting thresholds for these chemicals. Commenter states that EPA is incorrect in claiming support for the 1,000 BAF criterion under the FWQGGLS Guidance, since the Guidance appears to have used that criteria as a starting point and not as an end point for designating chemicals as BCCs. The commenter also stated that the FWQGGLS Guidance would indicate that at least nine of the proposed PBT chemicals should not be designated as bioaccumulative.

Response: EPA is fully aware of the FWQGGLS Guidance and the data used in that guidance. However, EPA disagrees that only chemicals designated as bioaccumulative chemicals of concern (BCCs) under the FWQGGLS Guidance should be classified as PBT chemicals under EPCRA section 313. The FWQGGLS was established to address concerns specific to the Great Lakes Basin. As stated in the FWQGGLS final rule (56 FR 15666, March 23, 1995) section 118(c)(2) of the Clean Water

Act required EPA to:

“...publish proposed and final water quality guidance for the Great Lakes System. This Guidance must conform with the objectives and provisions of the GLWQA (a binational agreement establishing common water quality objectives for the Great Lakes) and be no less restrictive than provisions of the CWA and National water quality criteria and guidance. The Guidance must specify minimum requirements for the waters in the Great Lakes System in three areas: (1) water quality standards (including numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life and wildlife); (2) antidegradation policies; and (3) implementation procedures.” (page 15368, column 2).

The FWQGGLS Guidance also stated that:

“The final Guidance also reflects the unique nature of the Great Lakes Basin Ecosystem by establishing special provisions for chemicals of concern. EPA and the Great Lakes States believe it is reasonable and appropriate to establish special provisions for the chemicals of most concern because of the physical, chemical and biological characteristics of the Great Lakes System, and the documented environmental harm to the ecosystem from the past and continuing presence of these types of pollutants. The Initiative Committees devoted considerable effort to identifying the chemicals of most concern to the Great Lakes System—persistent, bioaccumulative pollutants termed “bioaccumulative chemicals of concern (BCCs)” —and developing the most appropriate criteria, methodologies, policies, and procedures to address them. The special provisions for BCCs, initially developed by the Initiative Committees and incorporated into the final Guidance, include antidegradation procedures, to ensure that future problems are minimized; general phase-out and elimination of mixing zones for BCCs, except in limited circumstances, to reduce their overall loadings to the Lakes; more extensive data generation requirements to ensure that they are not under-regulated for lack of data; and development of water quality criteria that will protect wildlife that feed on aquatic prey.” (page 15369, column 2).

Clearly the FWQGGLS Guidance was developed specifically to address concerns within the Great Lakes basin and that purpose is quite different from the purposes related to the reporting of release and waste management information under EPCRA section 313. The fact that the FWQGGLS Guidance may be more stringent than the PBT criteria proposed by EPA for use under EPCRA section 313 is consistent with the fact that the purposes, goals, and requirements of the FWQGGLS Guidance also focus on much more stringent activities. For example, the FWQGGLS Guidance will be used to set water quality standards, establish antidegradation procedures, phaseout and eliminate mixing zones, etc., all of which are activities that go well beyond the provisions of EPCRA section 313. Therefore, EPA does not believe that a chemical cannot be classified as a PBT simply because it was not determined to be a BCC under the FWQGGLS Guidance.

EPA also disagrees with the commenters statement that “EPA is incorrect in claiming support for the 1,000 BAF criterion under the Guidance, since the Guidance appears to have used that criteria as a starting point and not as an end point for designating chemicals as bioaccumulative chemicals of concern.” As EPA stated in the proposed rule

“Support for a BAF criterion of 1,000 also comes from the Final Water Quality Guidance for the Great Lakes System (60 FR 15366). In that document EPA stated that bioaccumulation of persistent pollutants is a serious environmental threat to the Great Lakes Basin Ecosystem and that chemicals identified as bioaccumulative chemicals of concern (BCCs) (i.e., those with BAF values greater than 1,000) would receive increased attention and more stringent controls. That final Guidance designated as BCCs those chemicals with human health BAFs greater than 1,000 that were derived from certain field-measured BAFs or certain predicted BAFs. That previous designation of a high level of concern for chemicals with BAF values greater than 1,000 provides further support for the use of a BAF/BCF criterion of 1,000 for determining whether a chemical should be classified as bioaccumulative for purposes of section 313.”

EPA's statement did not claim that the FWQGGLS Guidance was the same as that proposed for TRI only that it provided some support for the use of BAF/BCF values of 1,000 and in fact EPA made it clear what the FWQGGLS Guidance for BAFs was. The fact that the FWQGGLS Guidance may be more stringent does not mean that the use of a BAF criteria of 1,000 under the FWQGGLS Guidance does not provide some support to the use of a BAF/BCF criteria of 1,000 for EPCRA section 313. EPA

continues to believe that the use of a BAF of 1,000 under the FWQGGLS Guidance does provide support for the criteria established for the purposes of EPCRA section 313 criteria because, although the underlying technical assessments may be more stringent, the bioaccumulation level of concern is still a BAF of 1,000.

Commenter List: C-1864

Comment: The commenter stated that the Great Lakes Initiative (GLI) Guidance was developed specifically for the Great Lakes basin and should not be used to justify a broad national program. The commenter stated that if EPA insists on doing so, the automatic inclusion of the "Binational Level 1 List" of substances from the Great Lakes Binational Toxics Strategy is unfounded.

The commenter states that as acknowledged in Article 21 of the strategy, as well as EPA's own description of the strategy, this list can include substances other than those which bioaccumulate. The commenter stated that the GLI went to great lengths using scientific principles to define how a substance meets the definition of bioaccumulative and that if EPA chooses to use this initiative as a reference source, these scientific principles, although imperfect, should serve as the primary basis for establishing the list of PBT chemicals. The commenter stated that this would remove such chemicals as aldrin, benzo(a)pyrene, and alkyl lead from the proposed rule.

Response: EPA did not claim to be using the GLI Guidance for the EPCRA section 313 criteria for persistence and bioaccumulation. EPA only cited the Binational Level 1 List as a list of chemicals that served as one source of chemicals that EPA had used during its screening process to identify candidates for further consideration in this rulemaking. As part of this rulemaking process, EPA conducted its own assessment of the data for those Binational Level 1 List chemicals included in the proposed rule to determine whether they met the TRI PBT criteria and did not rely simply upon the fact that they were on the Binational Level 1 List. EPA agrees with the commenter that the GLI Guidance was developed specifically for the Great Lakes basin, but since EPA is not using the GLI Guidance to establish criteria for persistence and bioaccumulation under EPCRA section 313 or to decide which chemicals will be classified as PBT chemicals under EPCRA section 313 the commenter's concerns are not warranted.

EPA should include additional chemicals in this rule.

Commenter List: C-5, C-41, C-42, C-69, C-74, C-98, C-105, C-117, C-120, C-249, C-304, C-306, C-391, C-426, C-428, C-429, C-433, C-445, C-447, C-539, C-553, C-560, C-575, C-577, C-579, C-581, C-582, C-583, C-585, C-586, C-591, C-593, C-594, C-600, C-601, C-603, C-608, C-610, C-611, C-613, C-617, C-632, C-697, C-791, C-802, C-824, C-835, C-844, C-846, C-847, C-850, C-852, C-855, C-858, C-859, C-862, C-864, C-865, C-981, C-983, C-988, C-992, C-993, C-1099, C-1355, C-1409, C-1803, C-1823, C-1829, C-1830, C-1831, C-1855, C-1873, C-1874, C-1875, C-1876, C-1877, C-1878, C-1880, C-1881, C-1882, C-1883, C-1884, C-1885, C-1887, C-1888, C-1891, C-1893, C-1895, C-1899, C-1901, C-1903, C-1904, C-1906, C-1907, C-1929, C-1908, C-1909, C-1915, C-1916, C-1917, C-1918, C-1920, C-1922, C-1923, C-1924, C-1925, C-1928, C-1931, C-1938, C-1989, C-2027, C-2113, C-2114, C-2115, C-2116, C-2117, C-2118, C-2119, C-2120, C-2121, C-2122, C-2123, C-2124, C-2125, C-2128, C-2129, C-2130, C-2131, C-2132, C-2133, C-2134, and C-2140

Comment: The commenters requested that EPA lower the EPCRA section 313 reporting thresholds for additional chemicals. Some commenters suggested that EPA should review the entire EPCRA section 313 list of chemicals and include all those that meet the PBT criteria as discussed in the proposed rule. Other commenters identified specific chemicals such as arsenic, cadmium, chromium, cobalt, lead, nickel and other metals that should have their the EPCRA section 313 reporting thresholds lowered. Some commenters suggested that all chemicals that appear on other PBT chemical lists should be covered under EPCRA section 313 and have lower reporting thresholds. In addition, several commenters suggested that all chemicals that persist or bioaccumulate should have lower reporting thresholds.

Response: As EPA stated in the proposed rule:

"This is EPA's first effort under section 313 to review chemicals for their persistence and bioaccumulation properties and it is limited to a relatively small group of chemicals. EPA may review additional chemicals in the future to determine if

they should be considered persistent and bioaccumulative under section 313 and, if not already on the section 313 list, whether they should be added.” (64 FR 698, column 1)

As part of future rulemakings, EPA may consider whether there are additional chemicals that meet the PBT criteria and thus should have lower EPCRA section 313 reporting threshold. In fact, EPA has issued a proposed rule to lower the EPCRA section 313 reporting thresholds for lead and lead compounds (64 FR 42222, August 3, 1999). In addition, as discussed elsewhere in these comment responses, EPA will consider whether the reporting thresholds should be lowered for chemicals that meet the criteria for persistence or bioaccumulation.

Comments on the addition of chemicals to the EPCRA section 313 list.

Commenter List: C-836 and C-1871

Comment: The commenters support the addition of the chemicals EPA identified in the proposed rule to lower the EPCRA section 313 reporting thresholds. The commenters stated that they also support EPA's use of quantitative structure activity relationship (QSAR) equations and other predictive modeling techniques to support such listings.

Response: EPA agrees with the commenter that the chemicals proposed for addition do meet the EPCRA section 313 listing criteria and that it is appropriate for EPA to use QSAR and other well established predictive modeling techniques.

Other comments concerning the identification of PBT chemicals

Commenter List: C-1417

Comment: The commenter stated that they especially object to the classification of groups of compounds including a specific chemical element as PBT chemicals based on the fact that some individual compounds containing that element are toxic. The commenter also stated that all the naturally occurring chemical elements are persistent and nearly all are contained in some compounds which are toxic but that does not mean that all chemicals containing a particular element should be treated similarly by regulation.

Response: The commenter appears to be referring to the inclusion of metals and metal compounds as PBT chemicals based on the persistence and bioaccumulative properties of the metal. The issue of characterizing a metal as a PBT chemical is addressed elsewhere in these comment responses. With respect to the inclusion of all metal compounds, EPA believes that this is appropriate. Only if a metal is not bioavailable from a metal compound through any biotic or abiotic processes would EPA consider that the metal may not be available to express its toxicity and bioaccumulative properties and that it therefore may not meet the EPCRA section 313 listing criteria. Unless data is provided to show that a particular metal compound is not toxic and that the metal is not bioavailable through any processes, EPA believes it is appropriate to include that metal compound on the EPCRA section 313 list of toxic chemicals. Therefore, if a metal compound meets the listing criteria of EPCRA section 313 EPA believes that it is appropriate to include that metal compound as a PBT chemical based on the persistence and bioaccumulative properties of the parent metal contained in the metal compound.

Commenter List: C-1865

Comment: The commenter stated that EPA has proposed criteria for identifying PBT chemicals under EPCRA section 313, but has only analyzed a small subset of the EPCRA section 313 chemicals against that criteria. The commenter stated that in order to accurately convey the potential scope and impact of the proposed criteria EPA must indicate, based on the criteria, which other chemicals on the EPCRA section 313 list might be designated by EPA as PBT chemicals in the future. The commenter stated that by not doing this comparison EPA misrepresents the potential costs and impacts of the proposed

criteria.

Response: EPA disagrees with the commenters statements. The issue here is not the “cost” of the PBT criteria and thus EPA has not misrepresented such costs. The only costs at issue in this rulemaking are the costs imposed by the final rule. As the criteria themselves impose no costs, EPA has not tried to assess them. Rather any costs result from e.g., lowered thresholds and listing additional chemicals. Nor is EPA required to consider the costs of some future rulemaking that may not ever take place. If in the future EPA proposes to lower the EPCRA section 313 reporting thresholds for another group of PBT chemicals, EPA will determine the costs of that rule separately. The cost of the TRI program as a whole is continually adjusted to reflect the impact of such rulemakings; thus the cumulative impacts of any changes to the reporting requirements are reflected in the overall cost estimates for the program.

Commenter List: C-1421

Comment: The commenter stated that in the proposed rule EPA has not presented an adequate scientific framework for singling out the 19 chemicals/categories from the more than 600 on the EPCRA section 313 list. The commenter stated that in choosing the chemicals and lower thresholds, EPA has conducted no comprehensive risk assessment, toxicity assessment, or exposure assessment and EPA has not applied any of its analyses to all of the EPCRA section 313 chemicals.

Response: EPA disagrees with the commenters statements. As discussed elsewhere in these comment responses, EPA has established a clear and adequate scientific basis for identifying the chemicals in this rulemaking as PBT chemicals and has explained why they should have lower reporting thresholds. EPA is only required to conduct hazard assessments for chemicals that are being added to the EPCRA section 313 list, and such assessments have been conducted for the chemicals being added in this rulemaking. For chemicals already on the EPCRA section 313 list no hazard assessment is required. EPA has not conducted any risk assessment since, as explained in detail elsewhere in these comment responses, EPCRA section 313 is not a risk-based statute. EPCRA section 313 does not require comprehensive risk assessments to lower the reporting thresholds or to add chemicals (except for the very limited risk assessments required for adding chemicals based on acute human health effects under EPCRA section 313(d)(2)(A)). Similarly, exposure assessments are not required to lower the reporting thresholds and are only necessary for adding chemicals under limited conditions (see 59 FR 61432, November 30, 1994). There is also no requirement that EPA apply any of the PBT analysis to the entire EPCRA section 313 list. As EPA stated in the proposed rule:

“This is EPA’s first effort under section 313 to review chemicals for their persistence and bioaccumulation properties and it is limited to a relatively small group of chemicals. EPA may review additional chemicals in the future to determine if they should be considered persistent and bioaccumulative under section 313 and, if not already on the section 313 list, whether they should be added.” (64 FR 698, column 1)

1.d. Statutory Authority

Commenters: 1421, 1850, 1865

Comment: Several commenters assert that section 313(f)(2) only grants EPA the authority to raise the statutory thresholds, but not to lower them. They agree that the substantial majority test is met “as a matter of logical necessity” when EPA lowers the reporting threshold, and argue that this makes the “substantial majority” test essentially meaningless when thresholds are lowered. They argue that this demonstrates that Congress did not intend for EPA to lower reporting thresholds, only to raise them.

Response: EPA disagrees with the commenters’ interpretations. Section 313(f)(2) clearly authorizes EPA to lower thresholds, as well as to raise them. The plain language of this provision provides that “the Administrator may establish a threshold *different from* the amount established by paragraph (1).” It does not state that the Administrator may only establish a *higher* threshold

from the amount established by paragraph (1), which appears to be the commenter's interpretation. Moreover, in the House debate on the conference report, Representative Edgar, one of EPCRA's sponsors, noted:

The EPA is authorized to revise these thresholds, but only if such revised thresholds obtain reporting on a substantial majority of total releases, especially if such revised thresholds raise the statutory levels...

(A *Legislative History of the Superfund Amendments and Reauthorization Act of 1986* Committee Print, vol. 6, 5315)(emphasis added). The clear implication of this statement is that Congress intended EPA to have the authority to lower, as well as to raise, the statutory thresholds.

The commenters' interpretation that EPA lacks the authority to lower the thresholds conflicts with Congressional intent in other ways. During debate on the Conference Report, Representative Edgar noted that "This act is intended to provide a *comprehensive view of toxic chemical exposure* and hopefully, provide a basis for more sensible and effective local, State, and national policies." *Legislative History* at 5316. See also, *Legislative History* at 5313 and 5338. And yet without the authority to lower thresholds, EPA cannot ensure that this objective is achieved. For example, Congress included PCBs on the original list of TRI chemicals, thereby indicating an intent to provide the public with a "comprehensive view of exposure" to PCBs; but under the original reporting requirements, EPA only received 6 reports (quoting *Legislative History* at 5315 on the purposes of section 313). Under no interpretation can six reports be characterized as obtaining "a comprehensive view of toxic chemical exposure." *Legislative History* at 5315.

EPA also disagrees with the comment that it has rendered this provision meaningless. The commenters' argument is based on a logical fallacy; a standard need not constrain agency action to the same degree in all circumstances to be meaningful. Congress may, if it so chooses, impose a standard that constrains actions to varying degrees in different circumstances. In this case, the Congressional debate on this provision indicates that Congress was most concerned with the loss of publicly available information that may result from raising the thresholds. See, e.g., *Legislative History* at 5315. It is therefore reasonable to assume that Congress chose to impose a standard that presented a greater constraint on the Agency's ability to raise the threshold, and therefore created a ceiling beyond which the Agency was not authorized to modify thresholds.

Further, notwithstanding the fact that under EPA's interpretation of section 313(f)(2), the Agency can meet the statutory standard without the need for quantitative support when it lowers the threshold, EPA does not believe that Congress has granted it unfettered discretion to establish a different threshold. For example, as discussed at length elsewhere in this response to comments document, Congress provided significant guidance in other provisions of the statute and the legislative history to guide the Agency's exercise of discretion under this provision.

Commenters: 1421, 1850, 1865

Comment: Several commenters also rely on the language of other provisions of EPCRA section 313 to support their argument that Congress did not grant EPA authority to lower thresholds. They rely on the fact that section 313(f)(2) does not provide that EPA can "raise or lower", unlike section 313(d), under which EPA can "add or delete" chemicals from the list, and section 313(b), under which EPA can "add or delete" SIC codes. In addition, the commenters argue that section 313(f)(2) is analogous to section 313(l), where, despite the use of the otherwise neutral term "modify," Congress clearly meant for EPA only to make the reporting requirements less frequent (i.e., less stringent). Based on these provisions, they also argue that, where Congress intended EPA to have the authority to both expand and restrict reporting, the statute explicitly provides the authority, but where Congress only intended to authorize EPA to reduce the reporting burden, it provided a neutral term, and then restricted it. The commenters argue that in section 313(f)(2), Congress qualified EPA's authority in this section with a substantial majority restriction that only makes sense if EPA raises the thresholds.

Response: EPA disagrees with the commenters' interpretations. In general, Congress established the basic framework of right-to-know reporting in EPCRA section 313, and authorized EPA to adjust the parameters as appropriate. For example, EPA is authorized to modify the chemicals on the TRI lists, the SIC codes and facilities covered by section 313, the reporting

frequency, and the reporting thresholds, but each grant of authority is constrained to varying degrees by the standards contained in each respective provision. As the commenters have correctly noted, where Congress intended to restrict the Agency's authority to modify the original requirements, it did so explicitly. For example section 313(l) specifically limits EPA's authority to modify the reporting frequency "...but the Administrator may not modify the frequency to be any more often than annually." Similarly Congress included no provision authorizing any amendments to the generally applicable employee threshold. It is therefore reasonable to assume that had Congress intended to only permit EPA to raise the thresholds, they would have included such an explicit restriction in the provision. Moreover, as noted above, the little legislative history that exists on this provision indicates that Congress intended EPA to have the discretion to both raise and lower the reporting thresholds. Further, EPA disagrees with the commenter's interpretation that Congress relied on different statutory construction to indicate its decision not to grant the Agency authority to decrease reporting thresholds, rather than relying on an explicit restriction in the plain language of the statute. EPA is aware of no indication of such Congressional intent in the legislative history, nor have the commenters cited to any. More to the point, the commenters' interpretation is clearly refuted by the inclusion in section 313(l) of an explicit restriction, demonstrating that where Congress intended to restrict EPA's authority, it did so explicitly

Commenter: 1421

Comment: One commenter argues that EPA lacks authority to lower the thresholds based on a comparison of the language in EPCRA §§311 and 312 authorizing EPA to revise the §311 and §312 thresholds, with the language of §313(f)(2). The commenter states that Congress could have used this same broad and simple language in section 313, and argues that because it did not, but instead chose to impose the "substantial majority" requirement, this demonstrates that Congress did not intend EPA to have the authority to lower the thresholds. Instead, the commenter argues, Congress was concerned with reporting burden when it crafted section 313, and so declined to grant EPA authority to lower the thresholds.

Response: EPA disagrees. There is no significant difference between the language in §§ 311, 312, and 313 that supports the commenter's interpretation. Unlike section 313, Congress did not establish thresholds in sections 311 and 312, but granted the Administrator broad discretion to determine whether a threshold was even appropriate; at what level to establish the threshold; and to modify it as appropriate. The language with which Congress conferred this authority provides that "the Administrator may establish threshold quantities..." This is almost identical to the language of 313(f)(2), which simply provides that "the Administrator may establish a threshold amount for a toxic chemical different from the amount established by paragraph (1)." The commenter's argument turns wholly on the inclusion of the "substantial majority" requirement, and as explained above, EPA does not believe that this standard either precludes EPA from lowering thresholds or demonstrates Congressional intent to do so.

Commenter: 1428, 1815

Comment: The commenters rely on two statements made during the debate on the Conference Report with respect to section 313(f)(2) to argue that EPA is only authorized to revise the thresholds if EPA presents a convincing analysis that revisions to the threshold will capture a substantial majority of the releases while also ensuring that it is not placing undue burdens on facilities which contribute little to such releases. The commenters argue that EPA has not satisfied the substantial majority requirement, and to do so, must conduct a more thorough assessment of the burden imposed on industry focused on the volume of releases that will be captured, not the number of reports. Another commenter compares the legislative history of sections 311 and 312 with 313, and concludes that Congress clearly intended EPA to factor burden into section 313 threshold questions.

Response: EPA disagrees with the commenter that it is required to balance the burden imposed by an alternate threshold against the releases that will be reported. Ultimately, irrespective of what Congress may have intended, EPA must comply with the statutory language, and section 313(f)(2) does not impose any requirement on the Agency to rely on the type of analyses described by the commenter. In addition, the commenters' reliance on the statements made during the Conference Report debate are misplaced. The commenter only quotes part of Representative Edgar's statement; the full quotation indicates only that EPA must present a convincing case, "based on verifiable, historical data" that the statutory thresholds warrant revision. As discussed in Unit VI.E of this preamble, EPA believes it has presented a convincing case that the thresholds should be lowered for PBT chemicals. The commenter also failed to include the portion of Representative Edgar's statement explaining that a

convincing case was particularly necessary if the effect of the modification was to raise the thresholds. See, *Legislative History* at 5315.

Nonetheless, as discussed in greater detail in Unit VI.E, EPA considered the burden that lower thresholds would impose on industry in selecting the PBT thresholds. EPA believes that the levels it has adopted will capture significantly more information about PBT chemicals than current thresholds, but will not be unduly burdensome on industry. In addition, as discussed elsewhere in this response to comments document, EPA believes that the number of reports filed is a more accurate measure of burden than the volume of releases.

As discussed elsewhere in these responses in more detail, EPA also disagrees with the commenter that it has failed to satisfy the requirements of section 313(f)(2), and that in lowering the thresholds, EPA could never rely on the number of reports rather than the volume of releases.

Commenter List: 1353,1423, 1421,1423, 1428, 1458, 1820, 1836.

Comment: Several commenters challenged EPA's finding that its alternate thresholds would capture a substantial majority of total releases, contending that the Agency had impermissibly relied on an increase in the number of reports submitted. The commenters assert that EPA is required to estimate releases at these facilities and determine, on a percentage basis, whether a "substantial majority" of all releases of each chemical, from all facilities subject to EPCRA § 313, will be captured. One commenter noted that, even if lowering the threshold for a TRI chemical results in an increase in the number of reports on the chemical, this does not necessarily mean that the additional reports will capture a substantial majority of the total releases from all facilities subject to TRI reporting. In order for the lower threshold to meet the statutory test, the threshold must result in capturing at least two thirds of all releases of the chemical at covered facilities. The commenter contended that the number of reports is irrelevant to the percentage of releases captured by the reports. If a certain chemical were present at only one facility in the country subject to EPCRA § 313, the submission of one report on the chemical accounting for at least 66% of the releases from that facility would satisfy the "substantial majority" test. By contrast, if a lower threshold generated a thousand new reports on a TRI chemical, the "substantial majority" test would not be met if those reports did not account for at least 66% of the total releases from all facilities subject to TRI. This may be the case, for example, if a large percentage of releases of the TRI chemical occurred at facilities otherwise subject to EPCRA § 313 that do not meet the threshold for that particular chemical that triggers the obligation to report the releases.

Response: EPA disagrees with the commenters' interpretation. As noted in the proposed rule, EPA interprets the language in 313(f)(2) "facilities subject to the requirements of [section 313]" to refer to those facilities that fall within the category of facilities described by sections 313(a) and (b). Subsection (a) lays out the general requirement that "the owner or operator of facilities subject to the requirements of this section" file a TRI report. Subsection (b) then further defines the facilities subject to the requirements of this section:

[t]he requirements of this section shall apply to owners and operators of facilities that have 10 or more full-time employees and that are in Standard Industrial Classification Codes 20-39¹,... and that manufactured, processed, or otherwise used a toxic chemical listed under subsection (c) of this section in excess of the quantity of that toxic chemical established under subsection (f) of this section during the calendar year for which a toxic chemical release form is required under this section.

Thus, to be subject to the requirements, a facility must meet all three of the requirements laid out in subsection (b). This means that the class of facilities subject to reporting under section 313 will vary according the individual chemical. Moreover, facilities that have not exceeded a threshold for a particular chemical are not "subject to the requirements" of EPCRA section 313 for that chemical.

¹EPA is also authorized under this provision to add or delete SIC codes.

To determine whether a particular threshold, either higher or lower, for an individual chemical meets the substantial majority test, one would compare the total national aggregate of releases of the chemical at the existing thresholds with the estimated total national aggregate of releases at the proposed alternate threshold, and determine whether a substantial majority of releases reported under the original thresholds would be reported. Logically, the universe of facilities subject to the requirements under a lower threshold will always be either equivalent to, or greater, than the universe of facilities that are subject to the requirements under the existing thresholds. Moreover, because facilities subject to the requirements of section 313 must report "the annual quantity of the toxic chemical entering each environmental medium," EPA can meet the substantial majority standard without the need for quantitative support; i.e., facilities that report, must report their releases and other waste management quantities. When lowering the thresholds, therefore, the number of reports serve as an adequate surrogate for releases because essentially all releases (and other waste management quantities) will be reported by facilities subject to the requirements of this section.

In other words, facilities "subject to the requirements of this section" are those that file TRI reports. Thus the baseline against which the "substantial majority of total releases" is measured, is the category of facilities that currently submit reports. Consequently, if quantitative support for its finding were necessary, EPA would be justified in relying on the number of reports to make its finding.

By contrast, although it is not exactly clear how the commenters interpret the phrase "facilities subject to the requirements of this section," it is clear that they do so without reference to all of the requirements in subsections (a) and (b). And essentially any interpretation that ignores any portion of subsection (b) results in an interpretation of EPCRA section 313(f)(2) as "facilities *otherwise* or *potentially* subject to the requirements of this section." This is inconsistent with the plain language of section 313(f)(2). The commenters can only support their argument that EPA has not met the "substantial majority" test by assuming that all facilities, irrespective of whether they are in a covered SIC code or they exceed the existing thresholds, are subject to EPCRA §313, and that EPA must ensure that it captures a substantial majority of releases from the universe of those facilities. If this were correct, the addition of certain SIC codes could be a prerequisite to lowering thresholds for certain chemicals. Such a requirement is not currently included in section 313. The commenters have provided no support in either the statute or legislative history for these interpretations. Nor have the commenters provided any support for the interpretation that "substantial majority" equates to a particular percentage, such as 66%.

Finally, EPA notes, as it noted in the proposed rule, that, for several reasons, it does not believe that it has the necessary information to develop even reasonably accurate estimates of the potential releases that would be reported at an average facility at each of the identified options for a lowered threshold. Specifically, EPA believes that (1) sufficient information is not currently available for these chemicals, and (2) there is insufficient information on the numerous processes employed by all the sectors involved to calculate a comprehensive release estimate for the sector. While there are some data available, comprehensive data are not available for all sectors and chemicals. EPA further notes that none of the commenters provided either any information or methodology to address this issue, notwithstanding EPA's specific request.

Commenter List: 1861

Comment: The commenter alleges that EPA incorrectly interprets section 313(f)(2) to mean that the "substantial majority" test applies only to the Agency's decision to increase a threshold, but that the test does not apply to a decision to lower a threshold. 64 Fed. Reg. 690. The commenter notes that statute says that a threshold amount that is "different" from the amount established by the Act must obtain reporting on a substantial majority of releases and that Congress clearly intended that the "substantial majority" test be applied to any revision to the thresholds, whether the revision is an increase or decrease. The commenter asserts that if Congress intended the test to apply to increased thresholds alone, it would have stated so expressly, and would not have drafted the provision so broadly.

Response: The commenter has misunderstood EPA's interpretation of § 313(f)(2). EPA has never denied that the "substantial majority" test applies to the Agency's decision to lower the thresholds. Rather, in the proposal EPA specifically noted that

While the substantial majority requirement of section 313(f)(2) applies whether EPA is raising or lowering the threshold,

EPA believes that as a practical matter this standard can operate to constrain EPA action only when the Agency is raising the thresholds and thereby reducing reporting.

64 Fed. Reg at 690. However, EPA agrees with the commenter that § 313(f)(2) authorizes EPA to both lower and raise the thresholds.

Commenter List: 1421

Comment: A commenter alleges that EPA contradicts its own prior statements regarding threshold changes. In the February 16, 1988 final rule promulgating TRI requirements, EPA stated

. . .the first few years' data should be evaluated to determine whether modifications of the threshold would meet the statutory test of obtaining reporting on a substantial majority of the releases (i.e., pounds released per year) of each chemical from subject facilities. EPA may consider changing the reporting thresholds based on several years of data collection.

EPA was clear in the original TRI rulemaking that the statute requires a substantial majority finding supported by actual data. For example, in the June 1987 proposed rule, EPA stated: "The Agency is interested in data that would support the necessary finding that a modified threshold would still generate reporting on a substantial majority of total releases, as the statute requires." The commenter also notes that nowhere in either the proposed or final rule establishing TRI requirements did EPA specifically assert that it had the authority to lower thresholds.

Response: EPA disagrees that its statements in this rulemaking contradict its prior statements in the 1988 rulemaking. As a preliminary matter, as noted elsewhere in these responses, EPA has never denied that the requirement that a revised threshold obtain reporting on a substantial majority of total releases applies to any action lowering the reporting thresholds. Specifically, EPA's discussion in the 1987 proposed rule was in the context of a response to proposals from SBA that the Agency raise the thresholds to capture only larger facilities. EPA's statements in the 1988 final rule also need to be evaluated with SBA's proposals in mind. Moreover, while it is true that the discussion to which the commenter cited did not distinguish between whether lowering and raising the thresholds (it was intended as a response to comments on both sides of the issue), EPA notes that the majority of the comment summary focuses on requests to raise the thresholds. Finally, while it is true that EPA did not specifically assert its authority to lower the thresholds in either rule, neither did EPA deny that EPCRA §313(f)(2) grants it this authority. However, it is worth noting that in the final rule, EPA responded to comments from environmental and public interest groups requesting that the Agency lower the thresholds, and that EPA never stated or implied that it lacked the authority to lower thresholds.

Commenter list: 1421

Comment: The commenter alleges that even under the Agency's interpretation that it has the authority to lower thresholds, EPA would need to enumerate general criteria for changing TRI thresholds and propose and take comment on the general criteria.

Response: EPA disagrees. Nothing in section 313(f)(2) requires EPA to develop criteria by rulemaking as a prerequisite to lowering the threshold. Nor does any other provision of EPCRA, or any other relevant statute require EPA to proceed in such a fashion. It is well established that, where Congress has not decided the issue, an agency's decision to implement its statute by rulemaking or by case-by-case adjudication "lies primarily in the informed discretion of the administrative agency." *quoting SEC v Chenery Corp.*, 332 U.S. 194, 203 (1947). It is also well-settled that an agency's decision to proceed by one procedure does not deprive it of the authority to continue implementing its organic statute by the other. See, *NAACP v. Federal Power Commission*, 425 U.S. 662 668-69 (1976) ("it is clear that the agency has discretion to decide these issues through rulemaking,

individual adjudication, or both"); *Chemical Manufacturers Association v. NRDC*, 470 U.S. 116, 131 (1985) (arguments over agency's choice of procedural means to effect requirements "are particularly persuasive cases for deference to the Agency's interpretation"). Certainly EPA may choose to develop criteria for determining when to alter the section 313(f) thresholds, and it may choose to do so through notice and comment rulemaking. However, EPA equally may choose merely to publish guidance, or even to establish no criteria, but to proceed case-by-case with individual rules altering the thresholds.

Commenter List: 1423, 1427, 1850

Comment: One commenter states that EPA's authority to lower reporting thresholds is not limitless. The commenter argues that a decision to lower the thresholds must be tied to the overall purpose of the Act, namely, to inform the public of potential health risks posed by the presence of toxic chemicals released to the environment in their communities. A regulatory decision to capture more release reports under EPCRA § 313 must be based in the need to inform the public of health risks associated with the releases captured in those reports. Otherwise, the usefulness of the TRI database begins to diminish. The commenter alleges that EPA needs to demonstrate that the releases of the PBTs at such small amounts pose a meaningful risk to the public health. Another commenter asserts that EPA is relying on the purposes of EPCRA to support its interpretation of section 313(f), and argues that, although section 313(h) does describe intended uses for TRI data, section 313(h) itself does not describe the purposes or intention of section 313. The commenter instead relies on several provision of section 313 and argues that the purpose and intention of Congress to make information available to the public was balanced by concerns about the potential burden of the TRI program. The commenter also states that the uses to which Congress anticipated TRI data to be put do not outweigh the balance that Congress intended between generating information and minimizing burden, and do not grant EPA blanket authority to expand the reporting requirements

Response: EPA agrees with the commenter that its authority to lower reporting thresholds is not limitless, and that its decision to lower the thresholds must be tied to EPCRA's overall purposes. However, EPA believes that Congress granted the Agency broad, but not unfettered, discretion to determine when it is appropriate to lower thresholds, and to determine the specific thresholds that are appropriate. As discussed in the preamble to the final rule in greater detail, EPA believes that its decision to lower the thresholds, and the thresholds it has chosen, reflect these principles.

However, EPA generally disagrees with the remainder of the commenter's conclusions. As discussed in more detail elsewhere in this response to comments document, EPA is not required to base its decisions under EPCRA §313 on the need to inform the public of health risks associated with reported releases and other waste management quantities. And as discussed elsewhere in this response to comments document, EPA believes that the information that will be reported as a result of this rulemaking will provide useful information to the public.

In large measure, the issues raised in the second comment closely relate to the specific thresholds and EPA's rationale for choosing them, and this issue is discussed in more detail in elsewhere in this response to comments document. However, to the extent it relates to EPA's interpretation of §313(f)(2), some response is also provided here.

As a preliminary matter, while it is true that EPCRA §313 does not explicitly identify the purposes of the section, the Conference Report makes clear that subsection (h) of section 313

Describes the intended uses of the toxic chemical release forms required to be submitted by this section and expresses the purposes of this section. The information collected under this section is intended to inform the general public and the communities surrounding covered facilities about releases of toxic chemicals, to assist in research, to aid in development of regulations, guidelines, and standards, and for other similar purposes.

(Conference Report at 299).

Contrary to the commenter's assertion, the Agency never indicated that it was relying on §313(h) to expand its authority

under §313(f)(2). Rather, EPA noted that it was relying on the purposes of section 313 as an additional source of Congressional direction to guide the Agency's exercise of discretion under this provision. EPA relied on section 313(h), in part, because the Agency believes that its implementation of EPCRA generally should be guided by EPCRA § 313's purposes. In addition, section 313(h) shares certain elements with the Congressional guidance on section 313 (f)(2) in the legislative history. As discussed in greater detail elsewhere in this document, EPA has distilled those common elements, and relied on them to guide its discretion in establishing the specific thresholds on §313(f)(2) .

EPA also disagrees with the commenter's assertion that the purpose of EPCRA is to achieve a balance between the public's right to information about their potential exposures to toxic chemicals and the reporting burden imposed on industry. EPCRA § 313(f)(2) does not require EPA to consider burden in establishing revised thresholds. Although EPA has included the reporting burdens imposed on industry as one consideration in determining the appropriate thresholds, the Agency is also mindful that the authors of EPCRA, while sensitive to the burdens EPCRA section 313 reporting placed on industry, never intended this consideration to outweigh the public's need for access to information concerning their potential exposure to toxic chemicals. See, e.g., *Legislative History* at 5315-16 and 5338-39. And with respect to the assertion that the general purposes of section 313 are to balance the public's right to know about toxic chemical releases and other waste management in their communities against the reporting burdens TRI imposes, EPA notes that reporting burden is not included anywhere in section 313(h). Nor does the strong policy directive underlying EPA's overall implementation of EPCRA §313 support such an interpretation. Representative Edgar, one of the bill's primary architects noted:

The heart of the Federal Right-to-Know Program is its reporting requirements, which are intended to provide a comprehensive picture of the community's and the Nation's exposure to toxic chemicals. As the Environmental Protection Agency, the States, and localities implement this program, they should be guided by several general principles.

First, Congress recognizes a compelling need for more information about the Nation's exposure to toxic chemicals. Until now, the success of such regulatory programs such as the Clean Air Act, the Resource Conservation and Recovery Act, and the Clean Water Act has been impossible to measure because no broad-based national information has been compiled to indicate increases or decreases in the amounts of toxic pollutants entering our environment. As a result, the reporting provision in this legislation should be construed expansively to require the collection of the most information permitted under the statutory language. Any discretion to limit the amount of information reported should be exercised only for compelling reasons....

Legislative History at 5313. (emphasis added). Significantly, Representative Edgar did not include reporting burden as one of the general principles that should guide the Agency's implementation of EPCRA §313. Rather, he stated

This is a new Federal initiative, and I recognize the desire of some of my colleagues to move ahead cautiously to ensure that burdens imposed on industry are not excessive. Frankly, my concern rest with the families that live in the shadows of these chemical and manufacturing plants. I have put myself in their shoes and have fought for a program that looks after their needs. This legislation gets us will on the path to the full disclosure they deserve.

Id. Nonetheless, EPA has considered the legislative history on §313(f)(2), including the excerpts cited by the commenter, and determined it would be reasonable to include some consideration of the reporting burdens in selecting its alternate thresholds. The degree to which EPA included burden in its selection of the thresholds established in this rulemaking is discussed at length in the preamble to the final rule and elsewhere in this response to comments document.

EPA agrees that section 313(h) does not grant EPA unfettered discretion to expand EPCRA's reporting requirements; as noted in a previous response, Congress established the basic parameters of the TRI reporting requirements, and selectively granted EPA carefully qualified authority to modify certain of them. In this action, for example, EPA is only affecting the activity thresholds, but Congress established other limitations that govern whether a facility is subject to reporting. For example, facilities with fewer than ten employees are not subject to reporting under subsection 313(b)(1).

Comment: One commenter noted that the only statutory guidance is that a threshold obtain reporting on "substantial majority of total releases" per the requirements of Section 313(f)(2) of EPCRA, and complained that there is nothing in the Preamble that enables EPA or commenters to make an assessment of how far beyond this minimum requirement each of the four options goes. Another commenter noted some of the thresholds EPA has established are unnecessarily low to meet the "substantial majority" test. Others may not meet the test no matter how low EPA makes them. Unless EPA can demonstrate that the new thresholds will satisfy this statutory test, the rule cannot withstand legal challenge.

Response: EPA disagrees with the comments, which appear to be premised on an incorrect interpretation of EPCRA section 313(f)(2). The comments assume that EPA may only lower the thresholds to the level that will obtain a substantial majority of total releases, and no more. This is inconsistent with the plain language of section 313(f)(2), which provides that "such revised threshold shall obtain a substantial majority of total releases of the chemical at all facilities subject to the requirements of this section." This requirement is merely the minimum that any revised threshold shall capture; it does not prohibit EPA from capturing more than the substantial majority of total releases. Thus there is no legal requirement that the Agency determine to what extent it is capturing more than a substantial majority of total releases.

1.e. Consistency and coordination with other EPA actions on PBT chemicals.

Commenter List: C-1421 and C-1865

Comment: Commenters stated that the stated goal of EPA's PBT Multimedia Strategy is to further reduce risks to human health and the environment from existing and future exposure to priority persistent, bioaccumulative, and toxic (PBT) pollutants. The commenters stated that the Multimedia Strategy recommends adding PBT substances to the TRI and lowering reporting thresholds for PBT chemicals as a measure "to track progress in reducing risks from PBT pollutants." The commenter stated that EPA's proposed lowering of EPCRA section 313 reporting thresholds will not provide an adequate measure for tracking progress in reducing risks. The commenters stated that lower reporting thresholds do not serve the goal of identifying and reducing risks from PBT chemicals, they simply require additional reports from facilities that manufacture, process, and use the chemicals. Commenters stated that risk is a function of exposure to a chemical and that EPA's proposal includes no rigorous risk assessment or exposure assessment. The commenters stated that the assumption behind the proposal seems to be that manufacture/process/use is equivalent to release, which is equivalent to exposure, which equates to risk. The commenters stated that this is an incorrect assumption, because exposure is determined by a number of factors including whether manufacture/process/use results in actual release, pathway of release, proximity of humans and organisms to the release, and bioavailability, and that risk should include consideration of toxicity at the level at which exposure occurs.

One commenter stated that EPA does not adequately explain how TRI data will be used to identify or reduce risk, or to track progress in reducing risks and that in fact, TRI data do not provide a useful metric for PBT risks or exposure. The commenter stated that EPA recognizes the availability of human biomarkers data such as the National Health and Nutrition Examination Surveys (NHANES) and studies such as the forthcoming *National Study of Chemical Residues in Fish* and that these are more appropriate measures used to track progress of efforts to reduce risks from PBTs.

Response: EPA disagrees with the commenters' statements. The commenter is mistaken in their interpretation of the statements EPA has made concerning the relationship between the Agency's Multimedia Strategy for PBTs and the tracking of PBT chemicals under EPCRA section 313. EPA has not stated that the information reported under EPCRA section 313 can be used to quantify a reduction in risk. However, the data will indicate whether releases of PBT chemicals are increasing or decreasing, what kinds of releases are occurring, where the releases are occurring, and whether there are new sources of releases. All of this information along with other data the Agency can access will help to determine the risks from PBT chemical releases and whether they are increasing or decreasing. Whatever the risks from PBT releases, if the releases are decreasing, then at some level the risks should also be decreasing, and it is the releases that can be effectively tracked under EPCRA section 313. Even if the TRI data could not be used in a risk assessment for PBT chemicals the data will still be useful since it will indicate what facilities are releasing PBT chemicals, how much is being released, and to what media the releases

are going. This information alone will advance the goals of reducing the risks from PBT chemicals since if the Agency does not know where the releases are coming from and what media they are going to it is very difficult to develop a strategy for reducing the risks from such chemicals. Therefore, EPA believes that the TRI data will advance the goals of the Agency's Multimedia PBT Strategy.

EPA did not assume that manufacture/process/use is equivalent to release, which is equivalent to exposure, which equates to risk. EPA clearly stated that:

“Because all PBT chemicals persist and bioaccumulate in the environment, they have the potential to pose human health and environmental risks over a longer period of time. Thus, even small amounts that enter the environment can lead to elevated concentrations in the environment and in organisms which can result in adverse effects on human health and the environment. The nature of PBT chemicals indicates that small quantities of such chemicals are of concern, which provides strong support for setting lower reporting thresholds than the current section 313 thresholds of 25,000 and 10,000 pounds.” (64 FR 710, column 3)

In order to capture small releases of PBT chemicals the EPCRA section 313 reporting thresholds must be low, this does not imply that EPA has determined that there is a specific risk from the manufacture, processing, or otherwise use of a chemical at these lower reporting thresholds. EPA is well aware that, in addition to release data, there is a great deal of information that must be considered in order to determine the risks associated with the release of PBT chemicals into the environment. However, information on releases and waste management quantities are fundamental to determining where to look for risks and possible ways to reduce those risks. The commenter should understand that if you don't know what is going on with a chemical then it is very hard to determine if there is a risk and how to address it.

Commenter List: C-1865

Comment: C-1865: The commenter stated that EPA's PBT strategy should focus on the highest risk PBT chemicals and identify specific activities to reduce those risks and must not be a pretext for EPA to use any authority that it believes it may have to promulgate additional regulations. The commenter stated that EPA must not automatically lower TRI thresholds for selected chemicals as an "action item" under the PBT strategy.

Response: EPA's Multimedia PBT Strategy is intended to focus on reducing risks from priority PBT chemicals but this is not the sole reason for EPA's proposed lowering of the EPCRA section 313 reporting thresholds for PBT chemicals. While the lowering of the EPCRA section 313 reporting thresholds is associated with the Agency's Multimedia PBT Strategy it is more than just an "action item" for the strategy. Even if the Agency were not developing its Multimedia PBT Strategy, EPA would still have proposed to lower the EPCRA section 313 reporting thresholds for PBT chemicals. As early as 1994, well before the Multimedia PBT Strategy was being developed, EPA asked for comment on this issue. For example, in the proposed rule EPA stated that:

“EPA discussed the issue of reporting on PBT chemicals under section 313 in its January 12, 1994 chemical expansion proposed rule (59 FR 1788) (FRL-4645- 6). In the preamble to the proposed rule, EPA specifically requested comment on whether PBT chemicals should be added to the section 313 list. EPA also asked for comments on what modifications to reporting requirements, such as lowering reporting thresholds or modifying the de minimis exemption, would need to be made in order to insure that release and transfer information would be collected for such chemicals. In response to EPA's request for comments on the reporting of PBT chemicals, 39 commenters responded, with 35 of these commenters fully supporting such reporting under section 313. In addition, of the over 620 comments EPA received on its 1997 proposal to add a dioxin and dioxin-like compounds category, over 520 commenters supported lowering the reporting thresholds for the proposed category. Many commenters also suggested that EPA lower the reporting threshold for all toxic chemicals that persist and bioaccumulate.” (64 FR 692, column 1)

While it would not be inappropriate for EPA to rely on the Multimedia PBT Strategy as a rationale for lowering the

EPCRA section 313 reporting thresholds for PBT chemicals, EPA believes that it is clear that this does not accurately reflect the facts surrounding the issuance of the proposed rule. More importantly, EPA will only lower the reporting thresholds for chemicals if it is determined that they meet the PBT criteria established for EPCRA section 313 and EPA can make the appropriate section 313(f)(2) findings.

Commenter List: C-1457

Comment: The commenter stated that EPA should not adopt any rule dealing with TRI reporting of PBT chemicals until completion of the single, consistent, agency-wide PBT list. The commenter stated that Tom Murray, Chief of the Prevention Analysis Branch of OPPT, announced on March 31, 1999 that EPA will adopt a single, consistent, agency-wide PBT list by the end of 1999 and that this list is anticipated to contain 20 to 25 chemicals.

The commenter stated that chemical compounds and their properties relative to persistence, toxicity and bioaccumulation vary continuously and independently, as noted by EPA in the proposal in 64 FR 692, 699/1 and 703/2. The commenter stated that EPA is in the position of attempting to regulate this continuum of independent PBT properties with a "yes" / "no" regulation. The commenter stated that while there may be some widely held scientific agreements that certain compounds are PBT chemicals and others are not PBT chemicals, there is no clear delineation of those chemical compounds which are found near the border of the two groups. The commenter stated that many different programs in EPA are attempting to regulate different aspects of PBT chemicals and that it is appropriate that EPA adopt a definitive list of PBT chemicals for all of these programs. The commenter stated that such a list will provide consistent information to the general public and the regulated public.

The commenter stated that EPA should delay the promulgation of this rule until the single, consistent, agency-wide PBT list is adopted. The commenter stated that EPA then could promptly issue a NODA with a short comment period, consider the additional comments, and still promulgate this rule in time for the July 1 reporting date. The commenter stated that a well advised delay to develop a single, consistent, agency-wide PBT list would not have any effect on the timing for generating TRI reports to include PBT emissions and that there is no reason not to temporarily hold up this proposal to support the agency-wide PBT effort.

Response: Commenter is correct in stating that EPA is in the process of developing a list of priority PBT chemicals of Agency-wide concern. This list development is a combined effort to finalize a list primarily for the purposes of implementing the Agency's Waste Minimization National Plan (WMNP) and for the purpose of identifying an additional set of PBT chemicals for National Action Plan development under the Agency's Multimedia PBT Strategy. The list will also help the Agency identify important sectors on which to focus general reduction efforts for these and other PBT chemicals. The lowering of the EPCRA section 313 reporting thresholds for PBT chemicals is very much related to these efforts in several ways. First, many of the substances proposed for lower thresholds are already identified in both the PBT Strategy and WMNP. In addition both these efforts will look to TRI as a source of data to both select priority PBT chemicals and to provide a measurement of progress for source reduction. The Agency is also sensitive to the need to articulate consistent criteria for identifying a chemical as a PBT. This Agency-wide list development is also considering persistence and bioaccumulation levels similar to those used for EPCRA section 313. However, the Agency-wide PBT chemical list development effort is not intended to dictate to all EPA programs an exclusive list of PBT chemicals for their activities. While the list will be of cross program derivation, EPA programs may focus on different PBT chemicals depending upon the purpose of their program. Thus, future identification of PBT chemicals for data collection under EPCRA section 313 will be related to, but not necessarily restricted by the establishment of an Agency-wide PBT chemical focus list. Therefore, EPA does not agree that it is necessary to restrict its information gathering under EPCRA section 313 only to those PBT chemicals which have been or will be identified for action under the Multimedia PBT Strategy, nor does the Agency believe that there is any reason to delay the lowering of the EPCRA section 313 reporting thresholds. As discussed elsewhere in this document, the persistence and bioaccumulation characteristics for all of the chemicals subject to the lower thresholds have been independently evaluated against the persistence criteria and bioaccumulation criteria adopted for purposes of EPCRA section 313. The Agency believes that all of the chemicals subject to this rulemaking persist and bioaccumulate at a level sufficient to warrant lowered reporting thresholds and that this action is consistent with the intent and purposes of EPCRA section 313 and not contrary to the Agency's Multimedia PBT strategy.

Comment: The commenter stated that in November, 1998, EPA made available its proposed Multimedia Strategy for Priority Persistent, Bioaccumulative and Toxic Pollutants (63 Fed. Reg. 63926 (Nov. 17, 1998)) and that the title alone is a significant statement of EPA's objective to focus on priority PBT pollutants. The commenter stated that the proposed TRI reporting rule, by contrast, does not focus on priority PBT chemicals but rather establishes a screening process and reporting requirement for a broad universe of chemicals. The commenter stated that insofar as the proposed EPCRA section 313 reporting requirements precede final action on the Agency's comprehensive, multimedia strategy on PBTs, the proposal prejudices the regulatory approach to PBT chemicals under specific statutes.

Response: EPA disagrees with the commenter's assessment of the proposed rule to lower the EPCRA section 313 reporting thresholds for PBT chemicals. The commenter states that the proposed rule does not focus on "priority PBTs" apparently because it includes chemicals which the Agency has not included in its Multimedia Strategy. However, since the strategy has just begun there is no way for the commenter to know whether the other chemicals in the proposed rule may ultimately be included in the Multimedia Strategy. In addition, there is no reason that the TRI list of PBT chemicals should precisely match the list of "priority" PBT chemicals that will ultimately be included in the Multimedia Strategy. The Agency-wide PBT chemical list development effort is not intended to dictate to all EPA programs an exclusive list of PBT chemicals for their activities. While the list will be of cross program derivation, EPA programs may focus on different PBT chemicals depending upon the purposes of their programs. Thus, future identification of PBT chemicals for data collection under EPCRA section 313 will be related to but not necessarily restricted by the establishment of an Agency-wide PBT chemical focus list. The Multimedia Strategy is meant to go well beyond the simple reporting of PBT chemical releases and other waste management data and will attempt to reduce risks associated with a certain set of "priority" PBT chemicals. It may well be that not all of the PBT chemicals identified under EPCRA section 313 will be included in the Agency-wide strategy but that does not mean that these other chemicals are not PBTs that warrant lower reporting thresholds. The lowering of the EPCRA section 313 reporting thresholds is related to the Multimedia PBT Strategy only in the sense that the Strategy will use data collected under EPCRA section 313. However, the lowering of the EPCRA section 313 thresholds is an independent action that would have been taken even in the absence of the Multimedia PBT Strategy and does not in any way determine, mandate, or restrict what regulatory actions may be taken in support of the Multimedia PBT Strategy under other statutes.

Commenter List: C-1421, C-1428, C-1431, C-1431a, C-1433, C-1435, C-1443, C-1815, C-1836, C-1841, C-1844, C-1852, and C-1867

Comment: The commenters stated that EPA should finalize the draft Agency Multimedia PBT Strategy before proceeding with other PBT initiatives including the lowering of reporting thresholds under EPCRA section 313. Commenters were concerned that several EPA programs have developed PBT lists and criteria used that are not consistent and that they are being developed prior to completion of the Agency's Multimedia PBT Strategy. The commenters stated that EPA should use the Multimedia Strategy to develop consistent criteria for the identification of PBT chemicals and develop a single Agency list of PBT chemicals before any program specific actions are taken. Some commenters state that EPA should develop standard PBT criteria for which there is consensus among the scientific community that such pollutants meeting the criteria represent true risks. One commenter stated that the Binational Level I substances identified in the draft Strategy should also be subject to review under peer reviewed PBT criteria.

Response: EPA does not believe that the Agency's Multimedia PBT Strategy must be completed prior to lowering the EPCRA section 313 reporting thresholds for certain PBT chemicals. While the Agency's Multimedia PBT Strategy does include the use of TRI data to help assess progress on the reduction of risks from PBT chemicals, the lowering of reporting thresholds under EPCRA section 313 is not tied to any decisions that are to be made under the Multimedia PBT Strategy. Thus it is not necessary to postpone finalization of this rule the Multimedia PBT Strategy is finalized. In addition, the information collected under EPCRA section 313 will not only be used to help assess the progress of EPA's efforts to reduce the risks from PBT chemicals but it will also help to further refine chemical specific National Action Plans since it will provide information on the sources of PBT chemical releases and the media to which PBT chemicals are being released. Even if EPA did not have a Multimedia PBT Strategy, lowering the EPCRA section 313 reporting thresholds will provide the public and government agencies with important information on the releases and other waste management quantities for PBT chemicals that currently is not available.

As for the comments regarding a single EPA list of PBT chemicals and PBT criteria, EPA is in the process of developing a list of priority PBT chemicals of Agency-wide concern. This list development is a combined effort to finalize a list primarily for the purposes of implementing the Agency's Waste Minimization National Plan (WMNP) and for the purpose of identifying an additional set of PBT chemicals for National Action Plan development under the Agency's Multimedia PBT Strategy. The list will also help the Agency identify important sectors on which to focus general reduction efforts for these and other PBT chemicals. The lowering of the EPCRA section 313 reporting thresholds is very much related to these efforts in several ways. First, many of the substances proposed for lower thresholds are already identified in both the PBT Strategy and WMNP. In addition both these efforts will look to TRI as a source of data to both select priority PBT chemicals and to provide a measurement of progress for source reduction. The Agency is sensitive to the benefits of articulating consistent criteria for identifying a chemical as a PBT. This Agency-wide list development is also considering persistence and bioaccumulation levels similar to those used for EPCRA section 313. However, the Agency-wide PBT chemical list development effort is not intended to dictate to all EPA programs an exclusive list of PBT chemicals for their activities. While the list will be of cross program derivation, EPA programs may focus on different PBT chemicals depending upon the specific purpose of their program. Therefore, EPA does not agree that it is necessary to restrict its information gathering under TRI only to those PBT chemicals which have been, or will be identified for action under the Multimedia PBT Strategy. In addition, future identification of PBT chemicals for data collection under EPCRA section 313 will be related to but not necessarily restricted by the establishment of an Agency-wide PBT chemical focus list.

EPA believes that it has used sound, generally accepted scientific principles, and has relied on much peer reviewed material in establishing the PBT criteria under EPCRA section 313. Any criteria developed under the Agency's Multimedia PBT Strategy will also be based on sound science. As for the inclusion of the Binational Level 1 substances in this rule, each chemical was subjected to an individual assessment to determine if it met the criteria set out in the proposed rule. Thus the fact that a chemical was on the Binational Level 1 list did not automatically mean that it met the criteria for PBT chemicals developed for the purposes of the EPCRA section 313 program.

Commenter List: C-1844, C-1847, and C-1866

Comment: Commenters stated that there are more appropriate regulatory programs to address exposures and risks associated with PBT chemicals than lowering the EPCRA section 313 reporting thresholds. Commenters cited provisions of the Clean Air Act such as MACT rules as well as various provisions of the Clean Water Act, and the Resource Conservation and Recovery Act (RCRA) as programs better suited to the regulation of PBT chemicals.

One commenter stated that TRI data is not related to the potential for human health risks from the reported releases and that the proposed rule further exacerbates what has always been a most troubling aspect of the TRI program. The commenter stated that communicating MACT standards to the public is a more effective vehicle to inform them about PBT emissions since the establishment of the standard communicates that the levels emitted from a complying facility are protective. This commenter stated that RCRA BIF permitting process and MACT standards are clearly more effective in providing the public with meaningful information about PBT releases, the relative risks, and associated controls being implemented. The commenter stated that in contrast the use of the TRI will result in the presentation of raw data to the public likely to create a perception of unacceptable risk where none exists.

Response: EPA does not believe that it is inappropriate to collect additional information on PBT chemicals under EPCRA section 313 or that other regulatory programs can be substituted for the kind of release and other waste management information collected under EPCRA section 313. The commenters are correct that EPCRA section 313 is not risk based and does not directly control risks, but Congress never intended the statute to be risk based or to provide a quantitative determination of, or control over, absolute exposures or risks. What EPCRA section 313 does provide is the type of basic information necessary for the public to understand the potential risks from chemical releases and other waste management activities. Without this basic information, the public and government lack the information to fully understand the potential exposures and risks and whether they are acceptable. Commenter has correctly identified other EPA programs intended to regulate and reduce risks. These programs are not a substitute for the basic release and other waste management information collected under EPCRA section 313. The fact that the information collected under EPCRA section 313 may be incorrectly

perceived by some users of the data is not a reason not to require that this information be provided to the public. Furthermore, the commenter has failed to cite any instances where presentation of TRI data to the public has resulted in confusion or misunderstanding. To the contrary, EPA has information indicating that the public, and others, have successfully understood and used TRI data in the past, and the Agency believes this rule will allow the TRI data to be even more informative and of greater value. (See Ref. 67 of the final rule, Unit 6). EPA makes every effort to ensure that the public understands that the data collected and reported under EPCRA section 313 does not represent a risk determination.

Commenter List: C-1852

Comment: The commenter stated that they were concerned that the “instant” proposal was developed in part based on the criteria of the Waste Minimization Prioritization Tool. The commenter urged EPA to modify the criteria adopted in the proposed rule in accordance with their comments on the WMPT criteria. The commenter provided the following table that they stated compared the WMPT criteria with the proposed PBT criteria for EPCRA section 313.

| | <u>OPPT Criteria</u> | <u>WMPT Criteria</u> |
|--|---|---|
| Persistence (water, soil, sediment) | t1/2 > 6 months (high) t1/2 > 2 months (moderate) days (medium) | t1/2 24 days (high) t1/2 > 5.8 days < 24 |
| Bioaccumulative (BAF or BCF) | > 5000 (high) 1000 (moderate) | 1000 (high) 250 to < 1000 (medium) |

Response: EPA disagrees with the commenter’s statements regarding the relationship between the PBT criteria set out under EPCRA section 313 and the criteria used for the WMPT and the extent to which the proposed rule relied upon the WMPT criteria. As explained in detail elsewhere in these comment responses, the WMPT was only used as preliminary screening tool and was not used to make any decisions in this rulemaking. In addition, the commenter has incorrectly identified the persistence and bioaccumulation criteria set out for EPCRA section 313. The only criteria for a chemical to be a PBT under EPCRA section 313 is that it have a persistence of 2 months or greater and a bioaccumulation potential (BAF or BCF) of 1000 or greater. The 6 months persistence and 5000 bioaccumulation levels were only used to establish lower reporting thresholds and were not the criteria EPA proposed to establish as the general EPCRA section 313 PBT criteria. Although the WMPT criteria are being refined, the comparison the commenter made with the draft criteria is incorrect since a BAF or BCF of 1000 under EPCRA section 313 would equal the highest ranking in the WMPT, which is also 1000. The persistence criteria are also similar with the EPCRA criteria being 2 months and the highest WMPT ranking being 24 days. EPA also takes issue with the commenter’s characterization of the EPCRA section 313 PBT rule as an “instant” proposal. EPA spent considerable time and resources preparing the proposed rule including significant time developing and evaluating the criteria that should be used, developing the support documentation for the proposed rule, and reviewing and considering comments received prior to the issuance of this final rule. The docket for this rulemaking contains considerable support material which clearly shows that EPA did not “instantly” prepare the proposed rule.

Commenter List: C-1420

Comment: The commenter stated that EPA should use non-regulatory voluntary programs to encourage PBT pollution prevention efforts. The commenter also stated that many of the PBT chemicals included in the proposed rule are produced unintentionally as by-products and that others are impurities found in raw materials. The commenter stated that in many cases there are no available substitutes for these raw materials and that products made from these processes include many which have greatly enhanced quality of life and substantially improved human health and safety. The commenter stated that EPA should consider this in moving forward with pollution prevention efforts aimed at PBT chemicals.

Response: While non-regulatory voluntary programs can be very useful they are not the only appropriate tool for addressing

concerns for PBT chemicals. EPA believes that reporting on PBT chemicals under EPCRA section 313 will provide valuable information on releases and other waste management quantities for PBT chemicals that would not otherwise be available from non-regulatory voluntary programs. Many PBT chemicals subject to this rule are unintentional by-products, but that does not mean that the releases and other waste management quantities are not of concern, or that such information should not be reported. Likewise, the fact that there may not be substitutes for some raw materials that contain PBT chemicals as impurities does not mean that the releases and other waste management quantities of PBT chemicals from these raw materials are not of concern, or that reductions in at least certain types of releases cannot be achieved. EPA is aware that many chemicals and chemical processes have enhanced the quality of life, and in some cases improved human health and safety, however, the releases of toxic chemicals, and especially PBT chemicals, are an important concern to communities, the public at large, and the government agencies that are required to control exposures and risks from such toxic chemicals.

Commenter List: C-1429

Comment: The commenter stated that national action plans and strategies for PBT chemical management should be based on risk reduction rather than based on chemical use or volumetric waste generation. The commenter stated that significant risk reduction may be achieved more efficiently by focusing on a few measures designed to address a prioritized list of primary exposures of concern. Commenter stated that an explicit media-specific risk assessment should be completed before an Action Plan or strategy is developed and that in many cases, consideration of cost-effectiveness, engineering feasibility, and environmental benefit and legal constraints must also be evaluated as an Action Plan or strategy is formulated. Commenter stated that a multi-stakeholder approach must be followed to compile the technical, legal, and social data as well as the concerns that an effective Action Plan or strategy must address. Commenter stated that further dialogue through a stakeholder panel could facilitate the development of a coherent risk assessment process which satisfies the needs, responsibilities, and expectations of both public and private parties in the sound management of chemical technologies and requested a continuing dialogue with the EPA on improving the assessment and regulation of PBTs.

Response: The commenter seems to be mainly addressing issues specific to the Agency's Multimedia PBT Strategy such as how to address risks and the need for a dialogue with those impacted by national action plans and strategies. These comments are not specific to the proposed lowering of EPCRA section 313 reporting thresholds and will not be addressed here since there is a separate process for providing comments on the Multimedia PBT Strategy. However, the comments concerning the focus on chemical use or volumetric waste generation appear to refer to the proposed lowering of reporting thresholds for PBT chemicals under EPCRA section 313. The collection of additional information on release and other waste management quantities for PBT chemicals under EPCRA section 313 is not a simple focus on chemical use or volumetric waste generation. The information reported will help to identify and track the releases of PBT chemicals which is an important part of understanding the potential risks from PBT chemicals and how to address those risks, on the local, state and federal level.

Commenter List: C-1421

Comment: The commenter stated that EPA has an inventory of dioxins emissions, and is in the process of completing its assessment of this and other information on dioxins. The commenter suggested that EPA focus on resolving issues associated with existing information, and use the plethora of data that it already has on dioxins. The commenter stated that a targeted collection of information may be deemed appropriate at a later date to fill specific data gaps but that in the meantime, EPA should not go forward with imposing dioxins reporting with such impracticably low reporting thresholds.

Response: Although the Agency has attempted to gather a significant amount of information on dioxin and dioxin-like compounds, the fact remains that there is no data base of facility specific information similar to that which can be collected and compiled under EPCRA section 313. The information collected under EPCRA section 313 will be calculated and provided by each individual reporting facility and will be based on site specific information that is not always available to EPA or the general public. In addition, it has been EPA's experience that TRI data frequently identifies unexpected sources of releases. Nothing in the current reassessment of dioxins, or the existing information EPA has on dioxins, will be a substitute for the EPCRA section 313 data that will be collected pursuant to this action. Therefore, EPA believes that it is appropriate to move forward with the collection of information on releases and other waste management quantities under EPCRA section 313. EPA also disagrees that the dioxin reporting threshold is "impracticably low," and has addressed this issue elsewhere in this document.

Commenter List: C-1433

Comment: The commenter believes that the proposed rule is inconsistent with, and in some instances contradictory to, the overall goal of the Multimedia PBT Strategy to provide uniform, consistent means by which to achieve significant risk reductions, and to utilize limited resources efficiently and effectively to address the presence of PBT chemicals in the environment.

Response: EPA disagrees that the proposal to lower the EPCRA section 313 reporting thresholds for PBT chemicals is in any way inconsistent or contradictory to the goals of EPA's Multimedia PBT Strategy. In fact, EPA has identified the collection of information on releases and other waste management quantities under EPCRA section 313 as an important tool in the overall Multimedia PBT Strategy, since this information will help to identify sources of PBT chemicals as well as track any reductions in releases that may occur. EPA believes that the additional reporting under EPCRA section 313 will also help to focus resources and measure progress. Thus, EPA believes that the lowering of the EPCRA section 313 reporting thresholds for PBT chemicals is part of a uniform, consistent program to reduce the risks associated with PBT chemicals and that the final rule does utilize resources efficiently and effectively.

Commenter List: C-1448

Comment: The commenter stated that after reviewing the criteria developed by various national and international organizations, EPA appears to have chosen the most stringent criteria, on the grounds that the purpose of TRI is to provide communities with "relevant information" on releases "that may present a hazard." The commenter stated that more information is not necessarily more valuable nor more "relevant" to communities. The commenter stated that citizens are likely to infer that releases that EPA deems worthy of reporting must represent real threats to their community and that EPA should take seriously its responsibility for informing, but not alarming, communities. The commenter stated that given the extensive information available to EPA on PBT chemicals, it should ensure that the criteria defined in this rule are consistent with what other EPA offices and other organizations have considered a significant health and environmental risk.

Response: EPA did not select persistence criteria and bioaccumulation criteria simply on the grounds that the purpose of EPCRA section 313 is to provide communities with relevant information on releases that may present a hazard. Although this is certainly a fundamental goal of EPCRA section 313, the criteria chosen were determined to be consistent with the identification of chemicals that persist and bioaccumulate in the environment. The fact that the EPCRA section 313 criteria may be more stringent than criteria established for activities such as severely restricting or banning the use of a chemicals does not mean that the EPCRA section 313 criteria are inappropriate. As discussed elsewhere in these comment responses there is no reason that the persistence criteria and bioaccumulation criteria used for EPCRA section 313 reporting should be consistent with criteria established for identifying chemicals that will have their use severely restricted or banned. Also, as discussed elsewhere in these comment responses, EPA believes that the persistence criteria and bioaccumulation used for EPCRA section 313 reporting are appropriate, and are consistent with the approaches other EPA offices are using to define PBT chemicals of concern.

The commenter is correct that in some instances more information may not necessarily be relevant information, which is the reason EPA has carefully considered the basis for lowering the EPCRA section 313 reporting thresholds for PBT chemicals. As applied to the PBT chemicals subject to this rule, however, EPA disagrees with the commenter's exceptionally general and unsubstantiated claim that more information on the release and other waste management practices of PBT chemicals is not more valuable information, or relevant to the public. As stated throughout this document, the primary objective for this rulemaking is to address one of the most significant gaps in information currently reported under EPCRA section 313 – information on releases and other waste management practices pertaining to PBT chemicals. Addressing this gap will improve the utility of the data on these chemicals and will provide the public, government agencies, and researchers with access to critical information on these chemicals. EPA believes that PBT chemicals have the potential to pose significantly increased exposure to toxic chemicals to local communities, but if the information on the releases and other waste management quantities are not reported there is no way for the public, or local, state, or federal governments to accurately evaluate the extent of releases, or to evaluate the breadth of industry sectors releasing PBT chemicals. Although the commenter indicates

that the additional reporting pursuant to the lowered thresholds mandated for PBT chemicals will serve to “alarm” the public, the commenter fails to cite to any instances where the availability of TRI data has resulted in significant public confusion or alarm. To the contrary, EPA has information indicating that the public and others understand and use TRI data (See Ref. 67 of the final rule), and the Agency believes that this rule will provide comprehensive and significant information on PBT chemicals that hereto has been unavailable. In an effort to inform the public about the release and other waste management of PBT chemicals reported pursuant to this rule, the Agency intends to provide appropriate context for the reporting of PBT chemicals in its annual data release.

Commenter List: C-1845

Comment: The commenter stated that while they agree with many elements of the current TRI proposal for PBT chemicals, they believe that some changes are needed to align this data collection activity more closely with EPA's Multimedia PBT Strategy, and to apply limited national resources in ways that provide maximum benefit in reducing the risks associated with these chemical pollutants. The commenter specifically stated that they are concerned that the current proposal: 1) will fail to provide the comprehensive picture of PBT emissions desired and needed by the public and the government; 2) will discourage rapid development of tailored, national risk management strategies to address individual PBT issues; and 3) will focus both attention and resources on a relatively minor segment of the total population of PBT sources while completely failing to address other significant sources.

Response: While reporting under EPCRA section 313 will not cover all sources of PBT emissions it will capture relevant information from those facilities that are covered. This information along with other information that EPA can access for other sources of PBT chemicals will help to identify other sources of PBT chemical releases. The fact that EPCRA section 313 cannot capture all of the relevant information is no reason not to lower the reporting thresholds; no one mechanism available to EPA is likely to capture all of the emissions of PBT chemicals. This rule, however, is an important step in filling a significant gap in information on the releases and other waste management of PBT chemicals. Part of the Multimedia PBT strategy will be to determine the sources of PBT emissions and that undertaking will include sources other than EPCRA section 313 facilities. EPA disagrees with the commenter's statement that this rule will focus attention and resources on a “relatively minor segment” of PBT sources. Although the rule may not capture data on all sources of PBT chemicals, even small releases of these chemicals are of significant concern to the public. This rule will capture significantly more information about releases of PBT chemicals than is currently reported, and will allow interested parties to identify PBT releases and other waste management practices at the facility level, as well as track patterns of such releases over time. EPA does not understand how any action to lower the EPCRA section 313 reporting thresholds will discourage rapid development of tailored, national risk management strategies to address individual PBT issues. Nor does the commenter provide information particular to this rulemaking adequately demonstrating that this rule will somehow discourage national risk management strategies for PBT chemicals. To the contrary, the lowering of the EPCRA section 313 thresholds will provide a tool for the Agency's Multimedia PBT Strategy, and EPA does not believe there is any reason to conclude that the rule will have a negative impact on the development of national action Plans for PBT chemicals.

Commenter List: C-538

Comment: The commenter stated that they believe that lowering the reporting threshold for PBT chemicals will be a burden to the electric utility industry. The commenter stated that EPA has recently required utilities to sample and report the mercury content of their fuels therefore, lowering the mercury threshold appears to be duplicative. The commenter also stated that the use and disposal of polychlorinated biphenyls (PCBs) is already tightly regulated under the Toxic Substances Control Act (TSCA).

Response: While the lower reporting thresholds may impose some additional burden on electric utilities, EPA believes that this burden will not be significant and that the additional information on PBT chemical releases and other waste management quantities that will be reported will be valuable information. More specific comments on the economic analysis for this rule are addressed elsewhere in these comment responses. The commenter refers to the information collection effort under Section 114 of the CAA that required all coal fired power plants over 25 megawatts to submit to EPA the results of analyses of the mercury content of their coal. A representative sample of these plant, stratified by type of plant and type of coal burned, have been required to perform stack testing to determine the amount (and species) of mercury emitted. The stack testing will allow EPA to

develop a set of emissions factors that can be applied to the mercury in coal analysis to generate mercury emissions for each coal-fired plant. The information collection effort under the CAA required that analysis be performed that power plant operators may not have otherwise performed, and thus will result in more precise emissions estimates than those that could otherwise be provided under EPCRA section 313. As EPA stated in the Federal Register notice (63 FR 50567, September 22, 1998) that announced the information collection for mercury under the CAA:

“The EPA expects that the information requested as part of this effort will only be required for one year. The Agency will shortly propose a regulation to lower the Emergency Planning and Community Right-to-Know Act (EPCRA) section 313 activity thresholds for reporting releases of certain toxic chemicals, including mercury and mercury compounds, to the Toxic Release Inventory (TRI). The EPA plans to begin collecting information on mercury emissions from electric utility steam generating units under the new threshold in the year 2000.

Under EPCRA section 313, facilities are not required to measure their emissions specifically to report to TRI, but may use readily available data (including monitoring data) collected pursuant to other provisions of law. This ICR is authorized by section 114 of the Clean Air Act, which allows EPA to require electric utility steam generating unit owners and operators to perform analyses that they may not currently perform and, therefore, that would provide emissions estimates that may be more precise than those that would otherwise be provided under EPCRA section 313. Facilities that have emissions information gathered through actual emissions monitoring or testing would be required to use the results of such monitoring or testing in compiling their reports under EPCRA section 313. Other facilities would be required to apply the results of the stack testing performed under this ICR (i.e., the publicly available data on coal mercury and the emissions factors developed from those data) to estimates of the mercury content of coal when reporting mercury releases to the TRI.

A final decision has not yet been made as to the new threshold for mercury under EPCRA section 313. If, after providing an opportunity for notice and comment, the EPA decides on a threshold for mercury that omits a significant portion of coal-fired power plants, the EPA may require that information be submitted under section 114 of the Act for additional years. Also, if for any reason, information collection on mercury emissions under the new lower threshold for mercury is delayed beyond the year 2000, the EPA may require the coal sampling, but not the stack testing, beyond one year.” (63 FR 50568, column 3 and 50569, column 1)

Thus, EPA does not believe that reporting for mercury under EPCRA section 313 duplicates the effort under the CAA: EPA does not intend to continue to require plants to submit either the coal analysis or the stack testing data beyond the current information collection request requirements. For the purpose of reporting mercury releases to the TRI, EPA expects coal-fired power plants that do not have monitoring or stack test data for the reporting year to use the emissions factors that EPA will develop and make available to the public in the summer of 2000. The generation of these emissions factors, and any necessary guidance, will serve to further limit the burden this rule imposes on the utility industry. Rather than being duplicative, the CAA information collection effort may result in better, and less burdensome, reporting by facilities under EPCRA section 313. Finally, contrary to the commenter’s statement, the intent and implementation of TSCA and EPCRA are significantly different. Unlike EPCRA, the regulation of polychlorinated biphenyls under TSCA does not provide the public with easily accessible information on releases and other waste management activities for PCBs. Although the use and disposal of PCBs is regulated under TSCA, this rule will provide easily accessible facility specific-information on releases and other waste management-information of importance to the public and significantly different from the type of information available on PCBs under TSCA.

Commenter List: C-1851

Comment: The commenter stated that issues relevant to this rulemaking were raised and discussed in the NACEPT TDR committee meetings, and that the final report of the committee has many suggestions and ideas germane to this proposal that should be addressed by EPA.

Response: EPA does not believe that the suggestions and ideas from the NACEPT TDR committee are directly relevant to this

rulemaking. However, EPA is considering the merits of the ideas and suggestions contained in the committee's report and will be determining whether any of these ideas and suggestions should be adopted. Comments received on the various burden reduction options discussed in the proposed rule are addressed elsewhere in these comment responses.

Commenter List: C-1870

Comment: The commenter stated that EPA has been involved in a number of Agency and international initiatives aimed at reducing risks associated with PBT chemicals and that none of these activities and programs has identified cobalt or vanadium as PBT chemicals. The commenter stated that the determinations and findings of these activities are consistent with the scientific knowledge on cobalt and vanadium, and their physical properties, and confirm that neither chemical should be included on a list of PBT chemicals for purposes of EPCRA section 313 reporting. The commenter states that an EPA decision to include cobalt and compounds or vanadium and compounds on a list of PBT chemicals for purposes of EPCRA Section 313 reporting would be inconsistent with the prior determinations of EPA and international bodies. The commenters stated that such a decision would further confuse, rather than inform, community residents about the relative risks associated with common industrial chemicals.

Response: The fact that cobalt or vanadium are not listed as PBT chemicals under other activities and programs does not mean that they should not be classified as PBT chemicals under EPCRA section 313. These other activities and programs have different purposes and criteria and do not automatically indicate that vanadium or cobalt cannot be considered PBT chemicals. However, comments specific to cobalt and cobalt compounds are not being addressed at this time since EPA is not making any final determination on the classification of cobalt and cobalt compounds as PBT chemicals in the final rule. EPA is deferring this decision until the Agency has time to evaluate all of the technical issues that the commenters have raised concerning the bioaccumulation data for cobalt. If EPA decides to move forward with the classification of cobalt and cobalt compounds as PBT chemicals in accordance with the EPCRA persistence criteria and bioaccumulation criteria, all of the comments on this issue, and received by the Agency, will be addressed. In addition, although EPA did include vanadium and vanadium compounds in its list of PBT chemicals, the Agency did not propose to lower the EPCRA section 313 reporting thresholds vanadium and vanadium compounds. Rather, EPA asked for comment on the sufficiency of the bioaccumulation data for vanadium and vanadium compounds.

1.f. Data accuracy issues

Commenter Numbers: C-1406, C-1407

Comment: The commenters assert that the TRI database has begun to be used as an implementation and tracking tool in a number of programs outside EPCRA section 313. However, they argue that the existing TRI database and Form R are not currently designed to collect and manage the types of data required by many of these programs. They recommend that the Agency undertake a concerted effort to integrate the TRI database with all other state and federal databases before requiring more data and adding generator burden. They contend that properly managing the data it already has would enable the Agency to gather significant information regarding permitted PBT chemical releases to air, water, and land which are below existing TRI reporting thresholds. One commenter (C-1406) cites permitted releases under the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, and the Toxics Substances Control Act as existing regulatory programs from which the Agency could gather information regarding actual measured releases. They contend that EPA could then identify where the data gaps exist. They support their contentions by citing to a GAO report that states: "[a]lthough EPA and the states collect a considerable amount of data, the agency's data systems are often outmoded and difficult to integrate in order to produce comprehensive environmental information." (United States General Accounting Office, "Major Management Challenges and Program Risks: Environmental Protection Agency," January 1999. (GAO/OCG-99-17)). Another commenter (C-1407) argues that the data submitted under other programs typically are more thorough and accurate than TRI data and therefore are more appropriate to: (1) Provide a complete profile of toxic chemical releases and other waste management activities; (2) compile a broad-based national data base for determining the success of environmental regulations. They contend that the existing information provided under TSCA, for PCBs provides better information than that which would be provided under the rule. The commenter believes that because the information acquired as a result of this rulemaking will likely be redundant or less

accurate than information already provided, the rule appears to conflict with EPA's data quality management strategy. They argue that another example which highlights this issue was provided by EPA in the proposal. EPA has submitted an information collection request to OMB for coal analysis data. This information would allow emissions estimates that may be more precise than those that would otherwise be provided under rule. Further, they argue that the inconsistencies between data reported under other statutory requirements and EPCRA are already causing confusion for data users. Any additional inconsistencies contribute to the data quality problems, rather than improving data quality.

Response: EPA disagrees with the commenters' assertion that EPA could obtain the type of information it will collect under this rule by simply gathering data from other EPA maintained databases. In the past, EPA has carefully analyzed existing sources of release information and has consistently found that none of these, either separately or taken together, can adequately substitute for the TRI program. As explained in the 1997 final rule that requires seven new industries to report under EPCRA section 313:

EPA maintains several other data bases that are designed to support the enforcement and compliance efforts of the Agency's major program offices. Existing data sources include the Aerometric Information Retrieval System (AIRS), the Permit Compliance System (PCS), the Biennial Reporting System (BRS), and the Tier I and II reports submitted under sections 311 and 312. However, these alternate data sources do not provide an adequate substitute for the information reported to TRI, nor do they create the same incentives to implement pollution prevention measures that TRI does. Currently available non-TRI sources of information cannot provide release and transfer, inventory, or pollution prevention data with the scope, level of detail, and chemical coverage as data currently included in TRI. (62 FR 23833; at 23881)

the final rule at (62 FR 23834, May 1, 1997) and the Response to Comment document (ref. 15 in the final rule) supporting that rule for a decision on this topic.

only specific example provided by these commenters, outside the databases discussed in the above quotation, was information collected under TSCA. However, the regulation of polychlorinated biphenyls (PCBs), as well as other PBT chemicals that are subject to the Toxic Substances Control Act, does not provide the public with information on releases and other waste management quantities.

In addition, EPA disagrees that the Information Collection Request EPA has submitted to the Office of Management and Budget under the CAA is an appropriate substitute for this rulemaking. The information collected under the CAA effort will only be required for a limited time and the data generated can be used to prepare better estimations for reporting under EPCRA section 313. As EPA stated in the Federal Register (63 FR 50567, September 22, 1998) that announced the information collection for mercury under the CAA:

The EPA expects that the information requested as part of this effort will only be required for one year. The Agency will shortly propose regulation to lower the Emergency Planning and Community Right-to-Know Act (EPCRA) section 313 activity thresholds for reporting releases of certain toxic chemicals, including mercury and mercury compounds, to the Toxic Release Inventory (TRI). The EPA plans to begin collecting information on mercury emissions from electric utility steam generating units under the new threshold in the year 2001.

Under EPCRA section 313, facilities are not required to measure their emissions specifically to report to TRI, but may use readily available data (including monitoring data) collected pursuant to other provisions of law. This ICR is authorized by section 114 of the Air Act, which allows EPA to require electric utility steam generating unit owners and operators to perform analyses that they may currently perform and, therefore, that would provide emissions estimates that may be more precise than those that would otherwise be provided under EPCRA section 313. Facilities that have emissions information gathered through actual emissions monitoring or testing would be required to use the results of such monitoring or testing in compiling their reports under EPCRA section 313. Other facilities would be required to apply the results of the stack testing performed under this ICR (i.e., the publicly available data on coal mercury emissions factors developed from those data) to estimates of the mercury content of coal when reporting mercury releases to the TRI.

A final decision has not yet been made as to the new threshold for mercury under EPCRA section 313. If, after providing an opportunity for notice and comment, the EPA decides on a threshold for mercury that omits a significant portion of

coal-fired power plants, the EPA may require that information be submitted under section 114 of the Act for additional years. Also, if for any reason, information collection on mercury emissions under the new lower threshold for mercury is delayed beyond the year 2000, the EPA may require the coal sampling, but not the stack testing, beyond one year.” (63 FR 50568, column 3 and 50569, column 1)

Thus, EPA does not believe that reporting for mercury under EPCRA section 313 duplicates the effort under the CAA since it will only be collected for a limited time and will not require each facility to estimate all of their releases and waste management quantities. Rather than being duplicative, the CAA effort may result in better reporting by facilities under EPCRA section 313. Therefore, EPA does not believe there is another EPA source from which to obtain this release and other waste management information on toxic chemicals.

Finally, regarding the commenter’s concern about inconsistencies of data between the various environmental statutes, these inconsistencies are often directly related to the fact that other authorities have different criteria and different purposes. As explained in the preamble to the proposed rule:

Many are aimed at supporting environmental decisionmaking and standard setting with community involvement in these processes. The thresholds established under EPCRA section 313 are designed to meet the statutory requirements of the Act as well as the overarching goal of informing the public about chemical releases and other waste management practices in their communities. Other EPA statutes such as the Clean Water Act (CWA), the Clean Air Act (CAA), and Resource Conservation and Recovery Act (RCRA) also have information collection provisions, whose criteria, coverage, scope and purpose maybe different from that of EPCRA section 313. (64 FR 712)

In addition EPA is investigating ways to integrate TRI data with RCRA, CAA, and CWA information to provide more comprehensive environmental information.

Commenter Number: C-1407

Comment: One commenter asserts that in the proposal EPA states that: It has been EPA’s goal, under the EPCRA section 313 program, to maintain a balance between community right-to-know and overall reporting burden for the affected industry. Yet, they argue, EPA omitted any discussion of the efforts the Office of Information Management currently has underway to better compile data from existing sources and make it more available to the public and how this proposal fits into that strategy. The commenter contends that this action by OPPT appears to conflict with not only the goals of this new office, but also goals set forth by EPA for improved data quality and environmental information management overall.

Response: EPA disagrees that any action taken under the PBT rulemaking is inconsistent with the activities occurring as part of the Agency’s efforts in the Office of Information Management (now called the Office of Environmental Information). Aside from the fact that the TRI Regulation Development Branch which develops TRI regulations is a part of this new office, all EPA rulemakings undergo interagency review to ensure that activities performed by one part of the Agency are not inconsistent or redundant with other parts of EPA.

Commenter Number: C-1815, C-1847, C-1431a, C-1847

Comment: The commenters contend that drastically lowering the reporting thresholds for a small subset of toxic chemicals is contrary to EPA’s characterization of TRI as a “neutral yardstick.” One commenter (C-1815) first argues that the TRI database contains a limited set of data, reported from a limited set of sources and that the majority of U.S. toxic releases and potential sources, are not included in the database. Thus, they contend, the TRI data overstates the role of reporting facilities in emissions of covered chemicals. Second, this commenter asserts, the TRI data are made available to the general public without context being provided. As a result, the general public is misled about the meaning and value of TRI data. A “complete” profile of emissions, they contend, is simply not available through the TRI database, particularly for those emissions

(such as PBTs) where the majority of releases come from non-TRI sources. Third, they argue, the changes in the PBT rulemaking will affect the Agency's guidance for reporting under the TRI, and which further impact the TRI as a "neutral yardstick." For example, EPA's past guidance on reporting "non-detects" at half the limit of detection is not appropriate at the lower thresholds proposed for PBTs. Unless the guidance is revised, there is a likelihood that PBT emissions will be overstated and thus less valuable as a source of reliable emissions data. Another commenter (C-1421) argues that with lower thresholds, elimination of *de minimis*, and different reporting rules for a small subset of EPCRA section 313 toxic chemicals, release numbers for these chemicals will not be comparable with release numbers for other chemicals. They argue that trends will be artificially distorted, because release "increases" may appear simply as a result of lower thresholds and different rules. They also contend that there is inadequate justification for targeting this subset of chemicals. The commenter believes that changes made to the TRI program should improve the consistency and management of the program, not simply serve to target chemicals which EPA is addressing at the moment. One commenter (C-1847) argues that the Agency has not demonstrated how the information collected on PBT chemical releases will be communicated to - or will benefit - the public. The commenter believes that the rule will render the TRI database even less useful and provide an even more blurred picture of reality. Another commenter asserts that the rule will lead the public to believe that the major emitters of PBT chemicals are only those sources required to report their emissions, that is facilities included in the covered SIC codes that are also subject to a MACT rule or other requirement for which they monitor PBT chemical emissions. It is quite possible, however, that the major sources of PBT chemicals will not be required to report at all. They argue that this may attach a stigma to those facilities working to reduce PBT chemical emissions while falsely implying that other sources with potentially higher emissions do not emit PBT chemicals at all.

Response: EPA disagrees with the implication by the commenters that simply because EPCRA section 313 may not capture all the sources of releases of PBT chemicals, EPA should not attempt to capture more information from the facilities that do report under EPCRA section 313. This comment has been voiced in every major rulemaking under EPCRA section 313 but, as EPA has stated in the past, this is not an argument that EPA believes should restrict any efforts to collect additional data under EPCRA section 313. The mere fact that for some chemicals significant release sources are not captured does not in any way diminish the importance of the information that can be provided by those facilities that are required to report under EPCRA section 313. The TRI data base consists of the most comprehensive data base of release information. However, Congress never envisioned that TRI would capture all releases -- for example, volatile organic chemicals (VOCs) cause the formation of tropospheric ozone which causes adverse respiratory effects, including asthma. EPA has made determinations pursuant to EPCRA section 313(d)(2)(B) and (C) that these chemicals meet the statutory toxicity criteria. EPA realizes that significant releases of VOC are from mobile sources including cars and trucks. These emissions are not covered by EPCRA section 313. However, EPA believes that the public has a right to know about releases of these chemicals from factories. The fact that cars are not subject to EPCRA section 313 does not diminish the value of the information reported by facilities. For those chemicals that do have large release sources not captured under EPCRA section 313, EPA will use whatever additional data it has to assist the Agency in actions that might be taken under the Agency's PBT strategy or other EPA PBT related programs and will not rely solely on the data collected under EPCRA section 313. In addition, if there are significant sources of PBT chemicals that are not reported under EPCRA section 313, EPA will attempt to let the public know that some sources are not captured. In fact, in the most recent TRI data release documents, EPA has been providing information to the public on other sources of releases for certain EPCRA section 313 chemicals. In addition, EPA will continue to improve and augment public information materials so that users of the data will have information available to put in context the releases and other waste management of PBT chemicals by industries reporting under EPCRA section 313 versus those industries that do not report under EPCRA section 313. Further, in attempts to provide a more "complete profile" of toxic chemical releases, EPA has undertaken a number of actions to increase the information available to the public on toxic chemical releases. These include 1) the expansion of the toxic chemical list by over 300 chemicals in a number of actions -- the most recent being the addition of 286 toxic chemicals in 1994, 2) the expansion of the list of industry sectors that must report to TRI, and 3) today's action to lower the reporting thresholds for PBTs. EPA will continue to evaluate the information that is available to the public and will determine if the TRI should be further expanded to provide a fuller picture of toxic chemical releases.

EPA understands the commenters concern but does not believe this is a justification for not collecting additional information about PBT chemicals. In fact, rather than an argument against lowering the reporting thresholds for PBT chemicals, EPA believes that the argument the commenters are making is one that supports expanding the types of facilities that should be required to report under EPCRA section 313 and not an argument that supports denying the public the right to know about PBT chemical releases from EPCRA section 313 covered facilities. In addition, EPA is considering adding industry sectors that are known to produce relatively large quantities of PBT chemical emissions such as medical waste incinerators to the list of

industries covered under EPCRA section 313.

EPA also disagrees with the commenters' assertion that the data will be presented without the appropriate context. EPA will continue to improve its annual public data release as well as its outreach and education efforts to assist users in understanding the data. It is also EPA's intention to make sure that the data on dioxin and dioxin-like compounds that will be collected under EPCRA section 313, will be presented in the context of what EPA knows about all of the potential sources of these chemicals.

Finally, as EPA explained elsewhere in these responses to comment, EPA's general guidance on the use of one half of the detection limit is intended to apply to circumstances when, based on its site-specific knowledge about its processes, a facility knows that a reportable chemical is present but that the detection method being used is not sensitive enough to detect the chemical. This discourages facilities from using insensitive detection methods just to avoid reporting under EPCRA section 313.

Commenter Number: C-1430, C-1450, C-1431a, C-1858

Comment: These commenters assert that the lower reporting thresholds proposed by EPA fail to fulfill the need for "information," as expressed in the rule. They argue that the low thresholds unreasonably assume that companies are capable of providing accurate and meaningful estimates of releases at such low levels. They contend that the lowered reporting thresholds will result in some numbers that are unnecessarily conservative such as for mercury and not founded in a risk-based evaluation of necessary reporting levels. Another commenter (C-1430) asserts that any TRI release data on the processing or use of hexachlorobenzene, or any other inadvertent byproduct, likely will be inaccurate and misleading. They further argue that most processors and users have limited information on trace PBT microcontaminants that may be present in their raw materials. Such companies might be motivated to file reports anyway to avoid possible enforcement for failure to report. Information reported under such circumstances is likely to be inaccurate and of no value to the TRI program.

Response: EPA disagrees. Since the program's inception, facilities have never been required to perform any additional monitoring or testing to comply with EPCRA section 313. However, as explained elsewhere in this document, pursuant to EPCRA section 313 (g)(2), facilities are required to use readily available data in making threshold determinations and release and other waste management calculations. For example, if facilities have monitoring data, they are required to consider it. Further, EPA believes that it is no more likely that covered facilities will have monitoring or testing data for toxic chemicals at the higher thresholds than they have for PBT chemicals at the lower thresholds. EPA also believes that in some instances, estimates may be more accurate than monitoring data. As EPA explains in the *1998 EPCRA Section 313 Questions and Answers* document, if covered facilities believe that monitoring data are not properly representative and they have other information which would contribute to more accurate reporting, the facility should use that other data. (See Q&A # 469)

In addition, EPA believes that there are several sources of high quality guidance concerning low concentrations of PBT chemicals available to covered facilities to help them make threshold determinations and release and other waste management calculations. For example, EPA has published guidance documents for the regulated community (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade associations provide guidance documents to their members (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). In addition, many facilities have access to the Internet to find relevant information. For example, the United States Geological Survey's U.S. Coal Quality Database which contains information about toxic chemicals contained in coal from across the country, has been made available on the Internet. (<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>)

Further, contrary to implications of the commenters' statements and as explained elsewhere in these responses to comment, EPCRA section 313 does not require that EPA consider risk-based evaluations in determining reporting levels. EPCRA section 313(f)(2) addresses revisions to the reporting thresholds. It does not require EPA to establish prior to the lowering of reporting thresholds, that releases at a particular threshold will result in specific quantitative risks. That section expressly provides that the Administrator may establish a threshold amount for a toxic chemical different from the 25,000 pound threshold for manufacturing and processing activities and the 10,000 pound threshold for otherwise use activities. The only prerequisite for revising the reporting threshold for a toxic chemical is that the revised threshold must obtain reporting on a substantial majority

of total releases of the chemical at all facilities subject to reporting.

Finally, EPA disagrees with the commenters assertion that covered facilities will or should overestimate and misreport the quantities of chemicals present to protect themselves from liability. Overestimating releases and other waste management quantities will result in information that is as misleading as information based on underestimating releases and other waste management quantities. For ten years, the TRI database has been a key tool in providing information to the public on release and other waste management quantities of toxic chemicals. Further, based on their best readily available information, facilities should report what they believe to be the most accurate amounts of releases and other waste management. As EPA has explained in guidance, facilities are instructed to document their reasoning and calculations when making estimates for threshold determinations and release and other waste management calculations. (See Q&As 470 and 472-474 in the 1998 *EPCRA Section 313 Questions and Answers* document (EPA 745-B-98-004)) These records are what EPA inspectors review for enforcement actions. Just as inspectors may enforce against facilities that deliberately under-report, they may also enforce against facilities that deliberately over-report. Therefore, given that facilities should report as accurately as possible and that facilities are increasingly encouraged to reduce their release and other waste management quantities, EPA does not believe that liability concerns provide a real incentive to covered facilities to over-report these quantities.

In addition, the commenter does not explain why the reporting of “inadvertent” byproducts will be misleading. If these are released into the environment, there is no less of a release because they are “inadvertant”. They will exhibit the same toxicity, persistence and bioaccumulation potential whether they are inadvertant or intentional byproducts or impurities.

Commenter Number: C-1825

Comment: One commenter argues that when establishing thresholds, EPA must consider that data uncertainty will increase as the threshold gets lower. What appears to be more information from reporters may be as much misinformation as information.

Response: The commenter does not provide information to support thier contention. EPA disagrees that the lower the threshold the greater the data uncertainty. Smaller numbers are not inherently inaccurate. Following the commenter’s logic, chemicals with thresholds at 25,000 or 10,000 pounds can be measured the most accurately, PBT chemicals, with thresholds at 10 or 100 pounds can be measured less accurately and dioxins, which have reporting thresholds of 0.1 gram would be very inaccurate. However, dioxins can be measured fairly accurately. Dioxin and dioxin-like compounds can be measured at concentrations as low as parts per trillion. Thus, the commenter’s assertion is incorrect.

Commenter Number: C-1457

Comment: The commenter contends that misleading the public about dioxin chemical exposure risks which do not exist has the danger of discrediting all of the TRI reporting scheme. While conservative assumptions have their place in various programs, they contend that the public is not scientifically sophisticated. They further assert that erroneously raising concerns which are later found to be based on faulty assumptions has the potential to significantly erode the perceived reliability and usefulness of the whole TRI reporting scheme. It is better to ensure the public that the TRI report is accurate, and that all the dioxin emissions reported actually occurred. There is no creditable halfway position with accuracy.

Response: TRI data provide the public with information on releases and other waste management quantities. As discussed elsewhere in this document, TRI data, in themselves, do not, nor are they intended to provide the public with quantitative information on risk. Therefore, the TRI data cannot mislead the public about risks associated with dioxins. EPCRA section 313(h) identifies various audiences for TRI data. These include the public, researchers, and governments. The level of scientific sophistication within these groups will vary. Congress did not direct the Agency to limit the chemicals covered, industries covered, or modifications of the thresholds based on varying scientific sophistication. EPA believes that any assumptions that are made by the users of the data, regardless of their level of sophistication, will not undermine the credibility of the database as a whole.

Commenter Number: C-1448

Comment: A reviewer of the TRI data cannot easily ascertain whether the “release” reflects responsible management and recycling, emissions allowed by regulation, or accidental spills. The inventory certainly offers no insight into whether the benefits of a chemical outweigh the potential risks due to exposure. Thus, even if the quality of the TRI data was high, data on quantities of certain chemicals, without any insight into the different toxicities or the risks they may pose, may serve to misinform and mislead communities about potential health and environmental risks.

Response: The potential risk that releases of a toxic chemical may pose are not mitigated if the release is allowed by regulation or if it is an accidental spill. One hundred pounds of a permitted release from a facility will present the same potential risk as one hundred pounds of an accidental release, *all other things being equal*. In addition to his misunderstanding about risk, the commenter is also unfamiliar with Congress’s intent in developing TRI. As Representative Edgar, one of the authors of EPCRA stated in the House of Representatives debate on the Conference bill:

With respect to the contents of the toxic release form, estimates of releases into each environmental medium must be provided. This shall include any releases to the air, water, and land, as well as releases from waste treatment and storage facilities. This shall include all releases of toxic chemicals into surface waters whether or not such releases are pursuant to the Clean Water Act permits (132 Cong. Rec. H9561, October 6, 1986).

The intent of Congress was not to bifurcate the information on toxic chemical releases into two types of releases. The intent of Congress was to provide information on all releases from facilities. As stated in EPCRA section 313(h), the intent of EPCRA is simply to provide “the Federal, State and local governments and the public, including citizens of communities surrounding covered facilities” with information on toxic chemical releases “to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, and standards.” Certainly one possibility is that governments and/or communities may determine based on TRI data and other factors that releases allowed by regulation may be too high.

Further, Congress directs EPA to add a chemical to the EPCRA section 313 list of toxic chemicals if the chemical meets the EPCRA section 313(d)(2) toxicity criteria. Specifically, the chemical can be added if it causes acute toxicity to humans, or if it causes cancer or any one of a number of non-cancer chronic effects or if it causes environmental toxicity. The toxicity criteria are not based on relative toxicity, nor does Congress direct EPA elsewhere in EPCRA to convey information on relative toxicity or to modify the TRI data based solely on the relative inherent toxicity of the toxic chemical.

Throughout his comments, the commenter consistently states that the intent of EPCRA is to provide risk information and that this information should be risk-benefit based. As discussed at length elsewhere in this document, the TRI data, in themselves, are not intended to convey risk information nor are they intended to reflect a risk-benefit analysis as other statutes, such as FIFRA, require. See FIFRA section 2(bb). Thus, TRI data do not inform the public about potential health and environmental risks because TRI data, in themselves, do not provide this information. However, TRI data can be used with other factors, e.g., the toxicity of the chemical, the physical/chemical properties of the chemical, site-specific factors, to estimate potential risk.

Commenter Number: C-1448

Comment: Information has both a quantity and quality dimension. Inaccurate or partial information can be worse than no information at all. Since TRI data are self-reported and not checked for accuracy on an ongoing basis, it is difficult to determine the accuracy of the inventory.

Response: The commenter is incorrect in his statement that the TRI data are not checked. EPA sends out notices of technical error (NOTE), notices of significant error (NOSE) and notices of non-compliance based on errors that the Agency finds

in the submitted Form Rs. (See Appendix C, pp. C-8 to C-11 in the Toxic Chemical Release Inventory Reporting Forms and Instructions: Revised 1998 Version February 1999, EPA 745-K-99-001) for a list of the errors which trigger these notices. Further, in preparation for the annual release of the TRI data, EPA assesses the quality of the data reported by the facilities that report the largest year to year increases and decreases of releases and production-related waste. Further, EPA has conducted a number of data quality site surveys to assess the quality of the data. The most recent are "1994 and 1995 Toxic Chemical Release Inventory: Data Quality Report" (EPA-745-R-98-002) and "1996 Toxic Release Inventory: Data Quality Report" (EPA-745-R-98-016). These recent reports indicate that for the industry sectors studied the facilities' estimates were very close to the surveyors' estimates. For example, the survey of the 1996 data indicated agreement of ± 3 .

Commenter Number: C-1448

Comment: The commenter states that EPA has conducted two data quality reviews of TRI reporting, which suggested significant errors in reported releases. They also contend that, despite extensive outreach, guidance documents, built-in error checking, and electronic reporting that have evolved between 1987 and 1995, the reporting accuracy has not improved. EPA should extend this examination to determine whether reports are more accurate for larger facilities or larger releases. The commenter describes the recent (for the 1994, 1995, and 1996 data) Data Quality Site Survey reports (discussed in the comment above), but does not reference these documents to support their contention that the TRI data are inaccurate. Rather, they reference reports from 1989 and 1990.

Response: The commenter cites several results from a statistical study conducted to assess the comparative impact of various real and "paper" changes on the TRI data between 1989 and 1990. The commenter provides no reason for citing changes in reporting that occurred 10 years ago near the beginning of the TRI program, but it is apparent that the commenter selectively chose statistics to support the position that TRI does not provide reliable information on inter-temporal and inter-facility trends.

The commenter fails to note that "estimation technique changes" accounted for only 3 percent of the net change in TRI releases and transfers between 1989 and 1990: a relatively small percentage. "Other factors" accounted for 48 percent of the net change in TRI releases and transfers between 1989 and 1990, but almost half of this change is attributable to the modification of the single chemical listing for ammonium sulfate. Other real (as opposed to "paper") reasons for changes in the "other factors" category include accidental releases, one-time releases, and increased recycling (EPA, "1991 Toxics Release Inventory – Public Data Release." 1991, p. 163).

The commenter also fails to note that production change was the most frequently cited reason for reported emissions changes. Nearly 70 percent of facilities contacted cited "production change" as responsible for at least part of their reported release/transfer change, and it accounted for a larger share of total net changes than "estimation technique changes." Furthermore, "source reduction" was cited as a reason for change by 40 percent of facilities. Source reduction accounted for 45 percent of the net change TRI releases and transfers between 1989 and 1990 (EPA, "1991 Toxics Release Inventory – Public Data Release." 1991, p. 163).

A less selective examination of the results of the study indicate that changes in reported releases and other are far more likely to be the result of real changes in facility operations such as the changes in production, source reduction activities, recycling, and accidental or one-time releases. "Estimation technique changes" are a relatively small contributor to inter-temporal or inter-facility trends, and when the change in the listing for ammonium sulfate is disregarded, "other factors" are more likely to be associated with real facility-level events that change actual releases and transfers of toxic chemicals.

Further as discussed above, the "1994 and 1995 Toxic Chemical Release Inventory: Data Quality Report" (EPA-745-R-98-002) and "1996 Toxic Release Inventory: Data Quality Report" (EPA-745-R-98-016) indicate that for the industry sectors studied the facilities' estimates were very close to the surveyors' estimates. For example, the survey of the 1996 data indicated agreement of ± 3 .

Commenter Number: C-1448

Comment: The commenter claims that information on chemical releases and other waste management activities may confuse rather than inform. The commenter cites the following example:

How does information on the pounds of certain chemicals emitted from certain facilities, even if it were perfectly accurate, advance an individual's knowledge of the potential risks he faces by living near those facilities? Consider the alarm that might be engendered by the revelation that a plant near one's home emitted quantities of the following toxic, and potentially carcinogenic, chemicals: acetaldehyde, benzaldehyde, caffeic acid, d-limonene, estragole, and quercetin glycosides. Informed citizens might demand that the facility minimize or prevent the use and release of these chemicals. In fact, these chemicals occur naturally and are likely to be found on a fresh fruit platter of apples, pears, grapes, and mangos.

Response: EPA disagrees with the commenter's underlying assumption that the public needs to be "protected" from *information* on toxic chemicals, as opposed to the toxic chemicals themselves. The commenter offers no evidence or examples to support the assumption that "informed citizens" are unable to evaluate data on toxic chemicals that are released by facilities to the air, water, or land of a surrounding community. Part of the commenter's scenario of alarm and confusion appears to be based on the fact that certain chemicals have unfamiliar, multi-syllabic names. EPA does not share the commenter's low opinion about the intelligence of the public or the ability of the public to process information on chemicals. For example, the public is able to process information on prescription drugs, which typically are synthetic chemicals. EPA does not believe that the use of a chemical name, in itself, will scare the public. Further, as discussed elsewhere in this document, the commenter does not appear to be familiar with the intent of EPCRA section 313 or with the intended audience for TRI data. The intended audience includes Federal, state and local governments, researchers and the public in communities surrounding facilities subject to EPCRA section 313 (see section 313(h)). There are varying levels of technical sophistication within and among these groups. However, even if the targeted audience is unsophisticated, this does not mean that this audience does not have a right to information on releases of toxic chemicals in their environment.

EPA believes that the commenter's comments reflect the level of sophistication that the commenter attributes to the public. The commenter notes that acetaldehyde, benzaldehyde, caffeic acid, d-limonene, estragole, and quercetin glycosides are components of fruit and implies that, thus, they are all innocuous. The first chemical in the commenter's list is acetaldehyde. While acetaldehyde is present in fruit, which humans eat rather than inhale, acetaldehyde has been shown to cause adverse effects via the inhalation route. Specifically, acetaldehyde is classified as a probable human carcinogen (B2) because it caused an increased incidence of nasal tumors in male and female rats and laryngeal tumors in male and female hamsters after inhalation exposure. In addition, acetaldehyde causes some non-cancer adverse effects via inhalation exposure (see Integrated Risk Information System: Acetaldehyde, CASRN 75-07-0 at <http://www.epa.gov/iris/subst/0290.htm> for a description of both the carcinogenicity and the non-cancer adverse effects induced by acetaldehyde). Clearly, acetaldehyde is not as innocuous as the commenter suggests. EPA believes that it would not be unreasonable of the public to want to further investigate the releases of acetaldehyde, particularly the 12.7 million pounds that were released to air in 1997 (12.6 million were released in 1996; 13.2 million were released in 1995).

In addition, in reference to the ingestion of fruit containing acetaldehyde, the commenter ignores the vast difference in scale between the acetaldehyde that occurs naturally in fruit and that released by facilities reporting to TRI. Acetaldehyde has been identified as a natural constituent of fruits in amounts ranging from 0.0005 to 230 ppm (Feron, V.J., et al., "Aldehydes: occurrence, carcinogenic potential, mechanism of action, and risk assessment" in *Mutation Research*, 259 (1991), 363-385). Therefore, a fresh fruit platter weighing 1 kilogram (2.21 pounds) might contain 115 mg (0.00025 lb) of acetaldehyde, assuming an average concentration of 115 ppm. By contrast, in 1996 the average annual amount of acetaldehyde released per TRI-reporting facility was 52,000 pounds (13 million lbs / 250 facilities). To reach this amount of acetaldehyde, the fresh fruit platter mentioned by the commenter would have to weigh 460 million pounds. Finally, EPA notes that the TRI data base includes releases on chemicals that meet the toxicity criteria of EPCRA section 313(d)(2). While the chemicals included in today's action and acetaldehyde meet these criteria, the other chemicals mentioned by the commenter that are components of fruit are not listed on TRI. Therefore, the public will not receive data on these chemicals.

Finally, EPA does not believe that TRI may "misinform and mislead communities about potential health risks." EPA is

very clear in communicating the limitations of TRI data in the annual public data release and other venues. With respect to risk, EPA recognizes that TRI reports reflect releases and other waste management activities. The determination of potential risk depends on many additional factors, including the toxicity of the chemical, the fate of the chemical after it is released, and the human or other populations that are exposed to the chemical after it is released. The commenter misunderstands the purpose of TRI data. As discussed at length elsewhere in this document, the TRI data, in themselves, do not convey risk information. Nevertheless, as discussed in the economic analysis, many users have found TRI data to be a useful input. Although additional information is necessary to assess exposure and risk, TRI data can be used to identify areas of potential concern. Furthermore, TRI data, in conjunction with other information, can be used as a starting point in evaluating exposures that may result from releases and other waste management activities of toxic chemicals.

2. GENERAL TECHNICAL COMMENTS

2.a. Relationship of the Rule to EPA and International programs on PBT Chemicals

Commenter Number: Delphi (C-1407); American Forest and Paper Association (C-1428); American Industrial Health Council (AIHC) (C-1429); Pentachlorophenol Task Force (C-1430); Chemical Manufacturers Association (C-1815); Rohm and Haas (C-1825); Eastman Chemical (C-1841); OxyChem (C-1844); PPG Industries (C-1845); Halogenated Solvents Industry Alliance, Inc. (C-1852)

Comment: Chemicals which are globally recognized as persistent bioaccumulative toxics should form the foundation of the EPCRA PBT list and criteria. The application of the criteria in this manner is consistent with several existing international agreements and programs, such as the Great Lakes Binational Strategy, the North American Commission on Environmental Cooperation (NACEC), the U.N. Economic Commission for Europe's (UNECE) agreement to address persistent organic pollutants (POPs), and the United Nations Environmental Programme (UNEP). These programs have prompted widely accepted numerical values for persistence and bioaccumulation and defined parameters for assessing toxicity. These criteria have also been adopted with U.S. support and leadership and it is not clear why EPA is now taking a vastly different approach to identifying PBT criteria in this proposed rule. The commenters suggest that EPA conform the criteria for PBTs on EPCRA section 313 with the criteria and chemicals that are part of the programs being implemented by the NACEC, UNECE, and UNEP. By doing so, EPA would harmonize the U.S. program with similar international programs that focus on a narrow set of PBT chemicals.

Response: EPA believes that it would be inappropriate to merely adapt the criteria for persistence and bioaccumulation and the list of chemicals considered to be PBTs under EPCRA section 313 to the criteria and list of chemicals managed under the international programs cited because the purposes of TRI are different the purposes of the cited international programs. The TRI was established by Congress under EPCRA section 313 in response to public demand for information on toxic chemicals being released in their communities. The TRI is national in scope, but the overriding goal is to provide information on releases to communities so that they can determine if the releases result in potential risks and to reduce risk for communities as a whole. The entire concept of TRI, and indeed other, similar pollutant release and transfer registries (PRTRs) since established in several nations, is founded on the belief that the public has the right to know about chemical usage and release in the areas in which they live, as well as the hazards that may be associated with these chemicals. This emphasis is fundamentally different from the global focus of the UNEP negotiation and residual risk. It is EPA's position that the domestic, community-based focus of TRI has important implications with regard to the criteria used to identify toxic chemicals as persistent and/or bioaccumulative, as well as the methods and models used to evaluate persistence and/or bioaccumulation.

Purpose of EPCRA section 313

EPCRA section 313 charges EPA with collecting and disseminating information on releases, among other waste management data, so that communities can estimate local exposure and local risks. The intent of EPCRA section 313 is to provide information to the public so that they can take an active role in determining what risks resulting from toxic chemicals releases in their community are acceptable. This basic local empowerment is a cornerstone of the right-to-know program.

EPCRA section 313(h) states that

The release forms required under this section are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available, consistent with section 11044(a) of this title, to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes.

EPCRA section 313 establishes an information collection and dissemination program. EPCRA section 313 requires that a facility use the best available information to prepare each chemical-specific TRI report. The statute does not require that the facility conduct monitoring or emissions measurements to determine these quantities. A facility must only estimate, to the best of its ability, the quantitative information it reports.

The purpose of EPCRA section 313 is not to ban the manufacture or use of a chemical, to restrict releases of the chemical or to dictate how it should be used or released. As a result, the burden and control EPCRA section 313 imposes is significantly less than that imposed by a statute that controls the manufacture, use, and/or release of a chemical. The focus of EPCRA section 313 and TRI is not equivalent to the focus of a statute or international agreements in which chemicals are to be banned, phased-out, or restricted.

Purpose of International Agreements Cited by Commenters

In contrast to EPCRA section 313, which is an information collection and dissemination program, the international agreements cited by the commenters are intended to ban, restrict, or phase-out the manufacture, use and/or release of a limited set of persistent organic pollutants and certain heavy metals that are highly persistent and highly bioaccumulative. Descriptions of the purposes of the Protocol on Persistent Organic Pollutants (POPs); Convention on Long-Range Transboundary Air Pollution (LRTAP), United Nations Economic Commission for Europe (UNECE), United Nations Environmental Programme on POPs, North American Commission for Environmental Cooperation's Sound Management of Chemicals (NACEC SMOC), as well as the International Council of Chemical Associations' position on POPs are presented below. The following quotes clearly illustrate that the intent of the international agreements is narrowly focused on that subset of toxic chemicals which are of regional (e.g., North America, Europe) or global concern.

UNECE LRTAP

The ultimate objective is to eliminate any discharges, emissions and losses of POPs. The Protocol bans the production and use of some products outright (aldrin, chlordane, chlordecone, dieldrin, endrin, hexabromobiphenyl, mirex and toxaphene). Others are scheduled for elimination at a later stage (DDT, heptachlor, hexachlorobenzene, PCBs). Finally, the Protocol severely restricts the use of DDT, HCH (including lindane) and PCBs. The Protocol includes provisions for dealing with the wastes of products that will be banned.

(The 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs); Convention on Long-Range Transboundary Air Pollution, United Nations Economic Commission for Europe (UNECE) at http://www.unece.org/env/env_eb.htm)

UNEP

International action to protect health and the environment through measures which will reduce and/or eliminate emissions and discharges of persistent organic pollutants, including the development of an international legally binding instrument

(Governing Council Decisions 20/24, 1999; United Nations Environmental Programme at <http://irptc.unep.ch/pops/newlayout/negotiations.htm>)

NACEC SMOC

NACEC SMOC has developed action plans for PCBs, DDT, chlordane, and mercury. The action plans include 1) for PCBs "work toward the virtual elimination of PCBs in the environment, which the task force is interpreting

as no measurable release to the environment”, 2) for DDT “gradual reduction of DDT use for malaria control” and “additional reductions,” 3) for chlordane “phase-out of chlordane use”, and 4) for mercury “reduce sources of anthropogenic mercury pollution.” The longer-term goal of the plan is to reduce the presence of mercury in the environment to achieve naturally occurring levels.”

(North American Cooperation for the Sound Management of Chemicals (June 1998); North American Commission for Environmental Cooperation at http://www.cec.org/english/profile/coop/Pollute_f.cfm?format=1)

ICCA

ICCA Position: ICCA member associations have demonstrated their commitment to sound chemicals management, and to the goal of reducing the potential human health and environmental risks that may be associated with POPs. Many POPs are already subject to considerable voluntary risk management by chemical companies, and the uses of most substances identified as POPs has been discontinued or extremely limited by chemical companies within the countries represented by ICCA member associations.

(International Council of Chemical Associations (ICCA) Briefing Note on Persistent Organic Pollutants (POPs) (April 21, 1998) at <http://www.icca-chem.org/issues.htm>)

In addition as directed under EPCRA section 313(h), EPA makes the TRI data available to various groups, including international organizations, that in turn, use the information to decide whether to ban, restrict, or phase-out chemicals. EPA disagrees with the assertion that only substances globally recognized as persistent organic pollutants (POPs) should provide the basis of persistence criteria for this rulemaking. POPs are organic chemicals whose characteristics of persistence in the environment, accumulation in biological organisms and toxicity make them priority pollutants which result in significant environmental risks to humans and ecosystems. The substances or substance categories being considered for implementation of global controls through the UNEP negotiations (UNEP/GC.18/32, 1995: DDT, dieldrin, aldrin, endrin, chlordane, heptachlor, mirex, toxaphene, hexachlorobenzene, PCBs, polychlorinated dibenzo-p-dioxins and furans)(1,1a) were selected largely because they or their degradation products pose risks that may occur far from their sites of initial entry into the environment. The UNEP action is the global counterpart to similar, regional negotiations, most notably the UNECE Convention on Long-Range Transboundary Air Pollution (LRTAP)(2); the North American Free Trade Agreement (NAFTA) CEC Initiative on the Sound Management of Chemicals (3); and the bilateral US/Canada agreement to control discharge or release of POPs in the Great Lakes basin (4). A central theme of the UNEP action, consistent with its global scope, is the notion of *residual risk*, meaning specifically that to be subject to the negotiations, it is not sufficient for a substance to pose risks within a nation or regionally, rather it must pose risks to populations and nations distant from release sites.

2.b. Persistence, Bioaccumulation and Toxicity criteria: development; definition

Commenter Number: C-1407, C-1421, C-1428, C-1433, C-1429, C-1430, C-1441, C-1455, C-1815, C-1822, C-1836, C-1841, C-1844, C-1845, C-1852, C-1860, and C-1865

Comment: The same commenters state that EPA should use the international criteria being applied by UNEP, UNECE LRTAP, NACEC SMOC, for persistence, bioaccumulation, and toxicity. Some of these commenters also include the criteria developed by CMA [CMA, PTB Policy Implementation Guidance: Product Risk Management Guidance for PTBs (February, 1996)]. One commenter includes the criteria developed by International Council of Chemical Associations (ICCA) for POPs. One commenter states that there is no reason to adopt criteria that are significantly more stringent than those used in other programs. One commenter states that EPA should consider the degree of toxicity and focus on the most toxic chemicals. Some commenters state that EPA should couple the persistence and bioaccumulation criteria to each other.. They believe that these criteria should not be considered independently. The numerical criteria presented by some of the commenters are provided below:

| | CMA PTB Policy 1/ | NACEC SMOC 2/ | UNECE (LRTAP) POPs 3/ | UNEP POPs/CEG FRAMEWORK 4/ | Environment Canada Toxic Substances Management Policy (June 1995) | ICCA 5/ |
|-----------------|---|---|---|---|---|--|
| Persistence | Half-life = 6 months in water or 1 year in soil | half-life \geq 2 days air; 6 mos. water/soil; or 1 yr. sediment | half-life $>$ 2 mos. water or 6 mos. soils/sediment; or otherwise sufficiently persistent to be of concern. | half-life $>$ [2 or 6] mos. soil/sediment; or other evidence that substance is sufficiently persistent to be of concern. | half-life \geq 2 days air; 6 mos. water/soil; 1 year sediment | Half-life = 6 mo. water, 1 yr soil sediments, or 5 days air. |
| Bioaccumulation | BAF/BCF \geq 5000 or estimation techniques | BAF/BCF \geq 5000 or LogKow \geq 5 | BAF/BCF $>$ 5000 or LogKow $>$ 5 or factors such as high toxicity | BCF/BAF $>$ 5000 or LogKow \geq [4 or 5]; evidence that substance with significantly lower BCF/BAF is of concern, e.g., due to high toxicity/ecotoxicity; or monitoring data in biota indicating sufficient bioaccumulation to be of concern. | half-life $>$ 2 mos. water or 6 mos. soils/sediment (or otherwise sufficiently persistent to be of concern) | BCF $>$ 5000 or log LogKOW $>$ 5 and $<$ 7.5, MW $<$ 700 and substance is not metabolized |
| Toxicity | Professional judgment in evaluation of aquatic toxicity, wildlife toxicity, oral/dermal/inhalation toxicity (mammals and birds), reproductive toxicity, neurological toxicity; carcinogenicity, mutagenicity, | Acute and chronic (including toxicity of breakdown products, if appropriate). | Potential to affect human health and/or the environment adversely. | Evidence that [chronic] toxicity or ecotoxicity data indicate a potential for damage to human health or the environment caused by the substance resulting or anticipated from long- | CEPA - toxic | Expert judgment that acute aquatic lethality, subchronic and chronic aquatic toxicity, acute wildlife toxicity, oral/dermal/inhalation toxicity in mammals and birds, carcinogenicity, mutagenicity, teratogenicity, |

| | | | | | | |
|--|---------------------------|--|--|---------------------|--|--|
| | and/or teratogenicity. | | | range transport. | | reproductive toxicity, neurological toxicity, and immune system effects must be demonstrated or expected to occur at the concentrations observed in the environment. |
|--|---------------------------|--|--|---------------------|--|--|

Response: EPA proposed criteria for the TRI program for persistence and bioaccumulation. EPCRA section 313(d)(2) provides toxicity criteria. While EPA chose in this rulemaking to focus on chemicals that are toxic and persistent and bioaccumulative, EPA did not state that the persistence criteria could only be applied in conjunction with the bioaccumulation criteria and vice versa. EPA did not tie the criteria together because there was no scientific rationale to define persistence criteria in terms of both bioaccumulation and persistence and to define bioaccumulation both in terms of persistence and bioaccumulation. As illustrated by the descriptions of persistence and bioaccumulation provided in the proposed rule, persistence and bioaccumulation are separate chemical and/or biological processes. They are not by definition dependent upon the other.

A chemical's persistence refers to the length of time the chemical can exist in the environment before being destroyed. (64 FR 698)

and

Bioaccumulation is a general term that is used to describe the process by which organisms may accumulate chemical substances in their bodies. (64 FR 703)

A chemical is not considered to be persistent only if it is bioaccumulative. For example, a chemical may be extremely persistent and yet not bioaccumulate appreciably. One example is metals. Metals cannot be destroyed in the environment and thus are extremely persistent. Some metals bioaccumulate appreciably while others do not. However, the degree to which a metal can bioaccumulate does not affect the metal's persistence in the environment. The connection suggested by the commenters is not scientifically justified. Thus, EPA does not believe that for purposes of EPCRA section 313 toxic chemicals, that persistence criteria can be applied only in conjunction with the bioaccumulation criteria. EPA reiterates that in this rulemaking, the Agency chose to focus on those toxic chemicals that meet both the persistence and bioaccumulation criteria proposed for EPCRA section 313.

A discussion of the individual criteria is presented below.

Persistence

EPA proposed as persistence criteria for the TRI program half-lives of 2 months in water, soil, and sediment and 2 days in air. EPA disagrees that it must choose for EPCRA section 313, an information collection and dissemination program, persistence criteria consistent with the criteria being applied to chemicals that are of global or regional (e.g., Europe, the Great Lakes) concern and that are being targeted for ban, restriction, or phase-out. Chemicals that meet the persistence criteria used in the international agreements are highly persistent chemicals. Applying these criteria to EPCRA section 313 would result in a very narrow list of chemicals that would focus on only the most persistent chemicals. This is inconsistent with the tenets of right-to-know which is to provide communities with information on toxic chemicals that may cause adverse effects in their community. There is no “bright line” that separates what is persistent from what is not persistent. The degree of persistence is a continuum. Chemicals with a half-life of 2 to 6 months are not non-persistent. They are less persistent than chemicals with a half-life of greater than 6 months. The degree of persistence that should be used as criteria is not an absolute science determination. Rather it is a combination of science and policy. As discussed in the proposed rule and below, organizations have generally used as persistence criteria half-lives of 2 months and/or 6 months for water, soil, and sediment. The determination of which set of numerical criteria to apply will depend on the final intent: for example, providing communities with information on persistent chemicals that can build up in their environment vs. banning the manufacture and use and eliminating releases of a chemical that has global impacts. For EPCRA section 313 which provides information on toxic chemicals to communities, the criteria should be in keeping with both science and the intent of the statute.

Long-range transport (LRT) and residual risk are relevant domestically, since chemical substances may be transported regionally and trancontinentally, resulting in exposures at sites distant from releases but still within US borders. Nevertheless, as a general rule the closer are source and receptor, the more likely it is that released material will reach that receptor. The 12 UNEP POPs or their degradation products all meet or exceed the half-life criterion of 6 months for soil, water or sediment, often by large margins (1,1a), and the 6-months criterion thus acts to isolate these substances for international attention aimed at limiting LRT. But a shorter half-life criterion is necessary to protect communities from bioaccumulative toxicants derived from sources closer to home, since, all other things being equal, a pollutant reaches nearby populations in less time than distant ones.

An article by Wania and Mackay (5) is often cited in discussions of “global distillation” of relatively mobile POPs such as lindane and hexachlorobenzene, which tend to have inverted concentration profiles such that concentrations increase with distance from the source (i.e., from temperate to polar regions) rather than the reverse. What may be less obvious is that the converse is also true; namely, that less volatile substances show no significant latitudinal dependence; that low-mobility POPs such as mirex and the more highly chlorinated PCBs tend to undergo *rapid deposition and retention* close to their sources; and that all but high or relatively high mobility chemicals are expected to show “normal” concentration profiles, such that concentrations decline with distance from warm source to colder remote regions (5). A recent study of organochlorine contaminants in sea otters illustrates this point. Although the levels of total DDTs observed were not considered toxicologically significant, Bacon et al. (5a) found the highest levels in California sea otters (ca. 850 ug/kg) but much lower levels in Aleutian otters (40 ug/kg) and southeast Alaska otters (1 ug/kg), and attributed the higher levels in the California otters to extensive DDT use and production in this region from the 1950s to the 1970s. Even UNEP’s Criteria Expert Group (CEG), which is charged with developing criteria and procedures for addition of substances beyond the original 12 POPs, has highlighted the importance of “near-field” exposures:

“In warmer climates exposures may occur closer to the source; e.g., occupational exposure during use, or local exposure caused by runoff from use or leaking from stockpiles. Food, such as fish, may be a major route of intake also in warmer climates [in contrast to Arctic and sub-Arctic regions] and POPs may accumulate in the food chain and reach high levels in predatory species in these conditions.” (UNEP/POPS/INC/CEG/1/2: 1998)(6)

An additional factor that argues for adopting the more protective persistence criterion is the need to provide information to different *subgroups*, which may be more highly exposed than the general population. Examples of such populations include toddlers who play in contaminated soil, local farmers who consume their own produce, and subsistence as well as sport fishers, who often consume large quantities of what they catch. The relative importance of any of these pathways depends on the properties of the substance, rates and media of release and other factors, but ingestion of bioaccumulating substances may

occur by all of these routes. Organization for Economic Cooperation and Development (OECD) guidance on the assessment of indirect human exposure to chemical toxicants is consistent with EPA policy, and states that in the case of local, site-specific emissions, one or more of these subgroups may be particularly endangered (8).

From a scientific perspective there is no one best persistence criterion. However, it is simply not accurate to state that there is no precedent or basis for using a persistence criterion of 2 months. As outlined in the proposed rule, similar values have been proposed by several authorities, including the Ontario, Canada Ministry of Environment and Energy (MOEE) for its *Candidate Substances List for Bans or Phaseouts* (9); the Canadian initiative for Accelerated Reduction/Elimination of Toxics (ARET)(10,11); the International Joint Commission's (IJC) Great Lakes Water Quality Agreement (GLWQA)(12); and the UNECE's LRTAP Convention, which did adopt 2 months as the persistence criterion of record for water (2). In each of these programs the focus was on persistent, bioaccumulative and toxic substances (PBTs), and it is noteworthy that all are national or regional, not global, in scope. Thus, a trend exists in which authorities with domestic or regional mandates to take action to reduce risks from indirect exposure to PBTs have recommended half-life criteria substantially lower than 6 months.

EPA's Office of Water maintains a Listing of Fish and Wildlife Advisories (LFWA) for the US and territories, which listed 2,299 advisories in 1997 (13). US states and territories and Native American tribes have primary responsibility for issuing advisories for the general population, which include recommendations to limit or avoid consumption of certain fish and wildlife from specific water bodies. The overwhelming majority of the advisories are for well-recognized PBTs (mercury, PCBs, chlordane, etc.), but many less familiar substances are also represented. The number and content of advisories in LFWA clearly indicate that toxicologically significant levels of chemical contaminants, specifically PBTs, are often found in fish and wildlife that are caught noncommercially and consumed by the US population. It is generally impossible to determine the exact source(s) of exposure for the species and locations included in any given advisory, but it seems highly unlikely that the majority of listed contaminants in US waters could be derived from non-US (i.e., geographically distant) sources. The LFWA thus lends further support to the contention that concern for exposure to PBTs is not limited to situations where the exposure results primarily from LRT.

A series of Toxic Substances Control Act (TSCA) section 5 Premanufacture Notifications (PMNs) submitted to EPA in 1990 illustrates this (14,15), and also demonstrates (i) why EPA believes that the persistence criterion for bioaccumulating substances in soil, water or sediment should be set substantially lower than 6 months; and (ii) that for purposes of EPCRA section 313, concern for potential exposures to persistent and bioaccumulative toxics must extend beyond the UNEP's 12 widely acknowledged POPs. The substances in question were alkylated diphenyls for use as solvents, and for which EPA expected discharge to receiving streams and rivers. The submitter supplied data on use and disposal, aquatic toxicity and biodegradability. The submitted environmental fate data and EPA estimates of biodegradability based on structural analogs suggested that half-lives in water would be well below 6 months, but not necessarily lower than 2 months. As a result of concerns expressed by EPA, use was limited to sites where resulting water concentrations could be limited to 1 microgram per liter or less; concomitantly, the submitter was also informed of EPA's belief that a potential for *long-term risk* existed, but that EPA could not quantify this risk since assessments typically evaluated releases over only one year. In 1998 results of monitoring were announced by the state EPA and revealed that the alkylated biphenyls had been found in fish fillets and sediment samples from the receiving stream. Measured bioconcentration factors (BCFs) exceeded EPA's criterion for identifying a substance as a Bioaccumulative Chemical of Concern (BCC)(16).

For the reasons given above, EPA reaffirms its intention to use 2 months as the half-life criterion for persistence in water, soil and sediment.

EPA did not use 6 months as the half-life criterion for persistence in water, soil, and sediment for EPCRA section 313. However, for purposes of setting reporting thresholds, the Agency did choose to focus on the subset of TRI-PBT chemicals that have half-lives greater than 6 months (and BCF/BAF greater than 5,000) by proposing a 10 pound reporting threshold.

Bioaccumulation

EPA proposed as bioaccumulation criteria for the TRI program bioaccumulation/bioconcentration factors of 1,000. EPA

disagrees that it must choose for EPCRA section 313, an information collection and dissemination program, bioaccumulation criteria consistent with the criteria being applied to chemicals that are of global or regional (e.g., Europe, the Great Lakes) concern and that are being targeted for ban, restriction, or phase-out. Chemicals that meet the bioaccumulation criteria used in the international agreements are some of the most bioaccumulative chemicals. Applying these criteria to EPCRA section 313 would result in a very narrow list of chemicals that would focus on only the most bioaccumulative chemicals. This is inconsistent with the tenets of right-to-know which are to provide communities with information on toxic chemicals that may cause adverse effects in their community. There is no "bright line" that separates what is bioaccumulative from what is not bioaccumulative. The degree of bioaccumulation is a continuum. Chemicals with a BCFs or BAFs of 1,000 to 5,000 are not non-persistent. They are less bioaccumulative than chemicals with BCF/BAF greater than 5,000. The degree of bioaccumulation that should be used as a criterion is not an absolute science determination. Rather it is a combination of science and policy. As discussed in the proposed rule and below, organizations have generally used as bioaccumulation criteria BAFs/BCFs of 1,000 and 5,000. The determination of which numerical criterion to apply will depend on the final intent: for example, providing communities with information on bioaccumulative chemicals that can accumulate in organisms vs. banning the manufacture and use and eliminating releases of a chemical that has global impacts. For EPCRA section 313 which provides information on toxic chemicals to communities, the criteria should be in keeping with both science and the intent of the statute.

From a scientific perspective there is no one bioaccumulation criterion. However, it is simply not accurate to state that there is no precedent or basis for using a bioaccumulation criterion of 1,000. As noted in the proposed rule, EPA has for a number of years used a BCF of 1,000 or more to indicate a high level of concern for bioaccumulation. In addition, this value has been used in some Canadian projects, many dealing with the Great Lakes basin. Also, Germany proposed a BAF/BCF criterion of 1,000 in negotiation of the LRTAP Protocol. Support for a BAF criterion of 1,000 also comes from the Final Water Quality Guidance for the Great Lakes System (60 FR 15366). In this document, EPA stated that bioaccumulation of persistent pollutants is a serious environmental threat to the Great Lakes Basin Ecosystem and that chemicals identified as bioaccumulative chemicals of concern (BCCs) (i.e., BAF values greater than 1,000) would receive increased attention and more stringent controls. That final guidance designated as BCCs those chemicals with human health BAFs greater than 1,000 that were derived from certain field-measured BAFs. Also, as noted by some commenters, EPA has proposed to use a BCF/BAF of 1,000 to trigger testing under TSCA section 5(e) (63 FR 53417). Specifically, for chemicals subject to TSCA section 5 that have a bioaccumulation factor of 1,000 or greater and that meet certain toxicity and persistence criteria (similar to the EPCRA section 313 persistence criteria) testing would be "triggered" by specific production limits. While the manufacturer of the chemical would be allowed to commercialize the substance, certain controls could be stipulated, including specific limits on exposures, releases, or uses. EPA notes that in the same Federal Register notice, the Agency has proposed that chemicals that have a bioaccumulation factor of 5,000 and that meet certain toxicity and persistence criteria (e.g., half-life of 6 months or greater in soil) be placed in a "Ban Pending Testing," bin. Chemicals meeting these criteria could be subject to more stringent control up to a ban on commercial production.

Not only is there precedent for the use a bioaccumulation factor of 1,000, EPA believes that the purposes of the statute argue for the use of the more expansive criterion. Data on PBT chemicals is the type of information that will be of particular use to specific communities such as those that consist of subsistence fishers. Subsistence fishers (as well as sports fishers) are more highly exposed to PBT chemicals than the general population. Subsistence fishers consume large quantities of what they catch. In addition, children are affected by lower doses of certain PBTs than adults are. Children of both subsistence fishers and sport fishers will consume larger quantities of lake- and seafood than children in other communities. As discussed above in the section on persistence criteria, EPA's Office of Water maintains a Listing of Fish and Wildlife Advisories (LFWA) for the US and territories, which listed 2,299 advisories in 1997 (13). The overwhelming majority of the advisories are for well-recognized PBTs (mercury, PCBs, chlordane, etc.), but many less familiar substances are also represented. The number and content of advisories in LFWA clearly indicate that toxicologically significant levels of chemical contaminants, specifically PBTs, are often found in fish and wildlife that are caught noncommercially and consumed by the US population. EPA believes that it would be inconsistent with the intent of EPCRA section 313 to limit the information on bioaccumulative toxic chemicals to only information for the most bioaccumulative.

For the reasons given above, EPA reaffirms its intention to use a BCF/BAF of 1,000 as the criterion for bioaccumulation.

Toxicity

EPCRA section 313 provides toxicity criteria at section 313(d)(2) to be used in adding a chemical to the EPCRA section 313 list of toxic chemicals. To delete a chemical from the EPCRA section 313 list the Agency must show that the chemical does not meet any of the EPCRA section 313(d)(2) criteria. These criteria are:

- (A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.
- (B) The chemical is known to cause or can reasonably be anticipated to cause in humans -
 - (i) cancer or teratogenic effects, or
 - (ii) serious or irreversible -
 - (I) reproductive dysfunctions,
 - (II) neurological disorders,
 - (III) heritable genetic mutations, or
 - (IV) other chronic health effects.
- (C) The chemical is known to cause or can reasonably be anticipated to cause, because of -
 - (i) its toxicity,
 - (ii) its toxicity and persistence in the environment, or
 - (iii) its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

Given that Congress has provided EPA with specific toxicity criteria and that chemicals that EPA has determined meet these criteria are statutorily defined as "toxic chemicals," the Agency does not believe that additional "toxicity" criteria would be appropriate. One reason is that the Agency is concerned that this would imply that TRI data on the toxic chemicals that meet the statutory toxicity criteria are of less value than TRI data that meet both the statutory toxicity criteria and the additional toxicity criteria that would be developed by EPA. EPA believes that bifurcating the list would be inconsistent with the intent of Congress. In addition, it is worth noting that some of the toxicity criteria presented by the commenters are fundamentally consistent with the toxicity criteria outlined in the statute. However, EPA notes that some of the criteria provided by the commenters are risk criteria rather than hazard criteria (For example, see International Council of Chemical Associations (ICCA) Briefing Note on Persistent Organic Pollutants (POPs) (April 21, 1998)). As discussed at length in the final rule adding 286 chemicals to the EPCRA section 313 list (November 30, 1994; 59 FR 61432), the EPCRA section 313(d)(2)(B) toxicity criteria (chronic toxicity) are hazard criteria not risk criteria. The EPCRA section 313(d)(2)(C) criteria are primarily hazard based with only a limited exposure component. To impose additional toxicity criteria for purposes of defining a PBT or a PT or PB chemical based on risk rather than hazard would be inconsistent with EPCRA section 313. Risk assessment may be appropriate for use under statutes that control the manufacture, use and/or release of a chemical. However, EPCRA section 313 is an information collection provision that is fundamentally different from other environmental statutes that control or restrict chemical activities. For these reasons, EPA believes that it is inappropriate to add toxicity criteria, in addition to the criteria provided by Congress at EPCRA section 313(d)(2).

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2.c. Additional Persistence Comments/Responses

Commenter Number: Delphi (C-1407); General Electric (C-1421); American Forest and Paper Association (C-1428); American Industrial Health Council (AIHC) (C-1429); Pentachlorophenol Task Force (C-1430); Chlorobenzene Producers Group (C-1433); Mercatus Center at George Mason (C-1448); Chemical Specialties Manufacturing Association (C-1455), Chemical Manufacturers Association (C-1815); Eli Lilly and Company (C-1822); Rohm and Haas Company (C-1825); Eastman Chemical (C-1841); OxyChem (C-1844); PPG Industries (C-1845); Halogenated Solvents Industry Alliance, Inc. (C-1852); Rubber Manufacturers Association (C-1860); American Petroleum Institute (C-1865); Brominated Flame Retardant Industry Panel of the Chemical Manufacturers Association (C-1919)

Comment: If EPA insists on using the 2 months criterion for designating substances as persistent, this will create confusion because the US will be unable to focus attention on genuine PBT risks. Confusion will be created even at the local level in community-based programs.

Response: EPA disagrees with the comment. A chemical need not meet certain persistence or bioaccumulation criteria in order for it to present a risk to humans or the environment. Whether a chemical poses a risk is dependent upon a number of factors, including the level at which the chemical induces toxicity (i.e., dose level), the environmental fate of the chemical including the degree to which it persists in the environment, the degree to which the chemical bioaccumulates, release patterns, local meteorological patterns. Thus, the commenter is incorrect in stating that if EPA uses the 2 months criterion for persistence that it will be unable to focus on "genuine" PBT "risks." Further, substances of potential concern are not limited to those with half-lives exceeding 6 months in soil, water or sediment. Therefore, it is not at all clear that, as implied by the comment, only the most highly persistent substances are "genuine PBTs."

As outlined in the above response to comments, risks resulting from exposure to PBTs may occur at sites distant from the sites of release, but populations closer to release sites may also be exposed, and exposures of certain subpopulations (e.g., consumers of locally caught fish and wildlife) may be even higher than for the general population. The tendency of a substance to bioaccumulate in exposed organisms depends on its rate of release relative to its rate of removal from the environment, in addition to its physical properties and other factors. In principle, it follows that even substances with degradation half-lives lower than 2 months can bioaccumulate given a sufficiently high rate of release to the environment and proximity of the exposed population. Indeed, several EPA programs (Office of Pesticide Programs' criteria for requiring bioaccumulation testing in support of pesticide registration for aquatic uses (1); chemicals of priority concern under the Clean Air Act Amendments of 1990 (2); chemicals listed as bioaccumulative chemicals of concern in the Office of Water's Bioaccumulation White Paper (1)) have recommended persistence criteria of one month or lower as indicative of potential risk. EPA reiterates its belief that 2 months represents a reasonable compromise. Thus, EPA believes given the purposes of TRI that 2 months is the appropriate criterion to use to identify EPCRA section 313 chemicals that are "persistent".

Alternatively, the commenter may be arguing that the "genuine PBT risks" that EPA should consider for TRI should be limited to those from PBTs that meet the criteria suggested by the commenter. As discussed in detail above, EPA does not believe that this is appropriate for TRI.

One or more commenters even claimed that use of the 2 months persistence criterion would cause confusion in implementing Community-Based Environmental Protection Programs (CBEPs), but offered no evidence to support this contention. To the contrary, community-based concerns are at the core of the right-to-know concept, and as demonstrated above, the more inclusive 2 months criterion is necessary to address the very exposures that are most relevant to these

populations.

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2. ICF Incorporated. 1991. Focus chemicals for the Clean Air Act Amendments Great Waters Study. Report prepared for the USEPA Office of Air Quality Planning and Standards. Draft, 15 August 91.

Commenter Number: Ohio Environmental Council (C-1355), Atlantic States Legal Fund (C-1451), Ecology Center (C-1454), Environmental Defense Fund (C-1855), Physicians for Social Responsibility (C-1932)

Comment: EPA's proposed persistence criteria are too weak. EPA should designate *all* substances that meet the lower proposed criterion for persistence in soil/water/sediment (2 months) as persistent for rule purposes.

Response: Although the comment seems to address persistence criteria, it actually concerns the process by which chemicals were selected for inclusion in the rule (64 FR page 692). This conclusion is based on the facts that, except for one commentor (Physicians for Social Responsibility), the commentors are not suggesting that EPA use a still *lower* criterion than the one already proposed (2 months); whereas in applying this criterion, EPA has been selective and has not included all possible substances that are either on EPCRA section 313 list of toxic substances already or may meet the EPCRA section 313(d)(2) toxicity criteria, and are or may be PBTs. However, the proposed rule does state that if a given chemical was not included, this does not necessarily mean that EPA has reached a final conclusion regarding that chemical's propensity to persist or bioaccumulate, or that further consideration of these characteristics is not warranted.

This rulemaking was not intended to include all toxic chemicals that meet the persistence criteria and/or the bioaccumulation criteria. This action was the Agency's first step at focusing on toxic chemicals that persist and bioaccumulate. The Agency may take action in the future to 1) lower the reporting threshold for EPCRA section 313 listed toxic chemicals that persist and bioaccumulate; 2) add chemicals that meet the EPCRA section 313 toxicity criteria that also persist and bioaccumulate and 3) focus on toxic chemicals that either persist or bioaccumulate.

Commenter Number: Physicians for Social Responsibility (C-1932)

Comment: The persistence criteria of half-lives of 2 months for water, soil, and sediment and 2 days for air may not be sufficiently protective (i.e., the criteria may be too high).

Response: EPA disagrees with the comment. EPA believes that it should adopt criteria that allow communities to *focus* on toxic chemicals that will build up in the environment while at the same time not limiting the list of persistent toxic chemicals to only those that are of global concern. As discussed above in the response to comments, EPA believes that 2 months is a reasonable half-life criterion given the purposes of EPCRA section 313 and the community right-to-know principle. However, EPA believes that application of lower criteria would include so many substances as to be impractical, and more importantly, would result in confusion rather than community empowerment, because citizens would be unable to clearly identify the chemicals that are likely to build up in their environment and focus their energies on those substances. Further, given the uncertainties that often exist regarding physical properties and environmental behavior of chemicals caution is especially appropriate for substances with shorter half-lives, since they are (all other things being equal) less likely to build up in the environment than more persistent substances. EPA believes that the adoption of criteria of half-lives of 2 months in water, soil, and sediment and a half-life of 2 days in air allows EPA to balance the need to provide communities with information on toxic chemicals that persist in their environment without being overly inclusive or restrictive.

Commenter Number: National Environmental Trust (C-1409); Environmental Defense Fund (C-1855)

Comment: EPA's lower persistence criterion of 2 months should be applied to anticipated degradation products even if the original substance is determined not to meet this criterion. Degradation to products potentially meeting the 2 months criterion is not necessarily limited to pesticides that undergo epoxidation.

Response: Although, in principle, EPA agrees with the suggestion that the P, B and T characteristics of degradates be

assessed and PBT criteria applied to these substances as well, the commentors do not explain how this might be accomplished. In fact, there are numerous technical difficulties which, taken together, make any comprehensive effort impractical if not impossible. First, it is unclear what the starting list would be for a comprehensive effort to identify persistent degradation products of nonpersistent parents. All substances? There are insufficient resources to perform such a search. Or a subset of all chemicals? If so, which? If the intention is to include all substances “known” to degrade to persistent products, it is unclear how these would be identified.

More importantly, the comment implies that it is possible to “know” with a high degree of accuracy what the principal degradation products of a given substance are likely to be, but this is rarely true. The proposed rule did include discussion of epoxidation of the cyclodiene pesticides aldrin, heptachlor and isodrin. For these substances epoxidation is a principal pathway of microbial metabolism. The rates and pathways of degradation are relatively well characterized, and the epoxides themselves are known to be persistent, bioaccumulative and toxic. However, few chemicals are as well characterized as these. These pesticides also offer a good example to illustrate the difficulty of predicting when persistent products might be formed, because for most other epoxides that have been studied the epoxide group itself imparts lability to the molecule (epoxides generally hydrolyze easily; e.g. ethylene oxide) rather than increased persistence. Put another way, based on prevailing knowledge for chemical substances as a group, the persistence of the pesticide epoxides would not have been predicted--it had to be observed experimentally.

There certainly does exist a substantial literature on pathways and products of degradation of chemical substances collectively, but most biodegradation pathway studies are conducted using pure microbial cultures obtained by enrichment culture techniques, not authentic grab samples of actual environmental media. And even if the reactions studied actually occur in the environment, they may represent only a portion of the entire degradation pathway; moreover, oftentimes a chemical can be degraded by more than one mechanism or pathway, making it difficult or impossible to predict the most likely products. What all this means is that for most chemicals for which data are available or that are similar enough to chemicals with data that inferences about pathways can be made, existing data only suggest *possible* pathways and products. Finally, existing data on degradation pathways and products for a given substance may be scattered throughout the literature, making the task of gathering and evaluating these data even more difficult.

Commenter Number: Environmental Defense Fund (C-1855)

Comment: A half-life criterion for air of 2-days should be considered sufficient in and of itself for designating substances as persistent.

Response: EPA agrees with the comment. EPA made the following statements in the proposed rule regarding the 2-day air half-life criteria and its use in the determination as to whether a chemical was a PBT under EPCRA section 313:

“For the purposes of determining whether a toxic chemical is persistent in the environment under section 313, EPA used a half-life criterion of 2 months for water/sediment and soil and a half-life of 2 days for air. Given the above discussions, EPA believes that, for purposes of reporting under section 313, these values are appropriate for determining whether a toxic chemical is persistent in the environment and will persist long enough in the environment to bioaccumulate or be transported to remote locations. Under these criteria, if a toxic chemical meets any one of the media specific criteria, then it is considered to be persistent. Thus if a toxic chemical’s half-life in water or sediment or soil is equal to or greater than 2 months or greater than 2 days for air then the toxic chemical is considered to be persistent for purposes of section 313. Note that when considering persistence in connection with the potential for a toxic chemical to bioaccumulate, meeting the air half-life criteria alone would not be sufficient, since a chemical’s potential to bioaccumulate is usually dependent on it being persistent in either water, sediment, or soil. In determining whether the chemicals in this proposal were persistent, EPA did not rely solely on the persistence in air.”

It is clear from the discussion above that EPA agrees with the commenter that when considering persistence alone an air half-life of 2-days would be considered sufficient to classify a chemical as persistent under EPCRA section 313. However, for the reasons explained above, if a chemical only meets the 2-day air half-life persistence criteria EPA does not believe that would be sufficient for classifying a chemical as a PBT under EPCRA section 313.

Commenter Number: Delphi (C-1407)

Comment: Persistence criteria should consider release patterns.

Response: A principal purpose for conducting multimedia fate modeling, as discussed in the proposed rule, was to account for all important sources and environmental loadings (this is EPA's understanding of what the commentor means by "release patterns") in an integrated fashion. Multimedia modeling was performed for all listed substances but as indicated in the proposed rule, for those substances for which adequate TRI data were available, modeling results are presumably more accurate because actual TRI releases were translated into amounts expected to be released to air, water, soil and sediment for input to the fate model.

Discussion of persistence in the multimedia environment, the importance of knowing the medium or media to which releases occur, and the details of multimedia modeling for the listed substances, including use of model results in this rulemaking, were all presented in the proposed rule. Beyond this, EPA notes that it is the very data that the rule is designed to gather that define the "release pattern" for a given substance; thus the comment seems to suggest that the desired information is needed before the desired information can legitimately be collected, a non-sequitur. As indicated below in the response to comments below, EPA agrees with that commentor's suggestion that multimedia model results be used such that a substance would not only need to meet a non-air half-life criterion of 2 months, but would also need to be distributed to some minimum extent into that medium, in order to be considered persistent for rule purposes. This may also be construed as a means of incorporating a release patterns into the persistence criteria.

Commenter Number: American Petroleum Institute (C-1865)

Comment: For each environmental compartment (soil, water, sediment), the persistence criterion should be inclusive of any and all processes; i.e., persistence criteria should represent "dissipation time" (DT), and ecosystems should be viewed as open. For example, for persistence in water the criterion should not exclude volatilization as a potential removal mechanism.

Response: EPA disagrees with the comment, and notes that the approach advocated is counter to EPA policy as well as common sense. It is also counter to the spirit of recommendations made at a 1998 Society for Environmental Toxicology and Chemistry (SETAC) international workshop on POPs (1), regarding good modeling practice for these substances. While it is true that in general processes other than transformation (e.g., volatilization) "may represent significant routes of dissipation", they may not, and it is difficult if not impossible to predict accurately for every substance which pathways of removal will lead to elimination of all potential for future exposure, as well as what these removal rates will be. If half-life criteria for individual media such as soil were inclusive of processes like volatilization, a substance otherwise considered persistent might be judged non-persistent, when the potential for exposure has merely been shifted from one medium to another. The approach advocated by the commentor also defies common sense because it is only through net degradative removal (assuming degradation is irreversible and no toxic products are formed) that all possibility of subsequent exposure to a toxic PBT can be eliminated. This was the spirit of the consensus of SETAC workshop participants (1), who suggested that net advection and sediment burial be deleted from multimedia fate models in modeling of POPs behavior (see response to comment B8), in order to focus on net degradative removal only. Finally, such a definition of persistence would violate EPA policy, which mandates consideration of pollution prevention via a multimedia approach, so that pollution prevention measures are real and not merely cross-media transfers of pollution. Avoidance of cross-media transfers of pollution is at the core of EPA's multimedia strategy on PBTs (2) as well as the Waste Minimization National Plan (WMNP; 3).

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2. PBTI strategy.
3. USEPA, OSWER. Waste Minimization Prioritization Tool Beta Test Version 1.0 User's Guide and System Documentation (Draft). Appendix D Draft Prioritized Chemical List. U.S. Environmental Protection Agency, Washington DC, EPA530-R-97- 019, June 1997.

Commenters: 1407, 1423, 1436, 1845, 1860

Comment: EPA's standards for acceptable data are inadequate and its methods for evaluating persistence do not follow

“generally accepted scientific principles.” EPA should use only the highest quality data, obtained from peer-reviewed, published and validated studies, in evaluating chemicals for persistence. EPA should use data from the FIFRA pesticide registration process in its assessment of PBTs.

EPA’s approach to determining persistence wrongly emphasizes experimental over field data.

Response: Commenter **1860** claims that EPA’s determination of persistence “does not follow generally accepted scientific principles”, but offers no specific information to document this claim, nor any explanation of how EPA failed to apply and follow “generally accepted scientific principles.” EPA’s methods for collecting and evaluating persistence data as well as its standards for acceptability of studies were described in the preamble to the proposed rule and supporting documentation, and will not be repeated at length here. It is useful, however, to reiterate some of the complexities of persistence, and in so doing highlight the difficulties faced in determining whether a given chemical substance does or does not meet the persistence criteria. This analysis will demonstrate that EPA’s standards and procedures are appropriate.

The most widely accepted measure of persistence in individual environmental media (air, water, soil, sediment) is a substance’s half-life, or the amount of time necessary for half of the substance initially present to be eliminated. Half-lives may or may not be inclusive of such processes as transport of the substance to another medium (e.g., volatilization from soil to atmosphere), sorption, complexation or sequestration, and reversible changes in speciation. If such factors are ruled out, measured half-lives will normally reflect the rate of transformation (degradation) of the substance. Transformation may occur by a variety of processes. In air, for chemicals in the gas phase, the most important process contributing to their destruction is oxidation by photochemically generated hydroxyl radicals [1]. Photolysis and oxidation by ozone and nitrate radicals are also important transformation processes for some chemicals. In water, soil and sediment the chief process resulting in net loss for most chemical substances is microbial (bio-)degradation, but hydrolysis, direct and indirect photolysis, and abiotic oxidation/reduction reactions may also play a role. Whether a given measurement does or does not include considerations of intermedia transport, sorption, etc.; and whether it reflects only one transformation process or more than one, depends not only on the molecular structure of the target substance, but just as importantly on *experimental design*. The investigator’s purpose in doing the study obviously determines the design of the study.

As indicated by Mackay [2] and others, half-lives for chemical transformation cannot be viewed in the same way as half-lives for radioisotopes. The latter are fundamental, highly reproducible properties of the radio nuclides, whereas degradation half-lives for chemical substances depend not only on chemical properties and structure, but also on characteristics of the surrounding environment. There are many environmental factors that can affect a substance’s half-life, including but not limited to, for example, temperature, pH, sunlight intensity, hydroxyl radical concentration, and microbial activity. Which environmental characteristics are most important for a given substance largely depends on which transformation processes are most important for that substance. The net result is that there is substantial variability in environmental half-lives in both space and time, and this variability is reflected in available measured half-lives.

This complexity led the authors of a respected series of handbooks of environmental data [3] to conclude “....it is impossible (and misleading) to document a single reliable half-life.” These authors further concluded that “the best that can be done is to suggest a semi-quantitative classification of half-lives into groups, assuming average environmental conditions to apply.” However, there is no such thing as average environmental conditions, nor is it possible to meaningfully compare qualitative or semi-quantitative judgments about half-lives to numerical persistence criteria. It is for this reason that EPA used an approach similar to the one used in Howard et al. [4], a handbook that is cited as the source for much of the data contained in the Mackay handbooks. The EPA approach, summarized in the proposed rule and described in more detail in the support document available in the public docket [5], requires collecting and reviewing all or sufficient relevant persistence data to characterize *quantitatively* a range of half-lives for each medium and substance, which fairly represents the range of actual values seen in existing data. This “reasonable range” of half-lives (language in the proposed rule) represents the balance of the preponderance of evidence (“weight of evidence”) and is the method EPA used to characterize persistence.

The commentors assert that studies must be “of the highest quality possible” (**1407**), and that substances be identified as PBTs based only on “peer-reviewed, published, and validated scientific data” (**1845**). In so doing they insinuate that EPA has relied on data that do not meet these standards. In fact, and as stated in the proposed rule (at 64 FR 700), the standards set forth there represent *minimum* standards for consideration of a study. All persistence studies reviewed by EPA for this rulemaking did properly identify test substance purity, test temperature, location and characteristics of sample collection sites, etc., and did meet reasonable standards for mass balance, degree of test vessel replication, and use of essential controls. It is also important to understand that there are no universally accepted definitions of precisely what constitutes a “high-quality”

study, or of what is sufficient validation, or indeed of what validation means in the first place. The commentors, EPA notes, offer no insight in these areas. In a weight-of-evidence approach, conclusions from any given study may or may not be supported by the other studies. This constitutes “validation” relative to the overall conclusion, and therein lies the value of this approach.

Commentor **1436** states that the highest quality persistence data are from studies performed in response to data requirements under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); further, the commentor suggests that EPA has failed to consider these studies in its evaluation of persistence. FIFRA Reregistration Eligibility Decision documents (REDs) describe EPA’s evaluation of data for specific active ingredients and include extensive lists of available studies. However, these comprehensive documents are available for only a handful of substances included in the proposed rule. Moreover, although many of the listed studies were indeed submitted to fulfill FIFRA requirements, many others are in the published and peer-reviewed scientific literature and were already obtained from other sources and used to develop the proposed rule. EPA also notes that commentors **1436** and **1845** directly contradict each other because, whereas commentor **1845** states that only published studies are acceptable, **1436** states that studies generated under FIFRA are the best available and should be used preferentially, but many are unpublished. EPA asserts that *all* studies meeting its data quality criteria are potentially useful and should be considered in determining persistence, and this is the approach the Agency has pursued. Specific studies cited in the REDs for pendimethalin and dicofol, and EPA’s determination of persistence for these substances, are addressed elsewhere in this response to public comments.

Finally, commentor **1407** complains that EPA does not seem to give adequate emphasis to results from field studies in its evaluation of persistence, and commentor **1436** agrees, citing the preamble’s statement (64 FR 699) that “Field studies, such as are often conducted to determine pesticide fate in the environment, are generally considered the most informative studies if properly conducted.” The comments are inappropriate because EPA has collected and used available data from field studies in its evaluation of persistence, *consistent with the limitations inherent in and difficulties associated with interpreting such data*. These difficulties were discussed briefly in the proposed rule and derive chiefly from the frequent lack of reproducibility and site-specific nature of study findings [6], as well as the inability to distinguish intermedia transfer and advective removal from net degradative removal of the test substance. Field dissipation studies conducted under FIFRA are just that--the intent is to determine a pesticide’s half-life for dissipation (disappearance) from soil at application sites, and removal may occur by any of the processes listed above, including volatilization; leaching through the soil column to deeper soil layers including, possibly, ground water; biotic or abiotic degradation, etc. However, as outlined elsewhere in this document (that commentor stated that persistence criteria should represent dissipation time rather than only net degradative removal), international consensus has developed in support of including only net degradative removal in the definition and criteria for persistence of POPs/PBTs [2,7]. Field sites in pesticide dissipation studies can be thought of as subunits of the larger, multimedia environment, so that dissipation by volatilization to and advection in air (for example) may simply represent transport from the exposed site to an adjacent, unmodeled site. What is critical to interpreting pesticide field dissipation data is that a studies allow clear inferences regarding degradative removal.

References

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Commenter: 1845

Comment: EPA should not rely solely on estimated, predicted or modeled persistence as a substitute for validated "real-world" data. Predicted or modeled persistence should only be used for initial screening out of substances that are not PBTs. Identification and regulation of PBTs should be based only on measured persistence data.

Response: EPA did not rely on estimated or predicted persistence for the majority of substances in the proposed rule. EPA's methods for collecting and evaluating persistence data, its standards for acceptability of studies, and the actual half-life values used to determine persistence were described in the preamble to the proposed rule and in supporting documentation, and will not be repeated at length here. Half-lives were determined for air, water, soil and sediment, and a toxic chemical was considered a PBT if it met (in addition to B) a persistence criterion (2 or 6 months) for any *one* of the last three environmental media. Therefore, even if estimation methods were used to supply half-lives for one or more media, the substance would still have been listed based on a measured half-life if the measured value(s) met the criterion for either water, soil or sediment. Estimated or predicted values were developed for some media and substances because the multimedia fate model used to determine overall persistence for the evaluative environment required net degradation half-lives for all four media.

Exceptions to the above were made for several polychlorinated biphenyls, polychlorinated dioxins, polychlorinated furans and polycyclic aromatic compounds (PACs), as well as octachlorostyrene. No measured half-lives were available for octachlorostyrene, but due to the substance's structural similarity to penta- and hexachlorobenzene, EPA believes that the latter can be used as structural analogs. The same reasoning applies to certain members of the biphenyls, dioxins, furans and PACs, which represent closely related (congeneric) series. In all cases only data for the most closely related analogs in a series were used; e.g., water and soil half-life data for benzo(a)phenanthrene, with four fused rings, were used for 5-methylchrysene. For air, half-life estimates derived from the Atmospheric Oxidation Program (AOP) of Syracuse Research Corporation, which is based on Atkinson's structure/reactivity correlations, are widely regarded as acceptable surrogates for measured half-lives for free (i.e., not particle-associated) substances (see response to comment below).

Commenters: 1356, 1407, 1436, 1871

Comment: EPA should not assume that rates of biodegradation in soil and water are, absent data to the contrary, about the same. This is analogous to the old adage, "If you have one foot in boiling water and one in ice water, on the average you are comfortable." EPA should fill data gaps by doing research rather than by making default assumptions.

EPA should apply safety factors to half-lives whenever there are missing persistence data. EPA should also perform a sensitivity analysis to determine the extent to which scaling factors affect its "persistence calculations," and should apply safety factors when using scaling factors.

Response: As noted in the response to comments elsewhere in this document, EPA is not obligated to perform research to obtain data needed for input to multimedia models or indeed for any other purpose under EPCRA. EPA did gather all readily available *existing* information for the listed substances, and used generally accepted estimation methods (as discussed in the proposed rule) to supply any missing measured values for physical properties and environmental fate. Extrapolation or "scaling" factors are sometimes needed in environmental assessment because multimedia fate models used to determine overall persistence require net degradation half-lives for air, water, soil and sediment, yet measured values often are unavailable for one or more of these media. It is true that scaling factors vary widely for organic substances individually [1,2], but it is by no means obvious that the overall average for all organic substances that have been studied must be close to one (which is interpreted as suggesting that biodegradation rates in soil and water can be assumed to be comparable, absent substance-specific data to the contrary). If that were the case, then the overall average for scaling factors observed for aerobic vs. anaerobic biodegradation should also have been one; but in fact the analysis clearly showed that anaerobic biodegradation is generally slower than aerobic biodegradation with a mean scaling factor of approximately four, which is completely consistent with long established rules-of-thumb based on anecdotal evidence [1]. It is also noteworthy that the two completely independent studies [1,2] came to essentially the same conclusions despite radically different approaches.

In any case, the commenters appear to overestimate the importance of these extrapolations. For this rulemaking, a

substance was considered a PBT if in addition to B and T criteria, it met a persistence criterion (2 or 6 months) for any *one* of three environmental media (water, soil, sediment); for most substances a measured value was available for at least one medium.

Therefore, even if estimation or extrapolation methods were used to supply half-lives for one or more media, the substance would still be listed. The sensitivity analysis suggested by commenter **1871** presumably would be designed to explore the effect on overall environmental persistence (derived from the multimedia fate model) of half-lives above and below an extrapolated value.

This is a good idea in principle and is or should be integral to good modeling practice in general [3], but it would not affect listing of substances in this rulemaking for the reason just mentioned.

Safety factors (called “assessment factors” in EPA’s Office of Pollution Prevention and Toxics) are routinely used in assessment of aquatic toxicity as a means of factoring into an assessment the uncertainty associated with extrapolation, depending on the type and amount of available data, from single species laboratory studies to field scale studies. Analogous safety factors for persistence are unnecessary because EPA’s methods of data collection and analysis, as outlined above and in the proposed rule, consider only measured half-life data derived from authentic environmental samples or actual field studies, and in most cases the half-lives used for this rulemaking represent ranges that encompass all or the majority of existing measured values. A way to characterize this is by saying that there is no persistence counterpart of single-species aquatic toxicity tests, or at least none was used for this rulemaking.

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Commenter: 1860

Comment: EPA has incorrectly ignored biotreatment studies in evaluating persistence for the listed substances. EPA has also ignored a large body of recent research on sequestration and other phenomena that collectively act to reduce the bioavailability of soil contaminants.

Response: Biotreatment studies include activated sludge or other wastewater treatment studies. As noted in the proposed rule (at 64 FR 700), the reason for excluding such studies is that wastewater treatment in general and activated sludge in particular represent conditions that are far removed from those found in ambient (surface) waters, soils and sediments. Data on environmental fate and persistence of substances in wastewater and activated sludge normally cannot be extrapolated to the other conditions. The commenter seems most concerned about land biotreatment (bioremediation) studies, but in fact goes well beyond the concept of treatability, appearing to infer that EPA has ignored *all* biodegradation studies of polycyclic aromatic compounds (PACs). However, this is incorrect because all mixed-culture biodegradation studies other than activated sludge tests--i.e., field tests as well as lab studies that used authentic soil, water and/or sediment grab samples--were considered in determining persistence for all of the listed substances.

The commenter also discusses recent research indicating that bioavailability of a substance may decline with time of incubation in soil, and suggests that EPA should include “reasonable bioavailability factors” in its determination of persistence. As an example of why this is relevant, there has been a concern that Superfund site remediation actions may be mistargeted if they are based on residues released from the soils by vigorous extraction procedures, since chemical substances in soil may become non-bioavailable yet still be extractable for analytical purposes. Additionally, bioremediation may fail to destroy all of a substance that such analysis shows is present, if some portion is sequestered in a non-bioavailable state.

All of this is true, but the commenter over-generalizes from the research findings, using selective citation and quotation from the literature [e.g., Alexander at 1] to give the impression that all is now known and any substance released to soil is as good as gone toxicologically speaking. Other reports can be quoted to the effect that the many factors determining bioavailability, sequestration, etc. are far from completely resolved, and deserve much further research. Moreover, sequestration

does not necessarily imply non-bioavailability. For example, in a study of PAC sequestration and bioremediation, Tang et al. [2] state that

The results of the present study suggest that extensive biodegradation by microorganisms does not necessarily remove all of the fraction of an aged compound that is bioavailable since some uptake by worms occurred even after the laboratory-scale bioremediation....it is also possible that a portion of a compound that is sequestered is available to different degrees to dissimilar organisms....It may be that the mass of material that becomes sequestered should be considered as existing in two forms. One form may be unavailable to all organisms because it is physically remote and thus inaccessible. The second form may be differentially available, and its assimilation, toxicity, and/or biodegradation may depend on the properties of the species and its ability to mobilize the molecules from this nonremote location (13).

Further, the same report states that,

[There is] danger if it is assumed that the disappearance of lethality denotes the absence of bioavailability....The point is reinforced by the case of DDT, which is sequestered in soil (13) and whose lethality to insects totally disappears as a result of such sequestration (5), yet a portion of that insecticide was still assimilated by earthworms introduced into soil that was treated in the field with DDT *more than 40 years before the bioassay was performed....* (emphasis added)

And in a similar paper on DDT and dieldrin, Robertson and Alexander [3] state that

The significance of soil properties in controlling sequestration is evident in the early observation that the degree of sequestration of lindane after 22 months was greatest in a muck, intermediate in extent in a loam, and least in a sandy loam (11). Thus, *soil properties must be considered in attempting to predict the bioavailability of persistent compounds*. It is also evident from the data presented herein that the bioavailability of a sequestered toxicant varies with the exposed species. Thus, the declines in toxicity of aged DDT and dieldrin to the three test insects were quite different; whereas the lethality of the sequestered compound to one species had almost disappeared, it still was effective against a second. (emphasis added)

The conclusion is manifest: although chemical substances released to soil may become sequestered over time, it cannot be assumed that this process necessarily leads to non-bioavailability even when the time horizon is years. Site- and species-specific factors, as substance properties, are important in determining bioavailability. Therefore, it is appropriate to be concerned about the bioavailability in soil and sediment of PACs and other substances that meet the PBT criteria established for this rulemaking.

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Commentor: 1865

Comment: In evaluating persistence data, half-lives should be calculated from the "initial dissipation rate", since this portion of the disappearance curve "most accurately reflects the actual rate of loss." Laboratory persistence studies (e.g., die-away tests) cannot be used because microbial viability declines over time. Long-term studies (defined as any study of more than 30 days' duration) should not be used either, because substances may become irreversibly bound and thus not further degraded owing to lack of availability to degrading microbial populations.

Response: EPA notes that the commentor provides no experimental data or other meaningful evidence to support any of its

claims.

(1) *Persistence determination should be based on initial dissipation rate.* EPA disagrees. EPA addressed the concept of dissipation vs. net degradative removal elsewhere in this document. If half-life data for individual media such as soil were inclusive of processes like volatilization, a substance otherwise considered persistent might be judged non-persistent, when the potential for exposure has merely been shifted from one medium to another. Therefore, the definition of persistence in a single medium should not be based on dissipation, initial or otherwise.

(2) *Studies of persistence must be limited in duration to 30 days or less.* The commentor does not define “initial” explicitly, but it appears to mean less than 30 days. As applied to studies of a substance’s fate in water/sediment, EPA agrees that studies should be limited in duration to the extent practicable, since changes in sediment geochemistry eventually cause test systems to diverge from field conditions [1]. However, there is no fixed time limit, and it is just as, if not more important, to monitor test systems over time to ensure microbial viability [2]. There is ample precedent for studies longer than 30 days. In addition, OPPTS Harmonized Test Guidelines that specify authentic grab samples (Sediment/Water Microcosm Biodegradation Test [3]; Anaerobic Biodegradation in the Subsurface [4]) state that the tests may be run for as long as 64 days. According to the OPPTS Support Document [2] prepared for the Sediment/Water Microcosm Biodegradation Test [3], published studies indicate that sediment/water microcosms have been successfully operated for as long as 2 years, but that most studies have been conducted over 1-2 months. For soil, lab and field studies are often run for well over 30 days with the data still being considered meaningful. This is reflected in hundreds of studies summarized in FIFRA Reregistration Eligibility Decisions (REDs) for pesticide actives, such as those for dicofol and pendimethalin, which are addressed elsewhere in these responses.

(3) *Laboratory studies are unacceptable; only field studies can be used for determination of persistence.* EPA disagrees. If appropriate precautions are taken as described above--e.g., limiting study duration to the extent practicable and monitoring important system parameters like microbial viability--laboratory persistence data are generally considered to be acceptable surrogates for field data [5]. Indeed, it is *universally* accepted that, quoting Painter’s [6] authoritative OECD monograph on biodegradability testing, “it is out of the question to test behaviour of all chemicals in the field, because of the enormous cost and time it would entail.” Moreover, field data are usually difficult to interpret. According to ECETOC [7], “...the findings obtained [in field studies] are usually difficult to interpret as a result of the complex interactions of and continuous changes in field parameters.” Because of the inherent difficulties with field studies, reliance on grab sample tests is necessary, justified, and scientifically acceptable in determining persistence.

(4) *Long-term persistence studies are unacceptable because microbial activity declines over time, and because chemical substances in soil and sediment become irreversibly bound, rendering them non-bioavailable. This process results in erroneously long dissipation times unless persistence is based only on the initial dissipation rate.* The process of forming irreversibly and presumably covalently bound residues is slow but still poorly understood [8]. It may be preceded by a sequestration process occurring over a time frame of months or even years, in which extractability is lost gradually [9]. However, as noted above in the response to comment **E6**, it cannot be assumed that sequestration necessarily implies non-bioavailability [10,11]. Therefore, for present purposes the definition of persistence should assume that any substance released to soil is bioavailable.

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2. USEPA. 1994. *Sediment/Water Microcosm Biodegradation Test Guideline Support Document*. Draft, 24 Jan 94.
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Commenter: 1423, 1827

Comment: EPA mistakenly highlights uncertainties associated with air half-life estimates derived from the AOPWIN model, and apparently uses this as a reason to limit use of multimedia modeling to override compartmental half-lives in persistence evaluation. In fact, AOPWIN estimates are sufficiently accurate for most organic chemicals.

EPA's decision to disallow use of multimedia modeling to override compartmental half-lives in persistence evaluation when model inputs are judged inaccurate appears strongly biased to maximize persistence findings. Moreover, if multimedia modeling results are rejected due to inaccurate input data, the same data should also be considered inadequate to judge persistence vis-a-vis single-media criteria.

If EPA judges sediment half-life data for a given chemical to be unreliable, then the chemical should not be designated as persistent based solely on that data.

Response: What the proposed rule (64 FR 710) said was as follows:

"Because of the uncertainties associated with air half-lives for these chemicals and the lack of sediment half-lives, which could affect the modified EQC modeling results, EPA does not believe that the modeling results should be used to override the medium-specific persistence data for these chemicals."

Immediately preceding this on the same page there is a brief discussion of the phenomenon of sorption of airborne substances to particulate matter in the atmosphere, and the effects this might have on air half-lives. It is this uncertainty associated with the atmospheric oxidation of substances in the particulate form which, when combined with the near total lack of sediment half-life data, lead EPA to its conclusion regarding multimedia modeling results. EPA agrees that estimates of hydroxyl radical and ozone reaction rates derived from the AOPWIN computer program (and, more generally, from the Atkinson methodology) should be regarded as generally reliable and sufficient, as regards air reaction rates for the *free, non-particle associated* substances.

All substances in the proposed rule were judged to reliably meet either the persistence criterion for water or the criterion for soil, or both, and this was considered sufficient evidence of environmental persistence for a substance to be listed. However, no substance in the proposed rule was listed solely on the basis of a sediment half-life, reliable or otherwise. Therefore, there was no substance for which single-medium persistence data were considered sufficient for listing, but for which the same data were considered sufficiently inaccurate to provide grounds for rejecting the results of multimedia modeling.

Commenter Number: C-1407

Comment: One commenter argues that in the PBT proposal EPA justifies the lowered thresholds by stating that: "releases of persistent toxic chemicals more frequently than once a year can rapidly result in large increases in the amounts of the

chemicals present at any one time in the environment because the environment does not have sufficient time to remove these through degradation.” The commenter does not disagree with this concept, but asserts that there is a lack of data or realistic examples provided to support it. They argue that the proposal does not provide sufficient information to demonstrate that expected releases to the environment from TRI sources will exceed degradation potential for these chemicals. They further argue that the Agency does not adequately demonstrate that the presence of these chemicals in the environment are primarily from TRI reporters. PACs, for instance, are ubiquitous in natural sources. They urge EPA to provide a more complete analysis of these factors in the final rule to ensure that the public can be assured that the additional information will actually be value-added.

Response: EPA disagrees that there is a lack of examples that the toxic chemicals included in today’s action persist for long periods of time. Ample “verifiable, historical data” exists to support EPA’s conclusions that PBT chemicals persist for long periods of time in the environment and that this persistence results in higher exposures to humans and the environment. For example, PCBs have been found throughout the Great Lakes in sediments, water, and aquatic organisms. Currently, the major source of PCBs is environmental reservoirs from past releases. PCBs have been detected in soil, surface water, air, sediment, plants, and animal tissue in all regions of the earth (3). Multimedia analyses indicate that the majority (80-90%) of human exposure to chlorinated organic compounds, such as PCBs comes from the food pathway, a lesser amount (5-10%) from air, and minute amounts (less than 1%) from water. Most of the data available on human exposure to PCBs in the Great Lakes come from the analyses of contaminant levels in drinking water and sport fish. The consumption of contaminated sport fish and wildlife can significantly increase human exposure to the Great Lakes critical pollutants, such as PCBs. The sport fish are exposed to PCBs by consumption of sediments and through water. (1). Further, Once toxaphene enters the environment, it breaks down very slowly. Therefore, even though the use of toxaphene has been banned in the United States for more than 10 years, exposures may still occur. After releases to surface water or soils or application to crops, the more volatile components of toxaphene readily partition to the atmosphere where they persist (4). Clearly the releases were able to build up in the environment and present potential exposures long after the quantity of the chemical was released. In addition, metals such as mercury are by definition persistent, i.e., mercury cannot be destroyed.

Further, EPA disagrees that even if the PBTs are naturally occurring that somehow lessens the importance of the information. Mercury occurs naturally and is distributed throughout the environment by both natural processes and human activities. Solid waste incineration and fossil fuel combustion facilities contribute approximately 87% of the emissions of mercury in the United States. Other sources of mercury releases to the air include mining and smelting, industrial processes involving the use of mercury such as chlor-alkali production facilities and production of cement. Mercury is released to surface waters from naturally occurring mercury in rocks and soils and from industrial activities, including pulp and paper mills, leather tanning, electroplating, and chemical manufacturing. Wastewater treatment facilities may also release mercury to water. An indirect source of mercury to surface waters is mercury in the air; it is deposited from rain and other processes directly to water surfaces and to soils. Mercury also may be deposited in soil and sediments. Sources of mercury in soil include direct application of fertilizers and fungicides and disposal of solid waste, including batteries and thermometers, to landfills. The disposal of municipal incinerator ash in landfills and the application of sewage sludge to crop land result in increased levels of mercury in soil. Mercury in air may also be deposited in soil and sediments (2). EPA disagrees that it must limit information on releases of mercury, or any other PBT chemical, because the chemical may occur naturally. In the case of mercury, there are numerous anthropogenic sources of mercury. Further, EPA disagrees with the commenter’s implication that PACs are solely naturally occurring. In addition to being a component of fossil fuels, they are also produced during the combustion of fossil fuels by electric generating facilities that combust coal and/or oil and industrial boilers that combust coal and/or oil (5).

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2.d Additional Bioaccumulation Comments/Responses

Comment:

C-1428, C-1436, C-1455, C-1815, and C-1841

The commenters contend that EPA did not provide scientific justification for its choice of the bioaccumulation criterion of a BCF/BAF of 1,000. Two commenters stated that the EPA's discussion of the origin of the 1,000 BCF/BAF value at a 1976 meeting sponsored by the American Society of Testing and Materials, and its reaffirmation in 1995 in a research article by two of the original authors, the use of the value by scientists in EPA's Office of Research and Development's Duluth Laboratories, by EPA's Office of Pollution Prevention and Toxics in the review of chemicals under TSCA sections 4 and 5, and EPA's Final Water Quality Guidance for the Great Lakes System, and the use by other authorities, such as the German government, to identify chemicals of high concern for bioaccumulation does not provide a technical basis for choosing a value of 1,000 as a criterion for bioaccumulation. They contend that a criterion of 5,000 is scientifically supportable because chemicals with a BCF/BAF of 5,000 have a high potential to biomagnify.

Response: As discussed above, there is no scientifically "best" bioaccumulation criterion. The degree of bioaccumulation is a continuum. A chemical does not bioaccumulate only if it has a BCF that is 5,000 or greater. A chemical that has a BCF of 1,000 will bioaccumulate, specifically the chemical will be present in an organism at a concentration that is 1,000 times greater than its concentration in the surrounding aqueous environment. Rather the choice of a value along the bioaccumulation spectrum is based to a large degree on how the criterion is to be used, e.g., to track chemicals entering a particular environment, to restrict the use of chemicals, etc. As such the choice of a bioaccumulation criterion is a combination of science and policy.

The commenter did not provide support for the contention that 5,000 was scientifically the "best" bioaccumulation criterion. Specifically, the commenter did not indicate why as a scientific matter a BCF of 5,000 was preferable to a BCF of, for example 4,000 or a BCF of 15,500. While the commenter did note that chemicals that have a BCF of 5,000 tend to have a high potential to biomagnify, the commenter did not indicate in what way this factored into his determination that a BCF of 5,000 is the scientifically "best" bioaccumulation criterion. In addition, a BAF or BCF of 5,000 does not indicate that a chemical will be more likely to biomagnify since biomagnification is a much more complex process. Biomagnification is not a separate process from bioaccumulation or bioconcentration, but is instead a specific example or subset of both. Biomagnification has been defined as: The result of the processes of bioconcentration and bioaccumulation by which tissue concentrations of bioaccumulated chemicals increase as the chemical passes up through two or more trophic levels (Ref. 43 of the final rule). The difference between bioaccumulation and biomagnification is that for a chemical to biomagnify its level of bioaccumulation must increase as it moves up the food chain. The whole concept of biomagnification can be viewed as being controversial (Ref. 9 of the final rule) and biomagnification has been studied for only a few chemicals. Most importantly, biomagnification is not required in order to have a concern for chemicals that bioaccumulate. This is because bioaccumulation in even one species can have a serious impact on that species or any other species that feeds on it. For example, if a chemical only bioaccumulates in fish then the fish will be exposed to higher concentrations of the chemical as will anything that eats the fish. Therefore, EPA believes that there is no reason to establish biomagnification as a criterion for PBT chemicals since bioaccumulation is of more than sufficient concern in and of itself.

None of the other commenters who believe that the bioaccumulation criterion of 1,000 is too expansive, suggested that EPA adopt another value, other than the 5,000 value used in international agreements. At most, several commenters took issue with the fact that the EPCRA section 313 bioaccumulation criterion (BCF/BAF of 1,000) is 5 fold less than the international bioaccumulation criterion of a BCF/BAF or 5,000. Given that for each of these programs the focus was on persistent, bioaccumulative and toxic substances that are of global concern, EPA believes that as a matter of public policy, it is more appropriate for a reporting program to use a more expansive criterion than that used in international agreements that seek to ban or severely restrict the use and/or release of chemical.

Comment:

Delphi (C-1407)

One commenter believes that EPA should not adopt a bioaccumulation criterion (BCF/BAF of 1,000) for EPCRA

section 313 that is more stringent than the criterion for a Great Lakes BCCs (a *human* BAF of 1,000).

Response: EPA notes that BCCs will receive stringent controls which is not the case for toxic chemicals identified as bioaccumulative (and persistent) under EPCRA section 313. As discussed above, EPA does not believe that the criteria used to identify chemicals whose manufacture, use, and/or releases are to be restricted should be the same as that used for a reporting program such as TRI. The issue of the use of the criteria for determining if a chemical is a BCC for the Great Lakes is discussed elsewhere in these comment response document.

Comment:

C-836, C-848, C-1355, C-1409, C-1428, C-1848, C-1855, and C-1871

Many commenters supported the proposed bioaccumulation criterion of a BCF/BAF of 1,000. However, some commenters believe that the criterion should be lower. One of these commenters believe that 1,000 should be the criterion only if the BCF or BAF is a measured value. If the BCF is an estimated value, then the criterion should be 500. Some commenters contend that EPA's two-tiered approach to the bioaccumulation criteria is confusing.

Response: EPA believes that this will add confusion by creating pseudo-two-tiered bioaccumulation criteria. Further, estimated or predicted BCFs are often based on measured data and equations. In addition, EPA believes that a BCF of 500 is overly expansive.

EPA believes that expanding the criteria to include estimated BCFs of 500 would label so many chemicals as bioaccumulative as to be impractical, and more importantly, would result in confusion rather than community empowerment, because citizens would be unable to clearly identify the chemicals that are likely to build up significantly in organisms. EPA believes that the adoption of the criterion of BCF/BAF of 1,000 allows EPA to balance the need to provide communities with information on toxic chemicals that bioaccumulate without being overly inclusive or restrictive.

EPA notes that it proposed only one bioaccumulation criterion for EPCRA section 313, a BCF/BAF of 1,000. The Agency did not propose to use a BCF/BAF of 5,000 as a second bioaccumulation criterion for EPCRA section 313. However, for purposes of setting reporting thresholds in this rulemaking, the Agency did choose to focus on the subset of PBT chemicals that have BCF/BAF greater than 5,000 (and half-lives greater than 6 months) by proposing a 10 pound reporting threshold.

COMMENT:

Delphi (C-1407); National Environmental Trust (C-1409); Chlorobenzene Producers Association (C-1433); Chemical Manufacturers Association (C-1815);

Instead of the two-tiered approach proposed, the commenter believes that a single set of criteria which are consistent with international criteria for defining high priority PBT chemicals of concern should be used.

Response: The commenters are incorrect. EPA did not propose two sets of criteria for the program as the commenter states. EPA proposed as persistence criteria half-lives of 2 months for water, soil, and sediment and 2 days for air. EPA proposed as bioaccumulation criteria a BCF/BAF of 1000. EPA did not propose criteria for hazard because EPCRA section 313(d)(2) provides hazard criteria. The commenter may have been confused because the Agency chose to set lower thresholds for a subset of PBT chemicals that are highly persistent and highly bioaccumulative.

Commenter list: C-1419

Comments: The use of BAFs is highly generic and results in reporting thresholds that are unnecessarily low. The use of biota-sediment accumulation factors (BSAFs) should be consistently applied. The Agency fails to use BSAFs in their listing of bioaccumulation data and should use these for chemicals that are not very water soluble.

Response: BAFs are less commonly calculated for chemicals than BCF values. However, the former are calculated for specific chemicals, metals included. Only a very few BSAFs have been calculated for chemicals. BCF values are preferred, instead of BSAFs, because of the absence of complicating factors due to the presence of sediments associated with BSAFs. Many more BCF values for chemicals have been calculated than BSAFs or BAFs. EPA notes that BAFs and BCFs are valid even for PCBs

which have very low water solubility.

Commenter List: C-1423, C-1426, C-1436, and C-1860

Comments: The EPA technical review of the PBTs does not appear to be based on good science and there are faulty criteria, assumptions, and methodologies in its review. A sound technical basis must be present before taking special action on PBTs. EPA encourages the use of appropriately measured or predicted BAFs but does not explain or provide any ground rules for determining when BAFs are appropriately measured or predicted. BCF should not be the sole indicator used to designate a material as bioaccumulative when additional scientific data, such as FIFRA reregistration data, is available to evaluate potential bioconcentration in the environment. Bioavailability must be considered to gain an accurate determination of the potential for bioconcentration.

Response: The Agency believes its technical review of PBTs is based on sound science and a solid technical basis. The commenter does not give specific examples of faulty criteria, etc. so a more detailed response to the comment cannot be given.

The Agency does provide explanations and ground rules for determining BAFs in the proposed rule. Mention is made of published procedural and quality assurance requirements for field-measured BAFs for the Final Water Quality Guidance for the Great Lakes System. These requirements provide a basis for some general factors to be considered when reviewing measured BAF data, and several are listed in the proposed rule. BCF values are used to determine the bioaccumulation of a chemical because such data are available for many chemicals or can be predicted using various methods. Additional scientific data are often not available. Persistence in a sense serves as a measure of bioavailability as the chemical must exist long enough in the environment in sufficient quantities to be bioaccumulated in organisms. Laboratory BCF values serve as worst-case indicators of bioconcentration and bioaccumulation. It is impossible to take into consideration all the mitigating factors and situations present in the environment that may influence bioconcentration or bioaccumulation. EPA believes that such assessments are more appropriately conducted at the local level so that site specific conditions can be considered.

Commenter List: C-1421, C-1430, and C-1815

Comments: One commenter indicated that EPA should not have concluded that a BCF value of 4,922 for a PCB was sufficiently close to 5,000 to be considered to have a value of 5,000. Other comments concluded that the technical basis for the 1,000 BAF/BCF criterion is that this value represents the level used to identify substances that may require chronic toxicity testing. The criterion of 5,000 should be used because it identifies those substances which have a high potential to biomagnify up the food chain.

Response: The Agency concludes that it was correct in considering a BCF value of 4,922 to have a value of 5,000. The BAF and BCF values for this class of chemicals are extremely high. For example the next lowest value EPA cited for a PCB was a BCF of 37,590 with many BCF and BAF values over 100,000. Given all of the data EPA believes that it is appropriate to classify the PCB listing as highly bioaccumulative. In addition, BCF values may vary somewhat due to, for example, mathematical rounding errors. The technical basis for choosing the 1,000 criterion is not that this level is used to identify substances that may require chronic testing, but that this criterion is used to identify chemicals of concern and potential to bioaccumulate. Concentrations tested in a laboratory BCF test (see references 25 and 26 in the proposed rule) must be lower than the acute and chronic toxicity values in order for no mortalities to occur during the BCF test. When ecotoxicological information is limited, for example, for TSCA section 5 chemicals, a BCF value sometimes can “trigger” the request for additional testing. The Agency does not disagree that biomagnification can be an important consideration in the hazard of a chemical, but as discussed above biomagnification is not required in order to have a concern for bioaccumulation.

Commenter List: C-1845 and C-1865

Comments: The use of validated, field-measured BCF values where BAF values do not exist is supported. However, it is inappropriate to rely solely on modeled or predicted bioaccumulation scores to regulate PBT chemicals. EPA does not discuss the depuration phase of bioconcentration testing. The assumption of steady state (the reason the commenter has assumed for EPA not to consider depuration) is not valid. It is important to consider how rapidly a compound is metabolized by organisms to obtain a reasonable index of the bioconcentration potential. EPA needs to consider and evaluate the metabolism by fish of compounds being designated as a PBT chemical, due to EPA’s heavy reliance on predictive procedures rather than actual data.

It is not clear from EPA’s definition of bioaccumulation, whether or not sediments are included as part of the other sources. EPA needs to perform additional analyses to determine whether or not concentrations in fish will be significantly greater than concentrations in sediment, since many PBTs will partition to soils or sediments.

Response: The Agency agrees in part that it is inappropriate to rely solely on modeled or predicted bioaccumulation scores, when other valid test data are available. In the absence of field BAF values, laboratory BCF values are appropriate and in the absence of any measured BAF or BCF values, modeled or predicted values are appropriate. The Agency believes that the assumption of steady state is valid, especially because this is what one is trying to attain during the test period in a laboratory BCF test (see reference 25 in the proposed rule). It is when steady state is reached that a steady state BCF (and theoretically a maximum value) can be calculated. The Agency agrees that it is important to consider how rapidly a compound is metabolized by organisms (and the chemical concentration in the test organism decreases) as this is part of the depuration phase of the BCF test. The Agency relies first on measured BAF/BCF information. In the absence of this information predicted BAF/BCF values are then used. Sediments are included in other sources in determining BAFs. Even though a chemical may partition to sediments it may still be taken up and accumulated by water column organisms (for example PCBs).

Commenter List: C-1407, C-1426, C-1437, and C-1815

Comments: EPA has defined the BAF as applying to situations where both the organism and its food are exposed and the ratio does not change substantially over time. Yet in the standards for acceptability of measured BAF and BCF data, it is noted that data obtained by the kinetic method were preferred to data from the equilibrium method, especially for chemicals with high Kow values, which are less likely to have reached equilibrium in standard tests. These are contradictory standards. The commenter recommends that EPA appropriately weight bioconcentration data according to a hierarchy ranging from data collected recently under GLP using well recognized protocols, to estimated values. A commenter noted that the BAF method may not properly be applied to quantify the bioaccumulation of substances for which a steady-state, linear relationship among the tissue, water, food, and sediment concentrations of a substance does not exist. It is requested that EPA clarify that a BCF, whether measured or calculated, should not be used unless the Agency has adequate evidence that the steady-state, linear relationship on which the definition is predicted actually exists.

Response: The Agency does not consider these statements contradictory. The second statement applies mainly to high Kow chemicals and the first statement to chemicals in general. Both statements allow some latitude in determining that the organism:water chemical concentration ratio has reached an equilibrium. EPA already uses a similar hierarchy to weigh bioconcentration data. Several critical questions are raised by the hierarchy suggested by the commenter, and first must be answered. These are that a well recognized protocol also must be valid and scientifically acceptable, there should be a specified level of GLP compliance, and there should be criteria established for judging data to be of acceptable quality. The Agency recognizes that for some chemicals the BAF value may be less accurate. However, in the absence of other data this may be all that is available. If the BAF were some number greater than 5,000, this would nevertheless be indicative that this chemical was highly bioaccumulative. The Agency agrees that it is critical to verify that a steady state in a test has been attained, and attempts to do this whenever possible.

Commenter List: C-1422 and C-1441

Comments: QSARs are not universally applicable. While predictions of BCF in aquatic organisms for lipophilic nonionic substances undergoing minimal metabolism or biotransformation may be satisfactory, there are exceptions, and the equations to predict BCF are best used only within a chemical class for which the QSAR was developed. Methods for predicting BAFs and BCFs are unreliable.

Response: The Agency agrees that QSARs are not universally applicable. QSARs must be based on valid toxicity test data. Over 140 QSARs have been developed by OPPT for use in predicting the acute and chronic toxicity of many classes and subclasses of chemicals to aquatic organisms.

The Agency disagrees that methods for predicting BAFs and BCFs are unreliable and explained the usefulness of these methods, especially in the absence of other information in the proposed rule. EPA believes that the methods used to predict BCFs for this rule have been shown to correlate very well with measured values and that the methods and values are scientifically sound.

COMMENT:

Delphi (C-1407); National Environmental Trust (C-1409); Chlorobenzene Producers Association (C-1433); Chemical Manufacturers Association (C-1815);

Several commenters contend that there is no relationship between the criteria and EPA should use only the international criteria to set one threshold for PBT chemicals.

Response: Chemicals with half-lives of 6 months or greater and a BAF/BCF of 5,000 or greater have a higher exposure potential than chemicals with half-lives of 2 months or greater and a BAF/BCF of 1,000 or greater. Chemicals that are highly persistent and highly bioaccumulative are of global concern, and thus are the subject of international agreements. Toxic chemicals that are persistent and bioaccumulative are of local and regional concern. For example, a chemical with a half-life of two months is released to the Mississippi River in Minnesota. Little of the chemical will degrade in the time that it takes the chemical to travel the length of the Mississippi, one month. A more detailed discussion of regional vs. global transport is provided above.

In attempting to determine the qualitative threshold relationship of PBT chemicals to that subset of PBT chemicals that are highly persistent and highly bioaccumulative, EPA considered the attributes of these chemicals and factors specific to thresholds. The manufacture, process, and otherwise use thresholds are not equivalent to release thresholds although, in many cases, the quantity manufactured or otherwise used will be very similar to the quantity released. Thus, even if EPA were able to quantitatively relate the exposure potential of PBT chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative based on the degree of persistence and the degree of bioaccumulation and their inter-relationship, the Agency would not select a quantitative relative *threshold* relationship between these two classes of chemicals because: (1) The manufacturing, processing, and otherwise use thresholds are not equivalent to release thresholds, and (2) the quantity released, not the quantity manufactured, processed or otherwise used, is a critical factor in determining exposure.

However, EPA does believe that the relative reporting thresholds should be based to some extent upon the qualitative differential between the potential exposures that may result from releases of PBT chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative. There is not a direct quantifiable relationship between the potential exposures that can result from equivalent releases of a toxic chemical that persists in the environment with half-lives of 6 months and that has a bioaccumulation factor of 5,000 and releases of a toxic chemical that persists in the environment with half-lives of 2 months and that has a bioaccumulation factor of 1,000. The potential exposure to humans and the environment will depend upon a number of factors, including release patterns, environment variables such as soil type, surface water chemistry, the types and distribution of flora and fauna, and fish consumption patterns. However, EPA did consider the relative differences in the potential exposures between these two classes. For example, after one year, there will be more than 15 times as much of a highly persistent chemical that remains in the environment than of a persistent chemical, all other things being equal. Similarly, fish will accumulate more than 5 times as much of the highly bioaccumulative chemical than of the bioaccumulative chemical, all other things being equal. While EPA believes that it can qualitatively describe the relative relationship of highly persistent chemicals to persistent chemicals and the relative relationship of highly bioaccumulative chemicals to bioaccumulative chemicals, the Agency cannot at the present time, define the relative relationship of persistence and bioaccumulation between the two classes of chemicals. This is in large part due to the many variables that must be considered in determining the potential exposures both due to the interaction of these chemical attributes and the large number of environmental factors that must be considered when evaluating persistence and bioaccumulation together.

Although EPA could not develop an exact quantitative threshold relationship between the two classes of chemicals, the Agency did consider the factors discussed above and did rely to some extent on the numerical relationships between the highly persistent and persistent chemicals and the highly bioaccumulative and bioaccumulative chemicals. Therefore, given that: (1) Highly bioaccumulative toxic chemicals will accumulate approximately 5 times greater than bioaccumulative toxic chemicals, (2) highly persistent toxic chemicals will remain in the environment after one year, at a level about 15 times greater than persistent toxic chemicals, (3) the fact that the EPCRA section 313 reporting thresholds are not release thresholds but that in some instances the quantities manufactured or otherwise used will be very similar to the quantity released, and (4) toxic chemicals that persist in the environment with half-lives of 2 months and bioaccumulation factors of 1,000 or greater can be of both local and regional concern, EPA believes that the threshold for PBT chemicals should be a factor of 10 greater than the threshold for that subset of PBT chemicals that are highly persistent and highly bioaccumulative. EPA believes that this ratio balances the uncertainties and factors, including numerical factors, that the Agency considered. Therefore, based solely on the chemicals' intrinsic characteristics, EPA would establish thresholds of one pound for that subset of PBT chemicals that are highly persistent and highly bioaccumulative and 10 pounds for PBT chemicals.

2.e. Evaluation of persistence using multimedia models

COMMENT:

Chemical Manufacturers Association (C-1815)

One commenter contends that EPA should clarify how and when multimedia models will be used in the evaluation of PBT chemicals. EPA should not use the EQC model or other multimedia models as the sole determinant of potential risk. If exposure and use information is available, a detailed technical evaluation based on these data is preferred over modeling based on hypothetical exposure and loading scenarios.

Response: The purpose of this rulemaking is to lower reporting thresholds for certain EPCRA section 313 substances that are being designated as potentially persistent and bioaccumulative, and to list several additional substances that meet EPCRA section 313 listing criteria and are also potentially persistent and bioaccumulative. Although neither quantitative risk nor exposure assessments have been performed, nor are they required under EPCRA, designation as a PBT does imply the existence of *potential* risk. However, contrary to the comment, EPA has not proposed that multimedia models be used as the sole factor in determining persistence. As clearly stated in the proposed rule, EPA intends to use such modeling “as an additional factor, in conjunction with reaction half-lives for individual media, bioaccumulation/bioconcentration factors, etc., in justifying [the] actions proposed.”

In the proposed rule EPA did explain in a general way (at 64 FR 703) how models would be used in PBT evaluation, and stated that results of multimedia modeling may be used to override compartment (medium)-specific degradation half-lives, but only if all model inputs are judged sufficiently accurate. This leaves unspecified what specific value(s) might be used for overall environmental persistence *criteria* (expressed either as an overall residence time or overall half-life). To date no international scientific or regulatory authority has proposed any such criterion for POPs/PBT chemicals, and the complex relationship between compartment-specific and overall persistence criteria is in fact a major topic of current research.

COMMENT:

General Motors (C-1406)

One commenter raises concerns regarding the modification EPA made to the EQC III model that deleted advective losses and sediment burial.

Response: EPA modified the model to exclude advective losses and sediment burial because if these processes are included the persistence based on destruction will be underestimated.

In multimedia modeling, advection can be viewed as any process which results in the physical removal of chemical from the evaluative environment or “box”. These include processes such as downstream flow in surface waters, dispersion downwind in air, and burial in sediments. The model considers these non destructive processes to result in loss from the evaluative environment in the same way that destruction does. However, these processes simply result in the transport of a chemical to another part of the environment downwind or downstream from where it is released, or its deposition into sediments, but not the destruction of the chemical.

The persistence of a chemical calculated by the model when the model is run considering advective losses include non-destructive transport processes which remove the chemical from the evaluative environment. For example, the environmental persistence of a chemical released to water which does not significantly partition to sediments, degrade, or volatilize will reflect the rate at which the water to which it is released flows out of the evaluative environment. In this example the relative rate of non-destructive transport out of the evaluative environment may be more rapid than the processes which result in the destruction of the chemical. Thus the persistence calculated by the model will be less than if advective transport from the evaluative environment was not considered.

EPA used the model to evaluate persistence based on destruction in a multimedia environment. This is consistent with EPCRA section 313 persistence criteria in that the criteria are based on destruction, not transport of the chemical. The Level III (non-equilibrium partitioning, steady state mass balance) models are preferred for developing qualitative and quantitative predictions of chemical distribution, pathways, and relative concentrations. (Cowan *et al* 1995). Level III models can also be used to assess persistence (Mackay 1996). At steady state (level III) conditions the amount of chemical is unchanging with time and the input and output rates for a compartment are equal. The overall residence time of the chemical is the mass of the chemical in the compartment divided by the input or output rates. This represents the average time the chemical will reside in

the compartment. Output may be by reactions that result in the destruction of the chemical or by advective flow (non-destructive) usually in air or water. When the model is modified to eliminate advective flow, the persistence of a chemical based on the rates of reactions that result in the destruction of the chemical can be assessed. Webster *et al* (1996) used this approach in evaluating the environmental persistence of chemicals using a multimedia fate model and noted that if advective loss is included, the residence time is reduced and can give a misleading impression of a short persistence. It was also noted that these advective losses "...merely relocate the chemical; they do not destroy it ." EPA also used a modified version of the EQC level III model as a tool to assist on the characterization of the persistence of the chemicals subject to this rule. In this version of the model only irreversible transformation contributes to net loss of a chemical. In other words, the model was modified to represent a "closed box" in which the effect of processes that serve only to move the chemical from within the evaluative environment to outside of it, primarily in air and water (advective losses) were nullified. Sediment processes responsible for transport of the chemical from the evaluative environment such as sediment burial were similarly treated. The intent of this modification was to make sure that only processes responsible for the destruction of the chemical were considered in evaluating its persistence in a multimedia environment. EPA supports the use of level III multimedia models modified as described above for their ability to simultaneously consider reaction rates and partitioning so as to give a reasonable assessment of the persistence of chemicals in the multimedia environment.

However, EPA notes that its reliance on the multimedia modeling was limited. As discussed in the proposed rule at 64 FR 703 and elsewhere in this document, EPA primarily considered media specific data and made a case-by-case determination about the persistence of each chemical.

COMMENT:

EPRI (C-1450)

The commenter states that because of its relatively long residence time, mercury (0) (Hg(0)) can be transported long distances before it is deposited and will have less of a local impact . Mercury (II) (Hg (II)), in contrast, is more rapidly removed and will have a greater local impact. The commenter suggests that because of this disproportionate impact higher reporting thresholds should be used for long range transport chemicals and chemicals more rapidly removed and thus locally deposited should be weighted accordingly. The commenter recommends that a source receptor consideration be incorporated into the rule by taking into account the mean source receptor distance to aquatic resources potentially impacted by emitted pollutants.

Response: The purpose of the proposed rule is to provide the public with information on the releases of PBT chemicals that would not be reported under the current thresholds. EPA believes that the public has a right to know even the small quantities of PBT chemicals because they remain in the environment for significant periods of time and concentrate in the organisms exposed to them. EPA does not believe that this would be consistent with a distinction between reporting thresholds between PBT chemicals which due to their physical chemical properties will remain in the atmosphere for long periods and undergo long-range transport and those which are more rapidly and locally deposited on water or land if both chemicals have the potential to cause serious human health and environmental effects even when the releases and exposures are low.

In addition, EPA believes that such a distinction would be inconsistent with the purposes of EPCRA section 313. The purpose of TRI data is to inform persons about releases of toxic chemicals to the environment; to assist government agencies , researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes.

The use of a source receptor consideration incorporating the mean-source receptor distance to aquatic resources potentially impacted by emitted pollutants was recommended by the commenter but no additional information describing the consideration or its use was provided. EPA disagrees that this consideration is necessary, relevant, or practical. The use of a source receptor consideration assumes that there is a different level of concern for releases of PBT chemicals in close proximity to aquatic resources than for those releases far from aquatic resources. However, EPA believes the concerns for releases are equal because even at the lower concentrations at distances far from the source, PBT chemicals, by their nature, have the potential to cause serious human health and environmental effects even when the releases and exposures are low. The practical implication of creating the SRC is that additional information spacially linking all facilities reporting releases of a given chemical and potentially impacted aquatic resources would have to be collected. Clearly this is an enormous task with prohibitive resource implications. It is unclear how this information, once collected, would be used to set reporting thresholds or its value in the process.

With the example of mercury, Hg (0) and Hg (II) are of equivalent concern. Hg (0) is ultimately transformed to the more readily removed Hg (II) and deposited to water and soil. Although the two forms of mercury released will have different residence times and thus be distributed over greater or smaller areas, EPA believes both are of concern because of the potential for exposure and adverse effects, and that no distinction should be made with respect to reporting thresholds between chemicals locally or globally transported.

COMMENT:

EPRI (C-1450)

If a pollutant is emitted into the atmosphere but bioaccumulates in the aquatic foodchain (e.g., mercury, dioxins), its impact will depend on how rapidly it is removed from the atmosphere.

Response: It is not clear from the comment whether the commenter uses the term “removed” to mean physical, non-destructive removal such as wet or dry deposition, or destructive removal such as photooxidation, reactions with hydroxy radicals or ozone. In the case of rapid physical removal processes the concentrations of the substances would be expected to be higher in relatively close proximity to the source and lower at a distance where dispersion of the remaining substance will occur. In the case of rapid destructive removal, concentrations would be lower both in close proximity due to the reactivity of the substance relative to its rate of transport and far from the source due to dispersion of the remaining unreacted portion of the chemical. In the first case the impact will be greater near the source because concentrations will be higher. In the second case impacts may be mitigated by the lower concentrations resulting from dispersion with a notable exception, PBT chemicals. For PBT chemicals, even though they may be transported relatively long distances and dispersed with resultant low concentrations, impacts could be of concern because they can persist and bioconcentrate from low levels in the environment to much higher levels in biota.

COMMENT:

EPRI (C-1419)

The commenter raises concerns that the use of the EQC model fails to properly characterize the potential impacts of emissions from an industrial facility because it is assumed that the receiving media are well-mixed. In fact, most such media are not well-mixed.

Response: EPA disagrees with this comment and suggests that the commenter has misunderstood the EPA’s application of multimedia modeling. The model was not used to characterize potential impacts of emissions from an industrial facility. Such an approach would have required site-specific information and involved the use of a different modeling strategy to determine site specific environmental concentrations. Most importantly, such an approach would have been inappropriate for the determination of whether chemicals meet the PBT criteria because PBT characteristics are chemically inherent, i.e., hazard determinations, not related to the environmental concentrations of the chemical resulting from emissions from an industrial facility, which is fundamentally a risk issue. And as noted elsewhere in this document EPCRA 313 is not a risk based program.

The intent of EPA’s use of multimedia modeling was to estimate overall environmental persistence from information on sources and loadings, chemical properties and transformation processes, and intermedia partitioning and provide information beyond that available on individual media half-lives. The model used generates a complete mass balance for the chemical of concern and calculates the chemical’s concentration at steady state in each environmental medium in a generic “evaluative environment”, along with the amount of chemical and the fugacity (escaping tendency) in each medium. All fluxes by reaction and intermedia transport are deduced. The overall environmental persistence, or residence time, is calculated as the total amount of the chemical in the environment at steady state divided by the total loss rate (or total input rate since these are equal at steady state). EPA calculated overall persistence half-lives from the overall persistence calculated by the model and used them in addition to media specific half-lives in the determination of whether chemicals met the PBT criteria described in this rule.

There is an abundance of evidence indicating that on a relatively large spatial scale, i.e., the scale on which the EQC model is run, the receiving media are indeed well mixed. Furthermore, the use of the assumption of complete mixing within individual compartments in environmental modeling is and has been routine from the inception of the field, and has been shown to be correct when models using these assumptions are validated against field studies in the real-world. When a chemical enters air or water it may be mixed into the receiving medium by several processes. Molecular diffusion is the mixing due to the

random motion of molecules and their tendency to move from areas of high concentration to low concentration. In general this process is relatively slow. Turbulent diffusion or eddy diffusion is the mixing of substances due to small scale turbulence. It is several orders of magnitude larger than molecular diffusion and is a major contributing factor to dispersion. Dispersion is the mixing resulting from the interaction of turbulent diffusion with velocity profiles in the medium. A combination of these processes, aided by winds in the troposphere (the portion of the atmosphere extending to a height of about 10 km) and surface water flow in the hydrosphere (the water environment) are responsible for the rapid and complete mixing that occurs on a large spacial scale when chemicals are released to these media.

The troposphere is divided into two equal hemispheres by the equator. As trade winds move across the ocean towards the equator they pick up water vapor and converge at the intertropical convergence zone. The heat released by the condensation of the moisture carried by these winds is the source of most of the energy required to create and maintain the wind patterns in the atmosphere. The magnitude of the transfer coefficient for chemicals moving from north to south between hemispheres has been evaluated and has been shown to range from 0.9 to 1.14 yr⁻¹ with an average of approximately 1 yr⁻¹. This implies that in one year a volatile gas will be uniformly distributed around the globe. Zonal mixing, around a latitude circle is generally more rapid (weeks to months). Compared to horizontal dimensions of transport, the vertical extent of the troposphere is very small, and thus, uniform mixing often occurs up to the interface between the troposphere and the stratosphere. EPA believes that continuous releases of chemicals to the atmosphere are subject to these mixing processes and if not removed from the atmosphere by other processes will become well mixed over a relatively short time scale.

The releases of chemicals to water can also undergo mixing over a large temporal and spacial scale. Gradients in the velocity of the flow of water are caused by shear forces at the boundaries of the water body such as wind shear at the air-water interface and vertical and lateral profiles due to shear stresses at the sediment-water and shore-water interfaces. Velocity gradients can also develop within the water body due to stream channel characteristics, meandering of the stream bed, and density and temperature stratification and instabilities of lakes and estuaries. Stream channel characteristics that contribute to dispersive mixing include dead spots, side channels, and pools where back mixing occurs. When turbulent diffusion causes a portion of fluid containing a dissolved substance to change position, that portion of fluid becomes entrained in the water body at a new velocity, either faster or slower. This causes the portion of fluid and the dissolved material to mix forward or backward relative to the water adjacent to it.

The proportionality constant relating the change in concentration of a material with time to the change in concentration with distance is known as the dispersion coefficient. These values have been measured for several rivers and streams in the United States. In units of m² sec⁻¹ the magnitude of these coefficients can be compared. A dispersion coefficient of 1490 m² sec⁻¹ for the Missouri River indicates that this water body is well mixed. In contrast, molecular diffusion in water occurs with dispersion coefficients on the order of 10⁻⁶ to 10⁻⁷ m² sec⁻¹.

EPA recognizes that consideration of the spacial scale of interest should be considered in selecting and using multimedia models. Concerns have been raised that multi-media models could be applied inappropriately to model the fate of chemicals at too small a scale (Cowan et al. 1995). At the smaller scale, the key assumption of uniform mixing of the chemical in the environmental media becomes invalid. For chemicals discharged to the atmosphere, the smallest recommended scale of the model would be the equivalent to the distance at which a dispersing plume reaches the mixed layer depth. This will generally be 5 to 10 km. Thus the model developers recommended that multi-media models box models (such as EQC) not be used to quantitatively predict concentrations of chemicals in areas less than a few hundred square kilometers. In accordance with this guidance, EPA used a model evaluative environment with an area of 100,000 square kilometers.

In summary, EPA reasserts that the purpose of the use of multimedia modeling was to estimate overall environmental persistence considering not only individual media half-lives, but other factors including intermedia partitioning. EPA disagrees with the commenters assumption that multimedia modeling was used to characterize the potential impacts of emissions from an industrial facility, it was not used for this purpose. EPA also disagrees with the comment that most receiving media are not well mixed. Environmental chemodynamic processes contributing to rapid and complete mixing on a large scale in air and water are well known and have been described earlier in this response.

References

C.E. Cowan et al. 1995. *The Multi-Media Fate Model: A Vital Tool for Predicting the Fate of Chemicals*. SETAC Press. Pensacola, FL.

COMMENT:

General Motors (C-1406)

EPA must do more research to actually measure partition coefficients that are needed as inputs to the multimedia fate model. More work is also needed to validate the model.

Response. Formally, EPA disagrees with the comment, since it is not EPA's responsibility to perform laboratory work to obtain data needed for input to multimedia models or indeed for any other purpose under EPCRA. EPA did gather all readily available *existing* information for the listed substances, and used generally accepted estimation methods (as discussed in the proposed rule) to supply any missing measured values for physical properties and environmental fate. With respect to validation, the need for further validation of multimedia models is widely recognized and has been duly noted by both model developers (1) and scientific authorities at a recent international workshop, whose specific purpose was to develop and reach consensus on a scientific framework for evaluation of persistence and LRT potential for POPs/PBTs (2). Nevertheless, while noting the need for much more work aimed at validating model predictions, the same groups have also confirmed the scientific validity of the general approach and strongly supported the use of multimedia models for research, chemical assessment, and regulatory purposes. Therefore, EPA reaffirms its intention to continue using multimedia models in its evaluation of persistence for potential PBTs under EPCRA.

References

1. Cowan CE, D Mackay, TCJ Feijtel, D van de Meent, A DiGuardo, J Davies and N Mackay, Eds. 1995. The multi-media fate model: a vital tool for predicting the fate of chemicals. SETAC Press: Pensacola, FL. 78 pp.
2. Klecka G, B Boethling, J Franklin, L Grady, D Graham, P Howard, K Kannan, B Larson, D Mackay, D Muir and D van de Meent, Eds. 1999. Persistence and long-range transport of organic chemicals in the environment: guidelines and criteria for evaluation and assessment. Draft proceedings of the SETAC workshop "Criteria for Persistence and Long-Range Transport of Organic Chemicals in the Environment", Fairmont Hot Springs, British Columbia, Canada, 13-19 July 98.

COMMENT:

Dupont (C-1827)

EPA should make the following two refinements in the process of evaluating substances for persistence. First, following a determination that a substance meets the half-life criterion for a non-air compartment (i.e., soil, water or sediment), the EQC model should be run (at level III) to see if that compartment is relevant. In order for the substance to be designated persistent, in addition to meeting the non-air criterion, it would have to be predicted by the multimedia model to be distributed significantly (e.g., > 10-20 %; exact number to be defined) to that compartment. Second, if EPA decides to use overall persistence as derived from multimedia models to *define* a substance as persistent (as opposed to just using the model to quantify partitioning), in addition to the above criteria the overall environmental half-life should be > 55-60 days for the substance to be so designated.

Response. As noted elsewhere in this document, EPA agrees in principle with these two suggestions. EPA intends to reexamine its modeling results for the listed substances, in conjunction with other available information, and recommend specific values for both the overall persistence criterion and minimum extent of partitioning into any compartment for which the compartmental half-life criterion for persistence is met. EPA notes that for all the toxic chemicals that are a part of this rulemaking, the multi-media modeling predicts that greater than 10-20% of each toxic chemical will partition to the non-air compartment in which the toxic chemical is persistent (i.e., the half-life in that compartment meets the EPCRA section 313 persistence criteria).

COMMENT:

Dupont C-1827

EPA should not use the lack of sediment half-life data for a given substance to preclude consideration of distribution of a substance into the various environmental compartments (via multimedia modeling) as part of the persistence evaluation process. If there are no data, default values should be used for sediment half-life, as inputs to multimedia models.

Response: The proposed rule noted (at 64 FR 702) the general absence of sediment half-life data for the listed substances, but did not say that this would necessarily preclude using multimedia modeling results in evaluating persistence for potential PBTs. As stated in the proposed rule and elsewhere in this document, EPA will *consider* using multimedia modeling results (specifically, overall persistence derived from such models) to override judgments based on compartmental criteria only when all model inputs are deemed reliable. Ultimately, the responsibility for determining what are and what are not “reliable” data rests with EPA alone. Hypothetically, a situation could arise in which EPA judges that the sediment (or indeed any other) half-life is not a critical determinant of overall persistence, implying that an accurate measured half-life for that compartment is not required (1). In this situation it may well be that default half-lives are quite acceptable, leaving open the possibility that modeling results could still be used to designate as non-persistent (whether by failure of the substance to meet an overall persistence criterion, or failure to meet a criterion for minimum extent of partitioning to a compartment) a substance for which a compartmental half-life criterion had been met. However, the judgment of what is and what is not a critical half-life, referred to as a sensitivity analysis in the lexicon of modeling, can be made only on a case-by-case basis, and is EPA’s responsibility alone.

The comment further suggests (indirectly) that sediment half-lives in general can be considered less important than other half-lives, since it claims that default half-lives should be generally acceptable. However, the commentor offers no evidence to support this claim. Indeed, it can be argued that the sediment compartment may be quite significant for some PBTs, depending on the details of use and release patterns, because most are hydrophobic and therefore expected to bind strongly to organic matter in soil and sediment. It follows that sediment half-lives should not be treated any differently from half-lives for the other compartments.

Reference

1. Webster E, D Mackay and F Wania. 1998. Evaluating environmental persistence. *Environ. Toxicol. Chem.* **17**: 2148-2158.

COMMENT:

PPG Industries (C-1845)

Multimedia fate modeling should only be used in tandem with “targeted data collection”, for the purpose of validating and refining the model.

Response. By “targeted data collection” EPA assumes the commentor means environmental monitoring. Based on this assumption, EPA disagrees with the comment. It is not EPA’s responsibility to conduct research or any other environmental studies under EPCRA. As stated elsewhere in this document, the purpose of this rulemaking is to lower reporting thresholds for certain EPCRA section 313 chemicals that are being designated as potentially persistent and bioaccumulative, and to list several additional substances that meet the EPCRA section 313 listing criteria and are also potentially persistent and bioaccumulative. EPA agrees that there is a general need for more use of targeted environmental monitoring to validate and refine multimedia fate models such as the EQC model. This need was identified as critical at a 1998 SETAC-sponsored workshop whose focus was POPs and LRT (1), and in which EPA was a full and active participant.

Reference

1. Klecka G, B Boethling, J Franklin, L Grady, D Graham, P Howard, K Kannan, B Larson, D Mackay, D Muir and D van de Meent, Eds. 1999. Persistence and long-range transport of organic chemicals in the environment: guidelines and criteria for evaluation and assessment. Draft proceedings of the SETAC workshop “Criteria for Persistence and Long-Range Transport of Organic Chemicals in the Environment”, Fairmont Hot Springs, British Columbia, Canada, 13-19 July 98.

COMMENT:

(C-1845)

EPA's modifications to the EQC model are too conservative. Risk *is* mitigated by elimination of exposure pathways regardless of the mechanism of elimination.

Response: EPA disagrees with the comment, and notes that the approach advocated (inclusion of net advection and sediment burial) is counter to generally accepted modeling practice as well as common sense. Consensus has developed in the scientific community that for POPs/PBTs, modifications are needed in conventional level III multimedia modeling approaches. Specifically, leading authorities (1,2) agree that net advection and sediment burial should be zeroed out, because including them would in effect allow apparent loss of a substance which in fact only constitutes movement out of the defined model environment. Multimedia fate models such as the EQC model represent the environment as a box of defined dimensions and composition. Therefore, net advection, which means movement of a substance out of the box by physical means such as atmospheric transport as particle-bound substance, only represents transfer to an adjacent environment. Risk is not necessarily mitigated because the potential exposure is not eliminated; it is merely shifted from one place to another. The commenter's statement about removal of exposure pathways also suggests confusion between the aforementioned modifications in the multimedia model on the one hand, and on the other, a change in the medium in which exposure occurs that is caused by partitioning of a substance from one medium to another (e.g., by volatilization). This issue is also addressed elsewhere in this document.

References

1. Klecka G, B Boethling, J Franklin, L Grady, D Graham, P Howard, K Kannan, B Larson, D Mackay, D Muir and D van de Meent, Eds. 1999. Persistence and long-range transport of organic chemicals in the environment: guidelines and criteria for evaluation and assessment. Draft proceedings of the SETAC workshop "Criteria for Persistence and Long-Range Transport of Organic Chemicals in the Environment", Fairmont Hot Springs, British Columbia, Canada, 13-19 July 98.
2. Webster E, D Mackay and F Wania. 1998. Evaluating environmental persistence. *Environ. Toxicol. Chem.* **17**: 2148-2158.

2.f. Applicability of persistence and bioaccumulation criteria to metals

2.f.i. Applicability of persistence criteria; evaluation of persistence

1. The persistence criteria proposed by EPA were developed for organic chemicals and cannot be applied to metals, or if applied, are not useful in screening for hazard. The critical parameter in determining risk is bioavailability, not persistence. This has been recognized by international organizations of which EPA is a member, so it is unclear why it is now necessary for EPA to deviate from these policies. Metals are not harmful if they are not in a bioavailable form. Moreover, metals are natural components of the earth's crust and many are accumulated by living organisms because they are essential nutrients.

Commentors: 1357, 1406, 1420, 1421, 1431, 1435, 1441, 1436, 1446, 1813, 1818, 1821, 1826, 1847, 1850, 1851, 1858, 1859, 1860, 1863, 1865, 1870

2. Persistence is defined as "the failure of a substance to readily biodegrade." However, this concept has no relevance for metals.

Commentors: 1851, 1858

Response to comments C1-2

The scientific literature contains many definitions of persistence which vary in detail, but center on a common theme: persistence is the *ability of a chemical substance to remain in a particular environment in an unchanged form*. This definition makes no mention whatsoever of any specific processes that may impact a substance's environmental fate, such as biodegradation. According to this definition specific metal compounds may or may not be persistent depending on the form of the metal and environmental conditions, but the elemental metal itself obviously meets the definition, and this was noted in the majority of comments received.

That elemental metals are persistent by definition is widely accepted. While they may take different oxidation states that can be interconverted, the elemental metal itself cannot be destroyed. For example, chromium (VI) may convert to chromium (III). Both are simply different forms of chromium. All elemental metals therefore meet the 6 months half-life criterion

automatically. Given this it is obviously false to assert, as did the majority of commentors on this issue, that EPA's proposed persistence criteria *cannot be applied* to metals. The position of many commentors was that in determining whether a metal or metal compound may actually pose a risk if released to the environment, bioavailability is much more important than the fact that a substance meets the formal "definition" of persistence. EPA agrees that bioavailability is important in determining the potential for the metal to be accumulated in organisms, but the Agency asserts that parent metals do have the potential to become available from metal compounds under common environmental conditions. Availability of the metal ion may be the result of biotic or abiotic processes. There are a number of environmental factors which EPA considers in determining the availability of the metal ion. These include hydrolysis, pH effects on solubility, photolysis, aerobic and anaerobic transformations, and *in vivo* transformations. As outlined below it *is* realistic to expect that, in general, released metals can encounter conditions in which they are available at levels sufficient to exert toxicity and bioaccumulate.

EPA also disagrees with the commentors' claims, direct or implied, that metals released to the environment as a result of human activity must be of negligible concern because they

- cannot be converted to bioavailable forms; or even if initially bioavailable are rapidly sequestered in such a way that subsequent exposure is impossible; or
- if bioavailable, are naturally wholesome and good because organisms need them to function.

EPA disagrees with this simplistic view. Metals can enter the environment in bioavailable forms or can be converted in the environment into bioavailable forms. As shown below, metals and metal compounds may be available to bioaccumulate under many realistic and common environmental conditions.

The commentors are correct in stating that metals released to the environment from anthropogenic sources are affected by prevailing environmental conditions, meaning broadly the wide variety of physical, chemical and biological processes that act upon them, and these collectively determine the form in which the metal ultimately exists.

According to Klein (1), interconversion of inorganic metal compounds can be quite rapid, especially for ionic forms, and as a result the chemical form in which an elemental metal is released may not be the predominant form post-release. Generally the ionic forms of inorganic metals are the most available. Availability is affected by many factors and its determination is complex, but many of the more important variables can be illustrated using lead² as an example (2). A detailed discussion of the environmental fate of lead, which is representative of other metals, and that is illustrative of many of the more important environmental variables that affect availability is provided in Refs. 2, 3, 4, 5, 6, and 6a.

Microbial transformations in soil, water and sediment are often important in determining the overall fate of metals and metal compounds, and therefore the potential for formation of bioavailable forms. Metals known to undergo microbial oxidation/reduction processes include mercury, arsenic, iron, antimony, selenium and tellurium (7). Arsenic microbiology illustrates the importance of environmental conditions in the interconversion of inorganic forms of arsenic. Microbial populations in activated sludge can oxidize arsenite to arsenate under aerobic conditions, but under anaerobic conditions such as often predominate in sediments, arsenate can be reduced to arsenite and beyond. Both arsenites and arsenates can be available in

²Lead is being used as an example to illustrate how environmental conditions can affect the availability of a metal in different environments. However, the same basic chemical properties and environmental variables will affect the degree of availability of a metal in the environment regardless of the specific metal. There is no metal that is unavailable under all conditions. EPA notes that the issue of bioavailability has been addressed for EPCRA section 313 chemical assessments through EPA's policy and guidance concerning petitions to delist individual members of the metal compound categories listed under EPCRA section 313 (May 23, 1991, 56 FR 23703). This policy states that if the metal in a metal compound cannot become available as a result of biotic or abiotic processes then the metal will not be available to express its toxicity, nor to bioaccumulate. If the intact metal compound is not toxic and the metal is not available from the metal compound then such a chemical is a potential candidate for delisting. EPA has received fewer than 10 petitions to delete individual metal compounds because the petitioner contended that the metal portion of the metal compound would not be available under environmental conditions or *in vivo*. EPA has not received a petition to delete a metal and its entire category of metal compounds subsequent to issuing the aforementioned policy and guidance.

the environment (7). Microorganisms can reduce mercury in the form of mercuric chloride to elemental mercury, and are also capable of producing elemental mercury from organomercurials such as phenylmercuric acetate and methylmercuric chloride. Although the reduction of Hg^{2+} to elemental mercury can be regarded as decreasing availability, the elemental mercury formed is volatile and more likely to enter the global atmospheric circulation.

Mercury is perhaps better known for its potential to be biomethylated by bacteria in the environment (7). Mercury has very high stability constants with organic ligands and can form true organometallic compounds (8). As indicated by Stumm and Morgan (9), metals and metalloids that form stable alkyl compounds are of special concern because they may be volatile; may accumulate in cells; and are toxic to the central nervous system of higher organisms. Methylmercury is highly bioaccumulative and is by far the best studied example of microbial bioalkylation. However, methylation of arsenic is also fairly well characterized, involves the replacement of substituent oxygen atoms by methyl groups (e.g., arsenate is biomethylated to form dimethylarsine), and is important in the transfer of arsenic from sediment to the atmosphere (7). Selenium, tellurium, tin, germanium, lead and several other metals can also be biomethylated (9).

Many of the commentators noted that certain metals are indeed micronutrients (e.g., iron; cobalt; copper), and are accumulated precisely because they are required for certain cellular functions. It does not follow, however, that any amount of the same metal is acceptable or desirable. Accumulation of essential elements is usually governed by homeostatic mechanisms that control uptake (1), but excessive uptake is possible and can be toxic to an organism (for example, selenium which is a micronutrient can cause selenosis³ at doses as low as 0.023 mg/kg/day (10); copper, which is an essential nutrient that at high doses can cause vascular injury and hemolytic anemia⁴ (11); inhalation of hexavalent chromium is known to cause cancer in humans (12) even though chromium in very small oral doses is a micronutrient (13). Moreover, the commentators freely cite Allen (14), Chapman (15) and other authors to the effect that metals are accumulated "deliberately" depending on the physiological needs of the organism, but it is clear that this applies only to metals that are essential nutrients. Metals are generally taken into cells by nutrient metal transport systems, and these are not sufficiently specific to completely exclude nonessential metals, some of which may be toxic and/or bioaccumulative. In this situation nutrient metals can be displaced from their binding sites by undesirable, toxic metals, which then gain access to the cell interior with concomitant exclusion of the essential metal (9). Toxic metal ions are then free to react with critical enzymes or otherwise disrupt cellular functions if they reach certain levels. Often this toxicity occurs at relatively low doses. For example, inorganic arsenic is a known human carcinogen and causes chronic toxicity at doses as low as 0.014 mg/kg-day (16). Lead has no known biological function in humans but is readily absorbed and has been shown to cause various toxic effects. For example, children can suffer permanent damage from lead poisoning, resulting in lowered intelligence, learning disabilities, hearing loss, reduced attention span, and behavioral abnormalities (17).

EPA concludes that under many environmental conditions, metals and metal compounds may be available to express toxicity and to bioaccumulate, and that these effects are not necessarily limited to metals that are not essential nutrients. It is appropriate, therefore, to be concerned about the potential for risk from these effects, and one step in this direction is to more accurately assess emissions from anthropogenic activities. EPCRA section 313 provides that opportunity. Precedent for this concern exists at the international level in the form of a protocol for heavy metals under the United Nations Economic Commission for Europe (UNECE) Convention on Long-Range Transboundary Air Pollution (LRTAP), which is currently being negotiated. The draft protocol expresses concern "...that emissions of certain heavy metals are transported across national boundaries and may cause damage to ecosystems...and may have harmful effects on human health...", and specifically

³Clinical signs include the characteristic "garlic odor" of excess selenium excretion in the breath and urine, thickened and brittle nails, hair and nail loss, lowered hemoglobin levels, mottled teeth, skin lesions and central nervous system (CNS) abnormalities (peripheral anesthesia, acroparesthesia and pain in the extremities).

⁴It should be noted that copper exhibits high acute and chronic toxicity to aquatic organisms that results in the death of the organism (11).

advocates assessing and controlling emissions caused by human activities (18).

Several commentors (1357, 1406, 1431, 1435, 1446, 1818, 1850, 1858, 1860, 1870) raised the issue of EPA participation in various international organizations, claiming that any attempt to apply EPA's proposed PBT criteria and/or assessment approach to metals would violate the policies of these organizations, whose positions EPA has previously endorsed. These claims are false because the commentors either misunderstand or misstate the aforementioned policies. The main focus of their attention is two documents, the Organization for Economic Cooperation and Development (OECD)'s *Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances* (19), and the North American Agreement on Environmental Cooperation (NAAEC)'s *Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative* (20). A report from a joint Canada/European Union Technical Workshop on metals (21) was also cited by commentors and reached similar conclusions.

The OECD document's pronouncements on metals are contained in paragraphs 22 and 23 of that document. Paragraph 22 reads as follows:

For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Equally, the use of bioaccumulation data should be treated with care. Specific guidance will be [but has not yet been] provided on how these data for such materials may be used in meeting the requirements of the classification criteria."

By "degradability as applied to organic compounds" OECD means molecular degradation, most often by microbial degradation and/or hydrolysis or other abiotic processes, to progressively simpler organic chemical structures, leading eventually to inorganic substances like carbon dioxide and water. But, note, paragraph 22 does not in any way suggest that metals are not persistent. Moreover, it does not suggest that OECD hazard classification criteria cannot be applied, only that "care" (i.e., professional judgment) is required in the interpretation of data relative to the classification criteria. In fact, EPA agrees that bioavailability is important in determining the potential for the metal to be accumulated in organisms. The Agency has analyzed information on the environmental fate of metals, and, as noted above, asserts its professional judgment that the parent metals do have the potential to become available from metal compounds under commonly encountered environmental conditions. Therefore, the Agency's treatment of metals is consistent with the OECD's intent.

The same holds with respect to NAAEC's pronouncements under the Sound Management of Chemicals Initiative (SMOC; 20). The focus of NAAEC/SMOC (20) is the development of North American Regional Action Plans (NARAPs) for substances that pose significant risk to human health and the environment in all three member countries (viz., Mexico; Canada; the United States). To date, NARAPs have been established for DDT/chlordane, PCBs, and mercury (note: a metal). NAAEC/SMOC (20) acknowledges the persistence of metals, but highlights the role of expert judgment in assessing potential bioavailability of metals and metal compounds:

For naturally occurring substances such as metals and minerals, the Task Force understands that the direct application of the persistence and bioaccumulation criteria proves very difficult.....Organo-metals can behave like other persistent organic pollutants in their metallic form, and as certain compounds, metals tend to be infinitely persistent though not necessarily in a form that is bioavailable, and in some cases, they naturally bioaccumulate for beneficial purposes in organisms (i.e., essential elements). Expert judgment is essential for a meaningful evaluation of these substances.

Further, an earlier section of the document (20) states,

It is understood that expert scientific judgment plays a significant role in acknowledging and addressing the difficulties posed by quantitative criteria for persistence and bioaccumulation, particularly in relation to naturally-occurring substances like metals and minerals where the potential for transformation to complexes or metallic species which are more or less bioavailable, are emerging as important considerations.

It is difficult to read into the preceding any intention to *exclude* metals and metal compounds from consideration, as many commentors imply, and more specifically, to declare that these substances have no potential to pose risk because they are never released in bioavailable forms; cannot be converted to bioavailable forms under any foreseeable circumstances; etc. On the contrary, it is clear from the preceding language as well as the inclusion of mercury among the NARAPs developed to

date that any substance judged to be potentially bioavailable and that otherwise meets the SMOC criteria, whether organic or inorganic, should not be excluded as a candidate for action. As outlined above, it is realistic to expect that, in general, released metals can encounter conditions in which they are available at levels sufficient to exert toxicity and bioaccumulate. Therefore, the Agency's treatment of metals is consistent with international policy under NAAEC/SMOC (20).

Finally, EPA reminds commentors that a mechanism already exists under EPCRA section 313 to address concerns for any metal compound for which the data show that the metal cannot become available. The issue of bioavailability was addressed previously for EPCRA section 313 chemical assessments through EPA's policy and guidance concerning petitions to delist individual members of the metal compound categories listed under EPCRA section 313 (May 23, 1991, 56 FR 23703). This policy states that if the metal in a metal compound cannot become available as a result of biotic or abiotic processes then the metal will not be available to express its toxicity, and by extension, to bioaccumulate. If the intact metal compound is not toxic and the metal is not available from the metal compound, then such a chemical is a potential candidate for delisting.

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3. COMMENTS ON SPECIFIC CHEMICALS AND CATEGORIES

3.a. Alkyl leads

Commenter List: C-1421, C-1447, C-1827, C-1855, C-1864, and C-1865.

Comments: Commenter states that requiring separate reports within a single compound category listing would introduce significant confusion and inconsistency into TRI reporting. Commenter states that it is inappropriate for EPA to choose to use broad compound categories to subject facilities to TRI reporting, then attempt to require separate reports within the categories. Commenter states that individual compound reporting requires individual compound TRI listing. Commenter urges EPA to consider requiring reporting on all chemical species when the information is available, including reporting on tetraethyl and tetramethyl lead separately, in addition to reporting on other lead compounds. Commenter states that since research indicates that alkyl lead is bioavailable, they support separate reporting for tetraethyl lead and tetramethyl lead. Commenter states that they do not support separate reporting of tetraethyl and tetramethyl lead from other lead compounds since this change in the reporting of lead compounds will increase burden for reporting facilities, and also increase confusion and quantitative uncertainty for both reporting facilities and the public. Commenter is opposed to any form of lead being included on the PBT chemical list because, under the Great Lakes Water Quality Initiative guidance determination, it was proven not to be bioaccumulative. In addition the commenter states that, these two forms of lead are included in the analysis of other lead salts and cannot be distinguished for the purposes of accurate reporting of releases on separate Form Rs. The commenter believes one report on lead compounds is sufficient for TRI reporting purposes. Commenter opposes requiring additional reports within the lead compounds category since this will create confusion and difficulty in the reporting process. Commenter also states that it is unclear how EPA would expect the regulated community to do supplier notification if individual reports are required (i.e., would supplier notification for the individual forms of lead be required?). Commenter states that if EPA wants to require separate reports for chemicals within a chemical category, the agency must do so through separate, individual TRI listings of the chemicals.

Response: While EPA does not agree with all of the comments concerning the proposed separate reporting of tetramethyl and tetraethyl lead, EPA is postponing a decision on the proposal to have separate reports filed for these chemicals. The reporting of lead and lead compounds at lower reporting thresholds, including tetraethyl and tetramethyl lead, is being addressed in a separate rulemaking. This separate rulemaking will address the technical issues concerning the classification of lead and lead compounds as PBT chemicals.

3.b. Comments about Dioxin and Dioxin-Like Compounds (Dioxins).

Commenter List: C-043, C-403, C-548, C-1439, and C-1932

Comment: These commenters stated that they support the addition of dioxin and dioxin-like compounds to the EPCRA section 313 list of chemicals. The commenters stated that these are highly toxic chemicals that should be included on the list. One commenter specifically cited recent studies which have shown that very low concentrations of dioxin, for example 60 parts per trillion (ppt) in tissue, can kill 50 percent of young lake trout (*Raloff, J., Those Old Dioxin Blues, Science News, V. 151, May 17, 1997*). The commenter stated that in addition, the International Agency for Research on Cancer (IARC) recently classified this most toxic dioxin compound as a known human carcinogen (*Forum, 1997, Environ. Health Perspect., Vol. 105(6):576-577*).

One commenter stated that they were aware of numerous studies that have shown that dioxins are among the most potent and persistent of all toxins. The commenter stated that chemicals in this class act variously as carcinogens, mutagens, endocrine disrupters, and cause developmental defects. The commenter stated that children are at special risk. The commenter stated that these aspects of this class of chemicals are well documented in United States Environmental Protection Agency (EPA) draft assessments and inventories and an extensive, peer-reviewed scientific literature.

Many other commenters provided similar support in their general comments on the proposed rule (see the section on "General Comments in Support of the Rule" elsewhere in these comment responses).

Response: The specific comments on the toxicity of dioxin-like compounds and the hazard data EPA relied upon in its listing determination are addressed in the response to comments on the proposal (62 FR 24887 (May 7, 1997)) to add dioxin and dioxin-like compounds to the EPCRA section 313 list of toxic chemicals (see Appendix X, Sections 1.1.3 and 1.2.2). EPA agrees with the commenters statements that dioxin and dioxin-like compounds meet the listing criteria of EPCRA section 313.

Commenter List: C-034, C-2254, and C-2301

Comment: The commenters referred to the 1993 EPA announcement, when the environmental community was informed that the draft dioxin reassessment would be available by the end of the year. The commenters stated that it wasn't until a year later that the draft document was actually released. Commenters stated that in 1995, EPA's Science Advisory Board (SAB) reviewed the draft reassessment and in September of that year, the SAB Executive Committee suggested some clarification and amplification of several chapters of the document. Most commenters conclude from this and similar information, it is apparent that TCDD and all the dioxin-like compounds meet the listing criteria at Section 313 of EPCRA. These commenters requested that EPA complete the dioxin reassessment, including addressing the issues raised by the SAB, and release it to the public without further delay.

Response: While EPA's final dioxin reassessment has not been published, and is not a part of this rulemaking, nothing in the reassessment indicates that the dioxin and dioxin-like compounds in question would not meet the listing criteria of EPCRA section 313 or that these compounds are not persistent and bioaccumulative. EPA will work to have the final reassessment published as soon as possible.

3.b.i. Whether Dioxin Meets PBT Criteria.

Commenter List: C-1428, C-1430, C-1442, C-1457, C-1814, and C-1845

Comment: The commenters did not specifically comment on the persistence or bioaccumulative properties of dioxin and dioxin-like compounds. However, the commenters did raise issues concerning the toxicity of some of the dioxin-like compounds. Most commenters suggested that the available data only supported the listing of 2,3,7,8 tetrachlorodibenzo-p-dioxin and that other dioxin-like compounds such as hepta- and octa-chlorodibenzo-p-dioxin and dibenzofuran do not meet the listing criteria of EPCRA section 313.

Response: EPA disagrees with the commenters conclusions that only 2,3,7,8-tetrachloro-dibenzo-p-dioxin or some other subset of the 16 dioxin-like compounds meet the listing criteria of EPCRA section 313(d)(2). The specific comments on the toxicity of dioxin-like compounds and the hazard data EPA relied upon in its listing determination are addressed in the response to comments received on the proposed rule (62 FR 24887 (May 7, 1997)) to add dioxin and dioxin-like compounds to the EPCRA section 313 list of toxic chemicals. These comments and others received on the May 7, 1997 proposed rule are addressed in detail in Part 1 of this document.

3.b.ii. Listing Dioxin and Dioxin-like Compounds as a Category Versus Individual Listing of Each Chemical.

Commenter List: C-403a, C-1408, C-1428, C-1430, C-1432, C-1443, C-1446, C-1447, C-1464, C-1457, C-1814, C-1856, C-1845, and C-1865

Comment: Some commenters contend that reporting dioxin and dioxin-like compounds as one category would not provide useful information and asked that the individual compounds be reported. One commenter recommended that reporting on individual chemical species should be required when the information is available.

One commenter who supported the reporting of all of the individual dioxin and dioxin-like compounds, stated that the amounts of individual dioxin compounds released from facilities is part of the important public information needed to assist research and policy development. The commenter claims that reporting as a category will not provide the public with the information to assess the relative hazards of releases since one dioxin-like compound can have a relative hazard several orders of magnitude less than the 2,3,7,8-tetrachlorodibenzo-p-dioxin. This commenter also stated that different sources often emit a different mix of dioxin compounds and that this information is widely used to trace dioxin contamination to specific root causes. The commenter stated that the relative amounts of the many different dioxin-like chemicals in a sample are compared to create a "profile" which might match the profile created by emission from a source. The commenter did not support the reporting of the category based on toxic equivalents (TEQs) but thought it important for the users of the data to be able to determine TEQs. Some other commenters made the same general argument that individual isomer reporting is needed to facilitate risk characterization including transport and fate of the different isomers.

Some commenters contend that certain dioxin-like compounds such as octachlorodibenzo-p-dioxin and octachlorodibenzofuran should not be reported since they are ubiquitous in the environment and are the least toxic under the

toxic equivalent factors (TEFs). One commenter stated that EPA should require reporting only for the most toxic congeners: the tetra-, penta-, and hexa-congeners and not the hepta- and octa-congeners which are less toxic and less relevant from a risk standpoint. Other commenters stated that only 2,3,7,8-tetrachlorodibenzo-p-dioxin should be reported. Some commenters contend that reporting for these compounds should not be required at the same reporting threshold as the other dioxin and dioxin-like compounds. Most commenters who would like to exclude certain dioxin-like compounds did not indicate that they wanted individual reporting of the remaining compounds.

Some commenters supported the reporting of dioxin and dioxin-like compounds as a category, as EPA proposed. One commenter stated that if reporting is not limited to just 2,3,7,8-tetrachlorodibenzo-p-dioxin, then the commenter supports EPA's proposal to limit the category to only the 7 dioxins and 10 furans listed in the proposed rule.

Response: After consideration of all of the comments on this issue, EPA has decided that the best way to report on dioxin and dioxin-like compounds is to report them as a category. This is consistent with the way EPA has addressed other groups of chemicals that share the same toxic effect and in this case are also generated as complex mixtures. As discussed elsewhere in these comment responses on dioxin and dioxin-like compounds, reporting as a category and based on TEQs would not provide users of the data with information on which compounds contribute the most to the TEQ total. In addition, requiring facilities to report each compound individually would impose an additional burden on the industries that will be required to report. However, EPA agrees that being able to determine the amounts of the individual dioxin and dioxin-like compounds would make the data more useful. Therefore EPA will add a section to the Form R that will require the reporting facility to provide the distribution of dioxin and each dioxin-like compound for the total quantity that the facility is reporting. If a facility has information on the distribution of the dioxin and dioxin-like compounds, the facility must report either the distribution that best represents the distribution of the total quantity of dioxin released to all media from the facility; or its one best media-specific distribution. This information is only required if it is available from the data used to calculate thresholds, releases, and other waste management quantities, no additional analysis is required. As with all other reporting under EPCRA section 313, this information will only be required if the facility has information that can be used to make a reasonable estimate of the distribution from the available data. With the distribution of congeners reported on each Form R the user of the data can determine the grams of dioxin and each individual dioxin-like compound that makes up the quantities reported on the Form R. Under this reporting mechanism all of the information that EPA believes is important for right-to-know and that the commenters have stated is important to determining the significance of quantities reported under this category, will be provided to the public but the reporting facilities will still only have to file one report. Any of the other possible options, such as reporting in terms of TEQs or reporting each individual compound separately, either do not provide the information both EPA and the commenters believe is important for commenters, or they impose too great an additional reporting burden without providing the public with additional information.

Commenter List: C-1430

Comment: The commenter stated that the reproposal is silent on the issue of whether hepta- and octa-dibenzo-p-dioxin and dibenzofuran meet the chronic toxicity criteria for listing, which was raised in comments on the proposed rule to add dioxin and dioxin-like compounds. The commenter stated that they fully expect EPA to explain why hepta- and octa-dioxin and furan are toxic within the meaning of Sections 313(d)(2) of EPCRA. The commenter stated that as pointed out in their earlier comments, the courts have admonished that EPA's general authority to add chemical categories to the TRI does not entitle the Agency to forgo a chemical specific analysis where data in the record suggest that an individual member of the category does not share the toxic effect of concern upon which EPA has constructed the category. The commenter stated that because they have supplied such data on hepta- and octa-dioxin and furan, they urge EPA to undertake a chemical specific review of those substances to determine whether they fall within the category.

Response: EPA disagrees with the commenters, and believes that hepta- and octa-dibenzo-p-dioxin and dibenzofuran meet the listing criteria of EPCRA section 313. The specific comments on the toxicity of dioxin-like compounds and the hazard data EPA relied upon in its listing determination are addressed in the response to comments received on the proposed rule (62 FR 24887 (May 7, 1997)) to add dioxin and dioxin-like compounds to the EPCRA section 313 list of toxic chemicals. The comments from this commenter and others received on the May 7, 1997 proposed rule are addressed in detail in Part 1 of this document. EPA does not agree with the commenters statements on EPA's authority to list categories, which is discussed in detail elsewhere in these comment responses. However, since EPA believes that the data do show that the hepta- and octa-dibenzo-p-dioxin and dibenzofuran can cause the same toxic effects as 2,3,7,8-tetrachlorodibenzo-p-furan, EPA believes that all of the members of the dioxin and dioxin-like compounds category do share the same toxic effect of concern. It should be noted that sharing the same toxic effect does not mean that all of the chemicals in a category must cause that effect at the same dose. In fact, the only way for the members of a category to cause the same effect at exactly the same dose would be for the category to include only one compound.

3.b.iii. Units of Measurement for Dioxin and Dioxin-like Compounds: Mass versus TEQ.

3.B.iii.a Using Mass versus TEF and TEQ for TRI Reporting

Commenter List: C-403, C-792, C-802, C-836, C-1354, C-1406, C-1408, C-1409, C-1419, C-1420, C-1422, C-1425, C-1428, C-1430, C-1436, C-1440, C-1442, C-1443, C-1448, C-1450, C-1457, C-1814, C-1815, C-1822, C-1841, C-1844, C-1845, C-1847, C-1853, C-1856, C-1865, C-1866, and C-1871

Comment: Most of these commenters suggested that EPA should require that release and other waste management data for the dioxin and dioxin-like compounds category be reported in terms of toxic equivalents (TEQs) rather than in terms of absolute grams. The following list is a summary of the various reasons provided by the commenters in support of reporting dioxin and dioxin-like compounds in terms of TEQs: 1) all dioxin data reported under other EPA programs as well as other federal and state regulatory programs are reported in terms of toxicity equivalents; 2) the public is familiar with dioxin data reported in terms of TEQs and reporting in other units would cause confusion and be misleading; 3) TEQs provide more meaningful information than total weights since they take into account the relative toxicities of the various dioxin-like compounds; 4) facilities that report under other regulatory programs are likely to rely upon TEQ data that they already have; 5) use of absolute mass may cause misleading comparisons between grams and grams TEQ; 6) releases reported in absolute mass make it difficult to assess the impacts these compounds may have on the environment due to the differences in their toxicities; and 7) reports based on TEQ would provide far more useful information about potential community risks than reports based on the total mass of compounds in the category since more risk information would be provided.

Commenters also disagreed with the concerns that EPA raised in the proposed rule, which were:

“...there are three significant disadvantages to reporting in TEQs. First, revisions in TEF factors for individual dioxin-like compounds in future years would require changes to the calculations in the reported release and other waste management quantities, thus making year to year comparisons more difficult, unless the particular dioxin-like compounds are identified. Second, some facilities may not be able to report in TEQs, since, although they may be able to estimate a mass quantity for the category as a whole, they may not have enough information to estimate the relative distribution of all category members. Third, TEQ reporting would be different from all other TRI reporting, which is mass-based, and may cause additional confusion.” (64 FR 712, column 3 and 713, column 1)

Some commenters stated that the first concern is not valid since TRI reporting requirements have been changed several times in the past in spite of difficulties in comparing future reports to past performance. Two commenters stated that this same logic could be applied to the use of AP-42 factors which EPA acknowledges have been revised and refined over the years, and that this also diminishes the value of year-to-year reporting comparisons. One commenter stated that EPA could minimize any confusion that might be caused by a subsequent change in one or more TEFs by each year specifically publishing or cross referencing the TEFs that must be used for that reporting period.

One commenter stated that the EPA's second and third concerns appeared weak in light of the much greater risk information provided by a toxic equivalent approach. Some commenters stated that EPA's third concern is not valid since the reporting requirement being proposed for dioxin and dioxin-like compounds is different whether TEQs are used or not. One commenter stated that the third concern is clearly dwarfed by the confusion that would ensue if all dioxin-like compounds were reported as equivalent, when the hazards vary by a factor of 500. One commenter stated that reporting dioxin on a TEQ basis will cause more rather than less confusion if the public mistakenly compares data in grams with data presented in grams TEQ.

Some commenters agreed with the concerns EPA's expressed in the preamble. One commenter stated that they agreed with these concerns but that the concern about year to year comparisons being more difficult also applies to the reporting of a single mass value for the entire category. The commenter stated that since the amounts of the individual dioxin-like compounds would not be known, if TEFs change, one cannot adjust previously reported values to reflect the changes in TEFs. This commenter suggested that in order to make the information reported of greatest use, the mass of dioxin and each of the dioxin-like compounds should be reported once a TEQ threshold is exceeded.

One commenter stated that EPA's justification for adding the category is based on assumptions about the toxicity of the other dioxin-like compounds relative to dioxin itself and that given these assumptions the reporting of TEQs makes sense. The commenter stated that under current TEQ schemes, these dioxin-like compounds are all less toxic than dioxin, as much as

1,000 times less and that TRI reports should not simply sum emissions for compounds with such drastically different toxicities. One commenter stated that because concentrations of all 17 dioxin-like compounds are routinely reported by analytical laboratories, companies can easily calculate TEQs.

One commenter suggested that EPA require the reporting of both grams and TEQs and if not both, then just grams. The commenter stated that if only grams are reported, the data will be somewhat difficult to interpret without any further information but if only TEQs are required to be reported, then there are uncertainties about what and how much is discharged.

Another commenter stated that if EPA is going to require dioxin reporting as a group and not by specific chemicals, TEQ reporting is an unnecessary complication. The commenter stated that the TEFs used to formulate the TEQ are constantly reviewed and changed, which would necessitate EPA review and possible reissuance of new TEFs each year. The commenter stated that this would make previous years' data impossible to compare once the changes were made. The commenter stated that neither total mass nor TEQ reporting provides sufficient information on reduction in potential exposure and risk. The commenter stated that it is possible that a facility could reduce its dioxin TEQ while releasing a greater mass of dioxin-like compounds, but neither total mass nor TEQ reporting would really provide a good picture of what a facility was doing. The commenter stated that if EPA wants to provide TEQ information to the public, it should also require facilities to report dioxins by individual chemical, rather than as a group.

One commenter stated that while TEQs are a valid and scientifically sound metric for reporting the likely health hazard of a compound, that was not the intended purpose of the EPCRA section 313 reporting requirement. The commenter stated that reporting dioxin and dioxin-like compounds in TEQs will cause confusion, since all other reporting under EPCRA is done in terms of mass and does not take into account toxicity.

One commenter that favors the reporting of dioxin and dioxin-like compounds as individual chemicals stated that reporting as a category but in TEQs would still fail to reveal the amounts of individual compounds released. The commenter stated that this alternative would provide no information on individual compounds for use in tracing dioxin source profiles. The commenter stated that reporting in TEQs would provide better information on the relative toxicity hazard based upon today's toxicity information but that information on the relative toxicity of the many dioxin-like compounds is improving and thus toxicity factors for some of these compounds will change in the future. The commenter stated that in future years the Inventory would have to choose between keeping the old toxicity calculation (and becoming irrelevant in comparison with other research data), or changing the toxicity calculation (and becoming irrelevant for tracking changes in dioxin release rates over time). The commenter stated that the need to aid research and policy development based on current science and the need to track release rates over time are fundamental to the Inventory's purpose and that this alternative must be rejected as just another ill-advised lump-sum reporting scheme. The commenter recommended that EPA require the reporting of dioxin and dioxin-like compounds in the way these compounds are measured and analyzed by scientists and government agencies, as individual chemicals, and consider an additional service by EPA to calculate and report dioxin toxicity as TEQ for the year-to-year data using the most recent toxicity information which becomes available.

Response: While EPA recognizes that TEQs are a common way of expressing quantities of dioxin-like compounds EPA does not believe that reporting in these units would be the best or most appropriate way to report for the dioxin and dioxin-like compounds category under EPCRA section 313. Although some commenters believe that TEQ reporting should be used since not all of the dioxin-like compounds are as toxic as dioxin itself, the fact is that EPA has determined that all of the dioxin-like compounds meet the listing criteria of EPCRA section 313. Since all of these compounds meet the listing criteria, the actual mass of each member of the category should be reported. To do otherwise would deny the public information on the actual quantities of toxic chemicals entering the environment. It would also be inconsistent with all other reporting of EPCRA section 313 toxic chemicals since none of them are reported based on relative toxicities. In addition, this would be inconsistent with EPCRA section 313(g)(C)(iv) which requires that "the annual quantity of the toxic chemical entering each environmental medium" be reported.

EPA believes, as do some of the commenters, that the concerns that were expressed in the proposed rule for reporting dioxin and dioxin-like compounds in terms of TEQs under EPCRA section 313 are valid. EPA disagrees with those commenters who claimed that since other changes in reporting have occurred, such as revisions to AP-42 emission factors, there should be no concern for the changes that might occur in TEFs and the resulting TEQs. The fact that certain changes have occurred in reporting requirements or methods of estimation and that those changes may make certain year to year comparisons more difficult does not reduce the concern for knowingly selecting reporting units that have changed in the past and may well change in the future. Also, EPA would be required to choose a particular set of TEFs (i.e., as of 1999) and would need to amend them

by rulemaking each time the TEFs were revised. Changes in TEFs and the resulting TEQs would be unlike any of the past changes in TRI reporting since none of these reporting changes were related to the relative toxicity of chemicals that meet the listing criteria of EPCRA section 313. The cross referencing or publishing of the TEFs that must be used for each reporting period would still not allow year to year comparisons since without knowing a facilities distribution of each of the category members the TEQ cannot be recalculated. EPA's concerns that some facilities may not be able to report in terms of TEQs are also valid. Although most facilities that will be able to make reasonable estimations for the dioxin and dioxin-like compounds category should be able to report in terms of TEQs, there may be some that can only report in actual mass units and they should not be exempt from reporting. EPA is also still concerned that TEQs would be different than other EPCRA section 313 reporting units, since they are not based on absolute mass, and that this could cause confusion. EPA does not agree with the commenters that stated that this does not matter since the reporting for the dioxin and dioxin-like compounds category is going to be different anyway. The only real reporting difference for the dioxin and dioxin-like compounds category is that the reporting units are in grams rather than pounds. To determine the amounts in pounds all that one would have to do is multiply the grams by 0.002204. However, TEQ reporting would be much different since in order to understand the reported value one would need to understand the basis for TEFs, what they are, how they relate to dioxin, and how TEQs are calculated from the individual TEFs. This obviously requires more knowledge on the part of the data user than simply understanding different units of mass and does have the potential to cause some confusion. It is also not clear, as some commenters stated, that the public is more familiar with dioxin data reported in terms of TEQs or that they will understand TEQs any better than grams.

Some of the commenters stated that TEQs should be used because they provide more risk information to the public than just reporting mass. While TEQs do provide information on relative toxicity EPA does not believe that increasing the amount of risk information is a basis for changing the EPCRA section 313 method for reporting from mass based to relative toxicity based. As discussed elsewhere in these comment responses, EPCRA section 313 is not a risk-based program, and reporting is not intended to communicate information about relative risks. Rather it provides local communities with data on release and other waste management quantities on listed toxic chemicals, so that they may use the data in conjunction with information on chemical properties (e.g., persistence and bioaccumulation) and site-specific information to determine if releases present a potential risk.

EPA does not believe that the fact that other programs require reporting in TEQs and that facilities will already have TEQ information is a sufficient reason to require TEQ reporting under EPCRA section 313. Since the first piece of information that is required to determine TEQs is the grams of dioxin and each dioxin-like compound these facilities should already have the gram-based information they would need. In addition, as stated above, TRI reporting serves the purposes of EPCRA section 313; other programs, e.g., the CWA, are risk-based programs.

Several commenters made the point that for dioxin and dioxin-like compounds neither reporting total mass nor reporting in terms of TEQs provides sufficient information on potential exposures and risks, and that neither would allow for the tracing dioxin source profiles. EPA agrees that neither approach would provide all of the data that the commenters would like to have reported and that being able to determine TEQs would provide additional useful information. A common solution to the TEQ issue that the commenters suggested, was to report dioxin and each individual dioxin-like compound separately rather than as a category. However, EPA believes that this approach would be overly burdensome and unnecessary to get the kind of data that would be the most useful. As discussed elsewhere in these dioxin comment responses many other commenters requested that dioxin and dioxin-like compounds be reported separately rather than as a category. After consideration of all of the comments on this issue EPA has determined that the best way to report for the dioxin and dioxin-like compounds category is to report in terms of absolute grams for the entire category. This is consistent with all other reporting under EPCRA section 313 and will provide the most consistent information from year to year. However, EPA agrees with most of the commenters that being able to determine TEQs from the reported data and being able to determine which individual chemicals are included in a facilities report would make the data more useful to the public. Therefore EPA will add a section to the Form R that will require the reporting facility to provide the distribution of dioxin and each dioxin-like compound for the total quantity that the facility is reporting. If a facility has information on the distribution of the dioxin and dioxin-like compounds, the facility must report either the distribution that best represents the distribution of the total quantity of dioxin released to all media from the facility; or its one best media-specific distribution. This information is only required if it is available from the data used to calculate thresholds, releases, and other waste management quantities, no additional analysis is required. As with all other reporting under EPCRA section 313, this information will only be required if the facility has information that can be used to make a reasonable estimate of the distribution from the available data. With the distribution of the individual members of the category reported on each Form R the user of the data can determine the grams TEQ that correspond to the absolute grams reported and can adjust the grams TEQ as TEF values change over time. Under this reporting mechanism all of the information that the commenters have stated is important to determining the significance of quantities reported for this category will be provided to the public on one Form R. This way all parties can express the data in whichever format they believe is best, and since the first thing that must be

determined under any reporting method is the mass of each member of the category there should be little additional burden associated with including the distribution.

3.B.iii.b. Using TEQ for Determining Reporting Thresholds

Commenter List: C-1408, C-1419, C-1420, C-1425, C-1428, C-1436, C-1442, C-1443, C-1448, C-1457, C-1814, C-1815, C-1841, C-1844, C-1845, C-1853, C-1856, and C-1865

Comment: All of the commenters on this issue requested that the reporting threshold for the dioxin and dioxin-like compounds be set in terms of TEQs. Most of these commenters indicated that the reasons they support a TEQ-based threshold were the same as the reasons they support reporting release and other waste management quantities in terms of TEQs (see the first paragraph of the preceding comment summary).

Two commenters argued that since EPA proposed to use TEQs for reporting release and other waste management quantities, that not basing the reporting threshold on TEQs would be inconsistent. The commenters stated that a facility may trigger reporting by having emissions that exceed the threshold (in terms of absolute weight) but having no significant reporting quantity (in terms of TEQ equivalent weight) and, therefore, no significant health risk. The commenters recommend the use of a consistent approach where TEQs are used for both threshold determinations and release and other waste management quantities. The commenters stated that such an approach would be consistent with the health risk rationale for EPCRA reporting, yet not rely on site-specific risk approaches that may evolve over time. Another commenter had similar concerns suggesting that it would be extremely burdensome and unnecessarily complex to have thresholds based on absolute grams and release and other waste management quantities reported in TEQs and recommended that EPA should use TEQs for both.

One commenter claimed that it may ease the reporting burden somewhat to base the EPCRA section 313 reporting threshold on a TEQ basis rather than attempting to develop mass-based estimates. Another commenter stated that in order to determine the sum of the mass of the 17 dioxin and dioxin-like compounds, one already will have determined the mass of each compound individually and that with data reported by compound, a TEQ can easily be calculated. The commenter also suggests that there are short-term screening bioassays for determining the TEQ of a sample that are less expensive, more sensitive, and can be done more rapidly than traditional analytical chemistry methods. The commenter stated that rather than facilities trying to guess what their releases may be by not spending money on expensive analytical chemistry methods, if the reporting threshold were based on TEQs, a facility can readily and more inexpensively screen its releases. The commenter argued that having a reporting threshold based on TEQ is more representative of potential health risks and recommended that EPA consider using some amount of TEQs as the reporting threshold. Another commenter suggested that one option would be to report releases of each dioxin-like compound if the total, in TEQ, exceeds some chosen threshold.

One commenter stated that TEQs should be used for thresholds and noted that reporting dioxin on a mass basis is quite different from reporting on a TEQ basis. The commenter asserted that since some of the dioxin-like compounds have TEFs of 0.001 then the 0.1 gram threshold could require facilities that produce 0.0001 gram TEQ of dioxin to report. The commenter claims that when compared to the estimate that there are 2,973 grams TEQ of U.S. dioxin emissions such amounts are insignificant and meaningless. The commenter maintained that using TEQs instead of the mass of each compound for determining whether an EPCRA reporting threshold for dioxin and dioxin-like compounds is exceeded would not deprive EPA or the public of information regarding meaningful releases of dioxin. The commenter also recommended that whatever units EPA decides to use they should be the same for thresholds and for release and other waste management quantities.

One commenter suggested that EPA should require sources to use toxicity factors in calculating the manufacturing threshold for dioxin and dioxin-like compounds to avoid triggering the threshold based solely on non-detection. The commenter stated that the 17 dioxin-like compounds to which the 0.1 gram proposed reporting threshold would apply vary in toxicity by a factor of 1,000 but that EPA does not take this variation in toxicity into consideration for the purpose of determining the manufacturing threshold. The commenter stated that given that sources must report one-half the detection limit if the source cannot confirm the absence of dioxin and dioxin-like compounds, they were concerned that sources will trigger the manufacturing threshold based solely on non-detection of each of the seventeen dioxin-like compounds.

Response: EPA did not proposed to use TEQs as the units of measurement for the EPCRA section 313 reporting threshold for dioxin and dioxin-like compounds. EPA has the same concerns for using TEQs for EPCRA section 313 thresholds as it does for reporting releases and other waste management quantities in terms of TEQs, and most of the issues raised here have been addressed in the preceding comment summary and response. Most importantly, since EPA has determined that each of the

dioxin-like compounds meets the listing criteria of EPCRA section 313, the actual mass of each member of the category should be included in threshold determinations. Also, the fact that the TEFs and thus the TEQs can change over time, is even more important for thresholds since TEF changes would in effect change the threshold because the same mass quantity that would have exceeded the threshold before the change may not exceed the threshold after the change.

As one of the commenters pointed out, using TEQs as the units for the reporting threshold is much different than using actual mass. The commenter showed how a 0.1 gram threshold for a dioxin-like compound with a TEF of 0.001 would be equivalent to a 0.0001 gram TEQ threshold. The opposite of this is that if the 0.1 gram threshold were in units of TEQ, then for dioxin-like compounds with a 0.001 TEF, it would take 100 grams to reach the reporting threshold. Using TEQs as the units for the reporting threshold would thus be equivalent to establishing separate thresholds for each member of the dioxin and dioxin-like compounds category based on their relative toxicity. EPA does not believe that any of the reporting requirements of EPCRA section 313 should be based on relative toxicities since, as discussed elsewhere in these comment responses, EPCRA section 313 is not a risk-based program and reporting is not intended to communicate information about relative risks. Rather it provides local communities with data on release and other waste management quantities on listed toxic chemicals, so that they may use the data in conjunction with information on chemical properties (e.g. persistence and bioaccumulation) and site-specific information to determine if releases present a potential risk.

Several commenters expressed concern about consistency between the units of measurement for the threshold for the dioxin and dioxin-like compounds category and the units of measurement used to report releases and other waste management quantities. While EPA is not adopting the use of TEQ as some commenters requested, EPA is being consistent since absolute gram quantities will be used for both thresholds and the reporting of releases and other waste management quantities.

EPA does not agree with those commenters who stated that the information collected under a 0.1 gram threshold would, in some cases, represent such a small portion of the estimated national amount of dioxin TEQs that the data would not be useful. On a facility-by-facility basis EPA expects that the amounts reported will be small but that does not mean that it will not be useful or meaningful to the public. Even information that shows little or no releases helps communities to understand what risks may be or may not be present in their communities and helps government agencies to target resources. In addition, since not all of the sources of dioxin and dioxin-like compounds will be reporting under EPCRA section 313 the amount reported will be a larger portion of the total amount reported under EPCRA section 313 than it will be on a national basis. The issues concerning how many sources of dioxin and dioxin-like compounds are captured by EPCRA section 313 are addressed elsewhere in these comment responses.

EPA does not agree that reporting in terms of TEQs will necessarily be less burdensome. As one commenter stated, in order to determine the sum of the mass of the 17 dioxin and dioxin-like compounds, one already will have determined the mass of each compounds individually and that with data reported by compound, a TEQ can easily be calculated. Since the TEQs are calculated from the relative amounts of dioxin and each dioxin-like compound that is present, it is an additional step to present the data in terms of TEQ and therefore it should not be less burdensome.

The commenters concerns about the reporting of 1/2 of the detection limit for dioxin and dioxin like compounds are addressed elsewhere in these comment responses for dioxin. However, EPA did not state that all sources must report one-half the detection limit if the source cannot confirm the absence of dioxin and dioxin-like compounds.

3.b.iv. Guidance for Reporting and Measuring Releases of Dioxin and Dioxin-like Compounds.

Overall Commenters: C-446, C-538, C-1168, C-1352, C-1353, C-1354, C-1406, C-1407, C-1409, C-1419, C-1421, C-1423, C-1427, C-1428, C-1430, C-1431, C-1432, C-1434, C-1436, C-1440, C-1441, C-1443, C-1457, C-1450, C-1453, C-1458, C-1460, C-1809, C-1812, C-1814, C-1815, C-1820, C-1824, C-1825, C-1836, C-1844, C-1845, C-1850, C-1853, C-1856, C-1858, C-1861, C-1862, C-1864, and C-1865

3.b.iv.a. Emission Factors, Estimation Methods, and Need for Guidance.

Commenter List: C-446, C-538, C-1168, C-1353, C-1354, C-1406, C-1407, C-1409, C-1419, C-1421, C-1423, C-1425, C-1427, C-1428, C-1430, C-1431, C-1435, C-1436, C-1450, C-1453, C-1458, C-1812, C-1815, C-1820, C-1825, C-1836, C-1844, C-1845, C-1858, C-1861, C-1864, and C-1865

Comment: Many of the commenters stated that the estimation of releases of dioxin and dioxin-like compounds will be too inaccurate for reporting under EPCRA section 313. Some commenters stated that there are no accurate methods for estimating dioxin and dioxin-like compound emissions particularly at the levels proposed for EPCRA section 313. Several commenters noted that EPCRA “does not require additional testing; it only requires reporting of existing data or in the absence of data, no reporting or best estimates of emissions.” The commenters stated that only a few industries are required (under other statutes) to actually measure dioxin emissions and that most of the facilities that are subject to EPCRA section 313 reporting will therefore need guidance to accurately estimate the projected dioxin releases. Some commenters stated that apart from Agency guidance to determine realistic emissions factors, these commenters suggest they will report zero releases. Several commenters specifically mentioned electric utilities as facilities that have never attempted to sample their dioxin emissions and will find it difficult or impossible to detect measurable amounts of dioxins at this low level. The commenters stated that these electric utilities are likely to attempt compliance by estimating their emissions using unreliable and overstated emission factors. While the commenters had differing comments on the ability to report for dioxin and dioxin-like compounds most commenters stated that if this is required then EPA must develop reporting guidance for the dioxin and dioxin-like compounds category. One commenter stated that the proposed reporting levels are not consistent with analytical detection limitations of stack measurement equipment and monitoring devices.

One commenter stated that the requirement that dioxins be reported in releases and waste management activities to the nearest 0.0001 grams per year will result in highly questionable data with an implied accuracy far beyond any realistic measure of actual quantities. The commenter cited EPA’s statement in the preamble that no monitoring of dioxin is required, but that EPA has not indicated how reporters should estimate release and waste management quantities. This commenter and others suggested that EPA should develop guidance on estimating dioxin quantities, including cases in which reporting zero is appropriate.

Most commenters agreed that emission factors for dioxin and dioxin-like compounds are very specific in nature, being applicable only to systems that are closely related to the original facility and conditions that were used to determine the factors. Commenters stated that the current state of knowledge cannot support the development of emission factors that can be used to accurately estimate emissions on an individual facility-specific basis. As an example, one commenter stated that emission factors determined from electric utilities equipped with hot-side ESP’s would only apply to similarly designed utilities. The commenter stated that when sampling was performed at these facilities, many instances of non-detectable levels of dioxins were observed and reported, even when sampling times were extended and state of the art techniques used. The commenter stated that raising the reporting threshold will avoid unsupported estimates. Another commenter stated that raising the thresholds would allow for more accurate estimations. Some commenters questioned how accurate the estimates could be, commenting that 0.1 grams seemed too precise a value to be derived by estimation or emission factors (considering dioxins are not intentionally manufactured and are not typically isolated). One commenter provided the example of using historical emission factors to predict that dioxins would be present in power plant emissions. Some commenters believe that the 0.1 gram threshold and the 0.0001 gram reporting limit is intended to force facilities to monitor and test since these levels are at such a low level.

Another commenter stated that the “incidental manufacture” of extremely minute amounts of these chemicals may be unavoidable and that whether they actually do so depends greatly on several variable factors, including fuel type, fuel quality and the unit’s operating parameters. The commenter stated that this complicates any determination of whether dioxin-like compounds are produced and even if these factors stayed constant, the ability to reliably estimate or measure any potential releases is extremely limited. The commenter stated that if they exist at all, the incidentally manufactured chemicals occur at levels so low, information would not be available from existing data sources.

Several commenters noted the Agency’s own comments regarding estimating the amount of dioxin and dioxin-like compounds formed and/or released indicate that current emission factors are not precise enough to calculate emissions from individual facilities. Some commenters cited the EPA draft “Inventory of Sources of Dioxin in the United States” published in 1998 (EPA/600/P-98 / 002Aa, April 1998); which states, “the current state of knowledge cannot support the development of emission factors that can be used to accurately estimate emissions on an individual facility basis.” The commenter stated that many industrial processes that coincidentally manufacture dioxin and dioxin-like compounds have very limited analytical data available and that a lack of guidance and data results in a costly burden on facilities, forcing them to analyze and monitor for low level dioxins. One commenter stated that this was confirmed by studies which had additional data from utility emissions and that the statistical analysis of the data indicated that emission factors were very unreliable. Another commenter noted that the Agency peer review process indicated “EPA’s recently updated national dioxins emissions inventory concluded that the best estimates are accurate only to within a factor of two, while estimates from many sources are inaccurate by at least an order of

magnitude.”, and that “the uncertainty in the emissions estimates for many sources ... was higher than EPA portrayed in the emissions inventory.”

Response: EPA disagrees with the commenters who suggest that the measurement of dioxin and dioxin-like compounds will be too inaccurate to allow for reporting under EPCRA section 313. The monitoring that does take place for these chemicals is able to detect these compounds at levels far below the 0.1 gram EPCRA section 313 reporting threshold or even the 0.0001 gram reporting requirement. In addition, the emission factors that have been developed are based on data from monitoring at levels far below the reporting levels for EPCRA section 313. The commenters’ statements that emission factors are closely related to specific conditions at the original facility are correct and EPA will take that into consideration in recommending any specific emissions factors. EPA disagrees with those commenters who suggested that the emissions factors contained in EPA’s most recent draft Inventory of Sources of Dioxin in the United States cannot be used to develop emissions factors on an individual facility basis. EPA’s previous statements on this issue relate to using the emission factors contained in that document for all facilities within a particular industry sector. However, EPA believes that with further refinement there are a subset of the emission factors that would be appropriate for making at least a reasonable estimation of threshold and release quantities under EPCRA section 313. This further refinement will take into consideration the very issues the commenters have raised about the importance of site specific conditions in the use and development of appropriate emission factors and will also take into account comments that the SAB has made on the latest dioxin inventory.

EPA does agree that there may be industries for which the Agency will not be able to provide reporting guidance. For these industries, EPCRA section 313(g)(2) states that:

“In order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation...”

Therefore, EPCRA section 313 does not require facilities to test or monitor for toxic chemicals but rather it requires that covered facilities make reasonable estimates using their best readily available data. Further, as EPA explained in the 1988 final rule, if a covered facility has no information, including no reasonable estimates or other information reasonably known, on the concentration of the toxic chemical in the mixture, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations.

In response to those commenters that suggested that EPA must provide guidance for reporting dioxin and dioxin-like compounds, EPA does agree that guidance should be provided to assist facilities in determining threshold and release quantities. As EPA stated in the proposed rule:

“EPA intends to develop reporting guidance for industries that may fall within this reporting category. The guidance developed will be consistent with the methods and procedures that EPA has developed for determining if dioxin and dioxin-like compounds are present in various industrial processes, including Method 23 (Ref. 77) developed for electric utilities. In developing the reporting guidance for the dioxin and dioxin-like compounds category EPA will work with interested parties to provide the best possible guidance for reporting facilities.” (64 FR 712, columns 2 and 3)

EPA will provide a guidance document to assist certain facilities in making thresholds and release determinations for dioxin and dioxin-like compounds. However, as explained previously, EPCRA section 313 does not require facilities to test or monitor for toxic chemicals but rather it requires that covered facilities make reasonable estimates using their best readily available data. In addition, as EPA explained in the 1988 final rule, if a covered facility has no information, including no reasonable estimates or other information reasonably known, on the concentration of the toxic chemical in the mixture, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations.

EPA disagrees with those commenters who stated that the requirement to report for dioxin and dioxin-like compounds will force facilities to monitor and test for these compounds. EPA believes that, as discussed above, the EPCRA section 313 statute clearly does not require additional monitoring or testing. If a facility does choose to monitor or test for these compounds it will not be as a result of the requirements for reporting under EPCRA section 313.

EPA also disagrees with the comment that the information reported for this category would be better if the thresholds

were raised because the engineering estimates and emission factors are acceptable for higher thresholds but not for those EPA has proposed. The fact is that whatever emissions factors or estimation methods that facilities will have available will be the same no matter what numerical value is established as the EPCRA section 313 reporting threshold. If the reporting thresholds were raised the only difference would be that, based on the same estimation methods and emission factors, less facilities would have to report. There would be no improvement in the accuracy or precision of the data since it will be based on the same estimation methods and emission factors. Such improvements only come when the estimation methods and emissions factors are based on better information. In addition, the statute only requires reasonable estimation not highly precise calculations based on monitoring or test data.

3.b.iv.b. Using a One-Half the Detection Level for Estimating Releases.

Commenter List: C-1352, C-1406, C-1425, C-1427, C-1428, C-1430, C-1432, C-1440, C-1441, C-1443, C-1453, C-1457, C-1460, C-1814, C-1824, C-1825, C-1836, C-1844, C-1845, C-1853, C-1856, C-1862, and C-1868

Comment: Most commenters believe that using the one-half the detection level (or any other artificially generated value) as an estimate of non-detected dioxin and dioxin-like compounds released to the environment will exaggerate the amount released. Some commenters stated that reporting at half the detection level would result in incorrect and misleading information, and that this information would not provide the public with meaningful and accurate information about actual emissions and the associated risks in their neighborhoods. Some commenters alleged release numbers are merely a mathematical consequence of multiplying a large throughput stream by the presumed amount of dioxins (for example: 1 part per trillion). Commenters stated that even when no dioxin is believed to be present based on monitoring data, the estimation using this methodology will exceed the 0.1 gram per year EPCRA section 313 reporting threshold. All commenters request guidance to determine emissions levels, especially when use of half the detection limit values is warranted (if at all) or when the use of half the detection limits would produce inaccurate results (in which case most commenters suggest reporting zero).

One commenter stated that, under existing TRI guidance, a facility conducting an analysis which does not detect the substance should not automatically assume that the substance is not present. Based on reasonable judgment, if there is reason to believe the substance is present, even if not detected, then the facility should use one-half its detection limit in determining whether a reporting threshold has been exceeded. The commenter stated that under the guidance, there are only two choices -- assume the substance is zero or report based on the assumption that the substance is present at one-half its detection limit. This commenter went on to state that if the reporting threshold for the dioxin and dioxin-like compounds category is set at near zero, i.e., 0.1 gram or 1 gram, then use of the one-half the detection limit approach for nondetects will always result in the reporting of a theoretical number for the category without a firm scientific basis.

Other commenters requested clarity about whether reporting of non-detects would be required as if each of the 17 different isomers were present to some degree or another. One of these specifically detailed the type of guidance needed, "If only one isomer has ever been detected in the emission stream, is that a reason to believe that the other 16 isomers are not present, or a reason to believe that the other 16 isomers are present below the detection level? If all 16 isomers are reported at 1/2 the detection level, this would "create" emissions on paper which are many times the levels which are known to be present through actual analysis, and which are not actually there."

Still other commenters seek clarity as to which EPA measuring techniques would allow a non-detect finding to be reported as zero (for example: air emissions monitored using Method 23), when the measurement techniques would require reporting at the proposed half detection limit. These commenters state the TRI rule is inconsistent with other EPA policies. One commenter cites the Great Lakes Binational Toxics Strategy protocols to treat all non-detects as zero. Commenters stated that several techniques have been developed to estimate dioxin content by EPA's Office of Research and Development ("ORD"). One commenter noted that ORD has issued guidance which discusses alternative statistical techniques for handling non-detects and the ORD guidance indicates that there are a variety of ways to handle data sets with varying percentages of detects and non-detects. For example, for data sets containing between 50% and 90% non-detects, the guidance suggests using the "tests for proportions." The commenter stated that if the Method 23 approach is not adopted, EPA should acknowledge in its final TRI rule that it is appropriate for facilities to use the ORD technique and any other appropriate statistical techniques to report PBT data.

One commenter said, "...nondetect values should be considered to be zero. This is consistent with the EPA Region 6 policy, *The Use of Minimum Quantitation Levels (MQLs) in Water-Quality Based Permits* issued on July 1, 1991. This approach was also used in the EPA draft *National Guidance for the Permitting, Monitoring, and Enforcement of Water-Quality-based Effluent Limitations Set Below Analytical Detection/Quantitation Levels* issued in March 1994."

One commenter notes several examples where additional monitoring has produced measurable dioxins when previous testing had reported no detectable dioxin levels. This supports using some estimation method if dioxins are expected to be present but are below the detection level. The commenter says "As the International Joint Commission of the U.S. and Canada states in its Sixth Biennial Report on Great Lakes Water Quality; 'zero discharge does not mean less than detectable.'" The same commenter stated the pollution prevention data will be required before non-detection can be presumed to be zero.

Another commenter stated that, "However, if a facility chooses to use an alternative, less-than-state-of-the-art method, and no dioxin is detected, then the facility should report a concentration equivalent to one half the detection limit. In this way, facilities will have incentive to seek out and use the best available method for detection."

Response: EPA did not propose to require that 1/2 the detection limit be reported for all non-detects for dioxin and dioxin-like compounds. The only reference to this appeared in the economics analysis for the proposed rule and it was only used there in order to determine a high end estimate for the possible number of facilities that might be required to report under the proposed thresholds. As the economics report clearly indicated, this was not intended as reporting guidance. As discussed in the previous comment response, EPA will provide a guidance document to assist facilities in making thresholds and release determinations for dioxin and dioxin-like compounds. This guidance will address the issue of when it is appropriate to use 1/2 of the detection limit when determining threshold and release and other waste management quantities under EPCRA section 313. For the reporting of dioxin and dioxin-like compounds there are circumstances and detection methods for which 1/2 the detection limit would be an appropriate estimate and others for which it would not. EPA's guidance document will address these issues and concerns. The guidance document will be consistent with the methods and procedures, including Method 23, that EPA has developed for determining if dioxin and dioxin-like compounds are present in various industrial processes. EPA's Office of Research and Development will be consulted and play a key role in the development of the guidance for the reporting of dioxin and dioxin-like compounds under EPCRA section 313. In addition, as EPA stated in the proposed rule, EPA will work with interested parties to provide the best possible guidance for reporting facilities.

Under EPCRA section 313 the general guidance on the use of 1/2 of the detection limit is intended to apply to circumstances when, based on its site-specific knowledge about its processes, a facility knows that a reportable chemical is present but that the detection method being used is not sensitive enough to detect the chemical. This discourages facilities from using insensitive detection methods just to avoid reporting under EPCRA section 313. It is also consistent with the fact that monitoring data alone is not always the best available information for making reasonable estimations.

3.b.iv.c. Other Issues Associated with Measuring/Reporting Low Level Dioxins.

Commenter List: C-1421, C-1423, and C-1865

Comment: The commenters stated that EPA has not addressed the issue of how to segregate quantities "manufactured" from quantities present as impurities or background levels and that the likely outcome will be that, in order to ensure compliance, facilities will be forced to make inaccurate, overly conservative estimates that will result in over-reporting. The commenter stated that this has the potential to mislead and needlessly alarm the public. One commenter stated that they supported EPA's statement that it is proposing an activity qualifier for dioxins "[i]n order to focus reporting on those facilities that actually add to the environmental loading of these chemicals.", but in reality, it is often difficult if not impossible to determine whether extremely low levels of dioxins or other PBTs are produced at a facility versus simply present due to background levels or other sources. The commenter stated that as an example, dioxins may be present in stormwater or intake water at a variety of industrial facilities. This problem is yet another aspect of the infeasibility and limited utility of using such low thresholds to compel TRI reporting for PBTs. EPA needs to address the issue of segregating background levels, and to clarify how it expects "manufacturers" to distinguish "manufactured" quantities from background quantities at such low levels.

Another commenter stated that EPA admits there are great problems with tracking chemicals at such low levels and cited EPA's statement that "facilities that process raw materials would be required to report simply because raw material contains background levels of these chemicals." (64 Fed. Reg. 710.) The commenter stated that EPA is obviously aware of the true difficulties and problems with reporting chemicals at such low levels. The commenter stated that at the levels proposed for these chemicals (e.g., dioxins), discernment of real data from background or from interferences and analytical errors, is difficult at best, impossible at worst, and certainly misleading in terms of useful information. The commenter stated that requiring facilities to submit potentially inaccurate reports on dioxin at these levels will compromise the integrity of the TRI database and will not provide the public with meaningful information. The commenter stated that EPA should not lower the threshold for dioxin

reporting to avoid this inaccurate reporting.

Response: EPA believes that since most of the processing and otherwise use activities for dioxin and dioxin-like compounds are excluded under the modified manufacture only qualifier, background quantities will not be a significant problem in most cases. The processing and otherwise use activities that are reportable involve chemicals that contain dioxin and dioxin-like compounds created as a result of their manufacturing process and will not be background quantities. With the exception of combustion processes, the coincidental manufacturing of dioxin and dioxin-like compounds will generally occur within controlled manufacturing processes and will be dependent on conditions of the process and feedstocks to the process which should not normally contain dioxin and dioxin-like compounds. Even for combustion processes any dioxin and dioxin-like compounds in the raw material are likely to be destroyed during initial combustion and the dioxin and dioxin-like compounds that exist after combustion will represent newly manufactured quantities. Therefore, background quantities should not be a significant problem within those processes. However, if there are other sources such as stormwater that contain dioxin and dioxin-like compounds then the facility will only have to report if it has data that would allow at least a reasonable estimation of the quantities that are not from background sources. In addition, certain background quantities may be exempt from reporting under the exemption for process water and non-contact cooling water drawn from the environment, see 40 CFR section 372.38(c)(3). As with all reporting under EPCRA section 313, the requirements of EPCRA section 313(g)(2) apply:

“In order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation. In order to assure consistency, the Administrator shall require that data be expressed in common units.”

EPA's statement that "facilities that process raw materials would be required to report simply because raw material contains background levels of these chemicals" was not an admission that there difficulties and problems with reporting chemicals at such low levels. In fact, this statement reflects just the opposite since EPA believes that there are data that facilities that process raw food materials (which as discussed elsewhere in these dioxin comment response, were the main facilities of concern) could use to make reasonable estimations of amounts involved. Given that facilities are not required to report unless they can make at least a reasonable estimation of the quantities involved, EPA does not believe that the data that will be reported will be misleading or that it will compromise the integrity of the TRI database. EPA does not believe that the commenters have identified any reporting problems that would justify not lowering the reporting thresholds for dioxin and dioxin-like compounds.

Commenter List: C-1432

Comment: The commenter stated that EPA will need pollution prevention information to verify compliance with EPCRA reporting requirements by any EPCRA facility in a dioxin-producing industry that does not report releases of a dioxin or dioxin-like compounds because it claims to have zeroed out the production of these chemicals. As an example, the commenter stated that zero dioxin was confirmed at pulp paper plants by a combination of chemical analysis and pollution prevention engineering data which showed that the chlorine source to the dioxin-forming process reaction was blocked by substitution of peroxide in place of chlorine bleaching. The commenter stated that since dioxin cannot be 'coincidentally manufactured' without chlorine, this example can be generalized to other types of facilities, and the details of this confirmation approach have been set forth for other processes. The commenter stated that data on pollution prevention coupled with chemical analysis of process and source releases can confirm zero dioxin at facilities which claim to achieve zero dioxin.

The commenter stated that end-of-pipe chemical analysis data alone cannot verify zero dioxin production if pollution prevention data are not obtained, because of significant measurement error related to the analytical detection limits achieved by the tools that are now available. The commenter stated that this error stems from failure to measure whether the dioxin-like chemical that was not detected in laboratory analysis of a low concentration sample is present at a level near zero or a level near the detection limit. The commenter stated that examples abound of the failure to verify zero dioxin from analytical detection limit data alone. The commenter cited the failure of two out of three stack tests of an oil-fired furnace at an oil refinery which failed to detect two specific dioxin-like compounds. The commenter stated that if a third test which confirmed the presence of both these dioxin-like chemicals had not been taken, the chemicals might have been reported at "nondetectable" or "zero" levels. The commenter stated that although production of all 17 dioxin-like dioxin and furan compounds is confirmed by process analysis at San Francisco Bay Area refineries, 89% of these dioxin-like chemicals were below detection limits in 34 tests of the facilities' waste water discharges, 2,3,7,8-TCDD was never detected in these Bay discharge tests, and 32% of these

tests failed to detect any of these 17 chemicals. The commenter stated that in 15 tests of these refineries' storm water runoff TCDD was always below detection and 59% of these 17 chemicals were "undetectable". The commenter stated that thirty tests of effluent from nine sewage treatment plants failed to detect any of seven dioxin-like dioxin compounds except OCDD, which was detected in 43% of the tests, and HpCDD, which was detected in 10% of the tests.

Response: EPA disagrees with the commenters conclusions that EPA will need pollution prevention information to verify compliance with EPCRA section 313 reporting for dioxin and dioxin-like compounds. While such information might be helpful, EPA can verify compliance through other mechanisms. For example, EPA will develop a guidance document for the reporting of dioxin and dioxin-like compounds and if such guidance applies to a facility that did not report, if questions are raised, then that facility will need to show why they did not report. In addition, if EPA believes that a facility should have reported for dioxin and dioxin-like compounds EPA can challenge their determination that they did not need to file. However, if EPA develops additional information that was not available to the facility, that information may be used in the future by the facility but it would not necessarily apply to previous reporting years in which the information was not available. The issue of non-detection will be addressed in EPA's guidance document and can be used to determine compliance. However, as explained previously, EPCRA section 313 does not require facilities to test or monitor for toxic chemicals but rather it requires that covered facilities make reasonable estimates using their best readily available data. In addition, as EPA explained in the 1988 final rule, if a covered facility has no information, including no reasonable estimates or other information reasonably known, on the concentration of the toxic chemical in the mixture, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations.

Commenter List: C-1434

Comment: The commenter stated that when traces of chemicals exist in products that are used in any volume, a facility would easily trip the limits set forth in the proposal and that for dioxin, the problem is exasperated because dioxins could be "manufactured" during chemical reactions and facilities would have no way to track these emissions. The commenter stated that in most cases the best information available to manufacturers is what is provided on material safety data sheets (MSDS) and that chemicals may not be included on the MSDS if they are present in a quantity which is less than 1% of mixtures or 0.1% for OSHA carcinogens. The commenter stated that therefore, facilities would have no way to know for certain that they released these chemicals at the low levels proposed by the agency without testing and that testing currently is not required for TRI reporting and would place an unreasonable burden upon manufacturing facilities. The commenter stated that dioxin in particular would only have to be present in levels of 10^{-14} to be reportable. The commenter stated that regardless, facilities would have to put more resources into attempting to monitor these chemicals and without specific records on MSDS sheets and without data from testing, facilities will not be able to defend their reporting.

Response: As EPA has stated in response to many of the issues raised concerning the reporting of dioxin and dioxin-like compounds, EPCRA section 313 does not require facilities to test or monitor for toxic chemicals but rather it requires that covered facilities make reasonable estimates using their best readily available data. In addition, as EPA explained in the 1988 final rule, if a covered facility has no information, including no reasonable estimates or other information reasonably known, on the concentration of the toxic chemical in the mixture, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations. If a facility truly lacks information that will allow reasonable estimations of quantities involved they would not have to test just to defend their reporting. For the manufacturing of chemicals, the information on a MSDS would not apply since the quantities involved are being manufactured at the facility. While quantities found in chemicals and mixtures would apply to the processing or use of those chemicals or mixtures if they contain dioxin created during their manufacture, most of these chemicals (such as pentachlorophenol) are well known and information on dioxin levels should be available.

Commenter List: C-1443

Comment: The commenter cited EPA's statement that some facilities may not have enough information to estimate the distribution of relative isomers, but could estimate the total mass. The commenter stated that this does not seem to make much sense: how could any facility have enough information to estimate total emissions without at least one analysis to prove that it does indeed have emissions at all? The commenter stated that this analysis certainly will be speciated and will provide the facility a fingerprint of which isomers are generated and relative quantities of each.

Response: While it is very likely that facilities that have monitoring or testing data will have at least some idea of the distribution of dioxin and dioxin-like compounds, there could be facilities with data that are not well speciated but that are

sufficient to make at least a reasonable estimate of threshold and release quantities. EPA wanted to make it clear that facilities that had such data would be required to report under a category but might not have enough data to report dioxin and each dioxin-like compound on an individual basis.

Commenter List: C-1856

Comment: The commenter stated the following with respect to the reporting of dioxin and dioxin-like compounds: (a) the majority of exposure to dioxin-like compounds comes through consumption of meat and dairy products, and that emissions into the local environment are unlikely to significantly increase typical exposures; (b) if releases are given neither in TEQ nor on a congener-specific basis, no estimates of incremental exposure or risk can be calculated; as discussed above, congener-specific release estimates are essential; and (c) releases by different modalities (air, water, to soil) are likely to result in substantially different exposures to local populations, and a single threshold will have substantially different risk implications for different modes of release.

In addition, the commenter stated that quantities of 0.1 gram TEQ and 0.1 gram total dioxin and dioxin-like compounds likely differ vastly in toxic potential, suggesting that the proposal of 0.1 gram was made without reference to potential exposure or health risk. The commenter stated that the toxic potential of 0.1 gram of dioxin and dioxin-like compounds (as opposed to 0.1 gram TEQ) from different industries is also likely to be substantially different because of different congener distributions, resulting in substantially different potential risks.

The commenter also stated that assumptions about non-detected congeners can strongly influence estimates of quantities, especially if they are reported in TEQ and that this is likely to be extremely important for publicly owned treatment works (POTWs), since they involve very large throughputs of very low concentrations of CDD/CDF congeners.

Response: The fact that the majority of exposures to dioxin and dioxin-like compounds may come from meat and dairy products does not mean that facilities that contribute to the loading of these compounds into the environment should not be required to report. As discussed in detail elsewhere in these comment response, EPCRA section 313 is not a risk based statute. EPA lowered the reporting thresholds based on the increased potential hazard for chemicals that persist and bioaccumulate not on the basis of the individual risks of the chemicals. The issues of reporting in terms of TEQ or by individual chemicals are discussed elsewhere in these dioxin comment responses but the fact that EPCRA section 313 is not a risk based statute also applies to these comments. In addition, the reporting thresholds are activity thresholds not release based thresholds as such they are not set based on the type of releases that occur. As for the specific comments on POTWs, they are not covered under EPCRA section 313 and thus this rule would have no impact on their ability to make reasonable estimations.

3.b.v. Manufacture-only qualifier for dioxin

Commenter List: C-022, C-041, C-311, C-403, C-553, C-1355, C-1407, C-1408, C-1409, C-1415, C-1421, C-1422, C-1428, C-1430, C-1432, C-1441, C-1443, C-1454, C-1457, C-1814, C-1822, C-1844, C-1845, C-1853, C-1856, C-1864, C-1865, C-1871, C-1899, C-1914, C-1932.

Comment: Comments were mixed with regard to EPA's proposal to add a manufacture-only qualifier to the dioxin and dioxin-like compounds category. Some commenters agreed with EPA's statements in the proposed rule concerning the burden reduction aspects of the qualifier and the fact that as a result, the dioxin reporting would focus on facilities that manufacture dioxin and dioxin-like compounds rather than those that process or otherwise use raw materials containing dioxin and dioxin-like compounds that have accumulated in those raw materials. One commenter stated that EPA should exclude background levels of dioxin and dioxin-like compounds from reporting. Some commenters stated that the qualifier would avoid duplicative testing and administrative costs among many processing and using industries which do not necessarily discharge dioxins or furans into the environment. Some commenters stated that all releases of dioxin and dioxin-like compounds must be reported not just those resulting from the manufacture of these chemicals. Other commenters noted that a significant gap is created by the manufacture-only qualifier because it would exclude the processing and otherwise use of chemicals that are contaminated with dioxin and dioxin-like compounds as a result of the processes used to manufacture them. Commenters specifically cited pentachlorophenol as an example of a chemical that is contaminated with dioxin and dioxin-like compounds from its manufacturing process. Commenters stated that the processing and use of such chemicals results in the release of dioxin and dioxin-like compounds that would go unreported under the manufacture only qualifier. One commenter stated that if the qualifier is finalized they would like to see language that requires facilities to report if the background levels of dioxin are modified,

concentrated, or somehow added to in the manufacturing process. Another commenter stated that if the Agency wants to exempt animal sources of dioxin, such as dioxin contained in meat and other animal products, it should craft the rule to do so and not cut out other significant sources of dioxin in the environment by exempting all facilities that process material containing dioxin.

Response: EPA believes that in order to obtain any reporting on dioxin and dioxin-like compounds a very low threshold is required, which is several orders of magnitude lower than the thresholds for other PBT chemicals. At such a low reporting threshold it is estimated that thousands of reports could potentially be filed by facilities, mainly food processing facilities, due to the amount of dioxins in the raw materials they process. The dioxins found in the meat and dairy products that food processors handle have been previously released, circulated in the environment, and bioaccumulated in animals, thus these are not additional loadings to the environment but loadings that have already occurred and cycled through the environment due to the persistence and bioaccumulative properties of these compounds. The unique combination of very low thresholds, the number of food processors that would be required to file, and the fact that they would be filing because of the bioaccumulation of previously released material led EPA to add the manufacture only qualifier to the dioxins category. The qualifier was added in response to the unique set of conditions that apply to the reporting of dioxin and dioxin-like compounds. The manufacture only qualifier was added to reduce reporting burden on facilities, mainly in the food processing industry, that results from the unique combination of circumstances related to the reporting for these chemicals and to focus on those activities that add to the loading of dioxins in the environment rather than on activities dealing with previously released and bioaccumulated chemicals.

However, EPA acknowledges that the commenters who noted that the processing and otherwise use of chemicals contaminated with dioxin and dioxin-like compounds as a result of their manufacturing process, are correct that these would be newly created and thus any releases of dioxin and dioxin-like compounds that are due to the processing and otherwise use of such chemicals would be new loadings on the environment. In addition, EPA agrees, and has never stated otherwise, that the processing or use of chemicals contaminated with dioxin and dioxin-like compounds could result in the release of these chemicals to the environment. Given the fact that the manufacture of certain chemicals also results in the manufacture of dioxin and dioxin-like compounds that remain with those chemicals as impurities, EPA believes that releases and other waste management quantities for the dioxin and dioxin-like compounds found as impurities with those chemicals should be reported under the dioxin and dioxin-like compounds category. Thus, EPA's original proposal would have created qualifier that was too broad. Consequently, EPA is modifying the qualifier to read as follows:

Dioxin and dioxin-like compounds (Manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical)

Chemicals that are contaminated with dioxin and dioxin-like compounds are considered chemical mixtures. EPA believes that narrowing its proposal in this fashion is consistent with EPA's intention to focus on new loadings to the environment for dioxin and dioxin-like compounds.

Commenter List: C-1407

Comment: The commenter stated that the activity qualifier for dioxin and dioxin-like compounds is intended to minimize the burden of reporting on naturally-occurring constituents of raw materials and that this qualifier would be consistent with the PBT criteria set forth by Canada's Department of the Environment in their Toxic Substances Management Policy. The commenter stated that the Canadian policy requires a chemical to be "predominantly anthropogenic" to be considered a PBT chemical. The commenter stated that EPA's assumption that these compounds are ubiquitous in the raw material may be incorrect. The commenter stated that these compounds may be formed in combustion processes due to the ubiquitous presence of *precursor* chemicals in coal, such as natural hydrocarbons and chlorine. The commenter argued that it is not reasonable to expect the hydrocarbon nor the chlorine to be removed from the raw material prior to combustion. Thus, the "incidental manufacture" of extremely minute amounts of these chemicals may be unavoidable.

Response: EPA disagrees that the sole basis for its qualifier was to minimize the burden of reporting. The qualifier was added in response to the unique set of conditions that apply to the reporting of dioxin and dioxin-like compounds. As noted above, EPA was, and remains, concerned that, because dioxin is ubiquitous in the environment, the reporting be focused on those facilities that actually add to the environmental loading of these chemicals. EPA did not state that dioxin and dioxin-like compounds would be ubiquitous in all raw material and did not intend to imply that all raw materials contain these compounds.

EPA stated that these compounds are ubiquitous in the environment and, thus, facilities that process raw materials containing these compounds might have to report because of the very low reporting threshold necessary to obtain reports from any sources including those facilities that coincidentally manufacture them. In addition, although the qualifier may be consistent with Canada's Toxic Substances Management Policy, EPA has not proposed any requirement that a chemical must be "predominantly anthropogenic" to be considered a PBT chemical under EPCRA section 313. The commenter is correct that dioxin and dioxin-like compounds may be manufactured in combustion processes due to the "ubiquitous presence of precursor chemicals" and that such "incidental manufacture" may be unavoidable. However, the mere presence of the dioxin precursors will not guarantee dioxin production. There are well documented conditions that favor the formation of dioxins during combustion, and in some cases it may be possible to stringently control fuel composition, flow times, temperature, and other conditions in order to substantially reduce or eliminate the incidental manufacture of dioxins during combustion processes.

3.b.vi. Providing Meaningful Information to the Public for Dioxin and Dioxin-like Compounds.

Commenter List: C-403, C-1352, C-1420, C-1423, C-1425, C-1434, C-1435, C-1436, C-1457, C-1460, C-1824, C-1836, C-1844, C-1858, C-1861, and C-1865

Comment: The commenters stated that the reporting of dioxin and dioxin-like compounds under a 0.1 gram thresholds would result in over-estimations and the reporting of inaccurate and misleading data because of the problems associated with accurately measuring these compounds at these levels. The commenters stated that inaccurate estimations and emission factors would be used and that reporting should be based on accurate data not estimations. The commenters did not believe that the reporting of dioxin and dioxin-like compounds would provide meaningful or useful information to the public. Some commenters stated that requiring facilities to submit potentially inaccurate reports on dioxin at these levels will compromise the integrity of the TRI database. Some commenters suggested raising the reporting thresholds to allow more accurate estimations of the manufacture and release of dioxin and dioxin-like compounds. Some commenters stated that the use of engineering estimates and emission factors is acceptable for higher thresholds but that reporting at the levels proposed by EPA requires more precise data. One commenter stated that TRI was never designed to gather or distribute this type of data. One commenter that supports more reporting for dioxin and dioxin-like compounds stated that they do not believe that meaningful information will be provide because not all facilities that potentially manufacture any of the 28 dioxin and dioxin-like compounds will have to report under the 0.1 gram threshold.

Response: EPA disagrees with the commenters that believe that the information reported under the dioxin and dioxin-like compounds category will be misleading to the public. Many of the commenters concerns are based on the assumption that the information that will be reported for dioxin and dioxin-like compounds will be so inaccurate that it will mislead the public, EPA disagrees with such conclusions. However, as explained previously, EPCRA section 313 does not require facilities to test or monitor for toxic chemicals but rather it requires that covered facilities make reasonable estimates using their best readily available data. In addition, as EPA explained in the 1988 final rule, if a covered facility has no information, including no reasonable estimates or other information reasonably known, on the concentration of the toxic chemical in the mixture, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations. Therefore, EPA believes that at a minimum the data that will be reported will represent at least reasonable estimations that will not mislead the public. Nothing in the EPCRA section 313 statute requires facilities to report over-estimations based on invalid or overly conservative assumptions. In addition, EPA will provide a guidance document for reporting on this category which should help to provide some consistency in the way facilities report for the category.

EPA also disagrees with statements that the information reported for this category would be better if the thresholds were raised because the engineering estimates and emission factors are acceptable for higher thresholds but not for those EPA has proposed. The fact is that the emissions factors or estimation methods that facilities will have available will be the same no matter what numerical value is established as the EPCRA section 313 reporting threshold. If the reporting thresholds were raised the only difference would be that, based on the same estimation methods and emission factors, less facilities would have to report. There would be no improvement in the accuracy or precision of the data since it will be based on the same estimation methods and emission factors. Such improvements only come when the estimation methods and emissions factors are based on better information. In addition, the statute only requires reasonable estimation not highly precise calculations based on monitoring or test data.

The issue one commenter raised that the data will not be meaningful because all facilities are not required to report for dioxin and all dioxin-like compounds is addressed elsewhere in these comment response in the response to those commenters that stated that many sources of PBTs, including dioxin and dioxin-like compounds, are not covered under EPCRA section 313.

The specific issue of the chemicals contained in the category is also addressed elsewhere in these comment response on dioxin and dioxin-like compounds. EPA also disagrees with the commenter who stated that TRI was never designed to gather or distribute this type of data. The data gathered as a result of this rulemaking is not different than the type of data currently collected under EPCRA section 313. EPCRA section 313 was designed to capture the releases and other waste management information for toxic chemicals that meet the statutory listing criteria. Nor has (or can) the commenter cite to anything in the statute that precludes EPA from using EPCRA section 313 to gather this type of information. Dioxin and dioxin-like compounds meet the listing criteria and to the extent that a facility can report at least reasonable estimations of the amounts involved, it is appropriate to collect this information under EPCRA section 313.

Commenter List: C-1442

Comment: The commenter provided several reasons why dioxin and dioxin-like compounds should not be added to the EPCRA section 313 list of toxic chemicals. Those comments not addressed elsewhere in these comment responses are summarized here. The commenter stated that EPA has been conducting the dioxin reassessment since 1991 and has been unable to formulate credible health policy with regard to dioxin let alone articulate to the general public the potential health concerns from environmental levels of exposure. The commenter stated that there continues to be debate on the health risks of low level exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin, the most widely studied of all of the dioxin-like compounds. The commenter stated that it is recognized that little toxicity data exist for the other dioxin-like congeners and that it is also recognized that there are shortcomings in the use of the TEQ approach for representing the contribution of all dioxin-like compounds as one relative potency-weighted value. The commenter questions how EPA can expect the lay public to deal meaningfully and responsibly with the TRI data on dioxin and dioxin-like compounds and suggests that the lay public cannot, and thus, dioxin and dioxin-like compounds should not be listed.

The commenter also stated that dioxin-like co-planar PCBs are not being treated the same way as dioxin despite the fact that one's exposure to co-planar PCBs may be even higher than to dioxin (on a TEQ basis). The commenter questioned the value of providing information to local citizens from releases that only make up a small percentage of overall releases and that omits co-planar PCBs, for which human exposure may be higher than the other dioxin and dioxin-like compounds.

The commenter stated that dioxin is already stringently regulated in the U.S. and in many industrialized countries around the world and that this is evidenced by a decline in dioxin levels in humans and in the environment over the past 10-20 years.

Response: Comments on the toxicity data for the members of the dioxin and dioxin-like compounds category are addressed elsewhere in these comment responses. Although EPA has not completed its dioxin reassessment there is a great deal known about dioxin and dioxin-like compounds which are among some of the most heavily researched toxic chemicals. Nothing in EPA's dioxin reassessment will change the fact that these chemicals are highly toxic, persistent, and bioaccumulative and easily meet the listing criteria of EPCRA section 313. Therefore, there is no reason not to collect information on releases and other waste management quantities for these chemicals. In addition, EPA does not share the commenters opinion that the "lay" public cannot deal meaningfully and responsibly with this information simply because EPA has not finished the dioxin reassessment and made any final determinations regarding its policy for these chemicals. EPA is not the only source of expertise available to the public; local universities are just one example of the many sources of technical expertise that the public and local communities can access for assistance if they so desire.

EPA disagrees with the statements that not including co-planar PCBs in a dioxin-like compounds category reduces the value of the information that will be collected. Elsewhere in these comment responses for dioxin and dioxin-like compounds, EPA has explained in detail the reasons the co-planar PCBs will remain listed with all of the other PCBs. Among these reasons are the lack of readily available estimation techniques for determining quantities of co-planar PCBs, as opposed to other PBT chemicals and the PCB listing as a whole (co-planar PCBs will be included in the estimation of PCBs), and the fact that EPA is lowering the threshold for the PCB category as a whole.

In addition, the fact that dioxin and dioxin-like compounds may be stringently regulated does not eliminate the concern for these chemicals. As long as they are still being produced and released into the environment the information on releases and waste management quantities will be important for communities and government agencies.

3.b.vi.a. Release Data is Not Associated with Actual Exposures or Risk.

Comment: One commenter stated that they believe that EPA has lost sight of the fact that the original purpose of the TRI program was to communicate and educate the general public about risks where they work and reside. The commenter stated that the proposal to reduce the reporting threshold for PBTs to what they call absurdly low and in some cases unmeasurable levels, will require large resource expenditures to generate estimates of releases that are of questionable value to the general public and have little or no relevance to the actual exposures of the general public.

One commenter stated that based on many published articles, greater than 95% of the exposure to dioxin and dioxin-like compounds is through the consumption of meat and dairy products and that for most people, these types of food are not produced locally. The commenter stated that thus, exposures locally are not indicative of local releases and that furthermore, as most of the dioxin releases are airborne and it is known that airborne releases travel great distances, this again leads to the situation where local exposures are not indicative of local releases. The commenter stated that EPA documents identify two groups as highly exposed to dioxin: breast-fed infants and subsistence fishermen and that they do not identify people who live near major known emissions sources, e.g., medical or municipal waste incinerators, as highly exposed. The commenter stated that dioxin should not be added to the TRI because local releases do not translate into local exposures and would add little to one's understanding of overall dioxin exposure and potential health risks and may unduly alarm the public.

In their comments on the use of TEQs for thresholds and reporting one commenter stated that such relying on TEQs for threshold and reporting would be consistent with the health risk rationale for EPCRA reporting, yet not rely on site-specific risk approaches that may evolve over time.

Another commenter projected that 0.01 ton per year is the maximum estimated amount of dioxin generated for fuel combustion by the electric utility subsidiary and questioned how this information is going to be helpful or enlightening about whether these releases, when spread over the course of a year, pose any level of risk or danger.

Response: EPA disagrees with the commenter's statements. As discussed in detail elsewhere in these comment responses, EPCRA section 313 is not a risk based statute and thus when lowering the reporting thresholds EPA is not required to make a finding that the data collected will reflect an actual risk to local communities or that they will represent the major source of exposures. Moreover, EPA believes that a risk-based approach to EPCRA section 313 reporting is at odds with the basic premise of EPCRA section 313 which is to provide the public with information on the releases and other waste management quantities of toxic chemicals in their communities, enabling the users to evaluate this information and draw their own conclusions about risk. However, while the highest exposure and/or risk for certain compounds, such as dioxin and dioxin-like compounds may come from pathways other than direct exposure to local releases, this does not mean that local releases and other waste management quantities are not of concern or that the public should be denied such release information. The extent to which exposure to any chemicals, dioxin and dioxin-like compounds, are a result of local releases depends on the type and magnitude of the local release as well as local weather conditions. For example, dioxin and dioxin-like compounds released to air may travel long distances but local weather conditions, such as rain, can result in local deposition and the increased potential for local exposures. In addition, not all releases are to air, local releases to water, such as releases of dioxin and dioxin-like compounds to the San Francisco Bay or to other local water bodies, certainly result in increased potential for exposures at the local level. These kinds of factors are best evaluated at the local level.

In addition, while providing information about releases and potential exposures in local communities is an important aspect of data collection under EPCRA section 313 it is not the only use of the data. In fact, the term "local communities" is not as limited as the commenters would suggest. All communities may be interested in release and waste management data because the chemicals that are involved may end up in their communities from releases and transfers at facilities in other communities. For PBT chemicals which can find their way into the food chain, it is important for local communities to understand whether there are local sources or whether the source of these chemicals found in their community is elsewhere. A knowledge of the sources of chemicals that are found in environment is important right-to-know information. Also, in addition to "local communities", the information is frequently used by state and federal government agencies.

EPA also disagrees with the commenter's statements that the reporting thresholds for PBT chemicals have been set absurdly low and in some cases unmeasurable levels. As discussed in detail elsewhere in these comment responses, EPA believes that the thresholds for PBT chemicals are appropriate given the concerns for these type of chemicals. In addition, none of the thresholds are set at "unmeasurable levels", even the threshold for the dioxin and dioxin-like compounds category is many orders of magnitude above the levels that can be measured.

3.b.vi.b. General Understanding of the Coincidental Manufacture is Unclear.

Commenter: C-1405

Comment: The commenter stated that the term “coincidental manufacture” was not defined in the proposed rule and no meaning or scope was provided for the term. The commenter stated that they take this term to include the inadvertent production of very small concentrations of dioxins which may be produced as a result of thermal treatment of solid wastes including trash, medical and animal waste.

Response: The Agency disagrees with this comment. The term “coincidental manufacture” has been defined and used under EPCRA section 313 since the reporting requirements were first established in 1988. The meaning of the term is any manufacture of a listed toxic chemical that was not intentionally manufactured for some specific purpose. In the current regulations EPA states that “manufacture” is defined to include “a toxic chemical that is produced coincidentally during the manufacture, processing, use, or disposal of another chemical or mixture of chemicals, including a toxic chemical that is separated from that other chemical or mixture of chemicals as a byproduct, and a toxic chemical that remains in that other chemical or mixture of chemicals as an impurity” (40 CFR 372.3). Those chemicals that are intentionally produced for some specific purpose are simply “manufactured.” Over the past 10 years EPA has also developed extensive guidance on the definition of coincidental manufacture, for example, the EPCRA section 313 Question and Answer document and the Form R reporting instructions. EPA also addressed this issue at length in its rulemaking to add facilities in certain SIC codes (at 62 FR 23,849-850). As to the commenters statement that they take the term to include the inadvertent production of very small concentrations of dioxins which may be produced as a result of thermal treatment of solid wastes including trash, medical and animal waste, they are correct that these would be included but the term is not limited to just these sources.

3.b.vi.c. Reporting in Grams Versus Pounds.

Commenter List: C-1354, C-1434, C-1436, C-1443, C-1457, C-1815, C-1822, C-1825, C-1836, C-1841, C-1844, and C-1853

Comment: The commenters stated that dioxin and dioxin-like compounds should be reported in terms of pounds not grams. Some commenters stated that reporting in grams would cause confusion and that all other chemicals in the TRI data base are reported in pounds and therefore so should the dioxin and dioxin-like compounds category. One commenter stated that they saw no logical reason to report dioxin and dioxin-like compounds to be reported in any other units.

Another commenter stated that it would be potentially and significantly confusing to the public to adopt for the first time in TRI reporting history both a different unit (note that tons were not used for large emissions) and a different measurement systems (metric rather than English engineering) on the same form. The commenter stated that the goal of the TRI is to inform the public and that the best way to do this is to use a consistent reporting system. The commenter stated that American public is much more familiar with pounds than with grams.

Another commenter stated that for ease of public understanding and for consistency with standard TRI reporting, the dioxin and dioxin-like compounds category should be reported in terms of pounds.

One commenter stated that since one pound is equivalent to 454 grams, reporting small quantities in grams would give the impression that “454” is larger than “1” and similar to other releases which are measured in pounds when in fact they are equal. Reporting dioxin and dioxin like compounds in grams would appear to be an intentional effort to mislead the public with respect to the actual releases.

Response: EPA believes that the best way to report for dioxin and dioxin like compounds is to report in terms of gram quantities. Gram quantities are the common unit of measurement for this class of chemicals, either as absolute grams or grams TEQ. There is no reason to convert the reporting for dioxin and dioxin-like compounds to pounds simply to be consistent with the reporting of other TRI chemicals. EPA believes that reporting in terms of grams is also more practical since if dioxin and dioxin-like compounds were to be reported in pounds then all of the quantities reported would contain additional leading zeros many of which can be avoided by reporting in grams rather than pounds. EPA believes that the public can easily understand the reporting of releases and other waste management quantities in grams and that the public will not be confused. The data for dioxin and dioxin-like compounds will be clearly labeled as being in units of grams rather than pounds and if anyone wants to convert the information to pounds its a simple matter of multiplying the quantities by a factor of 0.0022046226. EPA is not attempting to mislead the public by using grams rather than pounds, this is simply a more common way to track the quantities that will be reported for dioxin and dioxin-like compounds.

In addition, a common comment that EPA receives is that the public should not just compare the pounds released of one chemical with the pounds released of another since there are many other factors that must be considered, such as differences in toxicity and type of release. EPA has agreed that when assessing the TRI data these other factors should be considered. Therefore, the fact that dioxin and dioxin-like compounds will not be reported in the same units as other TRI chemicals will help avoid potentially misleading comparisons between pounds released of various chemicals.

3.b.vi.d. Dioxin Reporting Alternatives to EPCRA Reporting Under Section 313.

Commenter List: C-1430 and C-1814

Comment: The commenters cited EPA's 1998 draft "Inventory of Sources of Dioxin in the United States" as the best available data on dioxin sources and questioned whether reporting under EPCRA section 313 will provide any new useful information. One commenter stated that although TRI has the advantage of reporting emissions from individual sources there are no appropriate emissions factors to estimate emissions from individual sources.

The commenters stated that for air emissions, a separate reporting mechanism already exists for seven hazardous air pollutants (HAPs), including dioxin and furans, under the Clean Air Act section 112(c)(6) and that regulations require that emission reports be filed with air permit authorities. The commenters stated that the identified sources will account for not less than 90% of the aggregate emissions of each HAP. The commenters suggested that reporting under EPCRA section 313 would impose useless and duplicative burdens on businesses.

Response: EPA disagrees with the commenters statements. While EPA's 1998 draft "Inventory of Sources of Dioxin in the United States" is the most recent and complete inventory the Agency has produced it is not a substitute for information reported by facilities. Facility specific information can be very important in determining the amount of dioxin and dioxin-like compounds that may be produced or even if they are being produced at all. Most facility specific information is not available for EPA to consider when making estimation of the sources of dioxin and dioxin-like compounds. As discussed elsewhere in these comment responses on dioxin and dioxin-like compounds EPA does not agree that there are no emission factors that can be used for individual sources and will provide a guidance document to address the issue. In addition, reporting under EPCRA section 313 has historically identified previously unknown sources of emissions.

As with other partial sources of information, the data that may be collected under the Clean Air Act for HAPs is not a substitute for reporting under EPCRA section 313. Most importantly this only addresses air releases not water or land releases or the other waste management information collected under EPCRA section 313. In addition, to the extent that a facility is already estimating air releases under the Clean Air Act, this should reduce the burden on the facility because they can simply use that data to estimate the air releases reported under EPCRA section 313.

Commenter List: C-1442

Comment: The commenter stated that since dioxin and dioxin-like compounds are persistent and bioaccumulative, they do not make good candidates for listing on the TRI since local exposures are not indicative of local releases. The commenter stated that there must be more appropriate avenues than the TRI for EPA to pursue for providing information to the public that is more relevant to assessing the potential health risks to the environment and to humans. The commenter suggested that perhaps with exposure primarily a result of meat and dairy product ingestion, dioxin levels in these foods should be measured and reported. The commenter also suggested that perhaps a program for determining soil levels or human body burden levels would be more appropriate. The commenter stated that reporting these compounds on the TRI contributes little value to the general public's understanding of potential health risks and may, in fact, cause substantial undue alarm.

Response: EPA disagrees with these statements. The issue of the importance of local releases and risks are addressed elsewhere in these comment responses on dioxin and dioxin-like compounds. The alternatives that the commenter suggests would not answer the basic question of who is producing and releasing these compounds so that they can persist and bioaccumulate in the food we eat. We already know that these highly toxic chemicals are in our food and in our bodies, but unless all of the sources of these chemicals are identified and the amounts released reported it will be difficult to reduce the amount of these chemicals that get into our food and bodies. Reporting under EPCRA section 313 is just one step to help identify sources and quantities of these chemicals. The commenter provided no compelling reasons for why the public should be denied information from the sources of dioxin and dioxin-like compounds.

Commenter List: C-1814

Comment: The commenter stated that TRI facilities are only responsible for about 30% of dioxin emissions reported in EPA's source inventory and many large sources are excluded. The commenter stated that therefore the TRI data for individual communities will highlight some very small dioxin sources while ignoring more important ones. The commenter suggested that in order to help communities better understand how TRI emissions impact potential risks, EPA should provide TRI data within the context of overall dioxin emissions. The commenter stated that at the very least, EPA should explicitly state in both the preamble and the rule that the TRI will only report on a small percentage of the known sources of dioxin and dioxin-like compound emissions to the environment. The commenter suggested that in addition, any subsequent publications of TRI data for dioxin and dioxin-like compounds include a statement clearly indicating the percentage of the estimated total dioxin and dioxin-like compound emissions, based on the current understanding of dioxin inventories.

Response: The issue of the extent to which sources of dioxin and dioxin-like compounds will be captured under EPCRA section 313 is addressed elsewhere in these comment responses. With respect to how EPA presents the data on dioxin and dioxin-like compounds that will be collected under EPCRA section 313, it is EPA's intention to make sure that this data is presented in the context of what EPA knows about all of the potential sources of these chemicals.

Commenter List: C-1440

Comment: The commenter stated that they believed that the general public would be better served through EPA funding scientific research to better inventory the sources and fate of these PBTs rather than prematurely alarming the public with data, which is misleading at best.

Response: EPA disagrees. First, EPA does not believe that the public will be prematurely alarmed by reporting data under EPCRA section 313 or that the data will be misleading. The purpose of EPCRA section 313 is to collect and disseminate release and other waste management data on toxic chemicals. That is exactly what the reporting of PBT chemicals such as dioxin and dioxin-like compounds is intended to do. Second, EPA believes that there is more than enough scientific data to support the reporting of PBT chemicals under EPCRA section 313. And finally, the data collected under EPCRA section 313 will provide information to help build the better inventory of the sources of these chemicals that the commenter stated is needed.

3.b.vii. Withdrawal of proposal to include dioxin-like PCBs in the dioxin category.

Comments in support of the withdrawal

Commenter List: C-1407, C-1409, C-1421, C-1422, C-1457, C-1814, C-1844, and C-1871.

Comment: Several commenters support EPA's decision to withdraw the proposal to modify the current PCB listing and move the 11 co-planar PCBs to the proposed dioxin and dioxin-like compounds category and retain the co-planar PCBs as part of the current PCB listing. Two commenters support EPA's decision to leave co-planar PCBs out of the dioxin and dioxin-like compounds category since the structure, metabolism, gene regulation and toxicities of PCBs are substantially different from those of 2,3,7,8-tetrachlorodibenzo-p-dioxin. One commenter takes exception with the use of the term "dioxin-like" as a way of describing PCBs and other chlorinated compounds and agreed that the PCBs should be kept out of the "dioxin-like" class. Other commenters also argued that PCBs are more appropriately classified as PCBs not dioxin-like compounds.

One commenter contends that since these chemicals are no longer allowed to be distributed in commerce, maintaining a separate EPCRA section 313 category for these chemicals will streamline data management. This approach will also enable EPCRA section 313 reporting for this category of chemicals to be more consistent with existing data already collected for the purposes of complying with TSCA. Further the commenter asserted that the approach is also consistent with EPA's Reinvention Policy and will enable "one-stop" reporting.

Another commenter asserted that it is unclear just how many grams of dioxin-like compounds would be excluded from this reporting since there are conflicting Agency proposals at work: the first is a much lower threshold for dioxins. The second includes only dioxins manufactured on site. Since PCBs are not generally manufactured on site, these 11 dioxin-like compounds would not be reported under the proposal if they were included as dioxins. On the other hand, if all dioxins (manufactured, processed, and otherwise used) are included in the EPCRA section 313 threshold determination, these 11 PCBs

could make the difference between a facility's reporting or not reporting dioxins. If the dioxin threshold remains as proposed, then the 11 PCBs should remain with the PCB category. Further the commenter argued that if the threshold is expanded to include sources other than those that manufacture dioxin on-site, then the PCBs should be part of the dioxin-like compounds category. If EPA does not modify the dioxin threshold to include all dioxin uses, the 11 dioxin-like PCBs should remain with the PCB category.

Response: While EPA agrees with the commenters that the co-planar PCBs should remain as part of the current PCB listing, the Agency does not agree with all of the reasons the commenters have presented. As EPA stated in the proposed rule:

“...EPA has determined that all PCBs persist and bioaccumulate. Since PCBs persist and bioaccumulate, EPA believes that they should be subject to lower reporting thresholds, and thus there is no need to move the 11 co-planar PCBs to the proposed dioxin and dioxin-like compounds category. Therefore, EPA has decided to withdraw its proposal to modify the current listing for PCBs and instead proposes to lower the reporting thresholds for the current PCB listing which covers all PCBs. EPA believes that, since all PCBs persist and bioaccumulate, it is appropriate to lower the reporting threshold for this class of chemicals and that this proposal is less burdensome than requiring separate reporting on the dioxin-like PCBs as part of the proposed dioxin and dioxin-like compounds category.” (at 64 FR 710, column 2)

EPA did not base its decision on a determination that co-planar PCBs were not “dioxin-like” and keeping them under the current PCB listing should not be interpreted as such a determination. Also, since EPA is not expanding the qualifier for the dioxin and dioxin-like compounds category to include all processing and otherwise use activities, the amounts of co-planar PCBs that might be reportable under the category would not be expected to contribute significantly to threshold determinations for the category at most facilities.

Comments that do not support the withdrawal

Commenter List: C-403, C-537, C-1432, and C-1442

Comment: The commenters asserted that the aggregation of dioxin-like PCBs together with other PCBs will fail to provide reporting of useful information on dioxin-like PCBs. The commenters either stated that the PCBs should be included in the category or the PCBs and all dioxin-like compounds should be reported separately. One commenter stated that the aggregate reporting of dioxin-like PCBs and other PCBs fails to provide any information on the release of dioxin-like PCBs to meet the research, regulatory, or public information goals of EPA's proposal. This commenter raised several points. The commenter stated that even if some facilities releasing dioxin-like PCBs reported these releases as a portion of their total PCBs production of ten pounds annually or greater, information on dioxin-like PCBs release would still be unobtainable. The commenter stated that aside from the food chain, where some dioxin-like PCBs tend to concentrate disproportionately, available measurements indicate that these dioxin compounds are only a small portion of the mass of all PCB compounds. The commenter stated that, further, some of these dioxin compounds such as PCB-126 are far more toxic than other dioxin-like and non dioxin-like PCBs. Thus, the commenter states that, in addition to all of the problems of dioxin-like chemical aggregate reporting, one would not know what, if any, portion of the total PCBs reported were dioxin-like. The commenter stated that the dioxin-like co-planar PCBs should also be reported individually so that a TEQ for all 28 dioxin and dioxin-like compounds can be calculated. Another commenter stated that based on information about current body burdens of co-planar PCBs, they compose as much or an even greater percentage of one's overall exposure than the 17 dioxin and dioxin-like congeners. This commenter cited an EPA document that stated that, "Estimates of exposure to dioxin-like CDDs and CDFs based on dietary intake are in the range of 1-3 pg TEQ/kg/day. Estimates based on the contribution of dioxin-like PCBs to toxicity equivalents raise the total to 3-6 pg TEQ/kg/day." Some commenters contend that reporting the co-planar PCBs differently from the 17 dioxin and dioxin-like compounds would make any assessment of the overall release and potential health impact of these types of compounds difficult. One commenter argued that PCBs are currently contaminating sediments and industrial sites nationally and have ruined fish as a natural resource for human consumption across the nation and that the distinction between dioxin-like PCBs and dioxin-like compounds made under this rule is a distinction without a difference. This commenter urged EPA to include all dioxin-like compounds, including PCBs, in the dioxin-like compounds category and to require strict accounting from all sources which release these compounds and which manufacture them, incidentally or by design.

One commenter contends that the failure to report dioxin-like PCBs as a distinct entity separate from other PBT chemicals may hold back information on a significant portion of the total dioxin-like hazard from releases by facilities that report under EPCRA section 313, even if all dioxin and furan releases were reported. The commenter stated that environmental

exposure measurements, such as those from fish in San Francisco Bay and from human tissues nationally, indicate that dioxin-like PCBs contribute a very significant portion of the total toxicity hazard from exposure to all dioxin-like chemicals. The commenter also stated that PCB releases might in some cases represent an inadequately measured yet significant portion of the ongoing dioxin release hazard. If, for example, PCB-126 comprises even a tenth of the PCBs release measured from San Francisco Bay Area sources, it would contribute substantially to total dioxin-like toxicity emission from some of these facilities. The commenter stated that the failure to provide release information on dioxin-like PCBs under EPA's proposal may result in failure to inform the public about a significant portion of the total dioxin toxicity that is still released.

Response: EPA agrees that PCBs are toxic chemicals of concern that have caused significant contamination of the environment and that co-planar PCBs may have dioxin-like health effects. However, there is no requirement that the co-planar PCBs must be moved from their current PCB listing to the dioxin and dioxin-like compounds category. EPA does not believe that the co-planar PCBs must be reported separately from the non co-planar PCBs because they may be more toxic than other PCBs. In general, chemical categories consist of chemicals that vary in their level of toxicity but this variability alone does not mean that release information must be reported separately for each chemical in the category. EPA believes that all PCBs are of concern and that leaving the co-planar PCBs under the current PCB listing will still provide the public with useful and important information. In proposing not to move the co-planar PCBs to the dioxin category EPA considered any potential additional burden associated with splitting the reporting for PCBs into two different listings as well as the fact that facilities are not likely to be able to determine quantities of the specific co-planar PCBs in question. Specifically, EPA considered the lack of readily available estimation techniques for determining quantities of co-planar PCBs, as opposed to other PBT chemicals and the PCB listing as a whole (co-planar PCBs will be included in the estimation of PCBs). EPA determined that since all PCBs are of concern and since the reporting threshold for all of the PCBs under the PCB listing would be lowered substantially, that the additional burden of requiring separate reporting on the co-planar PCBs was not warranted.

Commenter List: C-403

Comment: The commenter states that the failure to report dioxin-like PCBs would fail to provide information on that subgroup of dioxin-like compounds for which there is the greatest need for additional information. The commenter argued that EPA's evaluation of the emission of dioxin-like chemicals nationwide shows that there is less information on releases of dioxin-like PCBs than there is for other dioxin compounds. The commenter states that similarly, their survey of source information in the San Francisco Bay Area shows that, despite many measurements of dioxin and furan releases, and despite a handful of source measurements confirming PCBs, there are few or no source measurements for dioxin-like PCBs. The commenter states that the information on releases from facilities is even less available for the dioxin-like PCBs than it is for the other dioxin-like chemicals and that EPA's analysis in the proposed rule fails to consider adequately this extreme need for source release information.

Response: EPA agrees that there is far less information available on co-planar PCBs than for dioxin and other dioxin-like compounds. Much less testing and analysis has been conducted for these chemicals. This is an additional problem for reporting on the co-planar PCBs separately from the other PCBs. EPA considered the ability to estimate quantities of specific co-planar PCBs and determined that there is a lack of readily available estimation techniques for co-planar PCBs. In fact, at this time, the Agency would not be able to provide a basis for making a reasonable estimate of quantities of co-planar PCBs that may be manufactured in certain processes. In addition, EPCRA section 313 does not require any additional monitoring beyond that required by other provisions of law or regulation so listing the co-planar PCBs separately would not mean that additional source measurements would be developed. Thus, listing under EPCRA section 313 will not require the development of additional monitoring data that could be used to make reasonable estimations of thresholds or releases and other waste management quantities. Given the lack of information available for estimating quantities of co-planar PCBs and the potential additional burden associated with splitting the reporting for PCBs into two different listings, EPA decided to leave the co-planar PCBs under the current PCB listing.

Commenter List: C-403

Comment: The commenter asserts that the burden on industrial producers of dioxin-like PCBs is not an appropriate reason for excluding dioxin-like PCBs from the dioxin and dioxin-like compounds category because this will not meet EPCRA's right-to-know goal for dioxin-like PCBs. The commenter contends that EPA's cost analysis does not address dioxin-like PCBs specifically and thus, EPA's rationale in section VI of the preamble of the proposed rule (64 FR 688) that "this proposal is less burdensome than requiring separate reporting on the dioxin-like PCBs" is not based on any cost analysis in EPA's proposal. Commenter states that in any case, aggregate reporting of dioxin-like PCBs with a 10 pound threshold will fail to obtain the

required reporting on a substantial majority of dioxin-like PCBs releases or to provide needed information about dioxin-like PCB releases and therefore, EPA's perceptions regarding reporting burden cannot properly outweigh the public's need for the information which is denied under EPA's new proposal. The commenter refers to the proposal to retain dioxin-like PCBs under the PCB listing as the "less than 10 pounds exemption." The commenter stated that existing evidence demonstrates that many dioxin producing processes such as waste incinerators, oil-fired boilers, and other processes also produce potentially significant amounts of PCBs which are released to the environment from these facilities. The commenter states that this evidence suggests that at least some facilities reporting under EPCRA section 313 are likely to be releasing dioxin-like PCBs as a portion of these PCBs releases. The commenter contends that the evidence also suggests that most or all releases of dioxin-like PCBs at these facilities may be associated with total annual PCBs production of less than 10 pounds per facility and thus, EPA may not meet the requirement that a substantial majority of dioxin-like PCBs will be reported under this exemption.

Response: Reporting burden was not the sole or even most important factor in EPA's decision not to move the co-planar PCBs to the dioxin and dioxin-like compounds category. In reaching its final decision, EPA considered the fact that additional information would be collected on all PCBs by lowering the threshold for the PCB listing and that the additional information that would be collected was sufficient for EPCRA section 313 purposes as well as less burdensome. Even in its proposal EPA did not conclude that reporting burden alone outweighed the public's right-to-know about chemical releases. As stated in other responses to this issue, EPA is also concerned about the ability to estimate quantities of specific co-planar PCBs since there is a lack of readily available estimation techniques for co-planar PCBs. It is correct that EPA did not attempt to quantify the reduction in burden that would result from not including the co-planar PCBs in the dioxin and dioxin-like compounds category. However, EPA believes that it would be inherently less burdensome since facilities would not have to attempt to determine if they can estimate co-planar PCBs and filing one form would obviously be easier and less confusing than attempting to track and adjust the amounts that must be applied to two different listings and filing two reports. With regard to the issue of obtaining reporting on a substantial majority of "dioxin-like PCB" releases, as stated in EPCRA section 313(f)(2), the determination of whether a revised threshold meets the "substantial majority" standard is measured against the "total releases of the chemical at all facilities subject to the requirements of this section." As EPA stated in the proposed rule:

"For purposes of determining what constitutes a "substantial majority of total releases", EPA interprets "facilities subject to the requirements" of section 313 as the facilities currently reporting, ..." (at 64 FR 689, column 3).

Currently facilities required to report on PCBs must report on all PCBs, not just the co-planar PCBs or any other individual PCBs. The current listing includes all PCBs. Consequently EPA does not believe that the requirements of section 313(f)(2) function as an impediment to its decision to withdraw its proposal to include the co-planar PCBs in the dioxin and dioxin-like compounds category. As EPA stated in the proposed rule, and as is discussed in detail elsewhere in these comment responses, EPA believes that it has satisfied the requirements of EPCRA section 313(f)(2), without the need for quantitative support.

3.b.viii. Persistence Data for Dioxin and Dioxin-like Compounds.

In the proposal, EPA preliminarily determined that dioxin and dioxin-like compounds have persistence half-life values in soil that ranged from more than 20 to 1.5 years with all but one chemical having a soil half-life of more than 20 years. EPA received no significant comments addressing dioxin and dioxin-like compounds' persistence potential. EPA has reviewed information and all comments received from commenters on dioxin and dioxin-like compounds' persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that dioxin and dioxin-like compounds persist in the environment with half-lives of 2 months or greater and therefore meet the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical category can be found in EPA's support documents for this rulemaking. (Refs. 7 of the final rule). In addition, dioxin and dioxin-like compounds persist in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 0.1 gram.

3.b.ix. Bioaccumulation Data for Dioxin and Dioxin-like Compounds.

In the proposal, EPA preliminarily determined that dioxin and dioxin-like compounds have BCF values that range from 42,500 - 1,259 with 6 chemicals over 5,000 and 6 chemicals between 3,500 and 5,000. EPA received no significant comments addressing dioxin and dioxin-like compounds' bioaccumulation potential. EPA has reviewed information and all comments received from commenters on dioxin and dioxin-like compounds' bioaccumulation characteristics. As indicated in Table 3 of the final rule, EPA finds that dioxin and dioxin-like compounds bioaccumulate in the environment with BAF/BCF values greater than 1,000 and therefore meet the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's

findings on this chemical category can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, most of the members of the dioxin and dioxin-like compounds category bioaccumulate in the environment with a value close to, or well above, 5,000, which supports EPA's decision to lower the threshold to 0.1 gram.

3.b.x. Toxicity Data for Dioxin and Dioxin-like Compounds.

Commenter List: C-034, C-043, C-548, C-1408, C-1428, C-1430, C-1439, C-1442, C-1457, C-1814, C-1845, C-1865 C-2301 and C-2254

Comment: There were a number of comments received on the addition of the dioxin and dioxin-like compounds category, additional responses to those comments are discussed in detail in Part 1 of this document. Most of the comments on the toxicity data that EPA presented in support of the addition of the category concern the dioxin-like compounds since most commenters seemed to agree that 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (dioxin or 2,3,7,8-TCDD) met the criteria for listing under EPCRA section 313(d)(2)(B). A number of commenters did not believe that there was sufficient information to add any of the dioxin-like compounds while several commenters argue that the data on the octa- and heptachlorodibenzo-*p*-dioxins in particular were not sufficient. Commenters also argue that reliance on established toxicity equivalence factors (TEFs) does not provide sufficient support for determining that the dioxin-like compounds meet the EPCRA section 313(d)(2)(B) criteria. Some commenters agreed that all of the dioxin-like compounds are highly toxic and meet the EPCRA section 313 listing criteria.

Response: EPA disagrees with the commenters that contend that there is not sufficient data to add the dioxin-like compounds pursuant to EPCRA section 313(d)(2)(B). Additional responses to the issue of the toxicity of dioxin and dioxin-like compounds can be found in Part 2 of this document. 2,3,7,8-TCDD is generally recognized as one of the most studied toxic compounds found in the environment. To require the degree of documentation supporting toxicological classification of 2,3,7,8-TCDD as a necessary criterion for determining that other dioxin-like compounds exhibit dioxin-like toxicity or for listing under EPCRA section 313 is an arbitrary and unrealistic criteria. A more scientifically supportable set of criteria for determining if compounds exhibit dioxin-like toxicity was proposed by the World Health Organization European Centre for Environmental Health (WHO-ECEH) and the International Programme on Chemical Safety (IPCS) consultation group. These criteria include: (1) A compound must show a structural relationship to TCDD; (2) a compound must bind to the Ah receptor; (3) a compound must elicit Ah receptor-mediated biochemical and toxic responses; and (4) a compound must be persistent and accumulate in the food chain. Each of the 2,3,7,8 substitute dioxins and furans included in the dioxin TEQ approach meet these criteria (Ref. 3 of the final rule).

The commenters often quoted from the EPA Science Advisory Board (SAB) review of EPA's draft dioxin reassessment, to help support the claim that dioxin-like compounds other than 2,3,7,8-TCDD should not be included in the toxic release inventory. The SAB report is a complex document containing a number of contrasting observations. Care must be taken to capture this contrast to accurately capture the SAB's concerns. For example, in their Executive Summary, the SAB concluded that, "The use of the TEFs as a basis for developing an overall index of public health risk is clearly justified"; they caution, however, "that practical application depends on the reliability of the TEFs and the availability of representative and reliable data. In their summary conclusions, the SAB stated

"The document (EPA Draft Reassessment) represents a departure from the earlier EPA risk assessment for dioxin, which dealt primarily with 2,3,7,8-TCDD. In addressing a broad range of dioxin-like compounds having the common property of binding to the Ah receptor and producing related responses in cells and whole animals, it creates opportunities for a holistic assessment of the cumulative impacts of these broadly distributed anthropogenic pollutants. Thus, while the environmental concentrations of each compound alone may be too low to produce effects of concern, the combined exposure may be producing effects that warrant concern. The use of the concept of TEFs and the concentrations of the compounds in foods and environmental media to produce an overall index of public health risk is clearly justifiable.

The character and thrust of these statements made by the SAB are significantly different from those chosen by many of the commenters opposing the addition of some or all of the dioxin-like compounds. The apparent contradiction between these broad concluding statements by the SAB and those cited by several commenters is due, in part, by confusing the SAB criticisms of the text of the draft reassessment with statements about the general state of scientific knowledge. The SAB clearly felt that EPA needed to do a more rigorous job of discriminating between the inferences it drew about the toxicity of 2,3,7,8-TCDD, other 2,3,7,8 substitute dioxins and furans and dioxin-like PCBs. Many of the comments cited were intended to help EPA generate a more rigorous scientific discussion in its final reassessment document rather than to represent substantive conclusions reached by the SAB on the nature of dioxin toxicology. Fully taking these concerns into consideration it was still

the SAB's over all judgement, as stated above, that "the use of the TEFs as a basis for developing an overall index of public health risk is clearly justified".

Some commenters argue that there are qualitative differences in the toxicity of the different 2,3,7,8 substituted isomers of poly chlorinated dioxins (PCDDs) and furans (PCDFs). Specifically, there are structural differences between the more toxic, lower chlorinated isomeric PCDDs and PCDFs and the higher chlorinated congeners to the extent that the octa- and hepta-PCDDs and PCDFs should not be added to the list of EPCRA section 313 toxic chemicals. These arguments are not necessarily valid for several reasons. First, there are data from subchronic studies for both octa- and hepta- PCDDs and PCDFs which demonstrate dioxin-like effects (Refs. 19, 21, 79, and 80 of the final rule). The new WHO TEFs are based on these subchronic studies (Ref. 78 of the final rule). While short-term studies indicate limited dioxin-like effects of these chemicals, these contrasting results are readily explained by the structural differences between the octa- and hepta- PCDDs and PCDFs compared to the lower chlorinated PCDDs and PCDFs. The relative potency of the dioxin-like compounds is related to both their ability to bind to the Ah receptor and their pharmacokinetic properties (Ref. 20 of the final rule). The water solubility of PCDDs and PCDFs decrease with increasing chlorine substitution. Hence the octa- and hepta- PCDDs and PCDFs are significantly less soluble in aqueous solutions compared to the lower chlorinated PCDDs and PCDFs. These solubility problems limit the amount of chemical that can be absorbed in high dose acute toxicity studies. The lack of effect observed in the high dose acute studies is consistent with the limited aqueous solubility of these compounds. However, low dose subchronic studies allow the chemicals to be better absorbed and bioaccumulate to concentrations which produce biochemical and toxic effects (Refs. 19, 21, 79, and 80 of the final rule). Once again this is consistent with the evidence of dioxin-like effects of these chemicals observed in the low-dose subchronic studies. It should be noted that human exposure to octa- and hepta-PCDDs and PCDFs are subchronic low dose exposures, similar to the experimental studies which demonstrate dioxin-like effects of these chemicals (Refs. 19, 21, 79, and 80 of the final rule).

While there are structural differences between the octa- and hepta- PCDDs and PCDFs compared to the lower chlorinated PCDDs and PCDFs, these differences result in quantitative not qualitative differences in the toxicity of these chemicals. The quantitative differences are demonstrated by the lower potency of the octa- and hepta- congeners compared to tetrachlorodibenzo-*p*-dioxin (TCDD). In addition, the TEFs reflect these quantitative differences by assigning lower TEF values to the octa- and hepta- PCDDs and PCDFs. While there is limited evidence that the shape of the dose-response curve for induction of CYP1A1 activity *in vitro* for octachlorodibenzo-*p*-dioxin (OCDD) is different from TCDD, *in vivo* evidence indicates that the dose response for CYP1A1 induction by OCDF in three tissues is equivalent to TCDD (Ref. 20 of the final rule). However, it should be noted that these are quantitative not qualitative differences.

Commenters also argue that octa- and hepta- PCDDs and PCDFs should not be listed because "there is a growing consensus in the scientific community that the potential risks posed by dioxins are largely driven by a limited number of dioxin and dioxin-like compounds (tetra-, penta-, and hexa-PCDDs and PCDFs and certain coplanar PCBs)." It is important to remember that, as discussed elsewhere in these comment responses, EPCRA section 313 is primarily a hazard-based rather than a risk-based statute. The "growing consensus" on dioxin toxicity is probably best captured by the revised TEFs recently established by the WHO (Ref. 78 of the final rule). In this review the scientific evidence for ascribing values of relative toxicity to octa- and hepta- PCDDs and PCDFs was specifically reviewed, as evidenced by the lowering of the TEF for OCDD and octachlorodibenzofuran (OCDF) by a factor of 10. In the course of the deliberations by the WHO panel of internationally distinguished scientists, there was the opportunity to remove both octa- and hepta- PCDDs and PCDFs from the TEF listings. However, the WHO panel concluded that the best scientific interpretation of the data available was to leave hepta- PCDDs and PCDFs unchanged and reduce but not eliminate OCDD from TEQ calculations. Even with this reduced toxicity OCDD and OCDF remain significantly more toxic than many of the chemicals listed under EPCRA section 313 and clearly meet the listing criteria of EPCRA section 313(d)(2)(B).

EPA disagrees with the commenters that contend that TEFs are not adequate support for listing chemicals under EPCRA section 313. The development of TEFs has been a rigorous scientific effort involving a number of international panels of scientific experts and has involved the careful review of all relevant scientific literature. EPA believes that the development and review processes used for the generation of the TEFs was sound and represents a reasoned and reliable judgement on the dioxin toxicity of each of the 17 dioxin and dioxin-like compounds. Part 2 of this document includes an extensive discussion of the history of the development of dioxin TEFs which demonstrates why EPA believes that the TEFs are well supported scientifically and consequently have been openly adopted by the international scientific and regulatory community. In addition, as EPA has previously explained (59 FR 61432), the Agency believes that EPCRA section 313 allows a chemical category to be added to the list, where EPA identifies the toxic effects of concern for at least one member of the category and then shows why those effects can reasonably be expected to be caused by all other members of the category. Here, individual toxicity data

are not available for all members of the category; however, there is sufficient information to conclude that all of these chemicals are highly toxic based on structural and physical/chemical property similarities to those members of the category for which data are available.

Thus, EPA reaffirms that there is sufficient evidence for adding dioxin and dioxin-like compounds on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available cancer and other serious chronic health effects data for these compounds. Therefore, EPA is finalizing the listing of dioxin and dioxin-like compounds on the EPCRA section 313 list.

3.c. Hexachlorobenzene (CAS No.118-74-1).

Persistence Data for Hexachlorobenzene. In the proposal, EPA preliminarily determined that hexachlorobenzene has persistence half-life values in soil of 6 to 3 years. EPA received no significant comments addressing hexachlorobenzene's persistence potential. EPA has reviewed information and all comments received from commenters on hexachlorobenzene's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that hexachlorobenzene persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule). In addition, hexachlorobenzene persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

Bioaccumulation Data for Hexachlorobenzene. In the proposal, EPA preliminarily determined that hexachlorobenzene has a BCF value of 66,000 to 29,600. EPA received no significant comments addressing hexachlorobenzene's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on hexachlorobenzene's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that hexachlorobenzene bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, hexachlorobenzene bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

3.d. Pentachlorobenzene (CAS No. 609-93-5)

Toxicity Data for Pentachlorobenzene. EPA proposed to add pentachlorobenzene to EPCRA section 313 pursuant to EPCRA sections 313 (d)(2)(B) and (C). No comments were received concerning the human health toxicity data that EPA presented in the proposed rule. Thus, EPA reaffirms that there is sufficient evidence for adding pentachlorobenzene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available hepatic, nephric, hematological, and developmental toxicity data for this chemical.

No comments were received concerning the ecotoxicity data that EPA presented for pentachlorobenzene in the proposed rule. Based on the available toxicity data, EPA has concluded that pentachlorobenzene is toxic. It has the potential to kill fish and mysid shrimp as well as cause other adverse effects on algae and daphnia, based on chemical and/or biological interactions. Pentachlorobenzene can cause these toxic effects at relatively low concentrations. Aquatic acute toxicity calculated values for pentachlorobenzene include a sheepshead minnow 96-hour LC_{50} of 0.83 mg/L, bluegill sunfish 96-hour LC_{50} s of 0.25 mg/L and 0.3 mg/L, a guppy 96-hour LC_{50} of 0.54 mg/L, and a mysid shrimp 96-hour LC_{50} of 0.16 mg/L. Because pentachlorobenzene can cause these toxic effects at these relatively low concentrations, EPA considers it to be highly toxic. Additional acute toxicity calculated values include algae 96-hour EC_{50} s of 1.98 mg/L and 6.78 mg/L, and daphnia 48-hour EC_{50} s of 1.3 mg/L and 5.28 mg/L. Considering pentachlorobenzene's persistence and bioaccumulation potential pentachlorobenzene is considered highly toxic to aquatic organism at these higher concentrations.

As discussed above, pentachlorobenzene is highly toxic. Because pentachlorobenzene is highly toxic at relatively low concentrations, EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish and mysid shrimp kills as well as other adverse effects on algae and daphnia, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

Thus, EPA reaffirms that there is sufficient evidence for adding pentachlorobenzene on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i), (ii), and (iii) based on the available ecotoxicity information for this chemical.

Therefore, EPA is finalizing the listing of pentachlorobenzene on the EPCRA section 313 list.

Persistence Data for Pentachlorobenzene. In the proposal, EPA preliminarily determined that pentachlorobenzene has persistence half-life values in soil of more than 22 years to 194 days. EPA received no significant comments addressing pentachlorobenzene's persistence potential. EPA has reviewed information and all comments received from commenters on pentachlorobenzene's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that pentachlorobenzene persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule). In addition, pentachlorobenzene persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

Bioaccumulation Data for Pentachlorobenzene. In the proposal, EPA preliminarily determined that pentachlorobenzene has a BCF value of 8,318. EPA received no significant comments addressing pentachlorobenzene's bioaccumulation potential. EPA has reviewed this comment and information received from commenters on pentachlorobenzene's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that pentachlorobenzene bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, pentachlorobenzene bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

3.e.i. Cobalt and Cobalt Compounds

Commenter List: C-446, C-448, C-717, C-1409, C-1421, C-1422, C-1423, C-1437, C-1444, C-1448, C-1815, C-1827, C-1846, C-1863, and C-1870.

Comment: Most commenters oppose the listing of cobalt and cobalt compounds as PBT chemicals. Some of the reasons commenters provided for opposing the inclusion of cobalt were that: 1) the bioaccumulation data in the docket was not described in enough detail to evaluate cobalt and was inadequate to make a determination on cobalt's bioaccumulative properties; 2) the high BCF values cited by EPA were only in lower trophic-level species, that higher trophic-level species did not have high BCF values, and thus cobalt should not be considered a PBT chemical; 3) PBT criteria are not appropriate for metals in general; and 4) specific types of cobalt compounds such as inorganic color pigments and metal dye coordination complexes should not be classified as PBT chemicals.

Response: Some of the generic comments on cobalt and cobalt compounds, such as metals in general cannot be evaluated using PBT criteria, are addressed elsewhere in this document. However, the comments specific to cobalt and cobalt compounds are not being addressed at this time since EPA is not making any final determination on the classification of cobalt and cobalt compounds as PBT chemicals in the final rule. EPA is deferring this decision until the Agency has time to evaluate all of the technical issues that the commenters have raised concerning the bioaccumulation data for cobalt. If EPA decides to move forward with the listing of cobalt and cobalt compounds as PBT chemicals then all of the substantive comments received by the Agency will be addressed.

3.e.ii. Mercury and Mercury Compounds

Persistence Data for Mercury and Mercury Compounds. Because metals may convert to different oxidation states but can never be destroyed, all metals meet the 6 months half-life criterion automatically. EPA received a few significant comments addressing mercury and mercury compounds' persistence. These are discussed below. EPA has reviewed information and all comments received from commenters on mercury and mercury compounds' persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that mercury and mercury compounds persist in the environment with half-lives of 2 months or greater and therefore meet the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical category can be found in EPA's response to comment document for this rulemaking (Ref. 69 of the final rule) and in EPA's support documents for this rulemaking. (Ref. 7 of the final rule). In addition, mercury and mercury compounds persist in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

Comment: The commenter asserts that EPA should not classify all forms of mercury as persistent. The commenter agrees that Hg (0) is properly characterized as persistent. However, the commenter contends that EPA is incorrect in characterizing Hg (II) as persistent because it is removed rapidly from the atmosphere via wet and dry deposition.

Response: EPA believes that the commenter confuses residence time with half-life; these terms do not represent equivalent processes. There is a distinction between atmospheric “half-life,” which is the amount of time necessary for half of the chemical present to be destroyed in the medium, and atmospheric “residence time” which is the length of time a chemical resides in a particular environmental medium. For the purposes of this rule “half-life” includes only irreversible chemical transformations resulting in the destruction of chemical whereas “residence time” includes factors such as transport of the substance to another medium, for example, wet and dry deposition, sorption, complexation or sequestration; and reversible changes in speciation (*i.e.*, oxidation reduction reactions). EPA agrees that Hg (0) has an average “residence time” in the atmosphere of about 1 year and that Hg (II) may be deposited relatively quickly by wet and dry deposition processes, leading to a “residence time” of hours to months (Ref. 42a of the final rule). But the short residence times noted for Hg (II) are due to physical transport from the medium, rather than irreversible transformations resulting in the destruction of chemical. Hg (0) released to the atmosphere is rapidly converted to Hg (II) through ozone-mediated oxidation. However, this is not an irreversible reaction, nor does it result in the destruction of the substance since the Hg (II) produced from oxidation of Hg (0) by ozone can be reduced back to Hg (0) by sulfite (Ref. 28a of the final rule). The persistence of mercury will not be mitigated simply by redox reactions of Hg (0) to and from Hg (II). Whether as Hg (0) or as Hg (II), mercury persists in the environment. Environmental processes may cause it to change oxidation states or to be transported from one environmental medium to another; however, these processes will not destroy it.

EPA agrees that the report cited provides reasonable estimates of the fraction of mercury emissions from each source category that are likely to be in the form of Hg (II) versus the fraction as Hg (0). However, this information is not relevant to the assessment of the persistence of mercury and mercury compounds because persistence considers destruction only.

Bioaccumulation Data for Mercury and Mercury Compounds. In the proposal, EPA preliminarily determined that mercury and mercury compounds have BCF values that ranged from 7,000 to 36,000. EPA received no significant comments addressing mercury and mercury compounds’ bioaccumulation potential. EPA has reviewed information and all comments received from commenters on mercury and mercury compounds’ bioaccumulation characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that mercury and mercury compounds bioaccumulate in the environment with BAF/BCF values greater than 1,000 and therefore meet the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA’s findings on this chemical category can be found in EPA’s support documents for this rulemaking. (Ref. 71 of the final rule). In addition, mercury and mercury compounds bioaccumulate in the environment with a value above 5,000, which supports EPA’s decision to lower the threshold to 10 pounds.

3.e.ii. Mercury

Commenter List: C-311; C-548; C-953; C-1439; C-1823

Comment: Commenters supported lower reporting thresholds for mercury. Commenter states that because mercury is a highly toxic substance (e.g., 1/70th of a teaspoon can contaminate a lake), EPA should have stricter reporting thresholds. Another commenter states that because even minute amounts of mercury can cause contamination in water-bodies or pose a threat to human health, consistent and comprehensive reporting of mercury emissions are critical to track trends and hold local industries accountable. Over 1.6 million women and children are at risk from mercury poisoning due to the consumption of contaminated fish. Commenter is pleased to see a lower reporting threshold for mercury. Mercury has been identified as a significant health problem in the eastern United States and Canada. Commenter notes that New Jersey’s Mercury Task Force has been working to collect information and develop strategies for controlling mercury in the environment, but that mercury is released into the environment in such low amounts that it has been difficult for the task force to effectively evaluate sources of mercury and how to control releases of mercury. Commenter states that mercury can cause long-term damage to the nervous systems of fetuses and young children, and that at least forty states have issued fish consumption advisories due to mercury contaminated fish. Another commenter urges EPA to use right-to-know to expand the public’s knowledge about any and all discharges, uses and releases of mercury.

Response: EPA has proposed to lower the reporting thresholds for PBT chemicals pursuant to EPCRA section 313(f)(2) based

on their persistence and bioaccumulation. EPCRA section 313(f)(2) does not require, nor does EPA believe it is appropriate, that modifications to the reporting thresholds be based on degree of toxicity (i.e., relative toxicity). Given that Congress has provided EPA with specific toxicity criteria in EPCRA section 313(d)(2), and that chemicals that EPA has determined meet these criteria are statutorily defined as “toxic chemicals,” the Agency does not believe that developing additional “toxicity” criteria, in an effort to set thresholds based on a new “toxicity factor” under 313(f)(2), would be appropriate. One reason is that the Agency is concerned that this would imply that TRI data on the toxic chemicals that meet the statutory toxicity criteria are of less value than TRI data that meet both the statutory toxicity criteria and some “additional toxicity criteria” that commenters appear to suggest should be developed by EPA for the purpose of lowering thresholds for a subset of “more toxic” chemicals. EPA believes that bifurcating the list of EPCRA section 313 toxic chemicals on the basis of additional toxicity criteria would be inconsistent with the intent of Congress and an important purpose of EPCRA: to provide the public and local communities with information on the release and other waste management of toxic chemicals so they can independently evaluate risks by taking local factors into consideration. Further, as discussed elsewhere in this document, EPA does not believe that, in general, risk should be a factor in making determinations under EPCRA section 313. Finally, EPA believes that by lowering the reporting thresholds to 10 pounds for mercury and mercury compounds, a more significant range of releases and other waste management quantities will be reported to TRI than is being reported under the higher thresholds. This will provide the public, including communities that live around facilities releasing these chemicals, researchers and local, state and the Federal governments with a better and broader picture of exposures to mercury and mercury compounds.

Commenter List: C-1353; C-1419; C-1421; C-1423; C-1427; C-1458; C-1836; C-1861

Comment: A number of commenters stated that the health effects of mercury are uncertain and that EPA should not lower thresholds until better data is available or consensus among scientists and/or federal agencies is reached on the risk posed by mercury exposure. One commenter stated that EPA is being premature in lowering the thresholds for mercury because of the current state of science with regard to: (1) levels of concern for mercury in blood; (2) actual mercury levels in the population; (3) the relationship between environmental mercury levels and levels of mercury in fish; and (4) the relationship between levels of mercury in the blood and fish consumption. Commenter states that Congress, in a recent appropriations report, stated their intention that “EPA not issue any regulatory determination for mercury emissions from utilities until EPA reviews the results” of an 18-month National Academy of Science (NAS) comprehensive review of mercury health research. Commenters state that EPA should wait until the Agency has reviewed the NAS report prior to lowering the thresholds for mercury. In general, commenter states, EPA should not lower thresholds for mercury until the NAS report, and other ongoing reviews of mercury are complete (e.g., the National Health and Nutrition Examination Survey (NHANES) and studies being conducted by other branches of EPA, such as by the Office of Air Quality Planning and Standards, on fish consumption and mercury ingestion). Another commenter stated that recent scientific findings from studies of children exposed to mercury have brought about a re-evaluation of mercury health effects by EPA and other agencies. Commenter points to two studies in particular: (1) a study done at two age points, finding a subtle developmental effect even in the group with the lowest mercury exposure measures; and (2) a second study, still ongoing, finding no effect even at the highest exposures. Several commenters point out that the agency for Toxic Substances and Disease registry (ATSDR) has considered a mercury exposure level three to five times less stringent than EPA’s current reference level. Commenter states that without consideration of these new health criteria for mercury, designation of release rates for reporting are meaningless. Commenter states that the White House Office of science and Technology Policy has organized an effort to resolve the differences of opinion on the health impacts of mercury. Commenters state that is premature to establish lower reporting thresholds for mercury prior to resolution of two issues (1) the level of mercury exposure that is considered “safe,” i.e., the reference dose; and (2) the relationship between releases of mercury at a given facility and levels of mercury found in environmental media. Commenters state that until the disagreement over the “safe” level is resolved, EPA should not lower the reporting thresholds because it will not be able to determine the health risk at these levels because the “safe” level is paired with exposure to determine health risk, Commenter states that EPA concluded in its Mercury Study that “most U.S. consumers need not be concerned about their exposure to methylmercury” and further acknowledged that additional scientific studies are needed to determine whether human populations are actually exposed to mercury at levels that present a health risk.

Response: EPA disagrees that there is disagreement concerning whether mercury and mercury compounds are toxic, i.e., cause adverse effects. Nor is there disagreement about the nature of these adverse effects. In addition, the commenters do not suggest that mercury and mercury compounds are not toxic. In fact, all of the commenters’ comments relate to one of the factors that is used in risk assessments—an issue that is not relevant to the modification of reporting thresholds being made in this rule. The commenters’ discussion surrounding mercury concerns the level at which the reference dose should be set. The reference dose (RfD) is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime

(See EPA's Integrated Risk Information System's Glossary of Terms at <http://www.epa.gov/iris/glossary.htm>). The commenters' term the RfD as the "safe" dose. While the commenters use headings in their comments such as "Mercury: The health effects of Mercury are Highly Uncertain" (C1419), their comments focus on the discussion of the Reference Dose. The commenters also state that ATDRS has considered a mercury exposure level three to five times less stringent than EPA's current reference dose level, which is 0.0003 milligrams/kilograms/day (mg/kg/d). Three to five times this level is a range of 0.0009 mg/kg/d to 0.0015 mg/kg/d. Again, this relates to the specific level that the "safe" dose should be set at. As noted by the commenter, one way this value is used is to determine if a given exposure will result in a risk. That is, if there is an exposure that is over this level, a person may exhibit the adverse effects that can be induced by mercury and mercury compounds. Again, there is no debate over the toxic effects of mercury and mercury compounds; the only issue of scientific debate is the proper level at which to set a dose for mercury that is "safe."

EPA disagrees that the scientific debate concerning the reference dose for mercury should preclude lowering the EPCRA section 313 reporting thresholds for mercury. As discussed in greater detail elsewhere in this document, EPA disagrees with the commenters' assertion that evidence of risk is required prior to lowering the threshold for any EPCRA section 313 chemical. Section 313(f)(2) addresses revisions to the reporting thresholds. It does not require EPA to establish, prior to the lowering of reporting thresholds, that releases at a particular threshold will result in specific quantitative risks. The comments that these commenters have submitted relating to the reference dose are not relevant to the modification of reporting thresholds being made in this rule. The data cited in the proposed rule clearly indicates that mercury is highly persistent and highly bioaccumulative, and these commenters have provided no information that leads EPA to believe that this determination was in error.

Commenter List: C-1353; C-1419; C-1427; C-1440; C-1861

Comment: Several commenters were concerned that EPA failed to appropriately consider the risk posed by mercury. Commenter states that unlike most TRI releases, the majority of mercury exiting coal-fired power plant stacks enters the regional and global pool of mercury. Mercury is a truly global pollutant and the solution about this element must be worldwide, considering anthropogenic mercury sources from other countries (e.g., China burns massive quantities of coal, all with much higher mercury content than the U.S.). Commenter states that, given (1) EPA's admitted uncertainty about the relationship between domestic releases of mercury and mercury in the environment; and (2) the effects of mercury exposure on human health, no definite conclusions may be drawn about the effect of domestic mercury emissions on human health. Commenter states that EPA believes TRI information requirements are important to the local community, even if only small amounts are released, but if populations around a facility face either no risk, or no significant risk from emissions, the value of lowering thresholds is not apparent. Commenter states that the threshold for mercury should not be lowered until EPA has first demonstrated health concerns that warrant the lower thresholds. Commenter states that there is no health risk basis for the mercury reporting threshold and, in particular, that EPA has not demonstrated that the 10 pound threshold is necessary to protect public health.

Response: As discussed elsewhere in this document, EPA disagrees with the commenters' assertion that evidence of risk is required prior to lowering the threshold for any EPCRA section 313 chemical. Section 313(f)(2) addresses revisions to the reporting thresholds. It does not require EPA to establish prior to the lowering of reporting thresholds that releases at a particular threshold will result in specific quantitative risks. That section expressly provides that the Administrator may establish a threshold amount for a toxic chemical different from the 25,000 pound threshold for manufacturing and processing activities and the 10,000 pound threshold for otherwise use activities.

Even if EPA were to consider risk in lowering section 313 reporting thresholds, which it has not, the Agency would consider a variety of additional data on mercury, for example, data indicating that it is released by many industrial sources, it is persistent in the environment, it builds up in the environment and in organisms and is prevalent in fish (it was detected at 92% of sites surveyed in the 1987 National Study of Chemical Residues in Fish (NSCRF), Fish Species in the Northeast (See USEPA/OW. Mercury Update: Impact on Fish Advisories. EPA-823-F-99-016. September 1999).

Commenter List: C-1353; C-1419; C-1427; C-1440; C-1823

Comment: Several commenters state the proposed 10 pound threshold for mercury is too low, particularly for electric generating facilities (EGFs). The electric utility industry is estimated to release about 50 tons of mercury a year, as compared to estimates of the total atmospheric mercury burden of 5,000 tons. Commenters point to a study conducted by EPRI that

concluded that mercury releases as high as 890 pounds per year have not been shown to cause adverse health impacts. Commenters cite analysis that shows that a mercury reporting threshold of 100 pounds per year would account for the overwhelming majority of mercury released by EGFs (96.3%), while not requiring 30% of all EGFs to incur the burden of preparing a Form R. Therefore the 10 pound threshold is too low. Several commenters state that lowering thresholds for mercury may put public pressure on utilities to reduce mercury releases before other reviews of the effects of mercury have been completed. Commenter states that a number of studies, by EPA, EPRI, and others, have quantified the relatively low risks resulting from emissions of mercury from coal utility stacks. These same studies have demonstrated the non-linear relationship among emissions, downwind air concentrations, deposition, and human exposure to mercury. Another commenter, however, states that releases of mercury from EGFs may occur in relatively small quantities, but the total volume of releases by the sector is quite significant both nationally, regionally and locally, posing a serious public health concern. These releases will not be captured unless reporting thresholds are lowered significantly. EPA should require EGFs to apply the same mercury monitoring protocol that facilities used to fulfill their sampling and reporting requirements under EPA's 1999 Information Collection Request for mercury.

Response: EPA disagrees with the commenters' assertion that evidence of risk is required prior to lowering the threshold for any EPCRA section 313 chemical. As addressed elsewhere in this section, EPCRA section 313(f)(2) addresses revisions to the reporting thresholds. It does not require EPA to establish, prior to the lowering of reporting thresholds, that releases at a particular threshold will result in specific quantitative risks.

EPA believes that the commenters attribute a purpose to EPCRA that is inconsistent with that clearly intended by Congress. Specifically, Congress stated in EPCRA section 313(h) that

The release forms required under this section are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available,...to inform persons about releases of toxic chemicals to the environment; to assist government agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes. 42 U.S.C. section 11023(h).

Neither EPCRA section 313(h) nor its legislative history directs EPA to limit the collection of information on releases to those releases that, from the federal government perspective, pose significant local human and environmental exposure and human health and environmental risks.

Federal and local perspectives on what may be an acceptable risk are likely to be very different. The roles of local government and the federal government differ significantly in terms of ensuring environmental quality. In passing EPCRA, Congress intended that the public take the information reported on the use, releases and other waste management of toxic chemicals, and determine whether these releases result in potential risks that the community determines warrant further action given an array of other factors, such as economic and environmental conditions, or particularly vulnerable human or ecological populations. Congress did not intend the federal government to consider these local factors prior to determining whether certain information should be made public, or prior to determining whether a different threshold should be established for one or more toxic chemicals.

The intent of EPCRA section 313 is to move the determination of what risks are acceptable from EPA to the communities in which the releases occur. This basic local empowerment is a cornerstone of the right-to-know program. EPCRA section 313 establishes an information collection and dissemination program. The burden it imposes is significantly less than the burden imposed by a statute which controls the manufacture, use, and/or disposal of a chemical. EPCRA section 313 requires that a facility use readily available data to prepare each chemical-specific TRI report. The statute does not require that the facility conduct monitoring or emissions measurements to determine these quantities. A facility must only estimate, to the best of its ability, the quantitative information it reports. This is in contrast to other environmental statutes that may require a facility to monitor releases, change its manufacturing process, install specific waste treatment technology, or dispose of wastes in a certain manner. As such, the Agency believes that the standard that must be met to require information submission under EPCRA section 313 is less than that to regulate a chemical under other statutes.

Further, contrary to assertions by some commenters, EPCRA section 313 does not require the collection or evaluation of quantitative risk data, nor does the statute require that risk data be disseminated to the public. Rather TRI data provide communities with information on releases and other waste management. TRI data cannot solely, in themselves, provide

information on quantitative risks to individual communities. A determination of the potential risk that a chemical release may pose is dependent upon a number of considerations, including the toxicity of the chemical, the physical-chemical properties of the chemical, the specific media to which the chemical is released, and site specific information that will determine the estimated exposures. While TRI data are not in themselves measures of risk, they are an important input that the public can use, along with the factors described above, to determine potential risks to themselves, their children, their communities and their environment that may result from releases of toxic chemicals.

EPA's decision to lower the reporting threshold for mercury and mercury compounds is rationally related to the EPCRA section 313 goals of informing communities, assisting research and data gathering, and aiding the development of regulations and guidelines. Because mercury persists in the environment for a significant period of time and bioaccumulates in animal tissues, it has the potential to be pervasive in the environment, in the food chain, and often in humans. In short, for PBT chemicals, such as mercury, releases and other waste management activities for relatively small quantities are of concern. Accordingly, pursuant to the intended purposes of EPCRA, even relatively small releases and other waste management activities for PBTs need to be reported in order to inform communities, assist those engaged in research and data gathering, and to aid the development of regulations and guidelines. Lowered reporting thresholds for PBTs are needed to obtain reporting on these relatively small releases and other waste management activities for PBTs.

EPA disagrees with the commenters who state that EPA should require EGFs to apply the same mercury monitoring protocol that facilities used to fulfill their sampling and reporting requirements under EPA's 1999 Information Collection Request for mercury. EPCRA section 313(g)(2) states that facilities should use

“readily available data (including monitoring data)...or reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation.”

Facilities are required to comply with this provision of EPCRA when calculating thresholds and reporting release and other waste management quantities. Facilities are not required by EPCRA to conduct the additional monitoring that the commenter requests.

Commenter List: C-1419; C-1421; C-1826; C-1857; C-1865

Comment: Commenters state that lowering TRI reporting thresholds for mercury will not provide additional useful information about mercury exposure, or will serve to mislead the public. Commenters state that lower reporting thresholds for mercury are unnecessary for the following reasons: (1) EPA already has a comprehensive mercury emissions inventory and has already extensively characterized emissions; (2) the top four sources of mercury emissions account for 80% of anthropogenic emissions and two of these four sources are not subject to EPCRA section 313 – municipal waste combustors and medical waste incinerators; (3) none of the 46 major research needs identified in the Mercury Study report to Congress can be fulfilled by lowering TRI reporting thresholds; (4) activities are underway that will generate more information on mercury releases (e.g., EPA's information collection request under the Clean Air Act (CAA) to require power plant sampling of mercury in coal and air emissions). Commenter states that EPA has not adequately considered alternatives to lowering the thresholds, e.g., EPA should have considered adding SIC codes rather than lowering mercury thresholds or focusing on research needs and other information that may be effective in risk-reduction efforts. Another commenter states that TRI does not, therefore, provide an appropriate "yardstick" for measuring progress towards reducing mercury emissions. Commenters states that EPA has failed to demonstrate why lowered EPCRA section 313 reporting thresholds are necessary in light of the existing data, and efforts underway to collect additional data, on mercury emissions. Commenter states that requiring mining facilities to report mercury releases due to the lower thresholds, will greatly increases the number of mine sites required to report, but will not improve the public's knowledge or understanding of the genuine risk associated with releases of bioavailable mercury compounds. Thus the lower thresholds will likely have the effect of misleading the public by producing an inflated estimate of risk by not accounting for environmental mobility, bioavailability, and mineral occurrence of toxic mercury species. The EPCRA section 313 program fails to provide the public with accurate information. Another commenter states that if local deposition of mercury is composed primarily of background sources, then a highly restrictive reporting requirement appears unnecessary. Commenter states mercury deposition is known to be remarkably uniform around the country (Mercury Deposition Network, 1997 data), strongly suggesting a large background component. This is supported by the fact that ranges of fish mercury concentrations are similarly narrow across a wide geographic range. Commenter suggests that U.S. mercury deposition is composed of one-third global sources; one-third regional sources; and one-third local sources.

Response: EPA disagrees with the commenters. EPA believes that the information collected under EPCRA section 313 will provide the public, researchers, and local, state and Federal governments with useful information on PBT chemical releases.

EPA disagrees that information in the Mercury Study Report to Congress (U.S. EPA, 1997) contains information that is equivalent to TRI data. This report, which include caveats acknowledging the uncertainties associated with the estimates it contains, does not provide community- or facility-level release estimates. The estimates in this report are derived using a “top-down” methodology in which emission factors are applied to entire industries. While having an estimate of multi-media PBT releases for a specific industry sector is a first step, other information would also be required to estimate the releases that would be reported under TRI. Even if multi-media release estimates were available for an entire industry sector, these releases would still have to be divided among individual facilities according to some currently unknown distribution. An even, or average, distribution of releases among facilities would be unlikely to reflect reality due to varying activity levels, pollution prevention practices, and control technology at facilities. In addition, there is the additional factor that TRI reporting thresholds are based on chemical throughput (manufacture, process, or otherwise use) rather than chemical release. The relationship between 1) a chemical throughput that triggers the submission of a report, and 2) the releases reported will vary in some currently unknown manner between industries, as well as among facilities within an industry. Further, TRI requires reporting on information in addition to releases. Pursuant to the Pollution Prevention Act (PPA), facilities report, as part of their TRI report, information on the management of waste at covered facilities.

EPA disagrees that it should not lower the reporting based on the commenter’s contention that 80% of the mercury releases are from 4 industry sources. One of the purposes of TRI is to provide information to the public in communities near facilities that are releasing toxic chemicals. For the commenter’s argument to stand, releases of mercury would have to dissipate and travel in such a way as to be deposited in all communities equally—this is not the case with mercury. Commenter (C-1450) notes “[s]ome investigators suggest that mercury deposition in the US is composed of about one-third from global sources, one-third local sources, and one-third regional sources.” Mercury and mercury compounds can be deposited in communities proximate to facilities releasing the chemical, and may also be subject to long-range transport and be deposited regionally and globally. In addition, as discussed elsewhere in this document, the duration of transport of mercury will depend on whether it is Hg(0) or Hg (II). The former will have a residence time in the atmosphere of about a year, while the latter will be deposited relatively quickly. Furthermore, as stated elsewhere in this document, even small releases of PBT chemicals are of concern, particularly to the community proximate to the release. Therefore, even if certain non-covered industry sectors account for a significant percentage of national releases of a chemical, the reporting of releases from covered facilities will still be valuable information to communities proximate to such facilities. Thus, EPA believes that the commenter’s contention that EPCRA section 313 lower reporting thresholds for mercury is not warranted because some industry sectors that release mercury are not covered by EPCRA’s reporting requirements is incorrect.

One commenter stated that none of the 46 major research needs identified in the Mercury Study report to Congress can be fulfilled by lowering TRI reporting thresholds. The commenter did not explain how it reached that conclusion. However, EPA does note that although one of the purposes of EPCRA section 313 is to provide information to researchers and governments (see EPCRA section 313(h)), that is not the only purpose of EPCRA. Another purpose of EPCRA section 313 is to provide information on releases to the public in communities near facilities releasing toxic chemicals. The Agency, however, believes that the lower reporting thresholds for mercury and mercury compounds will serve to fulfill all the purposes delineated by Congress in EPCRA section 313(h), including aiding the evaluation and study of mercury by local, state, and federal governments, and other researchers. EPA’s conclusion on this issue is further confirmed by comments submitted by C-311, which indicate that the lowered mercury thresholds will assist analysis and potential regulation of mercury by state and/or local government.

EPA disagrees that the Information Collection Request EPA has submitted to the Office of Management and Budget under the Clean Air Act is an appropriate substitute for this rulemaking. The information collected under the CAA effort will only be required for a limited time and the data generated can be used to prepare better estimations for reporting under EPCRA section 313. As EPA stated in the Federal Register notice (63 FR 50567, September 22, 1998) that announced the information collection for mercury under the CAA:

The EPA expects that the information requested as part of this effort will only be required for one year. The Agency will shortly propose a regulation to lower the Emergency Planning and Community Right-to-Know Act (EPCRA) section 313 activity thresholds for reporting releases of certain toxic chemicals, including mercury and mercury compounds, to the Toxic Release Inventory (TRI). The EPA plans to begin collecting information on mercury emissions from electric utility

steam generating units under the new threshold in the year 2000.

Under EPCRA section 313, facilities are not required to measure their emissions specifically to report to TRI, but may use readily available data (including monitoring data) collected pursuant to other provisions of law. This ICR is authorized by section 114 of the Clean Air Act, which allows EPA to require electric utility steam generating unit owners and operators to perform analyses that they may not currently perform and, therefore, that would provide emissions estimates that may be more precise than those that would otherwise be provided under EPCRA section 313. Facilities that have emissions information gathered through actual emissions monitoring or testing would be required to use the results of such monitoring or testing in compiling their reports under EPCRA section 313. Other facilities would be required to apply the results of the stack testing performed under this ICR (i.e., the publicly available data on coal mercury and the emissions factors developed from those data) to estimates of the mercury content of coal when reporting mercury releases to the TRI.

A final decision has not yet been made as to the new threshold for mercury under EPCRA section 313. If, after providing an opportunity for notice and comment, the EPA decides on a threshold for mercury that omits a significant portion of coal-fired power plants, the EPA may require that information be submitted under section 114 of the Act for additional years. Also, if for any reason, information collection on mercury emissions under the new lower threshold for mercury is delayed beyond the year 2000, the EPA may require the coal sampling, but not the stack testing, beyond one year.” (63 FR 50568, column 3 and 50569, column 1)

Thus, EPA does not believe that reporting for mercury under EPCRA section 313 duplicates the effort under the CAA since it will only be collected for a limited time and will not require each facility to estimate all of their releases and waste management quantities. Furthermore, the CAA ICR only applies to a portion of the universe of facilities that are covered by EPCRA's requirements and are expected to report mercury releases. Rather than being duplicative, the CAA effort may result in better reporting by facilities under EPCRA section 313. Therefore, EPA does not believe there is another EPA source from which to obtain this release and other waste management of toxic chemicals.

Commenter states that EPA has not adequately considered alternatives to lowering the thresholds, e.g., EPA should have considered adding SIC codes rather than lowering mercury thresholds. While EPA believes that adding additional industry groups would provide additional information on mercury and mercury compounds, the Agency believes that this is the appropriate first step providing a better picture of mercury and mercury compounds releases. Many facilities in the industry sectors subject to TRI (e.g., electric generating facilities that combust coal and/or oil, and facilities in SIC codes 20-39 that have boilers), have not reported releases of mercury and/or mercury compounds because they do not exceed the current threshold. Therefore, EPA believes lowering the reporting thresholds for these chemicals that have been well-documented to persist in the environment, build up in the environment, and accumulate in organisms is an appropriate first step. EPA will consider as part of a future action whether to add additional industry sectors.

Commenter List: C-1826; C-1827; C-1846

Comment: Commenter states that EPA's proposed 10 pound threshold for mercury will require reporting that will not represent true toxic releases, particularly at mining sites. Another commenter requests that mercury and mercury compounds specifically be removed from the final rule, or, in the alternative, that any reduction in threshold levels for mercury not include the naturally occurring constituents of the metal. Commenter states that it is a scientific fact that the total concentrations of a metal, such as mercury, that occur naturally in a rock do not represent the fraction of the mobile metal that is potentially toxic. In the case of mercury, the common toxic forms are elemental vapor and methylmercury, not the other forms of mercury in solution and mercury replacements in mineral lattices. Commenter states that in mined rock, mercury occurs partially in sulfide and oxide minerals. Its most common mineral form is cinnabar (HgS), a percentage of which may undergo oxidation in a mine rock pile, releasing elemental mercury. Numerous studies of sulfide oxidation have documented the fact that only a portion of sulfide mineralization will oxidize weathering conditions. The relative availability of a sulfide mineral for oxidation is controlled by its mineral associations (encapsulation by neutralizing or refractory minerals, such as quartz or oxides); net pH of the weathering environment; availability of oxygen and water; and other factors. Such factors, commenter claims, may render the mineral stable and refractory in the weathering environment. Commenter lists numerous reasons why the solubility of mercury is low, reducing its mobility in the aqueous environment. Only a small percentage of mercury undergoes biomethylation, which is the most significant toxic form of mercury. Although biomethylation by microorganisms enhances the volatility of mercury, while reducing its sorptive tendencies (Benhamin and Honeyman, 1992), and thereby promoting its bioavailability, this process occurs

under relatively reducing conditions where CH₃- and CH₄ compounds are chemically stable (Stumm and Morgan, 1996). Commenter states that this environment is most common in reducing carbonaceous sediments in lakes and swamps, not in tailings or waste rock impoundments. Another commenter states that, in some forms (e.g., the zero valence state of mercury), the metal is not bioavailable. But methylmercury is bioavailable and can accumulate in the food chain. Although bioavailability largely depends on site-specific factors, methyl mercury is significantly more bioavailable than other forms of mercury.

Response: EPA disagrees with the commenters' claim that because some forms of a metal may occur naturally in rock will therefore be non-toxic if released. EPA disagrees with this simplistic view. Metals can enter the environment in bioavailable forms or can be converted in the environment into bioavailable forms. As shown below, metals and metal compounds may be available to bioaccumulate under many realistic and common environmental conditions.

The commenters are correct in stating that metals released to the environment from anthropogenic sources are affected by prevailing environmental conditions, meaning broadly the wide variety of physical, chemical and biological processes that act upon them, and these collectively determine the form in which the metal ultimately exists.

According to Klein (1), interconversion of inorganic metal compounds can be quite rapid, especially for ionic forms, and as a result the chemical form in which an elemental metal is released may not be the predominant form post-release. Generally the ionic forms of inorganic metals are the most available. Availability is affected by many factors and its determination is complex, but many of the more important variables can be illustrated using lead as an example (2). A detailed discussion of the environmental fate of lead, which is representative of other metals, and that is illustrative of many of the more important environmental variables that affect availability is provided in Refs. 2, 3, 4, 5, 6, and 6a.

Microbial transformations in soil, water and sediment are often important in determining the overall fate of metals and metal compounds, and therefore the potential for formation of bioavailable forms. Metals known to undergo microbial oxidation/reduction processes include mercury, arsenic, iron, antimony, selenium and tellurium (7). Arsenic microbiology illustrates the importance of environmental conditions in the interconversion of inorganic forms of arsenic. Microbial populations in activated sludge can oxidize arsenite to arsenate under aerobic conditions, but under anaerobic conditions such as often predominate in sediments, arsenate can be reduced to arsenite and beyond. Both arsenites and arsenates can be available in the environment (7). Microorganisms can reduce mercury in the form of mercuric chloride⁵ to elemental mercury, and are also capable of producing elemental mercury from organomercurials such as phenylmercuric acetate and methylmercuric chloride. Although the reduction of Hg²⁺ to elemental mercury can be regarded as decreasing availability, the elemental mercury formed is volatile and more likely to enter the global atmospheric circulation.

Mercury is perhaps better known for its potential to be biomethylated by bacteria in the environment (7). Mercury has very high stability constants with organic ligands and can form true organometallic compounds (8). As indicated by Stumm and Morgan (9), metals and metalloids that form stable alkyl compounds are of special concern because they may be volatile; may accumulate in cells; and are toxic to the central nervous system of higher organisms. Methylmercury is highly bioaccumulative and is by far the best studied example of microbial bioalkylation. However, methylation of arsenic is also fairly well characterized, involves the replacement of substituent oxygen atoms by methyl groups (e.g., arsenate is biomethylated to form dimethylarsine), and is important in the transfer of arsenic from sediment to the atmosphere (7). Selenium, tellurium, tin, germanium, lead and several other metals can also be biomethylated (9).

1. Klein W. 1997. Persistence, bioaccumulation and ecological relevance of metals in the environment. ICME (International Council on Metals and the Environment) Newsletter **5**: 1-2.

⁵Contrary to the unsubstantiated claim by the commenter, forms of mercury other than the elemental form and methylmercury are toxic. See, e.g., the Integrated Risk Information System at <http://www.epa.gov/iris/subst/0692.htm> for a description of mercuric chloride.

2. Syracuse Research Corporation. The Environmental Fate of Lead and Lead Compounds. Prepared for David G. Lynch, U.S. Environmental Protection Agency, under contract number SRC 68-D5-0012, March 1999.
3. Zimdahl RL and RK Skogerboe. 1977. Behavior of Lead in Soil. *Environ. Sci. Technol.* **11**:1202-1207.
4. USEPA/ORD. 1986. Air Quality Criteria for Lead. Research Triangle Park, NC. EPA, Office of Research and Development, Office of Health and Environmental Assessment. EPA600/8-83-028bF.
5. Bondarenko GP. 1968. An experimental study of the solubility of galena in the presence of fulvic acids. *Geochem. Int.* **5**: 525-531.
6. Lovering TG, ed. 1976. Lead in the Environment. Washington, DC: US Department of the Interior, Geological Survey, professional paper no. 957. S/N 024-001-02911-1.
- 6a. USEPA, OPPT. 1999. Bioavailability of Metals. Memorandum from David Lynch to Maria Doa, Toxic Release Inventory Branch, October 1999.
7. Bodek I, WJ Lyman, WF Reehl and DH Rosenblatt, Eds. 1988. *Environmental Inorganic Chemistry. Properties, Processes and Estimation Methods*. New York: Pergamon.
8. Andreae MO. 1986. Chemical species in seawater and marine particulates. In Bernhard M, FE Brinkman and PJ Sadler (Eds.), *The Importance of Chemical "Speciation" in Environmental Processes*. Dahlem Konferenzen, Berlin: Springer-Verlag, pp 301-335.
9. Stumm W and JJ Morgan. 1996. *Aquatic Chemistry*, 3rd ed. New York: Wiley.
10. USEPA. Integrated Risk Information System. "Selenium and Compounds." Internet site: <http://www.epa.gov/iris/subst/0472.htm>. July, 1999.

Commenter List: C-1439

Comment: EPA has estimated that 6,148 more reports for mercury would be required if the reporting threshold is 1 pound . . . [assuming the worst case scenario, the unreported 61,480 pounds would be greater than the second largest known source sector of mercury.

Response: EPA disagrees with the commenters conclusions. The EPCRA section 313 reporting thresholds are activity based not release based and thus comparisons using the commenter's method can be very misleading. However, following the commenter's logic across all of the threshold options (1, 10, 100, and 1000 pounds) one would calculate, based on the final economics assessment, that for a threshold of 10 pounds or greater (5,346 reports) TRI would capture 2,768,400 pounds of mercury and that the additional 6011 forms that would be filed for 10 pounds or less would only capture an additional 60,110 pounds or an increase of only 2.2% from over 6,000 additional forms. All of these calculations are highly suspect since the estimated annual U.S. release of mercury to air is only 316,000 pounds with the largest point source category being 275,400 pounds and the second largest being 31,200.

3.e.iii. Vanadium.

Commenter List: C-1844 and C-1445

Comment: The commenters stated that two of the reasons that they do not support the addition of a vanadium compounds category are: 1) the category concept has repeatedly failed because it is overly broad and 2) individual vanadium substances of concern should be listed as the Agency is doing with the polycyclic aromatic compounds (PACs) category. The commenters stated that EPA has effectively acknowledged that the category concept has failed by defining the individual members of the polycyclic aromatic compounds (PACs) category in the present proposal. The commenters stated that they support EPA in this regard and encourage EPA to continue to define the individual members of a category. The commenters also stated that support for this approach comes from the fact that EPA felt the need to clarify the Glycol Ethers category which was so broad

that it included soaps and detergents that EPA apparently had never considered. The commenters also mentioned Polycyclic Organic Matter as another category requiring clarification. The commenters stated that broad categories invite inclusion of unforeseen and inappropriate substances for which further expensive, time-consuming delisting procedures or clarifications are required.

Response: The commenter is wrong in their statements that the category concept has repeatedly failed because it is overly broad. The fact that in some isolated cases EPA has created categories of more limited scope than others is no indication that the category approach has failed. This only indicates that depending on EPA's professional evaluation of the compounds in question there may be good reason for creating a broad or a narrow category. EPA has clearly stated its basis for the addition of the polycyclic aromatic compounds category and the reason it was limited to a subset of all PACs (59 FR 61463, column 3, November 30, 1994). The same is true for the modification to the glycol ethers category which is still a broad category based on a formula rather than a listing of individual compounds. The reference to polycyclic organic matter does not directly apply to EPCRA section 313 listing decisions since this is a category under the Hazardous Air Pollutants list. In addition, the commenter failed to recognize that in the same rulemaking that created the polycyclic aromatic compounds category, EPA also established several other categories including, nicotine and salts, nitrate compounds, polychlorinated alkanes, and strychnine and salts. None of these categories listed the members individually. Examination of the Agency's approach to listing categories, therefore, makes it clear that EPA has not "effectively acknowledged" that the category concept has failed. EPA does not believe that just because a listing is a category it will automatically result in unforeseen or inappropriate substances being included. Based on the data available, EPA believes that it is appropriate to include a category of vanadium compounds on EPCRA section 313 list due to concerns for the toxicity of vanadium which is common to all members of the category.

Commenter List: C-1827

Comment: The commenter claims that EPA has presented very little data in support of the proposal to include all vanadium compounds in a category under EPCRA section 313. The commenter stated that EPA apparently used information on "vanadium's persistence and bioaccumulation potential" (64 FR 698) to conclude that "vanadium is highly toxic to aquatic organisms at the higher concentrations", but the scientific literature does not support defining vanadium as bioaccumulative. The commenter stated that any changes in the vanadium-related listing should be limited to specific species of vanadium compounds for which the Agency and the scientific community at large have sufficient toxicity data to support such listing.

Response: As EPA stated in the proposed rule:

"Some of the aquatic toxicity data discussed above are at relatively low concentrations indicating that vanadium is highly toxic to certain aquatic organisms. In addition, considering vanadium's persistence and bioaccumulation potential (discussed in Unit V.C.1. of this preamble), EPA also believes that vanadium is highly toxic to aquatic organisms at the higher concentrations." (64 FR 697, column 3 and 698, column 1).

Even without considering vanadium's persistence or bioaccumulation potential, EPA believes that vanadium is highly toxic to certain aquatic organisms. It should be noted, however, that consistent with OPPT's procedures used to evaluate a chemical's ecological toxicity, EPA lowers the high concern level for toxicity by a factor of ten for persistent chemicals, and by another factor of ten if the chemical is also bioaccumulative. This issue is discussed in more detail in Unit VI.B.3 of the preamble to the final rule. While EPA has not made a final determination on the bioaccumulation potential of vanadium, EPA believes that the persistence of vanadium is well established and thus vanadium is considered highly toxic at levels above those considered highly toxic based solely on toxicity rather than toxicity and persistence. Elsewhere in these comment responses EPA addresses the issue of toxicity and what levels are considered highly toxic versus moderately toxic. Considering vanadium's persistence in the environment, EPA believes that it is highly toxic at concentrations between 1 and 10 mg/L.

EPA has also provided sufficient basis for the inclusion of all vanadium compounds in the category. As EPA stated in the 1994 chemical expansion final rule (59 FR 61432, November 30, 1994):

"The Agency believes it satisfies the statutory criteria to add a category to the list by identifying the toxic effect of concern for at least one member of the category and then showing why that effect may reasonably be expected to be caused by all other members of the category." (59 FR 61442, column 3)

EPA developed a hazard assessment for vanadium which reviewed the toxicity data for several vanadium compounds. The assessment indicated that the vanadium from these compounds is highly toxic to aquatic organisms. Since it is the vanadium

from these compounds that is highly toxic, rather than the intact chemical compound, EPA believes that all chemicals that are a source of vanadium meet the EPCRA section 313(d)(2)(C) listing criteria. Thus EPA has established the toxic effect of concern, the chemical species that causes the effect, the basis for why it may reasonably be expected that all members of the vanadium compounds category can cause the effects of concern, and has concluded that vanadium compounds will have a significant adverse effect on the environment of sufficient seriousness to warrant reporting under EPCRA section 313.

Commenter List: C-1836

Comment: The commenter stated that they only support the inclusion of those vanadium compounds which have been clearly demonstrated to be bioaccumulative and toxic. The commenter does not believe that the existing data referenced by EPA supports the designation of all forms of vanadium as bioaccumulative and toxic.

Response: As discussed elsewhere in these vanadium comment responses, EPA has concluded that the available data on vanadium compounds is sufficient to list the vanadium compounds category. Under EPCRA section 313(d)(2)(C) EPA is not required to determine that a chemical is both bioaccumulative and toxic in order to add it to the EPCRA section 313 list of toxic chemicals, a chemical can be added based solely on toxicity considerations, where the chemical is expected to cause a significant adverse effect on the environment of sufficient seriousness to warrant reporting. EPA has not designated all forms of vanadium as both bioaccumulative and toxic. EPA is still reviewing the comments and data on the bioaccumulation potential of vanadium and is not classifying it as a PBT chemical in this final rule.

Commenter List: C-1422c

Comment: The commenter stated that complex inorganic color pigments containing vanadium and bismuth vanadate pigments are far more stable and less soluble than metal alloys which contain either of these metals. The commenter stated that while they disagree that these metals are sufficiently toxic to warrant the listing under EPCRA section 313, the products they discussed should at a minimum, be treated with the same deference provided metal alloys, since these products are safer and more stable than metal alloys. The commenter identified the following complex inorganic color pigments as containing vanadium:

Zirconium Vanadium Yellow Baddeleyite CAS 68187-01-9
Titanium Vanadium Antimony Gray Rutile CAS 68187-00-8
Tin Vanadium Yellow Cassiterite CAS 68186-93-6
Zirconium Vanadium Blue Zircon CAS 68186-95-8
Bismuth Vanadate, CAS 14059-33-7

The commenter stated that complex inorganic color pigments made with vanadium are completely inert and that only under extreme conditions employing concentrated boiling acids can significant amounts of vanadium be removed from the pigment. The commenter stated that under more commonly encountered conditions, these pigments are virtually insoluble. The commenter stated that the vanadium within these pigments are not readily bioavailable which means that they are virtually non-toxic upon ingestion. The commenter stated that at the end of their useful life, these pigments remain intact, their metal constituents are interdiffused and encapsulated in the crystal matrix. The commenter stated that these pigments are also encapsulated in the resin, coating or ceramic which makes up the final product.

The commenter stated that complex inorganic color pigments have been manufactured and used for decades without any reported incidence and if these compounds were bioaccumulative or toxic to humans or the environment, manufacturers and users of these products would be aware of it. The commenter stated that even though the existing EPCRA section 313 listings do not sufficiently consider metal compound specification, it would seem at best an incomplete analysis for EPA to assume for future listings that all metal compounds, and particularly all vanadium compounds are equivalent.

Response: The issue that the commenter is raising is the bioavailability of vanadium from the compounds they have identified. However, the commenter has not provided sufficient data to substantiate their claim that vanadium is not bioavailable from these compounds. While water soluble compounds would obviously provide vanadium in an immediately bioavailable form, solubility is not the only factor to consider in determining the bioavailability of vanadium from a vanadium compound. While the stability of these pigments to various solvents and physical conditions may reduce their bioavailability, at least initially, there are numerous biotic and abiotic processes that can result in the bioavailability of vanadium from a vanadium compound. In addition to solubility items such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformation (both abiotic and biotic); and bioavailability when the

compounds is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs), need to be considered. If the commenters have data that can demonstrate that vanadium is not bioavailable from certain vanadium containing pigments then the appropriate action to take would be for the commenters to submit a petition pursuant to EPCRA section 313(e)(1) to delete such vanadium containing pigments from the list of chemicals subject to EPCRA section 313 reporting. EPA would address such a petition according to the Agency's stated policy and guidance concerning petitions to delist individual members of the metal compounds categories (May 23, 1991, 56 FR 23703). Under the metals policy EPA considers whether the metal from a metal compound can become bioavailable under abiotic or biotic conditions. As discussed elsewhere in these vanadium comment responses, EPA has established the basis for including all vanadium compounds in the category. Additional comment responses on the issue of the bioavailability of metals can also be found elsewhere in these comment responses.

The commenter's statements that after decades of manufacture and use there have been no reported problems with these vanadium pigments is irrelevant to a determination that they meet the listing criteria of EPCRA section 313(d)(2)(C). The EPCRA section 313(d)(2)(C) listing criteria does not require that EPA prove that environmental damage is being or has been caused by a particular compound in order to add it to the EPCRA section 313 list of toxic chemicals. In addition, the fact the manufacturers and users of these pigments are not aware of any specific problems caused by vanadium compounds cannot be accepted as conclusive evidence that these compounds have not caused any problems; it only means that no particular environmental problems have been identified that can be linked to these specific compounds. Identification of a specific chemical as the cause of an observed environmental problem is often difficult for many reasons including the fact that the problem may occur long after releases to the environment.

Commenter List: C-031

Comment: The commenter stated that they support EPA's proposal to include all vanadium compounds on the EPCRA section 313 list of toxic chemicals and to remove the fume or dust qualifier for vanadium. The commenter stated that they are particularly concerned with the potential impact on localized aquatic sediments and the aquatic food chain resulting from high-volume wastewater discharges. The commenter stated that their concern is heightened by the fact that heavy metals do not biodegrade like many other substances and continue to bioaccumulate. The commenter stated that while there has been surprisingly little testing for vanadium concentrations in aquatic sediment, early data shows concentrations as high as 2200 mg/kg in Lake Erie and 320 mg/kg in the Grand Calumet Canal. The commenter also stated that EPA's 1997 "National Sediment Contamination Point Source Inventory" showed vanadium bioaccumulation in fish flesh in a high percentage of samples that were tested for the presence of this metal. The commenter stated that they are convinced that the proposed expansion of vanadium will help manufacturers and processors recognize the actual magnitude of their vanadium releases and transfers and will encourage greater utilization of recycling processes. The commenter stated that while they strongly support EPA's proposal to expand the listing of vanadium, they are concerned that the Agency proposes to retain the current reporting thresholds for this persistent, bioaccumulative, and toxic substance.

Response: EPA appreciates the support for the proposal to add vanadium compounds to the EPCRA section 313 list of toxic chemicals and to remove the fume and dust qualifier for vanadium. As for the commenter's concerns about the reporting thresholds for vanadium and vanadium compounds, EPA is still evaluating the data on the bioaccumulation potential of vanadium and if appropriate may propose the classification of vanadium and vanadium compounds as PBT chemicals, with the corresponding lower reporting thresholds, in a future rulemaking.

Commenter List: C-448

Comment: The commenter supports EPA's proposed changes to the reporting of vanadium under EPCRA section 313.

Response: EPA appreciates the support for the proposal to add vanadium compounds to the EPCRA section 313 list of toxic chemicals and to remove the fume and dust qualifier for vanadium.

3.e.iii.1 Removal of the fume or dust qualifier for vanadium

Commenter List: C-1870

Comment: The commenter claims that EPA cannot expand the TRI listing for vanadium beyond "fume and dust" to include vanadium and vanadium compounds because: (1) EPA has not conducted an exposure assessment and determined that vanadium and vanadium compounds are present in the environment at concentrations that may present a risk of ecotoxicity; and

(2) EPA cannot list a chemical category without first determining that each member of the category will exhibit the same characteristics. The commenter stated that EPCRA section 313(d)(2)(C) requires consideration of exposure issues since the section requires the Administrator to determine that a chemical can reasonably be expected to cause "a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting." The commenter stated that the rulemaking record does not demonstrate that vanadium (or its compounds) are present in the environment at high enough concentrations to cause a significant adverse effect on the environment "of sufficient seriousness, in the judgment of the Administrator, to warrant reporting." The commenter stated that EPA has acknowledged that the environmental effects listing criterion "inherently contains a limited exposure component" because, "under certain circumstances, a chemical that could theoretically cause a significant adverse effect on the environment is unlikely to cause one of a magnitude to warrant listing."

The commenter acknowledged that EPA's position is that an exposure assessment is not needed because vanadium and compounds have high ecotoxicity but stated that "whatever the merits of EPA's view of its obligation to conduct exposure assessments for purposes of EPCRA Section 313 listings generally, EPA must consider exposure considerations where its listing decision eliminates a Congressionally-imposed limitation on the scope of a listing." The commenter stated that in listing vanadium for fume and dust, Congress implicitly agreed that releases of vanadium to the ambient air represented the health or environmental risk of significance to communities, and were relevant to community right-to-know initiatives. The commenter stated that EPA cannot expand on the listing, beyond Congressional intent, without a particularized showing that the chemical actually presents a risk through other pathways. The commenter stated that "where EPA expands a listing beyond that endorsed by Congress, particularly under the environmental effects standard in EPCRA Section 313 (d)(2)(C), EPA's rulemaking record must contain specific evidence that a chemical that could theoretically cause an adverse effect on the environment actually does so. Accordingly, before expanding the listing for vanadium, EPA must examine such measures of exposure as pollution controls, the volume and pattern of production, use and release, environmental fate, and other factors to determine whether vanadium and compounds actually are present in aquatic environments at high enough concentrations to cause aquatic toxicity."

The commenter also stated that "an exposure assessment is particularly appropriate here where EPA has not expressed concern previously about the human health or environmental risks presented by vanadium and compounds through routes other than inhalation. The rulemaking record for vanadium contains no exposure assessment, and no suggestion that releases of vanadium compounds from manufacturing operations present a risk of aquatic toxicity at concentrations present in the environment. Moreover, the findings made by EPA in connection with other initiatives suggest that vanadium compounds do not present a serious risk of ecotoxicity." The commenter stated that the RCRA PBT List evaluated the presence in the environment of vanadium and other compounds. The commenter stated that the index of environmental presence most relevant to vanadium's potential ecotoxicity is EPA's Fish Consumption Advisory database. This database identifies chemical compounds for which fish advisories have been posted throughout the country and represents the best available measure of whether, and how often, significant releases to water have occurred for vanadium and other chemicals. EPA scored vanadium as 0 on this criterion, because no advisories were reported for vanadium.

The commenter stated that EPA's *Hazardous Waste Characteristics Scoping Study*, conducted to characterize releases due to non-hazardous industrial waste management practices -- nearly all of which involve groundwater contamination -- and that EPA identified vanadium as one of only 4 chemicals that were not detected in any of the case studies at levels above state and federal standards. The commenter claims that therefore EPA's own prior analyses suggest that vanadium does not satisfy the statutory standard under EPCRA Section 313(d)(2)(C). The commenter also stated that the Agency for Toxic Substances and Disease Registry (ATSDR) profile for vanadium states that "[d]rinking water is not considered to be an important source of vanadium exposure" because detected concentrations were very low.

The commenter stated that based on findings they have cited, and absent any contrary evidence in the rule, EPA cannot make a determination that releases of vanadium and vanadium compounds into the environment can be anticipated to cause a significant adverse effect on the environment of sufficient seriousness to warrant reporting. The commenter stated that at a minimum EPA must conduct an exposure assessment and determine that the risk of ecotoxicity arising from manufacturing operations involving vanadium is more than theoretical before expanding the listing beyond fume and dust forms.

The commenter also stated that EPA cannot list vanadium and vanadium compounds without first determining that characteristics common to the category cause toxic effects. The commenter stated that EPA's hazardous assessment evaluates the ecotoxicity of only a few vanadium compounds, and EPA has not demonstrated that each member of the category exhibits the same characteristics.

Response: EPA does not believe that it is necessary or appropriate to conduct an exposure assessment in order to show that vanadium or vanadium compounds meet the listing criteria of EPCRA section 313(d)(2)(C) because EPA's hazard assessment clearly demonstrates that vanadium is highly toxic to aquatic organisms. The commenter cited statements that EPA made in its 1994 proposed chemical expansion rule (59 FR 1788, January 12, 1994), but does not provide the correct context because they left out portions of the statements most relevant to this rulemaking. The relevant paragraphs from which the commenter quotes state that:

"EPA believes that the environmental effects criterion inherently contains a limited exposure component because of the statutory requirement for EPA to find a "significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting" under EPCRA section 313. Unlike section 313(d)(2)(B), where EPA only has to determine whether certain kinds of effects are "known or reasonably anticipated" to occur, section 313(d)(2)(C) requires EPA to find the effect to be of sufficient seriousness to warrant reporting, which implies the possibility that under certain circumstances, a chemical that could theoretically cause a significant adverse effect on the environment is unlikely to cause one of a magnitude to warrant listing.

The extent to which exposure is factored into EPA's determination depends upon the inherent toxicity of a chemical, and a variety of other chemical-specific characteristics. EPA believes that when a chemical is inherently extremely toxic, that is, it is toxic at very low dose levels, an exposure assessment is not necessary because even minimal releases of such a chemical may reasonably be anticipated to result in significant adverse environmental effects. In such cases, EPA could rely on toxicity alone under section 313(d)(2)(C)(i) as a basis for listing.

However, for chemicals that exhibit adverse effects upon the environment solely based on toxicity at moderately low doses, EPA believes that consideration of potential exposure is warranted because minimal releases may not result in significant adverse effects upon the environment. These exposure considerations may include, among other factors, pollution controls, the volume and pattern of production, use, and release, environmental fate, as well as other chemical-specific factors, and the use of estimated releases and modeling techniques.

EPCRA sections 313(d)(2)(C)(ii) and (iii) allow EPA to consider the impacts of other characteristics of a chemical. Where a chemical exhibits significant adverse effects in the environment based on toxicity and persistence or toxicity and bioaccumulation at very low to moderately low dose levels, EPA believes that exposure considerations are not required in addition to those considerations implicit in evaluation of the chemical's potential for persistence and bioaccumulation. This is because even minimal releases of the chemical may result in elevated concentrations in the environment or in an organism that can reasonably be anticipated to result in significant adverse effects. This reflects the increased likelihood that there will be exposure to a chemical that persists due to its longer residence time in the environment. Repeated minimal releases of a persistent chemical may result in elevated concentrations in the environment. For a chemical that bioaccumulates, even low levels of the chemical in the environment may result in increased concentrations in an organism. Therefore, evaluation of a chemical's persistence or bioaccumulation potential may be considered the functional equivalent of an exposure analysis." (59 FR 1792, columns 2 and 3)

In the final chemical expansion rule of 1994 (59 FR 61432, November 30, 1994) EPA further explained its policy on the use of exposure considerations under EPCRA section 313(d)(2)(C) and the fact that the Agency does not consider exposure for chemicals that are highly ecotoxic. As EPA explained in the final rule, the Agency's policy on the use of exposure considerations under EPCRA section 313(d)(2) is consistent with the purpose and legislative history of EPCRA section 313:

"The Agency believes that exposure considerations are appropriate in making determinations... under section 313(d)(2)(C) for chemicals that are low or moderately ecotoxic but do not induce well-documented serious adverse effects as described below. The Agency believes that exposure considerations are not appropriate in making determinations ... under section 313(d)(2)(C) for chemicals that are highly ecotoxic or induce well-established adverse environmental effects. For chemicals which induce well-established serious adverse effects, e.g., chlorofluorocarbons, which cause stratospheric ozone depletion, EPA believes that an exposure assessment is unnecessary. EPA believes that these chemicals typically do not affect solely one or two species but rather cause changes across a whole ecosystem. EPA believes that these effects are sufficiently serious because of the scope of their impact and the well-documented evidence supporting the adverse effects." (59 FR 61441, columns 1 and 2)

EPA also stated that:

"EPA believes that its position regarding the use of hazard, exposure, and risk in listing decisions is consistent with the purpose and legislative history of EPCRA section 313, as illustrated in the following passage from the Conference report:

The Administrator, in determining to list a chemical under any of the above criteria, may, but is not required to conduct new studies or risk assessments or perform site-specific analyses to establish actual ambient concentrations or to document adverse effects at any particular location. (H. Rep. 99-962, 99th Cong., 2nd Sess., p. 295 (Oct. 3, 1986)).

This passage indicates Congress did not intend to require EPA to conduct new studies, such as exposure studies, or perform risk assessments, and therefore did not consider these activities to be mandatory components of all section 313 decisions. EPA believes that this statement combined with the plain language of the statutory criteria clearly indicate that Congress intended that the decision of whether and how to consider exposure under EPCRA section 313(d)(2)(B) and (C) should be left to the Agency's discretion. EPA has carefully considered when and how to use exposure to fully implement the right-to-know provisions of EPCRA. The Agency believes that in this final rule, EPA has appropriately used the discretion provided to it to assure the addition of chemicals that meet the right-to-know objectives of EPCRA section 313 while not unduly burdening the regulated community.

EPCRA section 313 specifically requires that exposure be considered for listing a chemical pursuant to section 313(d)(2)(A). The statute mandates that EPA consider whether "a chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries." EPA has, and will continue to look at exposures reasonably likely to exist beyond facility site boundaries when making a listing determination pursuant to EPCRA section 313(d)(2)(A).

The statute is silent on the issue of exposure considerations for the section 313(d)(2)(B) and (C) criteria. The language of section 313 does not prohibit EPA from considering exposure factors when making a finding under either section 313(d)(2)(B) or section 313(d)(2)(C). However, the language of sections 313(d)(2)(B) and (C) does not require the type of exposure assessment and/or risk assessment argued by the commenters. EPA believes that it has the discretion under both section 313(d)(2)(B) and section 313(d)(2)(C) to consider, where appropriate, those exposure factors that may call into question the validity of listing of any specific chemical on TRI. In exercising this discretion, EPA considers it appropriate to employ exposure considerations to a limited extent in making determinations under EPCRA section 313(d)(2)(C) because this criterion requires the Agency to find a "significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator to warrant reporting" under EPCRA section 313. This language recognizes the possibility that under certain circumstances, a chemical that could theoretically cause an adverse effect on the environment is unlikely to cause one of a magnitude sufficient to warrant listing. Moreover, because of the limitation on the number of chemicals listed pursuant to only section 313(d)(2)(C) that may be listed, EPA believes that it is appropriate to use both hazard and exposure factors as prioritizing considerations in these listing decisions. Therefore, to meet its obligation under section 313(d)(2)(C), in cases where a chemical is low or moderately ecotoxic, EPA may look at certain exposure factors (including pollution controls, the volume and pattern of production, use, and release, environmental fate, as well as other chemical specific factors, and the use of estimated releases and modeling techniques) to determine if listing is reasonable, i.e., could the chemical ever be present at high enough concentrations to cause a significant adverse effect upon the environment to warrant listing under section 313(d)(2)(C)." (59 FR 61441, column 3 and 61442, column 1)

EPA has clearly stated its interpretation of the statutory requirements of EPCRA section 313(d)(2) and specifically with those of section 313(d)(2)(C) and believes that its policy on the use of exposure is consistent with the language and requirements of the statute. EPA's interpretation has also been upheld in court. (See Troy Corp. v. Browner, 120 F.3d 277 (D.C. Cir. 1997)).

The commenter's claims that because Congress established the initial EPCRA section 313 list of toxic chemicals that contained vanadium with a fume or dust qualifier EPA must consider exposure and risk before removing the qualifier are wrong. Congress established the initial EPCRA section 313 list of toxic chemicals by combining two existing state lists without any indication of having conducted any assessment of the chemicals on those lists. However, Congress did establish criteria for adding or removing chemicals from the list and provided a petitions process for the public to request that chemicals either be added to or deleted from the list based on the statutory criteria as set forth in section 313(d)(2). There are no special provisions in the statute that require EPA to perform additional assessments to modify the listing for a chemical that was on the list as

established by Congress. The removal of the fume or dust qualifier is in effect the same as the addition of a chemical to the list, and the same statutory requirements apply to this modification as apply to the addition of any chemical to the list. EPA conducted a hazard assessment that provided the basis for the addition of vanadium and vanadium compounds to the EPCRA section 313 list and followed all of the Agency's stated policies and guidelines with regard to the addition of chemicals under the statutory requirements of EPCRA section 313(d)(2)(C).

EPA disagrees with the commenter's claims that because some programs have not identified vanadium as being present in the environment at a level of concern, that EPA must conduct exposure and risk assessments under EPCRA section 313. These other programs have different criteria and purposes than those of EPCRA section 313 so the fact that they have not identified vanadium as being present at a level of concern for their program is irrelevant to a determination as to whether vanadium or any other chemical meets the listing criteria of EPCRA section 313. For example, the commenter cited EPA's Fish Consumption Advisory database as the index of environmental presence they claim is the most relevant to vanadium's potential ecotoxicity. However, this database identifies advisories that have been issued because certain aquatic organisms contain high levels of a chemical that is toxic to humans. Such advisories indicate that a toxic chemical has bioaccumulated in those organisms to levels that exceed some established threshold for human consumption but does not necessarily reflect environmental presence as the commenter suggests. A chemical may be present in aquatic organisms below a level of concern for human consumption but that does not mean that it was not present in the environment at levels that could cause ecotoxicity, and, because of its ecotoxicity, a significant adverse effect on the environment. This is especially relevant to vanadium since the basis for listing vanadium and vanadium compounds under EPCRA section 313 is the high toxicity of vanadium to aquatic organisms rather than human health concerns. Thus the fact that no advisories were reported for vanadium does not lessen the concern for its high ecotoxicity. The commenter's statements on this issue also seem to conflict with their comments that vanadium is not bioaccumulative: if the commenter believes that vanadium does not bioaccumulate, it would appear to be contradictory to claim that the lack of bioaccumulation in fish conclusively establishes that vanadium is not present in the environment at any level. The commenter is also mistaken in the relevance of the statement quoted from the ATSDR that "[d]rinking water is not considered to be an important source of vanadium exposure." EPA's hazard assessment indicated that while vanadium is toxic to aquatic organisms at relatively low concentrations there is no human health basis for listing vanadium under EPCRA section 313. Therefore, even if drinking water intended for humans is not an important source of vanadium exposure, that has no bearing on EPA's assessment of, or concern about, vanadium's ecotoxicity.

EPA agrees with the commenter's statement that EPA needs to determine what characteristics common to the vanadium compounds category cause toxic effects but disagrees with the statement that EPA has not demonstrated that each member of the category exhibits the same characteristics. As EPA stated in the 1994 chemical expansion final rule (59 FR 61432, November 30, 1994):

"The Agency believes it satisfies the statutory criteria to add a category to the list by identifying the toxic effect of concern for at least one member of the category and then showing why that effect may reasonably be expected to be caused by all other members of the category." (59 FR 61442, column 3)

EPA developed a hazard assessment for vanadium which reviewed the toxicity data for several vanadium compounds. The assessment indicated that the vanadium from these compounds is highly toxic to aquatic organisms. Since it is the vanadium from these compounds that is toxic rather than the intact vanadium compound, EPA believes that all chemicals that are a source of vanadium meet the EPCRA section 313(d)(2)(C) listing criteria. Thus EPA has established the toxic effect of concern, the chemical species that causes the effect, and the basis for why it may reasonably be expected that all members of the vanadium compounds category can cause the effects of concern, and has concluded that vanadium compounds will have an adverse effect on the environment of sufficient seriousness to warrant reporting under EPCRA section 313.

EPA disagrees with all of the commenter's statements that EPA must conduct a risk assessment and determine that there is a specific risk associated with the releases of vanadium and vanadium compounds in order to list vanadium without the fume or dust qualifier or vanadium compounds. As discussed elsewhere in these comment responses, EPCRA section 313 is mainly a hazard based statute and does not always require EPA to conduct risk assessments in order to list chemicals under EPCRA section 313(d)(2).

Commenter List: C-1854

Comment: The commenter stated that pursuant to EPA's position, as outlined the 1994 chemical expansion final rule (59 FR 61432-61485, November 30, 1994), EPA should take exposure factors into consideration before listing vanadium without the

fume or dust qualifier.

Response: As discussed in detail in the previous comment response, EPA does not believe that exposure should be considered in the listing determination for vanadium and vanadium compounds. This determination is consistent with the Agency's stated policy on the use of exposure for listing decisions under EPCRA section 313(d)(2).

Commenter List: C-1407

Comment: The commenter stated that in another recent proposal (63 FR 31267, June 8, 1998) EPA is considering interpreting the exemption for hazardous chemicals found at EPCRA section 311 (e)(2) so that only the amount of fume or dust given off a piece of metal (or other manufactured solid) that is being modified be subject to EPCRA sections 311 and 312 and applied toward threshold determinations. The commenter stated that the retention of the "dust or fume" qualifier for vanadium would be more consistent with EPA's rationale expressed for the EPCRA 311 and 312 rule and more applicable to the incidental manufacture of metal particulate in metalworking operations or combustion processes.

Response: EPA does not believe that the proposed rule cited by the commenter is determinative of the determination under EPCRA section 313 that the vanadium fume or dust qualifier should be removed. EPCRA sections 311 and 312 are the emergency planning sections of EPCRA and deal with concerns about potential accidental releases of extremely hazardous substances. Furthermore, the action referenced by the commenter concerned a specific exemption that does not exist under EPCRA section 313. In the proposed rule cited by the commenter EPA stated that:

"EPCRA established a program to encourage state and local planning and preparedness for releases of extremely hazardous substances, and to provide the public, local governments, fire departments and other emergency officials with information concerning chemical releases and the potential chemical risks in their communities." (63 FR 31269, column 1);

"Today EPA is proposing modifications to several of the regulations that implement the emergency planning, emergency release notification, and the hazardous chemical community right-to-know portions of the EPCRA program (this rulemaking does not effect the implementation of EPCRA section 313, 40 CFR part 372, in any way)." (63 FR 31269, column 1).; and

"The reporting requirements under sections 311 and 312 of EPCRA are intended to enhance communities' and emergency response officials' awareness of chemical hazards, and to facilitate the development of State and local emergency response plans, thereby aiding communities and emergency response officials in preparing for and responding to emergencies safely and effectively." (63 FR 31269, column 3)

These statements clearly indicate that the focus of EPCRA sections 311 and 312 is on emergency preparedness and that the action proposed in the rule was not intended to affect EPCRA section 313 in any way. This is appropriate since the focus of reporting and the chemicals of concern are different under EPCRA section 313. The chemicals covered by EPCRA section 311 and 312 are defined in CFR Title 40 part 370.2 which states that a:

"*Hazardous chemical* means any hazardous chemical as defined under § 1910.1200(C) of Title 29 of the Code of Federal Regulations..."

The definition for a hazardous chemical at § 1910.1200(C) of Title 29 of the CFR states that a:

"Hazardous chemical means any chemical which is a physical hazard or a health hazard."

Thus the focus of EPCRA section 311 and 312 is on chemicals that pose a physical hazard or human health hazard. As stated previously, EPA is listing vanadium and vanadium compounds under EPCRA section 313(d)(2)(C) because of the Agency's concerns about these chemicals' ecotoxicity—a different assessment than whether vanadium poses a "physical hazard or human health hazard" as is required for chemical listing under EPCRA section 311 and 312. While it may be appropriate to focus on fume and dust forms of vanadium for human health concerns it does not limit the concern for forms other than fume or dust with respect to a concern for ecotoxicity.

Commenter List: C-1417, C-1445, C-1844,

Comment: The commenters stated that the Chemical Abstracts Service identifies over 100,000 vanadium compounds that

would be covered by the proposed vanadium compounds category.

Response: EPA conducted its own search and found less than 60,000 vanadium compounds in the File Registry of the Chemical Abstracts Service (CAS). However, the number of vanadium compounds listed under CAS is irrelevant to the issue of how many chemicals are likely to be reported under the EPCRA section 313 vanadium compounds category. Reports will only be required for vanadium compounds that are currently being manufactured, processed or otherwise used above applicable thresholds at covered facilities and will not include all of the vanadium compounds that researchers have identified and cataloged under CAS. A better measure of the number of chemicals covered by the vanadium compounds category is the number of vanadium compounds that are included in the Toxic Substances Control Act (TSCA) Inventory. This inventory includes the bulk of the commercial chemicals in use, excluding only pesticides or chemicals that only have uses regulated by the Food and Drug Administration. The number of vanadium compounds in the current TSCA Inventory is 97, and even if twice that number may be reported when pesticides and FDA chemicals are considered, it is still substantially less than the tens of thousands that the commenter suggests would be covered by the category.

Commenter List: C-1417, C-1445, and C-1844

Comment: In discussing what they believe were over 100,000 chemicals covered by the vanadium compounds category, the commenters stated that this huge number of compounds undoubtedly includes many inappropriate compounds since most vanadium compounds are insoluble and therefore have low bioavailability. The commenters stated that to remove these compounds from the TRI list using the delisting process is extremely cumbersome, time-consuming and costly. The commenters stated that with a single category, the EPA proposes to regulate over 100,000 compounds based on aquatic toxicity determined using five vanadium compounds.

Response: The number of compounds covered by the category is addressed in the previous comment response. The issue of solubility and bioavailability is being greatly over simplified by the commenters. While water soluble vanadium compounds would obviously provide vanadium in an immediately bioavailable form, solubility is not the only factor to consider in determining the bioavailability of vanadium from a vanadium compound. There are numerous biotic and abiotic processes that can result in the bioavailability of vanadium from a vanadium compound. In addition to solubility items such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformation (both abiotic and biotic); and bioavailability when the compounds is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs) need to be considered. The commenters have not provided data indicating that vanadium will not be bioavailable from any particular vanadium compounds. If the commenters have data that can prove that vanadium is not bioavailable from certain vanadium compounds then the appropriate action to take would be for the commenters to submit a petition pursuant to EPCRA section 313(e)(1) to delete such vanadium compounds from the list of chemicals subject to EPCRA section 313 reporting. EPA would address such a petition according to the Agency's stated policy and guidance concerning petitions to delist individual members of the metal compounds categories (May 23, 1991, 56 FR 23703). Under the metals policy EPA considers whether the metal from a metal compound can become bioavailable under abiotic or biotic conditions. In addition, the issue of persistence and bioavailability for metals in general is discussed elsewhere in these comment responses.

Commenter List: C-1854

Comment: The commenter stated that the proposal to remove the fume or dust qualifier from the EPCRA section 313 chemical listing for vanadium would require all forms of vanadium to be reported and that this change was promulgated under the contentions that:

"...Vanadium is toxic to certain aquatic organisms. In addition, considering vanadium's persistence and bioaccumulation potential, EPA also believes that vanadium is highly toxic to aquatic organisms at higher concentrations." (64 Fed. Reg. 698)

Response: The commenter has misquoted what EPA stated concerning the toxicity of vanadium. As EPA stated in the proposed rule:

"Some of the aquatic toxicity data discussed above are at relatively low concentrations indicating that vanadium is highly toxic to certain aquatic organisms. In addition, considering vanadium's persistence and bioaccumulation potential (discussed in Unit V.C.1. of this preamble), EPA also believes that vanadium is highly toxic to aquatic

organisms at the higher concentrations.” (64 FR 697, column 3 and 698, column 1).

The key word the that commenter left out is “highly” in the first sentence. Even without considering vanadium’s persistence or bioaccumulation potential, EPA believes that vanadium is highly toxic to certain aquatic organisms. It should be noted, however, that consistent with OPPT’s procedures used to evaluate a chemical’s ecological toxicity, EPA lowers the high concern level for toxicity by a factor of ten for persistent chemicals, and by another factor of ten if the chemical is also bioaccumulative. While EPA has not made a final determination on the bioaccumulation potential of vanadium, EPA believes that the persistence of vanadium is well established and thus vanadium is considered highly toxic at levels above those considered highly toxic based solely on toxicity rather than toxicity and persistence. Elsewhere in these vanadium comment responses EPA addresses the issue of vanadium toxicity and what levels of it are considered highly toxic versus moderately toxic. Considering vanadium’s persistence in the environment, EPA believes that it is highly toxic at concentrations between 1 and 10 mg/L. The issue of the persistence of metals in general is discussed elsewhere in these comment responses.

Commenter List: C-1407

Comment: The commenter stated that while they support the addition of a vanadium compounds category they oppose the removal of the fume or dust qualifier for vanadium. The commenter stated that it is broadly accepted that metal compounds or dissolved metals have the potential to become bioavailable, however, EPA has not provided any evidence in the rule that particles larger than fume or dust contribute to the effects discussed in the rule. The commenter stated that if EPA removes the fume or dust qualifier the Agency should provide more sufficient evidence that forms of the metal larger than dust or fume particle sizes are reachable to the aquatic environment.

Response: It is not clear whether the commenter is stating that forms other than fume or dust are not bioavailable or that just larger sizes are not released to the aquatic environment. As discussed above in previous comment responses, the issue of bioavailability is not simply one of solubility. Unless vanadium metal undergoes no abiotic or biotic transformations in the environment, which EPA does not believe is the case, then vanadium can become bioavailable to some extent from any particle size. Whether physical forms larger than a dust or fume can reach the aquatic environment is an issue of exposure not bioavailability and, as discussed above in a previous comment response, EPA does not believe that it is appropriate to consider exposure in listing chemicals that are highly ecotoxic such as vanadium. The issue of persistence and bioavailability for metals in general are discussed elsewhere in these comment responses.

Commenter List: C-1407, C-1417, C-1445, C-1827, C-1844, C-1854, C-1861, C-1865, C-1870

Comment: Commenters stated that they do not support the removal of the fume or dust qualifier for vanadium. Some provided specific comments others just stated that they did not support the proposed removal of the qualifier.

Response: EPA believes that it has provided sufficient basis for the removal of the vanadium fume or dust qualifier. This qualifier is related mostly to human health concerns since fumes and dust are the most easily inhaled physical forms of a metal such as vanadium. However, EPA’s assessment shows that vanadium is highly toxic to aquatic organisms and the form present in aquatic environments are not limited to fumes or dust. The detailed comments that some commenters provided are elsewhere in these responses to comments on the listing of vanadium and vanadium compounds.

Commenter List: C-1855 and C-404:

Comment: The commenters stated that they support the reporting of vanadium and vanadium compounds. The commenters also stated that large amounts of vanadium are frequently released in waste streams from certain processes at petroleum refineries. Commenter C-404 stated that the bioaccumulation data for vanadium indicate the need for listing vanadium as a PBT compound with lower reporting thresholds.

Response: EPA appreciates the support for the proposal to add vanadium compounds to the EPCRA section 313 list of toxic chemicals and to remove the fume and dust qualifier for vanadium. As for the commenter’s concerns about classifying vanadium and vanadium compounds as PBT chemicals, and lowering the corresponding reporting thresholds, EPA is still evaluating the data on the bioaccumulation potential of vanadium and, if appropriate, may propose lower reporting thresholds in a future rulemaking.

3.e.iii.2 Whether vanadium PBT data meets PBT criteria.

Commenter List: C-1409, C-1423, C-1448, C-1827, C-1854, and C-1870

Comment: The commenters stated that they do not believe that vanadium should be classified as a PBT chemical because the bioaccumulation data is insufficient to support a conclusion that vanadium is bioaccumulative based on the criteria and guidelines for bioaccumulation as laid out in the proposed rule.

Response: EPA did not propose to list vanadium as a PBT chemical but did ask for comments on the sufficiency of the bioaccumulation data for vanadium. EPA is still considering the data and comments received on this issue and is not making a determination as to the bioaccumulation potential of vanadium in the final rule. In the future, if EPA determines that vanadium does meet the bioaccumulation criteria, the Agency will undertake notice and comment rulemaking to classify vanadium and vanadium compounds as PBT chemicals and lower their respective reporting thresholds.

Commenter List: C-1854

Comment: The commenter does not believe that persistence criteria should be applied to metals. Commenter further states that vanadium should not qualify as a PBT chemical. The commenter stated that metals may not be destroyed, but they do undergo transformations that render them unavailable and thus nontoxic. The commenter stated that once a metal has been either bound or precipitated, its persistence as a toxicant is governed by the rate of desorption or dissolution and not the rate of release into the environment. The commenter stated that if EPA applies its persistence criteria to metals such as vanadium, EPA should consider solubility and bioavailability and should not attempt to apply criteria developed for organic compounds to metals.

Response: The issue of whether it is appropriate to apply the persistence criteria laid out in the proposed rule to metals is discussed in detail elsewhere in these comment responses. EPA believes that it is appropriate to consider metals, including vanadium, to be persistent in the environment. While water soluble compounds would obviously provide vanadium in an immediately bioavailable form, solubility is not the only factor to consider in determining the bioavailability of vanadium in the environment. There are numerous biotic and abiotic processes that can result in the bioavailability of vanadium even once it has become bound or precipitated. However, EPA is not classifying vanadium as a PBT chemical in the final rule since the Agency is still considering comments and data concerning the potential for vanadium to bioaccumulate.

3.e.iii.3 Toxicity Data for Vanadium and Vanadium Compounds

Commenter List: C-1827

Comment: The commenter noted that in the proposed rule EPA states, regarding vanadium, that "However, very few toxicity tests have been conducted with invertebrates. The commenter argued that beyond vanadium pentoxide (V_2O_5), the Agency appears to have very little toxicity data on vanadium compounds. The commenter contends that the paucity of toxicity data on many different forms of vanadium compounds in the proposal as well as in the literature does not appear to support the Agency's belief that "the evidence is sufficient to list vanadium and vanadium compounds on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(C) based on the available ecotoxicity information on vanadium and vanadium compounds" (at 64 FR 698).

Response: EPA disagrees with the commenter's conclusions. Although there is limited information on vanadium's toxicity on invertebrates, data that were available for invertebrates shows that vanadium is toxic to these species. Furthermore, EPA's assessment of vanadium's toxicity included algae and vertebrates, and showed that the chemical is highly toxic to aquatic organisms.

The data on vanadium are not limited to vanadium pentoxide, the ecological data provided in the proposed rule for vanadium evaluates vanadium toxicity based on data for other vanadium compounds including: sodium metavanadate, sodium orthovanadate, vanadyl sulfate, and ammonium vanadate. In assessing the ecological toxicity of vanadium and vanadium compounds, EPA evaluated the parent metal (vanadium) and determined that it is highly toxic to some aquatic species and anticipated to cause a significant adverse effect on the environment of sufficient seriousness to warrant reporting. Thus, vanadium, the parent metal in vanadium compounds, is the concern, not the other components of each vanadium compound. Many metals are tested in the salt form because these forms are readily soluble in aqueous solutions. The toxicity data for vanadium shows that the metal is highly toxic (aquatic toxicity < 1 mg/L) to the most sensitive species. This evaluation of

vanadium's toxicity is acceptable according to traditional guidelines for the assessment of toxic substances as conducted by the agency for over two decades. In addition, when consideration is given to vanadium's persistence it is also considered highly toxic at higher concentrations.

Commenter List: C-1417, C-1844, and C-1445

Comment: The commenters contend that since most vanadium compounds are practically insoluble, they consequently have very low bioavailability, and thus it is likely that they could qualify for delisting. The commenters argued that the delisting process is extremely cumbersome, time-consuming, and costly. One of the commenters contends that it is inappropriate to list all of these compounds based on aquatic toxicity of the few compounds cited in the proposed rule. The bioavailability of metals such as vanadium was also raised as an issue at the public meetings held for this rulemaking. It was suggested that the parent metal will not be bioavailable from certain metal compounds that may be released into the environment and that therefore the compounds cannot be properly characterized as a PBT chemicals.

Response: EPA disagrees with these comments. First, it should be noted that EPA has not addressed whether vanadium and vanadium compounds can properly be classified as PBT chemicals in this rulemaking. The sole issue, therefore, is whether vanadium and vanadium compounds meet the EPCRA section 313 (d)(2)(C) listing criteria. EPA's analysis of the environmental fate of vanadium and vanadium compounds shows that under many environmental conditions vanadium will be available and thus is able to express its toxicity. The commenters have not provided EPA with any data or acceptable scientific studies indicating that vanadium in any particular compound will not become available in the environment. In fact, at least one commenter appears to indicate that these vanadium compounds may merely have low solubility. In these compounds the parent metal vanadium, can become available. While water soluble vanadium compounds would obviously provide vanadium in an immediately bioavailable form, solubility is not the only factor to consider in determining the bioavailability of vanadium from a vanadium compound. In addition to solubility processes such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformation (both abiotic and biotic); and bioavailability when the compounds is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs) need to be considered. Elsewhere in these comment responses EPA discusses in detail the persistence and bioavailability of metals in general.

The issue of bioavailability has been addressed for EPCRA section 313 chemical assessments through EPA's policy and guidance concerning petitions to delist individual members of the metal compound categories on the under EPCRA section 313 toxic chemical list (56 FR 23703, May 23, 1991). This policy states that if the metal in a metal compound cannot become available as a result of biotic or abiotic processes then the metal will not be available to express its toxicity. If the intact metal compound is not toxic and the metal is not available from the metal compound then such a chemical is a potential candidate for delisting.

Comment: The commenters stated that vanadium is not listed in the National Recommended Water Quality Criteria (63 FR 237) and that this reflects the fact that the water office did not regard vanadium or vanadium compounds in water to be a significant threat to human health or the environment. The commenters stated that no effluent standards or criteria have been developed for this metal or for any compound containing vanadium. The commenters contend that over the last 27 years, USEPA has developed water quality criteria for 157 substances that could cause harm to aquatic species and/or humans who ingest them through consumption of water or organisms. The commenters stated that vanadium has not been designated a Priority Toxic Pollutant under paragraph 307(a) of the Clean Water Act, nor has a water quality criterion been established pursuant to paragraph 304(a) and that the latest compilation of such criteria by EPA (63 FR 68353, December 10, 1998) does not include any mention of vanadium or vanadium compounds.

Response: EPA disagrees with the commenter's conclusions. The Office of Water did not do an assessment of vanadium for designation as a Priority Toxic Pollutant. However, this is irrelevant to the listing of vanadium and vanadium compounds under EPCRA section 313. The relevant issue is whether or not vanadium and vanadium compounds meet the statutory listing criteria in EPCRA section 313 (d)(2). EPA has reviewed the available data and has determined that vanadium meets the listing criteria of EPCRA section 313 (d)(2)(C). Vanadium is highly toxic to certain aquatic organisms and anticipated to cause a significant adverse effect on the environment of sufficient seriousness to warrant reporting pursuant to EPCRA section 313.

Commenter List: C-1854

Comment: The commenter contends that EPA did not review any vanadium or vanadium compound study published later than

1983.

Response: The commenter's statement is inaccurate. EPA reviewed several studies published later than 1983. However, no information concerning the toxicity of vanadium was reported from these later studies because sufficient data were found to support the high aquatic toxicity finding for vanadium and vanadium compounds in the earlier studies. EPA's review of the information in the post-1983 studies had little impact on the Agency's conclusion that the earlier studies reported accurate and valid information.

Comment: The commenter notes that EPA states that "[v]anadium concentrations as low as 0.3 ppm are known to have a toxic effect on algae", but that no studies reporting any toxic response at 0.3 ppm are cited.

Response: The Agency inadvertently reported the wrong values for the range of toxicity of vanadium to algae. The ecological assessment of vanadium (EPA 1998 and supporting document) stated in the summary of vanadium's ecological assessment that the concentrations causing an adverse effect were as low as 0.3 ppm. However, this is inconsistent with the 0.003 ppm value that was reported in the algae assessment and Table 1. The 0.003 ppm value referenced in the assessment and Table 1 of the proposed rule was drawn from Hess, (1983) which was available in the public docket. This error will be corrected in the final rule.

Comment: The commenter stated that EPA cites Miramand and Unsal (1978) as finding that the lethal concentration for 50 percent of the study population (LC₅₀) for *Chlorella pyrenoidosa* was 20 g/L but that Miramand and Unsal (1978) did not report using this species in their study.

Response: EPA (1998) reported an LC₅₀ of 0.02 mg/L for *Chlorella pyrenoidosa* and cited this reference as Miramand and Unsal (1978) in Table 1 of the proposed rule (64 FR 688 at 706). The Agency inadvertently mis-cited this reference in the "Support Document for the Addition of Certain Chemicals to Section 313 of the Emergency Planning and Community Right-to-Know Act." The correct citation is Meisch and Benzschawel (1978). The Meisch and Benzschawel study was available in the public docket for this rulemaking during the public comment period. This change will be updated in the final rule.

Comment: The commenter states that the lowest toxicity value cited by EPA for a marine algal species was for *Dunaliella marina* with a 9-day LC₅₀ of 0.5 mg/L (Miramand and Unsal 1978) but that EPA omitted a study by Ballester and Castellvi (1979), who tested the same species and reported no significant adverse effects at a concentration of 50 mg/L.

Response: EPA believes that the the Miramand and Unsal (1978) study that reported the 9-day LC₅₀ of 0.5 ppm on *Dunaliella marina*, is accurate and was acceptably conducted within the guidelines for ecological assessments of hazardous chemicals. This study shows the most sensitive species' response to the chemical.

There are differences in the two studies that could explain the range of toxicity between the two. They are: (1) Differences in the exposure times, (2) the species used in the experiments, and (3) the form of vanadium that was exposed to the organisms. The exposure time in the Miramand and Unsal study was reported as a 9-day LC₅₀ of 0.5 mg/L. However, the Ballester and Castellvi study did not report an LC₅₀ duration. Also, the species for the Miramand and Unsal (1978) study reported the test species to be *Dunaliella marina (salina)*, but the Ballester and Castellvi (1979) study only reported the genus name for this organism. Furthermore, the Miramand and Unsal (1978) study reported the form of vanadium as sodium vanadate, but the Ballester and Castellvi (1979) study only reported using the vanadium compound without reporting the specific salt form.

It is clear that any one of the three factors mentioned, or some combination of these factors, likely accounts for the variation in toxicity between the two studies.

Comment: The commenter contends that EPA's review of vanadium's toxicity omitted a study by Nalewajko et al. (1995) on nine algal species that showed no significant reduction in productivity (as measured by chlorophyll synthesis) at vanadium concentrations in excess of 10 mg/L. The commenter contends that the authors also demonstrated that phosphate concentrations were critical in the toxicity of vanadium to algae.

Response: The Agency has not neglected to review any valid studies available to it. The toxicity values that were reported in the ecological assessment of vanadium toxicity were from well-conducted studies. However, EPA interprets that the Nalewajko et al. (1995) study as describing the competition uptake between vanadium and phosphorus in an algal medium containing two different kinds of phosphorus concentrations (i.e., phosphorus deficient and phosphorus sufficient). Also this study was performed only on freshwater algae and one form of vanadium (orthovanadate) which only exists in a pH range of 3 to 6. This

study did report a moderately high toxicity value for *Scenedesmus acutus* between 5 and 177 μ M which continues to support EPA's findings that vanadium is toxic to algae. Furthermore, EPA is aware that there are studies that were not included in the assessment that showed that the chemical was more toxic than the values reported in EPA's assessment. However, each study was carefully reviewed based on EPA's extensive evaluation process which reviews studies for conformance with generally accepted scientific standards principles and tests. The studies that were reported in EPA's assessment used the best scientific methods method for evaluating aquatic toxicity.

Comment: One commenter argues that it appears from a review of the data that the contention that vanadium is highly toxic to algae has no basis. The commenter contends that with the exception of one study on a single species, *Ceratium hirundinella*, none of the studies on freshwater algae showed significant toxicity at concentrations below 10 mg/L. The commenter stated that the lowest level of toxicity reported for a marine species (*Dunaliella marina*) was 0.5 mg/L, but that there is conflicting evidence that the threshold of toxicity for this species may be higher than 50 mg/L. The commenter concludes that there appears to be little evidence that vanadium is a highly toxic agent to algae. The commenter also argues that evaluating the toxicity of a compound based on the response of individual algal species can be misleading. The commenter contends that algae never exist within either marine or freshwater environments as monocultures, but rather as dynamic mixed populations (Wetzel 1983). The commenter concludes that unless a compound can be shown to have a broad effect over an entire assemblage or over numerous species of either freshwater or marine species, it is not likely to have a significant effect within the natural environment.

Response: EPA's assessment on algae toxicity shows that vanadium is highly toxic based on the most sensitive species' response to the chemical. There is no conflict in the threshold of toxicity of *Dunaliella marina*. As stated above, there are three factors that most probably accounts for the differences between the Miramand and Unsal (1978) study and the Ballester and Castellvi (1979) study. After careful review of the available data, it is EPA's professional judgment that the Miramand and Unsal (1978) study provides accurate and valid data.

Algae studies have been included in ecological risk assessments for over two decades. Several guidelines on different species have been written to show that these genera are important in the environment and show sensitivity in how chemicals affect the biota. EPA agrees that algae usually do not exist in monocultures in the marine or freshwater environment. However, testing monocultures species is the most accurate method to determine whether or not a chemical is directly harmful to that species. Therefore, if a compound is highly toxic to a particular species of algae or any species, its effects can be extrapolated to represent other species exposed to that chemical. This evaluation process has been in practice by the Agency and agreed upon by OECD for over two decades on thousands of chemicals. Vanadium's toxicity ranges from highly toxic to moderately toxic for algae in EPA's assessment. It is reasonable from the evidence in our assessment of vanadium that the species that is the most sensitive to the chemical can represent the toxicity for all other species based on this narrow range. EPA's final evaluation of any chemical's toxicity is based on the most sensitive species' response

Comment: The commenter states that the invertebrate toxicity studies (Table 1 in EPA's assessment) show a range of LC₅₀ values of 4.1-65 mg/L, indicating low sensitivity to vanadium. The commenter contends that in a remedial investigation of a ferrovanadium production facility (PTI 1996), sediment bioassay tests also indicated few effects on test invertebrates. The commenter stated that the apparent effects threshold of vanadium was 1,280 mg/kg for amphipods (*Hyallela azteca*) and > 5,570 mg/kg for midge larvae (*Chironomus tentans*). The commenter also noted that a benthic macroinvertebrate community assessment at the same facility (Exponent 1998) demonstrated that vanadium concentrations in excess of 10,000 mg/kg in wetland soils had no adverse effects on either abundance or diversity of macroinvertebrates.

Response: EPA disagrees with the commenter's interpretation of low sensitivity to vanadium. The agency interprets 1 - 100 ppm as moderately toxic for aquatic organisms. This range of toxicity has been used to assess ecological hazard and risk for over two decades. Also, considering vanadium's persistence in the environment, EPA believes that it is highly toxic at concentrations between 1 and 10 mg/L. The information from these bioassays, if accurate, do not discount the data the EPA has provided that show that vanadium is highly toxic to certain aquatic organisms.

Comment: The commenter stated that EPA reported a study by Knudtson (1979) on guppies (*Lebistes reticulatus*) that reported the 144-hour LC₅₀ of 0.4 and 0.5 mg/L for vanadyl sulfate (VOSO₄) and ammonium metavanadate (NH₄VO₃), respectively. The commenter contends that these values were actually for VOSO₄ and sodium metavanadate (NaVO₃) respectively. The commenter contends that the 144-hour LC₅₀ for NH₄VO₃ was 1.5 mg/L. The commenter argues that EPA also neglected to report from the same study a 144-hour LC₅₀ of 1.1 mg/L for vanadate pentoxide (V₂O₅) for this species. The commenter contends that Knudtson's (1979) findings of 144-hour LC₅₀'s of 2.5 to 8.1 mg/L in goldfish (*Carassius auratus*) for the

same four vanadium species were also omitted.

Response: The comment concerning the vanadium compounds for Knudtson (1979) is correct. EPA inadvertently cited to the incorrect compound in Knudtson, the correct vanadium compounds will be reflected in an update to the support document. However, sodium metavanadate is still a vanadium compound and the Knudtson study therefore continues to support the Agency's findings that vanadium is highly toxic to fish. The other values of 2.5 and 8.1 mg/L merely provide further support for EPA's finding that vanadium is moderately toxic to fish. However, considering vanadium's persistence in the environment, EPA believes that it is highly toxic at concentrations between 1 and 10 mg/L. Thus the goldfish values provide further support to EPA's finding that vanadium is highly toxic to aquatic organisms.

Comment: The commenter contends that EPA misquoted the findings of Giles and Klaverkamp (1982) when it cited a 96-hour LC₅₀ of 6.4 mg/L for rainbow trout embryos (*Salmo gairdneri*). The commenter argues that the actual value reported in this study was 118 mg/L and that this finding was 300 times less toxic than the LC₅₀ for copper, which was also tested in the same study.

Response: EPA inadvertently provided the wrong citation for the 6.4 mg/L value for the rainbow trout. The correct reference and citation for this value is: Stendahl, D.H. and J.B. Sprague. 1982. Effects of water hardness and pH on vanadium lethality to rainbow trout. *Water Res.*, 16: 1479-1488. This change will be corrected in an update to the support document.

Comment: The commenter contends that EPA, in assessing the toxicity of vanadium to fish, neglected to review the following studies: (1) Hamilton and Buhl (1997), who reported a 96-hour LC₅₀ for the flannelmouth sucker (*Catostomus latipinnis*) of 11.7 mg/L, (2) Taylor et al. (1985), who reported a 96-hour LC₅₀ for English sole (*Limanda limanda*) of 26.8 mg/L, (3) Ernst and Garside (1987), who reported a 96-hour LC₅₀ for the brook trout (*Salvelinus fontinalis*) alevins of 24 mg/L and for yearlings of 7-15 mg/L (the authors also reported that the method by which stock solutions are formulated could have a dramatic effect on the toxicity of vanadium through its effects on the polymeric form of the metal in the test study), and (4) Hamilton and Buhl (1990), who reported a 96-hour LC₅₀ for chinook salmon (*Oncorhynchus tshawytscha*) fry of 16.5 mg/L.

Response: EPA undertook an exhaustive review of vanadium toxicity. The studies that the commenter listed show that vanadium compounds are moderately toxic to fish which further support EPA's findings on the toxicity of vanadium. EPA's review of the studies cited in the proposed rule, and are not contradicted or undermined by the studies provided by the commenter, support the Agency's conclusion that vanadium and vanadium compounds are highly toxic to some aquatic species.

Commenter List: C-1421

Comment: The commenter states that the background document to support EPA's proposal to list vanadium and vanadium compounds indicates that the proposed listing is based on data for five vanadium compounds: vanadium pentoxide, sodium metavanadate, sodium orthovanadate, vanadyl sulfate, and ammonium vanadate. The commenter contends that EPA may consider listing under EPCRA section 313 for the individual compounds for which the Agency has data, but EPA is not justified in listing a broad "vanadium and vanadium compounds" category based on data for only five compounds. The commenter suggests that EPA consider individual listings for these compounds, or a category consisting only of the compounds for which the Agency has data.

Response: EPA disagrees with the commenter's characterization of the Agency's assessment of vanadium and vanadium compounds. In assessing the ecological toxicity of vanadium and vanadium compounds, EPA evaluated the parent metal (vanadium) and determined that it is highly toxic to some aquatic organisms and can reasonably be anticipated to cause a significant adverse effect on the environment of sufficient seriousness to warrant reporting pursuant to EPCRA section 313(d)(2)(C). Thus, vanadium, the parent metal in vanadium compounds, is the concern, not the other components of each compound. Many metals are tested in the salt form because they are readily soluble in aqueous solutions. The toxicity data for vanadium shows that the metal is highly toxic (aquatic toxicity < 1 mg/L) to the most sensitive species. In addition, because vanadium is persistent, EPA considers any toxicity values between 1 and 10 mg/L as indicating high ecotoxicity. This evaluation of vanadium's toxicity is acceptable according to traditional guidelines for the assessment of toxic substances conducted by the agency for over two decades.

EPA has also provided sufficient basis for the inclusion of all vanadium compounds in the category. As EPA stated in the 1994 chemical expansion final:

“The Agency believes it satisfies the statutory criteria to add a category to the list by identifying the toxic effect of concern for at least one member of the category and then showing why that effect may reasonably be expected to be caused by all other members of the category.” (at 59 FR 61442, column 3)

EPA developed a hazard assessment for vanadium which reviewed the toxicity data for several vanadium compounds. The assessment indicated that the vanadium from these compounds is highly toxic to aquatic organisms. Since it is the vanadium from these compounds that is highly toxic rather than the intact chemical compound EPA believes that all chemicals that are a source of vanadium meet the EPCRA section 313(d)(2)(C) listing criteria. Thus EPA has established the toxic effect of concern, the chemical species that causes the effect, and the basis for why it may reasonably be expected that all members of the vanadium compounds category can cause the effects of concern.

3.e.iv. Other Metals

Commenter List: C-1422b

Comment: The commenter states that organic pigments should not be considered PBT chemicals and should not be subject to reporting for PBTs just because they may contain parts per million quantities of PBT chemicals. The commenter stated that the data on organic pigments shows that these compounds are stable and are not bioaccumulative, toxic or bioavailable to humans or the environment. The commenter specifically discusses the properties of diarylide pigments and states that although traces of dichlorobiphenyl may be generated in the manufacturing of diarylide pigments, there is no evidence that diarylide pigments are carcinogenic or mutagenic. The commenter stated that the PBT chemicals that may be trace contaminants in organic pigments are rendered insoluble by the pigment molecule and the ink coating resin or plastic the pigment is encapsulated within. The commenter stated that trace amounts of contaminants in low part per million quantities, which may be contained in organic pigments, are not bioavailable. The commenter stated that further reporting and disclosure for the public is not required, since there is no significant risk associated with PCBs, other contaminants or finished organic pigments.

Response: EPA did not include organic pigments as PBT chemicals in the proposed rule. Thus the commenters statements concerning the toxicity of organic pigments and their bioaccumulative properties are not relevant to this final rule and will not be addressed here. The commenter's statements that are relevant to this rule concern the reporting of PBT chemicals that may be present as contaminants in organic pigments. The commenter's main claim is that the PBT chemical contaminants contained organic pigments will not be bioavailable from the organic pigments and the products they are used in.

EPA believes that any PBT chemical impurities, including PCBs, contained in organic pigments should not be treated any differently than other chemical mixtures. Thus, any PBT chemicals that might be contained in organic pigments must be included in threshold determinations and release and other waste management reporting for those chemicals. The commenters statement that PBT contaminants in organic pigments do not pose any risk to human health or the environment is not relevant to a determination as to whether the contaminants they contain meet the listing criteria of EPCRA section 313 and the PBT criteria as set out in the proposed rule. The issue of considering risk under EPCRA section 313 chemical listing decisions is addressed elsewhere in these comment responses.

The commenter's main point is that contaminants in organic pigments should not reported under EPCRA section 313 since they are not bioavailable. PBT chemicals are PBTs independent of whether they are contained in pigments or any other material. The commenter has not provided sufficient information to show that the PBT chemical contaminants will not be bioavailable when contained in organic pigments. If the commenter has data that can prove that the contaminants found in organic pigments are not bioavailable then the appropriate action to take would be for the commenter to submit a petition pursuant to EPCRA section 313(e)(1) to delete such contaminants, when contained in organic pigments, from the list of chemicals subject to EPCRA section 313 reporting. EPA would address such a petition in a manner similar to the Agency's stated policy and guidance concerning petitions to delist individual members of the metal compounds categories (May 23, 1991, 56 FR 23703). Under the metals policy EPA considers whether the metal from a metal compound can become bioavailable under abiotic or biotic conditions. An assessment of the bioavailability of contaminants in organic pigments would include items such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformation (both abiotic and biotic); bioavailability when the compounds is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs); and bioavailability when the compound is inhaled (solubilization in and/or absorption from lungs, especially taking into account the likelihood that the compound will lodge in the lungs and be converted to soluble forms by the lung's defense mechanism).

Commenter List: C-1422b

Comment: Under the heading of "Copper Phthalocyanine Compounds" the commenter stated that phthalocyanine compounds are inert substances and that no significant health or environmental effects have been found for these substances. The commenter stated that these organometallic compounds are unusually stable in all environmental media and have a pronounced lack of solubility and bioavailability. The commenter then cited a number statements that EPA made in a Federal Register Notice (60 FR 18361, April 11, 1995) that deleted all copper phthalocyanine compounds substituted with only chlorine and/or bromine and/or hydrogen from the EPCRA section 313 list of toxic chemicals. The commenters citations included:

"EPA's assessment included metabolism, absorption, acute and chronic toxicity, neurotoxicity, carcinogenicity, mutagenicity, reproductive system effects, development toxicity and ecotoxicity. In all cases, the conclusion was that phthalocyanine compounds could not be anticipated to cause harm by any of these pathways." (60 FR 18636).

[EPA notes that the above FR citation appears to be incorrect, no such statements can be found in the April 11, 1995 FR notice and in addition that notice ended on page 18364]

"phthalocyanine compounds that are substituted with only hydrogen and/or bromine and/or chlorine do not meet the toxicity criteria of EPCRA Section 313(d)(2)(B) because that copper phthalocyanine compounds cannot reasonably be anticipated to cause cancer, developmental toxicity, reproductive toxicity, neurotoxicity, gene mutations, or chronic toxicity. These intact copper phthalocyanine compounds cannot reasonably be anticipated to cause such effects... " (60 FR 18363).

"believes that its conclusions regarding the toxicity of this intact compound and the availability of soluble copper from these substituted compounds apply to all copper phthalocyanine compounds that are substituted with only hydrogen and/or bromine and/or chlorine". (60 FR 18362).

The commenter then states that therefore, even though some phthalocyanine pigments may contain trace amounts of PBT chemicals, such as PCBs, there is no reason to believe that these stable compounds pose any risk to health or the environment. The commenter stated that any trace contaminants contained in phthalocyanine pigment compounds would be contained both in the matrix which makes up the phthalocyanine molecule and the resin, ink or coating in which the pigment is used.

Response: EPA's assessment of copper phthalocyanine compounds substituted with only chlorine and/or bromine and/or hydrogen was limited to this specific group of copper phthalocyanine pigments and does not imply anything with regard to other phthalocyanine pigments. Any other phthalocyanine pigments would need to be evaluated on an individual basis. The commenter is concerned about the requirement to report on PBT chemicals that are contaminants in phthalocyanine pigments but fails to cite the most relevant statement that EPA has made concerning the reporting of such contaminants. As EPA stated in response to comments received on its first delisting of three specific copper phthalocyanine pigments:

"...mixtures that contain copper compounds (except the three copper phthalocyanine pigments) in excess of the *de minimis* concentration should be factored into threshold and release determinations. EPA does not believe that phthalocyanine pigments contaminantd with other copper compounds, and/or PCBs should be treated differently than other mixtures." (56 FR 23652, May 23, 1991).

EPA continues to believe that the impurities in copper phthalocyanine compounds should not be treated any differently than other chemical mixtures. Thus, the PCBs, or other PBT chemicals that might be contained in copper phthalocyanine pigments must be included in threshold determinations and release and other waste management reporting for those chemicals. The commenter's statement that copper phthalocyanine pigments do not pose any risk to human health or the environment is not relevant to a determination as to whether the contaminants they contain meet the listing criteria of EPCRA section 313 and the PBT criteria as set out in the proposed rule. The issue of considering risk under EPCRA section 313 is addressed elsewhere in these comment responses.

The commenters main concern appears to be that PCBs that may be contaminants in phthalocyanine pigments should not reported under EPCRA section 313 since the phthalocyanine pigments are stable compounds and the contaminants not be bioavailable from the phthalocyanine pigment and/or the material in which they are used. PCBs and other PBT chemicals are PBTs independent of whether they are contained in phthalocyanine pigments or any other material. The real issue that the commenter is raising is the bioavailability of PCBs and other contaminants found in phthalocyanine pigments. The commenter

has not provided sufficient information to show that PCBs or any other contaminants will not be bioavailable from copper phthalocyanine pigments. The commenter mentions lack of solubility as an indication that the contaminants will not be bioavailable but bioavailability is not limited just to solubility. If the commenter has data that can prove that the contaminants found in copper phthalocyanine pigments are not bioavailable then the appropriate action to take would be for the commenter to submit a petition pursuant to EPCRA section 313(e)(1) to delete such contaminants, when contained in phthalocyanine pigments, from the list of chemicals subject to EPCRA section 313 reporting. EPA would address such a petition in a manner similar to the Agency's stated policy and guidance concerning petitions to delist individual members of the metal compounds categories (May 23, 1991, 56 FR 23703). Under the metals policy EPA considers whether the metal from a metal compound can become bioavailable under abiotic or biotic conditions. An assessment of the bioavailability of contaminants in phthalocyanine pigments would include items such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformation (both abiotic and biotic); bioavailability when the compounds is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs); and bioavailability when the compound is inhaled (solubilization in and/or absorption from lungs, especially taking into account the likelihood that the compound will lodge in the lungs and be converted to soluble forms by the lung's defense mechanism).

Commenter List: C-1813

Comment: The commenter is concerned about the possible inclusion of cadmium and cadmium compounds as PBT chemicals under EPCRA section 313 and provided extensive comments on this issue. The commenter stated that the inclusion of other metals and metal compounds as PBT chemicals under EPCRA section 313 and the inclusion of cadmium and cadmium compounds as PBT chemicals under other EPA PBT chemical related programs means that there is a possibility that cadmium and cadmium compounds could be identified as PBT chemicals under EPCRA section 313. Some of the other statements the commenter makes include that: cadmium and cadmium compounds are already heavily regulated; exposures have been declining; and the EPA PBT programs only focus on cadmium products and ignore other sources of exposure.

Response: EPA did not include cadmium or cadmium compounds in the proposed rule to lower the EPCRA section 313 reporting thresholds for certain PBT chemicals and EPA did not evaluate cadmium or cadmium compounds in the development of the proposed rule. Therefore, since these chemicals are not part of this rulemaking and since EPA has not evaluated them against the PBT criteria as explained in the proposed rule, EPA is not responding to the comments specific to cadmium or cadmium compounds and their possible inclusion as PBT chemicals under EPCRA section 313. If, in the future, EPA proposes to include cadmium and cadmium compounds as PBT chemicals, the commenter should resubmit relevant comments.

3.f. Octachlorostyrene (CAS No. 29082-74-4)

Toxicity Data for Octachlorostyrene. EPA proposed to add octachlorostyrene to EPCRA section 313 pursuant to EPCRA sections 313 (d)(2)(B) and (C).

Commenter List: C-1814

Comment: The commenter argues that octachlorostyrene (OCS) should not be included in the EPCRA section 313 PBT chemical list. The commenter contends that OCS was included as a PBT chemical simply because it appears on several lists of persistent and bioaccumulative chemicals and not based on a thorough evaluation of its toxicity. The commenter argues that there is limited toxicity data for OCS and cited two statements that were in EPA's support document for the addition of OCS and the other chemicals being added in this rulemaking. The two statements the commenter cited were:

"The health hazard data which support TRI listing are very limited. Human health data were not located." (Support document p. 48)

Response: EPA disagrees with the commenter's conclusions. The commenter did not comment on the actual toxicity data that EPA provided as the basis for listing OCS pursuant to EPCRA section 313(d)(2)(B). Rather the commenter takes two statements that were contained in the support document out of context to support their apparent contention that there are insufficient data to list OCS under EPCRA section 313(d)(2)(B). The fact that the commenter has taken these statements out of context is demonstrated by the content of the rest of the paragraph that contained the statements the commenter cited:

"Laboratory studies on rats suggest OCS may have acute and chronic effects on the liver, kidneys, and thyroid. In a long-term study (one year) of rats a LOAEL of 0.31 mg/kg/day was determined based on significant histological effects

on these organs.” (Support document p. 48)

The statements the commenter cited only acknowledged that there was not a vast amount of toxicity data for OCS, they do not support the commenters' conclusion that OCS does not meet listing criteria of EPCRA section 313(d)(2)(B). In addition, these statements were from the summary section of the discussion on OCS, more detailed discussion of the toxicity data for OCS was contained in the other sections on OCS toxicity but the commenter provided no comments on this information.

EPA reaffirms that there is sufficient evidence for adding OCS to the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(B) based on the available hepatic, nephric, and thyroid toxicity data for this chemical.

The same commenter also claims that the toxicity comparisons to hexachlorobenzene are not supported and that no references or rationale are provided to support basing the aquatic toxicity of OCS on that of hexachlorobenzene. As with the human health data, the commenter argues that there is limited environmental toxicity data for OCS and cited some statements that were in EPA's support document. The statements the commenter cited were:

“So far as is known, after a search of former EEB chemical files, the ecological hazard of OCS has never been formally reviewed under TSCA section 4 or in the OPPT Risk Management (RM) process. OCS was briefly reviewed for aquatic toxicity in August 1986, as part of an OTS (now OPPT) chemical scoring project. Thus, available information on OCS is very limited.” (Support document p. 52)

EPA disagrees with the commenters conclusions. The commenter has not commented on the actual toxicity data but rather states that the data are limited and that hexachlorobenzene is not an appropriate analogue for predicting the aquatic toxicity data for OCS. The statements the commenter cited only acknowledged that there was not a vast amount of toxicity data for OCS, they do not support the commenters conclusion that OCS does not meet listing criteria of EPCRA section 313(d)(2)(C). Contrary to the commenter's statement, EPA did provide a reference to the use of hexachlorobenzene as an appropriate analogue for OCS. As EPA stated in the same section of the support document the commenter cited:

“OCS is one of 7 compounds in this chemical class (chlorinated styrenes) with the generic formula $C_8H_{8-x}Cl_x$, where x equals 8 for OCS. This class is analogous to the chlorinated benzenes; for example hexachlorobenzene (HCB), is considered to be an appropriate analogue chemical for OCS (2).” (Support document p. 52).

The reference cited by the commenter was a previous EPA analysis of this class of chemicals that also used hexachlorobenzene as an appropriate analogue for OCS, thus a reference was cited. EPA believes that since OCS and hexachlorobenzene are both highly chlorinated derivatives of benzene they can reasonably be anticipated to have similar toxicities. However, in addition to aquatic toxicity data on hexachlorobenzene, EPA provided the results of a QSAR analysis of OCS, using a measured $\log K_{ow}$ of 7.7, that gave a predicted 14-day LC_{50} value of 6 ($\mu\text{g/L}$) for guppies.

Based upon QSAR equations and analogue data, EPA has concluded that OCS is toxic. It has the potential to kill fish and inhibit photosynthesis in algae, among other adverse effects, base on chemical and/or biological interactions. OCS can cause these toxic effects at relatively low concentrations. The predicted aquatic toxicity value for OCS, based upon QSAR analysis using a measured K_{ow} of 7.7, is an estimated 14-day LC_{50} of 6 $\mu\text{g/L}$ for guppies. Based on the chemical analogue hexachlorobenzene, OCS can reasonably be anticipated to inhibit photosynthesis in algae at a concentration of 30 $\mu\text{g/L}$ and have a calculated subchronic EC_{50} value of 16 $\mu\text{g/L}$ for daphnids.

OCS can cause its toxic effects at these relatively low concentrations, EPA considers it to be highly toxic. Since OCS is toxic at relatively low concentrations, EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish kills, and inhibition of photosynthesis in algae and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

EPA reaffirms that there is sufficient evidence for listing OCS on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) based on the available ecotoxicity information for this chemical.

Therefore, EPA is finalizing the addition of OCS on the EPCRA section 313 list.

Persistence Data for Octachlorostyrene. In the proposal, EPA preliminarily determined that OCS has persistence half-life

values in soil of 6 to 3 years. EPA received one significant comment addressing OCS's persistence potential which is discussed below. EPA has reviewed information and all comments received from commenters on OCS's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that OCS persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule). In addition, OCS persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

Commenter List: C-1814

Comment: The commenter believes that OCS should not be considered to be a PBT chemical. The commenter admits that OCS has the potential to bioaccumulate and may theoretically persist in the environment, but cites falling environmental levels of OCS and the lack of evidence of human and environmental toxicity as justification for why OCS should not be considered to be a persistent, bioaccumulative and toxic chemical. The commenters contend that pentachlorobenzene and hexachlorobenzene are not good analogs for OCS.

Response: EPA disagrees. As discussed elsewhere in these comment responses on OCS, EPA believes that OCS meets the EPCRA section 313 toxicity criteria. Further, EPA believes that OCS is highly persistent. No measured half-life data for soil or water that met the standards for data acceptability could be located for octachlorostyrene (CAS No. 29082-74-4). Therefore, EPA used half-lives for the structural analogs pentachlorobenzene (CAS No. 608-93-5) and hexachlorobenzene (CAS No. 118-74-1) for estimating half-lives for OCS. EPA believes that pentachlorobenzene and hexachlorobenzene are good analogs for OCS because they, like OCS, are highly chlorinated benzene derivatives, which are structurally very similar. By analogy, OCS is expected to have a half-life in soil of greater than 6 months and greater than 2 days in air (Ref. 7 of the final rule). These half-lives are sufficient to designate OCS as persistent using the criteria described in the proposed rule. EPA believes that its use of analog data is scientifically supportable because like OCS both analogs are highly chlorinated monocyclic aromatics.

EPA believes that the degree of toxicity as well as the degree of persistence and bioaccumulation are inherent to a chemical. The absolute level of a chemical in the environment does not affect its degree of persistence, bioaccumulation, or whether or not it has been shown to cause adverse effects to aquatic organisms. The absolute level in the environment is a factor of both how much is entering the environment and the persistence of the chemical in the environment. The degree to which a chemical is present in aquatic organisms is not only a measure of the bioaccumulation factor, but also inputs into the environment and persistence. The assertions made by the commenter do not support their contention on toxicity, persistence, or bioaccumulation.

Bioaccumulation Data for Octachlorostyrene. In the proposal, EPA preliminarily determined that OCS has a BCF value of 33,113. EPA received one significant comment addressing OCS's bioaccumulation potential which is discussed below. EPA has reviewed this comment and information received from commenters on OCS's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that OCS bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, OCS bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

Commenter List: C-1814

Comment: The commenter argued that OCS should not be included in the EPCRA section 313 PBT chemicals list. The commenter contends that OCS was included as a PBT chemical simply because it appears on several lists of persistent and bioaccumulative chemicals and not based on a thorough evaluation of its bioaccumulation. The commenter states that OCS has the potential to bioaccumulate, but nonetheless, OCS levels in fish and aquatic species in the Great Lakes continue to decline. The commenter provides a report on the Great Lakes region and argues that OCS should not be considered a PBT chemical since environmental concentration data show OCS levels in the environment are decreasing at a rate of 8% to 30% per year.

Response: EPA disagrees with the commenter's conclusions. The commenter does not dispute the bioaccumulation values EPA presented in the proposed rule. Rather the commenter agrees that OCS has the potential to bioaccumulate but contends

that since environmental concentrations are declining in the Great Lakes region OCS should not be considered a PBT chemical. The fact that OCS levels in the Great Lake region may be declining is not a basis for concluding that OCS is not a PBT chemical or that it cannot bioaccumulate. There are a number of reasons that could explain a decrease in environmental concentrations of OCS but they do not change the fact that OCS has been shown to be highly bioaccumulative. Octachlorostyrene was included as a PBT chemical because it meets the EPCRA section 313 criterion for bioaccumulation laid out in the proposed rule, not simply because it has appeared on several other lists of PBT chemicals.

3.g. PACs

Commenter List: C-1440

Comment: Commenter observed that among the chemicals proposed for addition to the EPCRA 313 reporting list are three chemicals in the PAC category: benzo(j,k)fluorene (CAS #206-44-0), 3-methylcholanthrene (CAS #56-49-5), and benzo(g,h,i)perylene (CAS #191-24-2). Commenter stated that all three of these compounds are listed as PACs in Table 1 of the *Federal Register* notice (64 FR 707), however, in the regulatory amendments for 40 CFR 379.28 and 372.65 (64 FR 727-729) only the first two compounds are included in the PAC category; benzo(g,h,i)perylene is listed as a separate entry. Commenter stated that they believe this is an administrative error since benzo(g,h,i)perylene is listed in Table 1 as a PAC and that correction of this error could reduce the number of Form R submissions for facilities which meet the threshold for the PAC category.

Response: This is not an error. In the *Federal Register* notice (64 FR 688) at the end of the discussions on the carcinogenicity data for benzo(j,k)fluorene (CAS #206-44-0) and 3-methylcholanthrene (CAS #56-49-5) there is a statement that addresses this issue. For example at the end of the discussion on the carcinogenicity data for benzo(j,k)fluorene (fluoranthene) (page 694 column 3) the following statements are made: "Section 313 contains a listing for polycyclic aromatic compounds (PACs). All of the members of this category are listed based on concerns for their carcinogenicity. Since part of the basis for listing fluoranthene under section 313 is a concern for carcinogenicity this chemical is being proposed for addition to the section 313 PACs category." Since the basis for listing benzo(g,h,i)perylene does not include a concern for carcinogenicity, no statement was included that indicated that it would be added to the PACs category, and indeed it is not being added to the PACs category. Therefore the proposed regulatory text was not in error.

Commenter List: C-1418

Comment: The commenter stated that they had estimated releases of a total of 55 Volatile Organic Compounds (VOCs) including biphenyl, and six compounds of the designated PACs from the combustion of coal, oil, and natural gas at a 700 MW coal fired generating plant. The commenter stated that this was done to evaluate how much of those various compounds might be released from burning fuel. The commenter stated that their evaluation used both AP-42 and EPRI PISCES factors to estimate the amounts manufactured or otherwise derived from the use of the fuel. The commenter stated that the results indicate extremely small amounts of PACs were actually released (less than 20 pounds) and that including the VOC compounds resulted in total release estimates on the order of several hundred pounds a year. The commenter stated that these releases are being generated from the use of approximately 240,000 gallons of number 2 fuel oil and approximately 1.4 million tons of bituminous coal. The commenter stated that they were offering this information to give the EPA an idea of the likely amounts of PACs that might be reported under the proposed rule. The commenter stated that based on these numbers, it appears to be a useless exercise to require utilities to make these estimates.

Response: EPA has determined that the PACs category, to which the lower reporting threshold applies, contains highly persistent and highly bioaccumulative compounds. Since PACs are PBT chemicals, the fact that the commenter's estimation of the amounts of PACs released from the combustion of fuel were, in the commenter's opinion, relatively small does not negate the concern for these chemicals. As EPA stated in the proposed rule:

"Because all PBT chemicals persist and bioaccumulate in the environment, they have the potential to pose human health and environmental risks over a longer period of time. Thus, even small amounts that enter the environment can lead to elevated concentrations in the environment and in organisms which can result in adverse effects on human health and the environment. The nature of PBT chemicals indicates that small quantities of such chemicals are of concern, which provides strong support for setting lower reporting thresholds than the current section 313 thresholds of 25,000 and 10,000 pounds." (64 FR 710, column 3)

Therefore, assuming the commenter's estimated release numbers are correct, EPA believes there is concern for these relatively small releases of PBT chemicals. It should also be noted, however, that in some instances electric generating facilities (EGF) may be able to use actual monitoring data, as opposed to emissions factors, to calculate their threshold, release and other waste management amounts.

Commenter List: C-1438

Comment: The commenter stated that PACs associated with carbon black manufacturing are not bioavailable and are thus, by definition, not bioaccumulative and that there is no justification for EPA's actions with regard to the PACs found on carbon black.

The commenter claimed that because of the large surface area of carbon black particles and a minute quantity of adsorbed organic compounds, the adherent organics are tightly bound to the carbon surface because they adhere as a monolayer. The commenter claimed that in order to remove the adsorbed organic materials in the laboratory, carbon particles had to be bathed in a Soxhlet apparatus using boiling organic solvents, such as toluene. Commenter stated that such conditions do not exist in the human body, and therefore the release of the adsorbed organics from ingested or inhaled carbon black is minimal. The commenter stated that for the majority of organic compounds extracted from carbon blacks, enzymatic activation is required before the compounds can exert mutagenic effects in living cells. Because of this, the commenter states, that these compounds are termed indirect mutagens. The commenter stated that therefore their bioactivity presumably is dependent on the compounds being released from the carbon particle, which does not readily occur in physiologic conditions.

In summary, commenter stated that the bioactivity of carbon-black-adsorbed PAHs is limited; the quantity of organic compounds is very small and constitutes less than 1% of the carbon particle mass; individual PAHs are present in the part-per-million range; the organic compounds are tightly adherent to the carbon particle, and removal requires extensive extraction in strong organic solvents at elevated temperatures; and the organic compounds require enzymatic activation in order to exert mutagenic effects.

The commenter further stated that as a result, PACs found on carbon black cannot appropriately be characterized as PBT chemicals and therefore the proposed agency actions cannot be justified by the same rationale as relied upon for the other PBT chemicals. The commenter stated that, at a minimum, the PACs found on carbon black should be subject to higher reporting thresholds and/or should retain the *de minimis* exemption when released as an impurity on carbon black.

Response: PACs are PBT chemicals independent of whether they are contained in carbon black or any other material. The commenter is really contending that when PACs are contained in carbon black they are not bioavailable; this is an entirely different issue from whether a chemical has been properly characterized as a PBT or not. EPA does not believe that the commenter has provided sufficient information to conclude that PACs are not bioavailable from carbon black. Commenter has not submitted any scientific studies supporting its claim that PACs are not bioavailable from carbon black. Furthermore, commenter does not state that no PACs will be released from carbon black if inhaled or ingested, but only claims that such releases will be "minimal." Secondly, commenter states that these organic compounds require enzymatic activation to exert mutagenic effects, but does not claim that their bioactivity is definitively dependent on being released from the carbon black, rather commenter merely state that "their bioactivity presumably is dependent on their being released." The issue of bioavailability, for EPCRA section 313 chemicals, is a broader than just its implications for whether a chemical is a PBT. If the commenter has data that can prove that PACs are not bioavailable when contained in carbon black then the appropriate action to take would be for the commenter to submit a petition pursuant to EPCRA section 313(e)(1) to delete PACs contained in carbon black from the list of chemicals subject to EPCRA section 313 reporting. EPA would address such a petition in a manner similar to the Agency's stated policy and guidance concerning petitions to delist individual members of the metal compounds categories (May 23, 1991, 56 FR 23703). Under the metals policy EPA considers whether the metal from a metal compound can become bioavailable under abiotic or biotic conditions. An assessment of the bioavailability of PACs from carbon black would include items such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformation (both abiotic and biotic); bioavailability when the compounds is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs); and bioavailability when the compound is inhaled (solubilization in and/or absorption from lungs, especially taking into account the likelihood that the compound will lodge in the lungs and be converted to soluble forms by the lung's defense mechanism).

EPA does not believe that the commenter has provided a sufficient basis for treating PACs contained in carbon black any differently than other PACs and therefore EPA does not believe that it would be appropriate to report PACs in carbon black at higher reporting thresholds or to retain the *de minimis* exemption.

Commenter List: C-1860

Comment: The commenter stated that EPA's decision to lower the reporting levels for all of the PACs on the TRI list is inconsistent with other regulatory decisions concerning these chemicals. Commenter stated that EPA has not listed many of the PACs that are on the TRI list on the Clean Water Act's section 311 list or priority pollutant list, the Resource Conservation and Recovery Act section 3001 list, the Superfund section 102(a) list of hazardous substances, or the Emergency Planning and Community Right-To-Know section 302 list. Commenter stated that most of the PACs are not listed on the United Nation's list of persistent organic pollutants, the Great Lakes Water Quality Guidance list of chemicals of concern, or virtually any other international program's list of persistent and bioaccumulative toxins. The commenter stated that the regulatory decisions involving these chemicals under other programs were typically made after a careful risk assessment which considered, among other things, the chemicals' different toxicity, soil to water partitioning, bioaccumulation, biodegradation. The commenter stated that in each regulatory program, EPA determined which specific PAC chemicals, among the large number of PACs, were chemicals of concern and needed to be regulated to protect human health and the environment. As an example the commenter stated that EPA determined that PACs were not chemicals of concern for the rubber manufacturing industry in the NESHAP hazardous air pollutant program, except when emitted from a combustion source. The commenter stated that in effect, the EPCRA section 313 program is using a gross screening model to reverse determinations made under these other statutes and programs and require undifferentiated and misleading reporting of all PACs. The commenter stated that, at most, only a few PACs from certain industries should be considered for the lower TRI threshold (e.g., benzo(a)pyrene), and that the activity thresholds for all 21 PACs on the TRI should not be lowered.

The commenter stated that although the wisdom of including all 21 compounds in the EPCRA section 313 list of PACs might be questioned, that regulatory decision has already been made. The commenter stated, however, that the proposal to require reporting on all 21 PACs at much lower thresholds dramatically changes the cost to benefit comparison, and EPA must re-evaluate the benefits of reporting on all 21 PACs at the lower thresholds. The commenter stated that the fact that most other EPA programs have chosen to be more selective in the PACs that they regulate is relevant, if not telling.

Response: EPA disagrees with the commenters statements that EPA's decision to lower the EPCRA section 313 reporting thresholds for those PACs in the PACs category subject to the lower reporting thresholds is inconsistent with other regulatory decisions concerning these chemicals. The other regulatory and international programs that the commenter refers to serve different purposes and have different statutory and regulatory requirements. Since the criteria and purpose of other programs differs from those of EPCRA section 313 there are any number of reasons for why the programs cited by the commenter do not regulate all PACs. The fact that these other regulatory or international programs do not cover all of the PACs on the EPCRA section 313 list does not negate the fact that these chemicals meet both the statutory EPCRA section 313 listing criteria and the Agency's section 313 criteria for persistence and bioaccumulation as set out in the proposed rule. EPA also disagrees with the claim that the Agency has not been selective with regard to the PACs covered under EPCRA section 313, or that the Agency is using a "gross screening model" to reverse the determinations of the Agency's other programs and thereby require undifferentiated and misleading reporting of all PACs. EPA carefully evaluated the PACs that are listed under EPCRA section 313 and only added those that met the listing criteria. The current EPCRA section 313 PACs category is by no means a list of all PACs and is more selective than the broad category definitions that some other programs use to define this class of chemicals. The economics analysis for this rule contains an assessment of the cost and benefits of this rule which includes the lowering of the EPCRA section 313 reporting thresholds for the PACs category. Thus EPA has already reevaluated the cost-benefit analysis for reporting on the PACs category at the lower thresholds.

Commenter List: C-1820

Comment: Commenter stated that evaluating process streams for PBT chemicals would be particularly nettlesome given the large uncertainties present in the emissions factor data. Commenter stated that as a member of the Electric Power Research Institute (EPRI) they participated in several collaborative programs to measure emissions of dioxins and poly-aromatic hydrocarbons and that through these activities they found out that the estimation of trace level emissions is more magic than science. The commenter stated that they found more than one compound for which emissions factors existed but either these compounds could not be detected in flue gas or their emissions were orders of magnitudes lower than the emissions factors estimated.

Response: Any difficulties in estimating quantities of PACs, or other PBT chemicals, using established emission factors is the same whether the reporting threshold is 10 or 10,000 pounds. The same uncertainties exist in the emission factors regardless of the reporting threshold. As with any emission factor, site specific information may need to be considered, where available, if

the facility believes that the emission factor is either under or over-estimating the quantities of EPCRA section 313 chemicals when making threshold determinations, or release and other waste management calculations. EPCRA section 313 requires that facilities make threshold determinations and release and other waste management calculations by using “readily available data (including monitoring data) collected pursuant to other provisions of law, or where such data are not readily available, reasonable estimates of the amounts involved.” Nothing in the statute requires a facility to conduct additional monitoring or measurements for the purpose of reporting pursuant to EPCRA section 313, and if the available data is insufficient to make an estimate using emission factors or other available methods, then the facility is not required to report.

Commenter List: C-446

Comment: The commenter stated that PAH (i.e., PACs) are naturally present in petroleum products and a significant background level of PAH exists. The commenter urges EPA to recognize this important fact and consider establishing an exemption from reporting for those sources emitting below a *de minimis* amount of PAH. Commenter observed that in the proposed rule the PAH compounds category covered 19 specific Chemical Abstract Service Numbers but that it is unclear from the proposal whether this category would become inclusive of all chemicals in this class. Commenter stated that the listing of families of compounds like PAH is too difficult to comply with. The commenter stated that compounds need to be listed as individual chemicals with Chemical Abstract Service Numbers so that facilities can use available search mechanisms to identify purchases and components of trade name formulations when determining whether reporting is required. Moreover, and similar to the situation with dioxin and dioxin compounds, there is currently no requirement to test exhaust emissions for PAH compounds. The commenter stated that if this proposal is finalized without exemptions for facilities which incidentally manufacture small quantities of PAH compounds, the Agency must establish clear estimation guidance, in the form of a look up table from which the PAH emissions can be read dependent on fuel types and combustion conditions and in lieu of endorsing a testing program.

Response: EPA is aware that there are background amounts of PACs in the environment, and that they are present in petroleum products, in particular. In fact, EPA used the information on PACs in petroleum products in the Agency’s estimation of the number of reports that are expected to be filed with the lowered reporting threshold. However, EPA does not believe that it would be appropriate to establish a *de minimis* emission level for the reporting of PACs from petroleum or other products. As EPA stated in the proposed rule:

“Because all PBT chemicals persist and bioaccumulate in the environment, they have the potential to pose human health and environmental risks over a longer period of time. Thus, even small amounts that enter the environment can lead to elevated concentrations in the environment and in organisms which can result in adverse effects on human health and the environment. The nature of PBT chemicals indicates that small quantities of such chemicals are of concern, which provides strong support for setting lower reporting thresholds than the current section 313 thresholds of 25,000 and 10,000 pounds.” (64 FR 710, column 3)

Given the stated concern for even small quantities of PBT chemicals such those in the PACs category subject to lower activity thresholds, EPA does not believe that it is appropriate to establish a *de minimis* emission level for PACs.

The Agency did not indicate in the proposed rule that the PACs category was intended to be inclusive of all chemicals in the PACs class. EPA has carefully evaluated each of the PACs that has been added to the category and intends to continue to make individual determinations and list PACs either in the category by CAS number or list them individually by CAS number as appropriate. Therefore, the commenter’s concerns about the possible lack of CAS numbers for tracking are not warranted.

As for the comments that EPA should provide guidance for reporting on PACs and not endorse a testing program, EPCRA section 313 does not require any testing or monitoring beyond that required under other provisions of law or regulation, and EPA will continue to provide reporting guidance as appropriate.

Commenter List: C-1865

Comment: The commenter stated that EPA has shown no reason for lowering the thresholds for PACs at this time, and it certainly has not demonstrated that the benefits of doing so would outweigh the costs.

Response: The issue of costs versus benefits is addressed elsewhere in these comment responses. However, EPA has provided a reason for lowering the reporting thresholds for PBT chemicals including PACs. As EPA stated in the proposed rule:

“Because all PBT chemicals persist and bioaccumulate in the environment, they have the potential to pose human health and environmental risks over a longer period of time. Thus, even small amounts that enter the environment can lead to elevated concentrations in the environment and in organisms which can result in adverse effects on human health and the environment. The nature of PBT chemicals indicates that small quantities of such chemicals are of concern, which provides strong support for setting lower reporting

3.g.i. Whether PACs data meets the persistence criteria

Persistence Data for PACs. Polycyclic aromatic compounds category. In the proposal, EPA preliminarily determined that PACs have persistence half-life values in soil that ranged from 13 years to more than 20 days. All but a few had half-lives well in excess of 6 months. These chemicals had persistence half-life values in water that ranged from 44 years to 79 days. EPA received one significant comments addressing the persistence potential of PACs, which is discussed below. EPA has reviewed information and all comments received from commenters on PACs’ persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that PACs persist in the environment with half-lives of 2 months or greater and therefore meet the persistence criterion established in this rulemaking. A complete discussion of EPA’s findings on this chemical category can be found in EPA’s support documents for this rulemaking. (Refs. 7 of the final rule). In addition, most of the PACs persist in the environment with a half-life of greater than 6 months which supports EPA’s decision to lower the threshold to 10 pounds.

Commentor: C-1860

EPA has incorrectly ignored biotreatment studies in evaluating persistence for the listed substances. EPA has also ignored a large body of recent research on sequestration and other phenomena that collectively act to reduce the bioavailability of soil contaminants.

Response: Biotreatment studies include activated sludge or other wastewater treatment studies. As noted in the proposed rule (at 64 FR 700), the reason for excluding such studies is that wastewater treatment in general and activated sludge in particular represent conditions that are far removed from ambient (surface) waters, soils and sediments. Data on environmental fate and persistence of substances in wastewater and activated sludge normally cannot be extrapolated to the other conditions. The commentor seems most concerned about land biotreatment (bioremediation) studies, but in fact goes well beyond the concept of treatability, appearing to infer that EPA has ignored *all* biodegradation studies of polycyclic aromatic compounds (PACs). However, this is incorrect because all mixed-culture biodegradation studies other than activated sludge tests--i.e., field tests as well as lab studies that used authentic soil, water and/or sediment grab samples--were considered in determining persistence for all of the listed substances.

The commentor also discusses recent research indicating that bioavailability of a substance may decline with time of incubation in soil, and suggests that EPA should include “reasonable bioavailability factors” in its determination of persistence. As an example of why this is relevant, there has been a concern that Superfund site remediation actions may be mistargeted if they are based on residues released from the soils by vigorous extraction procedures, since chemical substances in soil may become non-bioavailable yet still be extractable for analytical purposes. Additionally, bioremediation may fail to destroy all of a substance that such analysis shows is present, if some portion is sequestered in a non-bioavailable state.

All of this is true, but the commentor over-generalizes from the research findings, using selective citation and quotation from the literature [e.g., Alexander at 1] to give the impression that all is now known and any substance released to soil is as good as gone toxicologically speaking. Other reports can be quoted to the effect that the many factors determining bioavailability, sequestration, etc are far from completely resolved, and deserve much further research. Moreover, sequestration does not necessarily imply non-bioavailability. For example, in a study of PAC sequestration and bioremediation, Tang et al. [2] state that

“The results of the present study suggest that extensive biodegradation by microorganisms does not necessarily remove all of the fraction of an aged compound that is bioavailable since some uptake by worms occurred even after the laboratory-scale bioremediation....it is also possible that a portion of a compound that is sequestered is available to different degrees to dissimilar organisms....It may be that the mass of material that becomes sequestered should be considered as existing in two forms. One form may be unavailable to all organisms because it is physically remote and thus inaccessible. The second form may be differentially available, and its assimilation, toxicity, and/or biodegradation

may depend on the properties of the species and its ability to mobilize the molecules from this nonremote location (13).”

Further (same report),

“[There is] danger if it is assumed that the disappearance of lethality denotes the absence of bioavailability....The point is reinforced by the case of DDT, which is sequestered in soil (13) and whose lethality to insects totally disappears as a result of such sequestration (5), yet a portion of that insecticide was still assimilated by earthworms introduced into soil that was treated in the field with DDT *more than 40 years before the bioassay was performed....*” (emphasis added)

And in a similar paper on DDT and dieldrin, Robertson and Alexander [3] state that

“The significance of soil properties in controlling sequestration is evident in the early observation that the degree of sequestration of lindane after 22 months was greatest in a muck, intermediate in extent in a loam, and least in a sandy loam (11). Thus, *soil properties must be considered in attempting to predict the bioavailability of persistent compounds*. It is also evident from the data presented herein that the bioavailability of a sequestered toxicant varies with the exposed species. Thus, the declines in toxicity of aged DDT and dieldrin to the three test insects were quite different; whereas the lethality of the sequestered compound to one species had almost disappeared, it still was effective against a second.” (emphasis added)

The conclusion is manifest: it is that although chemical substances released to soil may become sequestered over time, it cannot be assumed that this process necessarily leads to non-bioavailability even when the time horizon is years. Site- and species-specific factors, as well as substance properties, are important in determining bioavailability. Therefore, it is appropriate to be concerned about the bioavailability in soil and sediment of PACs and other substances that meet the PBT criteria established for this rulemaking.

References

1. Alexander M. 1995. How toxic are toxic chemicals in soil? *Environ. Sci. Technol.* **29**: 2713-2717.
2. Tang J, MJ Carroquino, BK Robertson and M Alexander. 1998. Combined effect of sequestration and bioremediation in reducing the bioavailability of polycyclic aromatic hydrocarbons in soil. *Environ. Sci. Technol.* **32**: 3586-3590.
3. Robertson BK and M Alexander. 1998. Sequestration of DDT and dieldrin in soil: disappearance of acute toxicity but not compounds. *Environ. Toxicol. Chem.* **17**: 1034-1038.

Commenter: C-1860

Comment: The commenter argues that based on the limited review possible of the administrative record, the record is inadequate to characterize many of the PACs (in particular) as persistent and that EPA selectively relies upon data to [conclude] include chemicals, such as, benzo(j,k)fluorene are persistent (64 Fed. Reg. at 208).

Response: EPA disagrees with this statement. EPA used all available information from scientifically valid studies on atmospheric oxidation, aqueous photolysis, and soil biodegradation in the determination of the environmental persistence of benzo(j,k)fluorene (fluoranthene). Although the estimated half- life of fluoranthene in air is estimated to range from 2 to 20 hours based on estimated hydroxy radical oxidation, the compound is expected to exist mainly in the particulate phase in the atmosphere, which may result in longer half-lives. Fluoranthene removed from the atmosphere by wet or dry deposition will enter soil or water. Six studies on the persistence of fluoranthene in soils gave a half-life range for fluoranthene biodegradation of 110 days to 13 years. The 13 year half-life value is based on the results of a field study (as explained elsewhere, properly conducted field studies are preferred over grab sample studies) and thus fluoranthene was determined to persist in soil for greater than 6 months. No information on the biodegradation of fluoranthene in surface waters was found.

Commenter list: C-1860

Comment: The commenter states that, for many PACs, EPA derived half-life values by extrapolation rather than through direct measurement.

Response: It is not clear whether this comment is a criticism or simply an observation and the commenter does not contest the use of extrapolation in general, or the use of specific analogs in the determination of the persistence of PACs.

If available, EPA utilized measured half-lives in air, water, soil, and sediment from well conducted studies in determining whether PACs met the persistence criteria. For the PACs, half-life data were available for 16 of 22 chemicals. In cases where measured half-lives were not available, measured half-lives for closely related structural analogs were used. Analogues were chosen that were as structurally similar as possible to the subject chemical. Analogues were used in the characterization of the persistence of six chemicals, dibenzo(a,h)pyrene, dibenzo(a,l)pyrene, dibenzo(a,e)pyrene, dibenz(a,h)acridine, 5-methylchrysene, and dibenzo(a,e)fluoranthene. The persistence characterization of dibenzo(a,h)pyrene, dibenzo(a,l)pyrene, and dibenzo(a,e)pyrene, (all pyrene chemicals that consist of six aromatic rings fused together) was based on their analogy to the structurally similar dibenzo(a,i)pyrene, another pyrene chemical that consists of six aromatic rings fused together. This analog differs solely in the position of attachment of one of the aromatic rings to the central pyrene portion of the molecule. Soil biodegradation data on the analog indicated a half-life range from 232 to 371 days. Thus, based on their analogy to dibenzo(a,i)pyrene EPA believes these compounds meet the persistence criteria. The persistence characterization of dibenz(a,h)acridine was based on its analogy to dibenz(a,j)acridine, another acridine chemical which differs only in the attachment of one of the aromatic rings to the central acridine portion of the molecule. Soil biodegradation data on the analog indicated a half-life value of greater than 160 days. Thus, based on its analogy to dibenz(a,j)acridine EPA believes this compound meets the persistence criteria. The persistence characterization of 5-methylchrysene was based on its analogy to chrysene, another four-member fused ring system which differs only in the absence of the methyl group attached to the chrysene molecule. Soil biodegradation data on the analog indicated a half-life range from 255 days to 2.7 years. Thus, based on its analogy to chrysene, EPA believes this compound meets the persistence criteria. The persistence characterization of dibenzo(a,e)fluoranthene was based on its analogy to dibenzo(a,i)pyrene, another aromatic molecule that consists six fused rings which differs in the position of the fused rings and contains a five carbon ring. Soil biodegradation data on the analog indicated a half-life range from 232 to 371 days. Thus, based on its analogy to dibenzo(a,i)pyrene, EPA believes this compound meets the persistence criteria.

Benzo(g,h,i)perylene. In the proposal, EPA preliminarily determined that benzo(g,h,i)perylene has persistence half-life values in soil of 1.8 years to 173 days and persistence half-life values in water of greater than 100 days. EPA received no significant comments addressing benzo(g,h,i)perylene's persistence potential. EPA has reviewed information and all comments received from commenters on benzo(g,h,i)perylene's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that benzo(g,h,i)perylene persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref.7 of final rule). In addition, benzo(g,h,i)perylene persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

3.g.ii. Bioaccumulation data and whether the PACs category should be split

Bioaccumulation Data for PACs. Polycyclic aromatic compounds category. In the proposal, EPA preliminarily determined that PACs have BCF values that ranged from 31,440 to 800 with 15 of the 20 members of the category having BCF values greater than 5,000. EPA received several comments concerning the PAC's category listing and the bioaccumulation data which are addressed below. EPA has reviewed information and all comments received from commenters on PACs' bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that PACs bioaccumulate in the environment with BAF/BCF values greater than 1,000 and therefore meet the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical category can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, most of the PACs bioaccumulate in the environment with a value well above 5,000, which supports EPA's decision to lower the threshold to 10 pounds.

Commenter List: C-1407, C-1420, C-1817, C-1844, and C-1865

Comment: Three of the commenters support the retention of a single PACs category while one commenter believes that splitting the category into two categories would be the most appropriate option. Additional specific comments were as follows. Commenter stated that PACs are typically found as mixtures in incoming natural organic raw materials, such as coal and that it would be difficult to separate information into two reporting categories. Commenter stated that reporting as one category is also more consistent with the Great Lakes Binational Toxics Strategy Level 2 listing for these chemicals. Commenter stated that the

alternate proposal to create two PAC categories would be unnecessarily burdensome for the regulated community since reporting facilities would be required to speciate their PAC releases, and, if chemicals from both categories exceeded reporting thresholds, file two Form R reports, instead of one. Commenter stated that use of a single PACs category will simplify the reporting requirements; thus, it will reduce reporting burden. Commenters stated that according to the proposed rule, 15 of the 20 members of the category had BCF values greater than 5,000 and that one proposal would regard the entire PAC category to be highly persistent and bioaccumulative, regardless of each individual PAC's actual persistence and bioaccumulative properties. This commenter stated that they believed that splitting the category into two categories would be the most appropriate course. Another commenter stated that no chemical should be added to the highly persistent/bioaccumulative category when it does not fit the criteria and that in order to gain the most accurate information, two separate categories would be the superior solution. The commenter stated that lowering the reporting threshold for the PACs category to 10 pounds is unjustified considering that, according to EPA data, many of the individual PACs within the category do not meet the PBT criteria.

Response: EPA considered splitting the PACs category into 2 or 3 categories or listings, but EPA believes, as do most of the commenters, that the most appropriate option is to retain a single PACs category. The PACs category was created because the members of the category are chemically and structurally very similar, share the same toxicological effect (carcinogenicity), and typically are produced, released, and otherwise managed as waste as complex mixtures rather than individual chemicals. As such it would be more difficult to estimate releases if the category were split into two or three categories based on the currently available bioaccumulation data. These reasons support retaining a single PACs category. EPA agrees with those commenters that stated that the retention of a single PACs category would be the simpler and less burdensome option. EPA also recognizes that, based on currently available information, not all members of the PACs category meet the highly persistence and highly bioaccumulative criteria. Of the 21 chemicals in the PACs category proposed for a lower threshold, 5 have BCF values that nominally do not meet the highly bioaccumulative criteria while the rest exceed the highly bioaccumulative criteria. Given the structural similarities of the members of this category and the higher bioaccumulation values for 16 of the 21 PACs, the 5 BCF values below 5,000 may underestimate, to some extent, the bioaccumulation potential of these compounds. For purposes of this rulemaking EPA is classifying the PACs category as persistent and bioaccumulative rather than highly persistent and highly bioaccumulative. Thus, the PACs category will have a reporting threshold of 100 pounds. However, the Agency will continue to assess the bioaccumulation potential of this category and specifically whether the lower bioaccumulation values for 5 members of the category are appropriate.

Commenter list: C-1860

Comment: The commenter stated that a rule that required reporting of all PACs at these new much lower thresholds will generate a substantial amount of information that is irrelevant to risk. The commenter stated that EPA explicitly assigned a bioaccumulation factor of 5,000 to all PACs, even though some of these individual compounds did not meet this criterion. The commenter stated that it is particularly relevant that, despite the arbitrary assignment of a high bioaccumulation factor to PACs, few State fish advisories (and none in Canada) are based on the 21 PACs listed on the Section 313 list. The commenter stated that there is little data indicating that the small amounts of the vast majority of PACs on EPA's TRI list could accumulate to a degree where they would cause a significant risk. The commenter stated that the ranking of PACs as highly bioaccumulative is based on pure theory, and bad theory at that, and that as a matter of law, EPA simply cannot and should not ignore reality.

Response: The issue of the bioaccumulation values and degree of bioaccumulation for PACs is discussed above. However, EPA disagrees that the bioaccumulation potential of PACs is pure theory, the bioaccumulation data for the PACs were based for the most part on measured BCF values. While the lack of fish advisories does not mean that a chemical cannot bioaccumulate, the commenter acknowledges that fish advisories have been based on PACs which is further evidence that this class of chemicals does bioaccumulate. With regard to the issues related to risk, as discussed in detail elsewhere in these comment responses, EPCRA section 313 is not a risk-based program.

Benzo(g,h,i)perylene. In the proposal, EPA preliminarily determined that benzo(g,h,i)perylene has a BCF value of 25,420. EPA received no significant comments addressing benzo(g,h,i)perylene's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on benzo(g,h,i)perylene's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that benzo(g,h,i)perylene bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, benzo(g,h,i)perylene bioaccumulates in the environment with a BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

3.g.iii. Toxicity Data for 3 added PACs

Benzo(g,h,i)perylene (CAS No. 191-24-2). EPA proposed to add benzo(g,h,i)perylene to EPCRA section 313 pursuant to EPCRA section 313 (d)(2)(C).

Commenter List: C-1865

Comment: The commenter states that EPA should not add benzo(g,h,i)perylene to the EPCRA section 313 list of toxic chemicals because there are insufficient data to support the EPCRA section 313 (d)(2)(C) determination. The commenter states that EPA used predicted aquatic toxicity values based on quantitative structure activity relationship (QSAR) analysis but did not provide any toxicity data. The commenter contends that EPA's did not provide any evidence to support the statement that aquatic QSAR equations show a high correlation between predicted and measured toxicity values, and did not provide any other information to support use of QSAR for this type of chemical.

Response: EPA disagrees with the commenter's statements. EPA provided the following discussion in the proposed rule:

"Three of the chemicals being proposed for listing (benzo(g,h,i)perylene, 3- methylcholanthene, and octachlorostyrene) have been found to meet the EPCRA section 313(d)(2)(C) criteria for ecotoxicity based on predicted aquatic toxicity values generated from quantitative structure activity relationship (QSAR) equations and other predictive techniques. As previously stated (58 FR 63500, December 1, 1993), EPA believes that, where no or insufficient actual measured aquatic toxicity data exist upon which to base a decision, toxicity predictions generated by QSARs and other predictive techniques may constitute sufficient evidence that a chemical meets the section 313 listing criteria. EPA's authority to use such predictive techniques derives from section 313(d)(2) of the statute, which states that EPA shall base its listing determinations on, inter alia, "generally accepted scientific principles." EPA believes that the aquatic QSAR equations that are in widespread use and show a high correlation between predicted and measured aquatic toxicity values can be considered to be "generally accepted scientific principles" and can appropriately form the basis of a listing determination (Ref. 70)." (at 64 FR 693, column 3)

EPA believes that QSAR data is valid predicted aquatic toxicity data and the fact that no actual toxicity studies were provided does not mean that the available data were insufficient to determine that benzo(g,h,i)perylene met the listing criteria of EPCRA section 313(d)(2)(C). In addition, EPA did provide support for the statement that aquatic QSAR equations are in widespread use and show a high correlation between predicted and measured aquatic toxicity values. The docket for the proposed rule contained a document titled "SAR/QSAR in the Office of Pollution Prevention and Toxics" In: Environmental Toxicology and Risk Assessment: 2nd Volume, STP 1216. One of the articles in this reference was titled *Validation of Structure Activity Relationships Used By the USEPA's Office of Pollution Prevention and Toxics for the Environmental Hazard Assessment of Industrial Chemicals*. This includes the methods of SAR for the class of neutral organic chemicals which, as discussed in the support document, was used for benzo(g,h,i)perylene since it is a neutral organic chemical. Thus, EPA did provide support for the its conclusions about QSAR analysis and for the use of QSAR for benzo(g,h,i)perylene.

This commenter also states that EPA uses an estimated log K_{ow} in its aquatic toxicity prediction and argues that Log K_{ow} is an inaccurate predictor for many chemicals particularly if it is estimated rather than measured. The commenter contends that EPA's basis for the listing of benzo(g,h,i)perylene is a prediction based upon a prediction, with no actual data and that this is not a sufficient basis for listing under EPCRA section 313 and it does not meet the statutory conditions for listing that a chemical is "known to cause or can reasonably be anticipated to cause" a significant adverse effect.

EPA disagrees with the commenter's conclusions. The majority of the SAR calculations in the ECOSAR Class Program are based upon the octanol/water partition coefficient (K_{ow} or Log P) since there is a correlation between Log P and toxicity. Using the measured aquatic toxicity values and estimated Log P values, regression equations can be developed for a class of chemicals. Toxicity values for a chemical within that class may then be calculated by inserting the estimated K_{ow} into the class regression equation and correcting the resultant value for the molecular weight of the compound. The ecological assessment guidelines for predicting the toxicity of chemicals with limited measured aquatic toxicity data have been used for over a decade. The commenter has not provided the Agency with any concrete information or data indicating that this approach either is not a generally accepted scientific approach or is unreliable and the Agency finds no reasonable basis to change these techniques at this time. In addition, the commenter did not provided any data to indicate that the predicted Log K_{ow} for benzo(g,h,i)perylene was inaccurate.

This commenter also contends that EPA's failure to consider exposure in this proposed rule is particularly important for benzo(g,h,i)perylene. The commenter argues that given the properties of benzo(g,h,i)perylene, any release into water will result in the vast majority (more than 99 percent) of the compound being partitioned to sediment or adsorbed onto suspended particulates and organics in the water column and thus the potential for this chemical to be in toxic form and pose risk in natural systems is low.

EPA disagrees with the commenters' contention that EPA should consider exposure in its determination that benzo(g,h,i)perylene meets the EPCRA section 313(d)(2)(C) listing criteria. As discussed in Unit VI.F., EPA is only required to consider exposure under a limited set of circumstances. In the final chemical expansion rule (59 FR 61432) EPA further explained its policy on the use of exposure considerations under EPCRA section 313(d)(2)(C) and the fact that the Agency does not consider exposure for chemicals that are highly ecotoxic. As EPA explained in the final rule:

"The Agency believes that exposure considerations are not appropriate in making determinations (1) under section 313(d)(2)(B) for chemicals that exhibit moderately high to high human toxicity (These terms, which do not directly correlate to the numerical screening values reflected in the *Draft Hazard Assessment Guidelines*, are defined in Unit II.) based on a hazard assessment, and (2) under section 313(d)(2)(C) for chemicals that are highly ecotoxic or induce well-established adverse environmental effects." (at 59 FR 61441, columns 1)

Although EPA does not believe that it would be appropriate to consider exposure, EPA also disagrees with the commenter's characterization of the fate of benzo(g,h,i) perylene. Environmental fate models show that the chemical will only partition about 60 percent to the sediment. Also, the Agency cannot rely on the environment to serve as a sink for this chemical. Other environmental conditions such as turbidity, biological activity, or the chemical activity in water could cause redistribution of the chemical into the water column again.

Based upon QSAR equations and other predictive techniques, EPA has concluded that benzo(g,h,i)perylene is toxic. It has the potential to kill fish, daphnia, and algae, among other adverse effects, based on chemical and/or biological interactions. Benzo(g,h,i)perylene can cause these toxic effects at relatively low concentrations. The predicted aquatic toxicity values for benzo(g,h,i)perylene, based upon QSAR analysis using the equation for neutral organics and an estimated K_{ow} of 6.7, included calculated values of 0.030 milligrams per liter (mg/L) for the fish 96-hour LC_{50} (*i.e.*, the concentration that is lethal to 50% of test organisms) and 0.0002 mg/L for fish chronic toxicity; 0.012 mg/L for daphnia 48-hour LC_{50} and 0.027 mg/L for the daphnid 16-day chronic LC_{50} ; and 0.03 mg/L for the algae 96-hour EC_{50} (*i.e.*, the concentration that is effective in producing a sublethal response in 50% of tests organisms) with an algal chronic toxicity of 0.012 mg/L.

Benzo(g,h,i)perylene can cause its toxic effects at relatively low concentrations, therefore EPA considers it to be highly toxic. Since benzo(g,h,i) perylene is toxic at relatively low concentrations EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, *e.g.*, fish, daphnia, and algae kills, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

EPA reaffirms that there is sufficient evidence for listing benzo(g,h,i)perylene on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) based on the available ecotoxicity information for this chemical. Therefore, EPA is finalizing the addition of benzo(g,h,i)perylene on the EPCRA section 313 list.

Benzo(j,k)fluorene (fluoranthene) (CAS No. 206-44-0). EPA proposed to add fluoranthene to EPCRA section 313 pursuant to EPCRA sections 313 (d)(2)(B) and (C). EPA received no comments specific to the carcinogenicity data that EPA presented in the proposed rule in support of the addition of fluoranthene to the EPCRA section 313 list of toxic chemicals. Thus, EPA reaffirms that there is sufficient evidence for adding fluoranthene to this list of EPCRA section 313 toxic chemicals pursuant to EPCRA section 313(d)(2)(B) based on the available carcinogenicity data for this chemical.

Commenter List: C-1865

Comment: The commenter argues that EPA should refrain from listing fluoranthene pending additional assessment of the data. The commenter contends that EPA's reported toxicity values for fluoranthene span a range of about two orders of magnitude and that for such a wide range, it is necessary to evaluate potential exposure to determine which scenarios, and therefore which types of data, are most relevant to this compound following a release. The commenter argues that fluoranthene is a highly lipophilic compound that will bind primarily to sediment and suspended organics, so it is not clear whether the reported toxicity

values on which EPA relies for the listing are applicable to this compound in the environment. EPA assumes the commenter was referring to data used to support EPA's proposal to list fluoranthene.

Response: As discussed elsewhere in these comment responses, EPA does not believe that it is appropriate to consider exposure for chemicals that are highly ecotoxic as the data for fluoranthene clearly shows it is. However, even if EPA were to consider exposure, the commenter provided no data to support the assumption that fluoranthene will bind primarily to sediments and suspended organics and EPA believes that fluoranthene will partition to water as well as sediment. While the ecotoxicity data for fluoranthene does range over about two orders of magnitude that does not, in itself, form a basis for conducting an exposure assessment. There are data that clearly show that fluoranthene is highly ecotoxic. Thus, an exposure assessment is not required. While it does not impact EPA's assessment, EPA notes that of the ecotoxicity values presented in the proposed rule, 9 were within the same order of magnitude, 4 were one order of magnitude higher, and 2 were two orders of magnitude higher. Thus, 60% are within the same order of magnitude and 87% are within one order of magnitude. EPA does not believe that this represents a very wide distribution as the commenter implies.

Based on the available toxicity data, EPA has concluded that fluoranthene is toxic. It has the potential to kill mysid shrimp, a variety of freshwater benthic species and various saltwater species and it can also cause other adverse effects on fish and mysids, based on chemical and or biological interactions. Fluoranthene can cause these toxic effects at relatively low concentrations. Ecotoxicity values for fluoranthene include a calculated 96-hour LC₅₀ of 0.04 mg/ L for mysid shrimp. Using standard acute toxicity tests, fluoranthene has been tested in 12 freshwater species from 11 genera. For freshwater benthic species, the acute 96-hour LC₅₀ calculated values are 0.032 mg/L for an amphipod (*Gammarus minus*), 0.070 mg/L for a hydra (*Hydra americana*), 0.17 mg/L for an annelid (*Lumbriculus variegatus*), and 0.17 mg/L for a snail (*Physella virgata*). For saltwater species, the 96-hour LC₅₀ values are 0.051 mg/L for a mysid (*Mysidopsis bahia*), 0.066 mg/L for an amphipod (*Ampelisca abdita*), 0.14 mg/L for a grass shrimp (*Palaemonetes pugio*), and 0.50 mg/L for an annelid (*Neanthes arenaceodentata*). Fathead minnows exposed to fluoranthene at a concentration of 0.0217 mg/L for 28 days in chronic early life-stage test showed a reduction of 67% in survival and a 50.2% reduction in growth relative to the controls. In a 28-day chronic study, mysids exposed to 0.021 mg/L of fluoranthene showed a 26.7% reduction in survival and a 91.7% reduction in reproduction; at 0.043 mg/L all mysids died. In a 31-day study, mysids showed a reduction of 30% in survival, 12% in growth, and 100% in reproduction relative to controls at a concentration of 0.018 mg/ L of fluoranthene.

Fluoranthene can cause its toxic effects at these relatively low concentrations, therefore EPA considers it to be highly toxic. Since fluoranthene is toxic at relatively low concentrations EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., kills of mysid shrimp, a variety freshwater benthic species, and various saltwater species, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

Thus, EPA reaffirms that there is sufficient evidence for adding fluoranthene on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(I) based on the available ecotoxicity information for this chemical.

Therefore, EPA is finalizing the listing of fluoranthene on the EPCRA section 313 list.

3-Methylcholanthrene (CAS No. 56-49-5). EPA proposed to add 3-methylcholanthrene to EPCRA section 313 pursuant to EPCRA sections 313 (d)(2)(B) and (C). EPA received no comments on the carcinogenicity data that EPA presented in the proposed rule in support of the addition of 3-methylcholanthrene to the EPCRA section 313 list of toxic chemicals. Thus, EPA reaffirms that there is sufficient evidence for adding 3-methylcholanthrene to the list of EPCRA section 313 toxic chemicals pursuant to EPCRA section 313(d)(2)(B) based on the available carcinogenicity data for this chemical.

No comments were received concerning the ecotoxicity data that EPA presented for 3-methylcholanthrene in the proposed rule. Based upon quantitative structure activity relationship (QSAR) equations and other predictive techniques, EPA has concluded that 3-methylcholanthrene is toxic. It has the potential to kill fish and daphnia as well as cause other adverse effects on fish, daphnia, and algae. 3-Methylcholanthrene can cause these toxic effects at relatively low concentrations. The predicted aquatic toxicity values for 3-methylcholanthrene, based on QSAR analysis using the equation for neutral organics and an estimated log Kow of 7.05, include a calculated fish 96-hour LC₅₀ of 0.009 mg/L and a chronic fish toxicity value of 0.003 mg/ L, a daphnia 48-hour LC₅₀ of 0.005 mg/ L and a 16-day chronic LC₅₀ of 0.015 mg/L, and an algae 96-hour EC₅₀ of 0.0105 mg/L with a calculated chronic toxicity value of 0.014 mg/L.

3-Methylcholanthrene can cause its toxic effects at these relatively low concentrations, EPA considers it to be highly

toxic. Since 3-methylcholanthrene is toxic at relatively low concentrations EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish and daphnia kills, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

Thus, EPA reaffirms that there is sufficient evidence for listing 3-methylcholanthrene on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) based on the available ecotoxicity information for this chemical.

Therefore, EPA is finalizing the listing of 3-methylcholanthrene on the EPCRA section 313 list.

3.h. Polychlorinated biphenyls (PCBs)

Persistence Data for PCBs. In the proposal, EPA preliminarily determined that polychlorinated biphenyls (PCBs) have persistence half-life values in soil that ranged from 7 to 1 years and persistence half-life values in water that ranged from 98-56 days. EPA received no significant comments addressing PCBs' persistence potential. EPA has reviewed information and all comments received from commenters on PCBs' persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that PCBs persist in the environment with half-lives of 2 months or greater and therefore meet the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical listing can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule). In addition, all of the PCBs persist in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

Bioaccumulation Data for PCBs. In the proposal, EPA preliminarily determined that PCBs have bioaccumulation BCF values that ranged from 4,922 to 196,900. All of the PCBs, except one, had BCF values far exceeding 5,000. The one exception, 2,3,3',4,4',5,5' heptachlorobiphenyl, had a BCF value of 4,922. EPA received no significant comments addressing PCBs' bioaccumulation potential. EPA has reviewed information and all comments received from commenters on PCBs' bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that PCBs bioaccumulate in the environment with BAF/BCF values greater than 1,000 and therefore meet the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical listing can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, with one exception, all of the PCBs listed bioaccumulate in the environment with a value far exceeding 5,000, which supports EPA's decision to lower the threshold to 10 pounds.

3.i. Pesticides

Persistence Data for Pesticides.

Aldrin. In the proposal, EPA preliminarily determined that aldrin has persistence half-life values in soil of 9 years to 291 days and a persistence half-life value in water of 24 days. EPA received no significant comments addressing aldrin's persistence potential. EPA has reviewed information and all comments received from commenters on aldrin's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that aldrin persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule).

Chlordane. In the proposal, EPA preliminarily determined that chlordane has persistence half-life values in soil of 8-0.4 years and a persistence half-life value in water of 239 days. EPA received no significant comments addressing chlordane's persistence potential. EPA has reviewed information and all comments received from commenters on chlordane's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that chlordane persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule). In addition, chlordane persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

Heptachlor. In the proposal, EPA preliminarily determined that heptachlor has persistence half-life values in soil of 4 years to 8 days and a persistence half-life value in water of 129.4-23.1 hours. EPA received no significant comments addressing heptachlor's persistence potential. EPA has reviewed information and all comments received from commenters on heptachlor's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that heptachlor persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion

established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule). In addition, heptachlor persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

Isodrin. In the proposal, EPA preliminarily determined that isodrin has persistence half-life values in soil of 5 years to 180 days. EPA received no significant comments addressing isodrin's persistence potential. EPA has reviewed information and all comments received from commenters on isodrin's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that isodrin persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule). In addition, isodrin persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

Methoxychlor. In the proposal, EPA preliminarily determined that methoxychlor has persistence half-life values in soil of 136 to 81 days and persistence half-life values in water of 15.2 to 5 days. EPA received no significant comments addressing methoxychlor's persistence potential. EPA has reviewed information and all comments received from commenters on methoxychlor's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that methoxychlor persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule).

Pendimethalin. In the proposal, EPA preliminarily determined that pendimethalin has a persistence half-life value in soil of 1300-54 days. EPA received several significant comments addressing pendimethalin's persistence potential which are addressed below. EPA has reviewed information and all comments received from commenters on pendimethalin's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that pendimethalin persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule).

Commenter list: C-1436

Comment: The commenter states that EPA should remove pendimethalin from the lowered threshold list because pendimethalin has been miscategorized as a PBT based on limited screening data which is in conflict with conclusions reached by EPA during the FIFRA risk assessment. The commenter believes that the characterization of pendimethalin is inaccurate and will lead to misplaced effort and misplaced focus on listed chemicals with no benefit to the public or the environment in lowering the reporting threshold for pendimethalin.

Response: EPA disagrees with the commenter. EPA did not base its determination that pendimethalin meets the EPCRA section 313 persistence criteria, nor that pendimethalin is highly persistent on "screening" data. EPA's conclusion that pendimethalin persists with a half-life greater than six months is based on a well-conducted study in which pendimethalin degrades in soil with a half-life of 1322 days. Further, even if these data were discounted, there are numerous data submitted in support of reregistration of pendimethalin under FIFRA that provide strong evidence that pendimethalin meets the EPCRA section 313 persistence criteria, i.e., a half-life greater than two months. A more detailed discussion of these data is presented in the following responses. Contrary to the assertion by the commenter, the categorization of pendimethalin as a PBT as described in the proposed rule is not in conflict with the conclusions reached by EPA during the FIFRA assessment. As discussed elsewhere, EPA believes that PBT chemicals are of special concern because they have the potential to cause adverse effects even when released to the environment in small quantities because they can be bioaccumulated in organisms to levels much greater than those present in the environment. EPA believes that lowering the reporting threshold for pendimethalin will provide information to the public that will increase their awareness of low levels of releases to the environment which have the potential to concentrate in organisms and cause adverse effects, which is fully consistent with the purposes of EPCRA 313.

Comment: The commenter states that EPA has ignored bioavailability in designating pendimethalin as a PBT chemical and argues that the true bioaccumulation potential for pendimethalin is greatly overestimated based on the results of the standard laboratory fish bioconcentration study. The commenter asserts that when data on bioavailability, degradation and depuration are all considered the real world bioconcentration potential for pendimethalin is low and, therefore pendimethalin should not be misbranded as a PBT.

Response: The bioavailability data the commenter refers to was not specifically identified. Bioavailability of a chemical will vary from environment to environment and soil type to soil type. Caution must be taken, however, not to draw the erroneous conclusion that because a chemical has been shown to have a high affinity to sorb to sediments in aquatic environments that it will not be available for uptake by aquatic organisms. Examples like the PCBs indicate that although some of these compounds have sorption coefficients much greater than pendimethalin they are still widely found in the tissues of aquatic organisms in contaminated waters. Further, it would be erroneous to state that pendimethalin is not bioavailable because if it were not it could work as a herbicide as it does.

Comment: The commenter claims that using the EPA's own criteria (half-lives longer than two months in water sediment, or soil, or a half-life longer than two days in air) pendimethalin cannot be classified as persistent. Rather the commenter contends that pendimethalin has "low" or "low to moderate" persistence.

Response: The commenter is incorrect. The Agency has set persistence criteria of half-lives for soil, sediment, and water greater than two months and a half-life in air of greater than two days. Chemicals meeting these criteria are considered persistent for purposes of EPCRA section 313. There are, in fact, no qualifiers such as "low," "moderate," or "high" associated with the persistence criteria. The commenter's characterization of the persistence of pendimethalin as "low" or "low to moderate" is thus not particularly relevant. It appears, based on the comments, that the commenter defines low to moderate persistence as a half-life of greater than two days in air and greater than two months in soil, sediment or water. If this is the case, then the commenter in fact concurs with EPA's assessment of pendimethalin as persistent (half-life greater than two months in soil or water and greater than two days in air).

If the commenter, instead, meant that pendimethalin has half-lives of less than 2 months in soil or water, and 2 days in air, EPA notes that the commenter has failed to provide data to support that assertion, and that EPA's review of the data support the Agency's conclusion.

Comment: The commenter cites numerous laboratory and field dissipation studies in support of the claim that pendimethalin does not meet the persistence criteria.

Response: EPA disagrees that the degree of persistence of pendimethalin can be characterized by the field dissipation studies cited by the commenter. Field dissipation studies are not equivalent to the studies which measure the half-life for destruction of a chemical in a specific medium (i.e., soil, water or air). Field dissipation studies are designed to measure the rate or extent of chemical loss from the medium after application of the chemical. The processes by which the chemical is lost may include not only those that result in destruction of the chemical, but those which only transport the chemical from one medium to another such as volatilization. The studies cited by the commenter measure the dissipation of pendimethalin from soil. For a relatively volatile chemical such as pendimethalin, field dissipation studies are of limited use in assessing persistence because an unknown amount of pendimethalin will be transported from soil to air, resulting in a measured loss from that medium, but not destruction. Thus, the field dissipation studies cited by the commenter will underestimate the persistence of pendimethalin in soil. A more detailed discussion of the persistence of pendimethalin in soil, and why EPA believes that the persistence of pendimethalin in soil meets the criteria set forth in this rule, is presented in the following comments.

Comment: The commenter cites several laboratory experiments on the degradation of pendimethalin in soil to support the argument that pendimethalin does not meet the persistence criteria:

Laboratory aerobic soil degradation studies have been conducted in which pendimethalin was applied to soil grab samples and incubated under controlled conditions. Pendimethalin degraded in laboratory soil studies with half-lives ranging from 31 to 1322 days. In the *Reregistration Eligibility Decision (RED) for pendimethalin (Ref I)* document, EPA explained that 172 days was used instead of 1322 days because "The half-lives for aerobic soil metabolism ranged from 42-563 days in the literature studies referenced below with a guideline study reporting a half-life of 1322 days for a total of 27 total observations. Because of the range of values, statistical analyses of the available data were performed. The mean, median, and modal half-lives are 126, 122, and 122 days, respectively, with a standard deviation of 66 days (n=24). The half-life values of 409, 563, and 1322 days were not included in the final statistical analyses because they were greater than three standard deviations from the mean. Based on soils and crops that are normally treated with pendimethalin, the reviewer assumed that temperatures would likely range from 20-30 C and soil moisture contents from 50-75% Field Capacity (FC). The range of observed half-lives in the above experimental conditions was 72-172 days." If the 1322-day value is assumed to be an outlier (*Ref II*), the range was 31 to 172 days. Thus, laboratory studies also indicate that pendimethalin has a low to moderate persistence according to the EPCRA section 313 persistence criteria.

Response: EPA believes that the guideline study reported half-life of 1322 days represents an accurate and representative value for the assessment of the persistence of pendimethalin in the environment. In situations where multiple values for half-lives are submitted under FIFRA to EPA's Office of Pesticide Program's (OPP), statistical analysis may be conducted to determine mean values and standard deviations. The analysis permits the use of a value for exposure assessment modeling that takes into account the variability in data, and allows the exclusion of values more than three standard deviations outside the mean as "outliers." The designation as an outlier does not invalidate the study, and in fact, EPA maintains that even a study designated as an "outlier," if valid, gives useful half-life information.

In their assessment of the persistence of chemicals in soils, OPP focuses on studies using soil types, soil moisture contents and temperatures consistent with the field application of the chemical in its intended use. In the OPP review of the studies the reviewer assumed that in the field application of the chemical, temperatures would likely range from 20 - 30 C and that soil moisture would range from 50 to 75% field capacity. The consideration of data from studies conducted under these conditions resulted in a half-life range of 72 - 172 days for pendimethalin. It should be noted that even after the elimination of outliers and consideration of studies relevant to normal field application, the upper end of the half-life range is approximately six months, clearly meeting the criteria for persistence in soil, i.e., a half-life of two months.

The releases of pendimethalin subject to EPCRA section 313 reporting, in many cases, will not be to agricultural soils under typical application scenarios. EPA, therefore, contends that even though some soil half life values were not considered by OPP, either because they were derived using studies that did not represent the desired field conditions, or because they were labeled as statistical outliers, the study conditions still represent realistic scenarios for releases reported under EPCRA section 313 and are valid for use in the determination of persistence.

Comment: The commenter cites studies conducted using flooded soils to support the argument that pendimethalin does not meet the persistence criteria.

The studies involved the use of pendimethalin spiked into soil grab samples covered with a shallow layer of water and incubated in the laboratory under controlled conditions. In laboratory flooded soil studies, pendimethalin degradation half-lives ranged from seven to 104 days with the majority of studies giving half-lives of less than two months. Degradation of pendimethalin was more rapid in flooded soils than in nonflooded soils in most instances. The commenter asserts that these results demonstrate that pendimethalin has a low to moderate persistence in flooded soils according to the EPCRA section 313 persistence criteria.

Response: EPA agrees that the reported degradation half-lives in laboratory flooded soils studies range from seven to 104 days. The studies are reviewed for quality and preferred methodologies. Of the studies that are of acceptable quality, EPA chose the highest value (most protective) of the range to determine if the chemical meets the EPCRA section 313 persistence criteria. In this case, the value of 105 days was used to characterize pendimethalin as persistent in flooded soils. However, there is not a separate persistence criterion for flooded soils, nor are data on flooded soils preferable to other soil data. EPA notes that other soil studies, discussed above, indicate a half-life of up to 1,322 days in soils.

Comment: The commenter states that while pendimethalin is stable to hydrolysis, it will degrade in natural water and water/sediment systems under laboratory conditions with degradation half-lives ranging from four to 22 days. Photodegradation is also rapid with half-lives of approximately 3.5 days. The commenter concludes that these results indicate that pendimethalin has a low persistence in both water and its underlying sediment according to the EPCRA section 313 persistence criteria.

Response: Two of the aerobic aquatic degradation studies cited by the commenter were provided or are publicly available, (i.e., they are internal American Cyanamid studies). It is unclear from the summary provided whether the cited studies measured destruction of pendimethalin or its loss from the medium by non-destructive water to air transport processes. If the latter is the case, the "dissipation half-lives" cited cannot be used to characterize persistence. EPA agrees that if the half-lives reported for aerobic aquatic degradation represent half-lives for destruction of the chemical, they do not meet the criteria for persistence in water. However, as noted above, the full studies were not available for review and as such, EPA cannot assume that the studies followed destruction of pendimethalin, or that the studies meet the quality criteria outlined in the proposed rule.

The commenter cites a half-life range of 6 - 22 days derived from an anaerobic aquatic degradation study to support the argument that pendimethalin has a low persistence in both water and its underlying sediment according to the EPCRA section 313 persistence criteria. EPA agrees that the persistence half-life values cited by the commenter do not meet the EPCRA section 313 persistence criteria, but points out that additional data submitted in support of the re-registration of pendimethalin indicated that half-lives in aquatic environments could be longer. OPP used flooded soil degradation studies to assess the

persistence of pendimethalin under anaerobic aquatic conditions. Half lives in these studies ranged from 6 to 105 days. In its discussion of the potential impact of pendimethalin on water resources, OPP in the RED notes that pendimethalin has an anaerobic aquatic metabolism half-life of 60 days. EPA believes that after review of the available data on its persistence in water pendimethalin it meets the EPCRA section 313 persistence criteria.

EPA agrees that rapid aqueous photodegradation under laboratory studies has been reported for pendimethalin. However, the photolysis screening tests used are designed to allow the determination of rates of photolysis at shallow depths in pure water as a function of latitude and season. EPA believes that the environmental relevance of these tests should be considered in their use to determine persistence, and that the results are most applicable to shallow, clear waters. EPA believes that the application of the results beyond these environments is tenuous due to the attenuation of light by suspended mater and increasing depth in the aquatic environment. EPA believes that pendimethalin's tendency to sorb to soil and sediments may result, under some circumstances, in its deposition in bethic environments beyond the effects of aqueous photolysis. Therefore EPA does not believe that the half-life for pendimethalin in water should be based on aqueous photolysis

Comment: The commenter claims pendimethalin will not persist in air according to the EPCRA section 313 persistence criteria for air of a half-life of less than two days. The commenter discusses the estimation of pendimethalin's atmospheric half-life and a study on its photodegradation in air. The commenter cites the results of a calculation according to the method of Atkinson performed to determine the rate constant for reaction of pendimethalin with OH radicals in the gas phase (Ref III). A tropospheric half-life of 3.4 hours was calculated using the method. The photolysis of pendimethalin was investigated by Bossan, et al, 1995 (Ref IV), who reported on the photoreactivity of pendimethalin on airborne fly ash and kaolin using simulated sunlight. Approximately 70% of applied pendimethalin degraded within 30 minutes when adsorbed to fly ash but little degradation was observed after 100 minutes when pendimethalin was bound to kaolin.

Response: EPA agrees that pendimethalin does not meet the persistence half-life criterion for air of greater than two days, but since it meets the persistence criteria for soil and water, this does not affect EPS's conclusion. As noted in the proposed final rule at 64 FR 702, a chemical need only meet 1 of the media-specific criteria (other than air) to be considered persistent.

Comment: The commenter cites EPA/OPP pendimethalin Reregistration Eligibility Decision (RED) document and cites its conclusion in support of the argument that pendimethalin does not meet the persistence criteria. The commenter describes the RED conclusions as follows:

"Pendimethalin dissipates in the environment by binding to soil, microbially-mediated metabolism and volatilization. It is essentially immobile in soil.

Based on laboratory studies and limited field study information, pendimethalin is slightly to moderately persistent in aerobic soil environments. Persistence decreases with increased temperature, increased moisture and decreased soil organic carbon."

Response: EPA disagrees with the commenters suggestion that the OPP RED for pendimethalin concludes that it does not meet the EPCRA 313 persistence criteria.

As stated in an earlier response, "moderate" persistence has no relevance in the context of the proposed rule. A chemical is considered persistent if it has half- lives of two days in air, and two months in soil, sediment or water, respectively.

The commenter implies that OPP has concluded that pendimethalin does not meet the persistence criteria by selectively citing the OPP Reregistration Eligibility Decision (RED) while failing to acknowledge other information OPP discussed in the document confirming the persistence of pendimethalin. OPP did not make any formal summary conclusions regarding the overall environmental persistence of pendimethalin. The commenter has selectively cited from the RED taking a few comments out of context while ignoring additional findings which demonstrate that pendimethalin meets the persistence criteria.

The first statement cited by the commenter addresses dissipation in the environment. Two of the three processes (soil binding and volatilization) responsible for dissipation do not result in the destruction of the chemical and cannot be directly related to persistence. Volatilization results in the relocation of the chemical to the atmosphere. Binding to soil does not destroy pendimethalin and under some soil conditions has been shown to increase persistence. While microbial metabolism of pendimethalin can result in its destruction, it has been shown to be a slow process under many environmental conditions.

The commenter cites/quotes OPP's qualitative description of the persistence of pendimethalin in aerobic soil environments as

slight to moderate. This does not serve as, nor did OPP intend for this statement to represent, a quantitative description of pendimethalin's persistence in soil. OPP does not attempt to relate this characterization to a numeric range of persistence values in the RED, and the commenter does not provide a rationale for concluding that OPP's language indicates that pendimethalin does not meet the persistence criteria.

The final sentence of the quote points out factors that decrease persistence, but a more detailed reading of the RED on the subject of pendimethalin persistence in aerobic soils reveals that its persistence increases as temperature and soil moisture decrease, and soil organic carbon increase.

Comment: The commenter performed a Level III EQC Multimedia Modeling assessment (this is discussed at length elsewhere in this document) by for pendimethalin assuming "best case, reasonable case, and worst case" scenarios. The calculated overall environmental persistence was determined for pendimethalin to be five days, 58 days, and 142 days under the "best, reasonable, and worst case" scenarios, respectively. The results of the multimedia model indicated that pendimethalin will have a persistence in the environment of less than 2 months, assuming a reasonable case scenario. The commenter claims that multimedia modeling results indicate that pendimethalin will not be persistent according to the EPCRA section 313 persistence criteria.

The commenter notes that the values calculated by American Cyanamid using the EQC model are much lower than the 30 days and 487 days calculated for the EPA (Ref V) assuming best case and worst case scenarios. The SRC assumed that half-lives in soil, sediment and water were identical, 54 days and 1322 days, respectively. The data presented above, however, indicate that these were erroneous assumptions. The half-lives for pendimethalin dissipation in water, soil, and sediment are not identical, and the 1322 day half-life is an outlier.

The commenter concludes that pendimethalin will have a low to moderate persistence whether found in the air, water, soil, or sediment compartments of the environment. This is supported by field and laboratory degradation studies, multimedia modeling and the US EPA's FIFRA registration environmental assessment of pendimethalin. Therefore, pendimethalin should not be classified as persistent for purposes of inclusion on the Toxics Release Inventory list of PBT chemicals.

Response: EPA disagrees that pendimethalin will have a low persistence in the environment whether laboratory and field studies or multimedia modeling are considered.

Multimedia mass balance models offer the most convenient means to estimate overall environmental persistence from information on sources and loadings, chemical properties and transformation processes, and intermedia partitioning. For the chemicals included in this proposed rule EPA used the EQC model (Ref. VI) to estimate overall environmental persistence. Overall persistence estimated in this way is used as an additional factor, in conjunction with reaction half-lives for individual media, bioaccumulation/bioconcentration factors, etc., in justifying actions proposed in this rule.

The EQC model is based on the fugacity approach first delineated by Mackay (Ref. VII) and subsequently applied to numerous environmental processes (Ref. VIII). It uses an "evaluative environment" in which environmental parameters such as bulk compartment dimensions and volumes (e.g., total area, volume of soil and sediment, etc.) are standardized, so that overall persistence for chemicals with different properties and rates of transformation may be compared on an equal basis (Ref. IV). EPA used a version of the EQC level III model (Ref. VI) which was modified to focus on net losses by deleting model terms for advective losses (movement out of the evaluative environment of air and water potentially containing a chemical) and sediment burial (Ref. X). In this version of the model only irreversible transformation contributes to net loss of a chemical.

The overall persistence obtained from this model is calculated as the total amount in the evaluative environment when steady state is achieved, divided by the total loss rate. The results thus obtained are neither an overall environmental half-life nor a compartment (or transformation)-specific half-life; rather they are equivalent to an environmental residence time. When only irreversible transformation contributes to net loss--i.e., under the conditions of this version of the EQC model--overall environmental persistence times can be converted to half-lives by multiplying the former by $\ln 2$ (i.e., 0.693). The overall half-life calculated in this way is for dissipation in the environment as a whole and cannot be related directly to any individual compartment.

The commenter selected media specific environmental half lives for use as input to the EQC model. The values were characterized as "best", "reasonable" and "worst" case. No justification was given for this classification. It appeared that the shortest half lives were categorized as "best case". Based on the information provided by the commenter, it was not always

possible to determine whether the half-lives for soil or water selected by the commenter for use as input to the EQC model were for destruction of chemical, or its dissipation from the medium. As noted previously, dissipation half-lives do not necessarily represent destruction of the chemical since non-destructive transport processes such as volatilization can be responsible for loss from the medium. Their use in multimedia modeling could potentially underestimate overall environmental persistence. This is particularly important since the EQC model predicted that greater than 90% of the pendimethalin would partition to soil at steady state. If a soil half-life based on loss from soil by nondestructive processes was used rather than one based on the destruction of pendimethalin, its persistence would have been underestimated.

In its modeling of the overall environmental persistence of pendimethalin EPA used the highest, lowest and mean values for the ranges of media specific half-lives from valid studies as inputs to the EQC model, not the highest and lowest as stated by the commenter. These included a half-life for pendimethalin in soil of 1322 days. EPA determined that the study was properly conducted, and chose the half-life value of 1322 days for soil because it represented the most environmentally protective half-life derived from a valid study. The EQC calculated overall environmental persistence half-lives were one month, eight months, and sixteen months based on the highest, mean, and lowest half-lives, respectively. For chemicals in this rulemaking, EPA considered the EQC results in characterizing persistence in the overall environment. EPA only intended to use multimedia modeling results to override the medium specific persistence data in limited circumstances, e.g., only if all model inputs are judged to be accurate (and, as noted above, the commenter's inputs cannot be determined to be accurate). But even if EPA were to use the EQC model to assess persistence pendimethalin would be considered persistent because, with the EPA inputs described above, EQC overall environmental persistence half-lives were calculated to be greater than six months using the mean and maximum air, soil and water half-lives calculated.

In response to this comment (even though it was unclear whether the commenter was basing his assertion on degradation data or dissipation data) EPA conducted a new EQC assessment for pendimethalin using the same half-life inputs selected by the commenter. The calculated overall environmental persistence half-life was greater than two months using the longest half-lives provided by the commenter for air, soil water and sediment. These results support EPA's assertion that the persistence of pendimethalin in the environment will meet the EPCRA section 313 persistence criteria.

Comment: The commenter argues that the scientifically based risk assessments conducted on pendimethalin as a part of the pesticide registration process should not be ignored, and that EPA should review pesticide PBT classifications with EPA registration information to ensure an accurate analysis has been performed.

The commenter notes that EPA has determined through the review of a complete set of studies that this material used at an approximate rate of 1.0-2.0 pounds of active ingredient per acre does not present an unreasonable risk to human health or the environment, that low levels of pendimethalin in manufacturing wastewater releases do not pose an unacceptable risk to the environment and that reported EPCRA section 313 air releases do not pose a significant risk to human health or the environment.

The commenter concludes that based on the weight of evidence it is clear that releases of pendimethalin from manufacturing do not pose a significant threat to human health and the environment and that pendimethalin should not be branded as having a high potential for harm as indicated by the proposed listing as a PBT and lowering of the reporting threshold.

Response: EPA disagrees that the risk assessments cited by the commenter are relevant to the characterization of pendimethalin as a PBT chemical. The characterization of chemicals as PBT for the purpose of this proposed rule are based on intrinsic physical-chemical properties as described fully elsewhere. Risk is not an intrinsic property of a substance, but rather the result of the combination of intrinsic hazard (toxicity) a substance possesses and the exposure to a target organism under a defined set of circumstances. It is possible for a substance to present a risk under one set of exposure conditions, but not another. In contrast, a substance characterized as a PBT will remain a PBT, regardless of the exposure to it or its levels in the environment.

EPA conducted a hazard assessment on each chemical being proposed for addition to the EPCRA section 313 list of toxic chemicals. This assessment was separate and independent from the review conducted to determine each chemical's persistence and bioaccumulation potential, although EPA considered some of the same data in certain of its hazard assessments. EPA found that each chemical being proposed for addition meets the criteria for chronic human toxicity and/or environmental toxicity, as set forth at EPCRA section 313(d)(2)(B)-(C). EPA believes that the degree of toxicity as well as the degree of persistence and bioaccumulation are inherent to a chemical. The absolute level of a chemical in the environment does not affect its degree of persistence, bioaccumulation, or whether or not it has been shown to cause adverse effects to aquatic

organisms.

Toxic chemicals that persist and bioaccumulate are of particular concern because they remain in the environment for significant periods of time and concentrate in the organisms exposed to them. Furthermore, these persistent bioaccumulative toxic (PBT) chemicals can have serious human health and environmental effects resulting from low levels of release and exposure.

EPA believes that the substances subject to this rule have been characterized as PBTs using scientifically sound indicators based on the intrinsic properties of the substances. The PBT characterization is independent of the risk the substance may pose under a given set of circumstances. These substances have been characterized as persistent, bioaccumulative and toxic and, therefore, meet the criteria for lowered reporting thresholds under the proposed rule.

Further, FIFRA requires the Agency to determine that pesticidal uses of a chemical do not cause "unreasonable adverse effects on the environment." This is defined in FIFRA section 2(bb) as "any unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of pesticides" (7 U.S.C. section 136(bb)). FIFRA is a regulatory statute, and the impacts of regulation can be immediate and direct (e.g., banning of a chemical), and as such EPA examines not only the hazards presented by the chemical, but also the specific exposure scenarios, and weighs the risks against the benefits of the chemical. The "unreasonable adverse effects" determination under FIFRA is specific to the intentional use of the chemical as a pesticide and does not address other uses or releases of the chemical that may result from manufacture, processing, or other use. Furthermore, a determination under FIFRA that the use of a chemical will not result in an "unreasonable adverse effect" is not a determination that the chemical is not hazardous or persistent or that the use of the chemical is without risk, but merely that the benefits of agricultural use as a pesticide outweigh its risks as an agricultural pesticide, and a determination that the pesticide chemical residues on food meet the standard of section 408 of the Federal Food Drug and Cosmetic Act. Finally, EPCRA section 313 was not enacted to serve the same purpose as FIFRA. Listing on EPCRA section 313 provides communities with some of the information required to determine what risks may result from the manufacture, processing and non-pesticidal use of a chemical, and to allow local communities to determine for themselves whether such resulting risks are acceptable, information not provided through FIFRA.

Comment: The commenter disagrees with EPA's proposal that the half-lives in both aerobic surface water and soil can be considered to be equivalent since the average soil/water half-life ratio for the chemicals evaluated is approximately one. Each chemical must be handled independently. [For example, pendimethalin will rapidly dissipate from surface waters. Thus, it will have a much shorter half-life in water than in soil (soil/water ratio does not equal 1) demonstrating that a generalized indicator should not be used when real data is available. This is certainly the case with pendimethalin here the experimental data does not equate with EPA's generalized conclusion (i.e. pendimethalin's water/soil half-life ratio is not 1).

Response: EPA disagrees with the comment and asserts that it is appropriate, for the purposes of estimating soil or water half-lives in the absence of data for one medium or the other, to assume that the ratio of surface water to soil biodegradation half-life equals one. While in some cases the assumption may not be correct, EPA contends that in the absence of data, this assumption can be used to fill key data gaps in information needed for the purposes of multimedia modeling. This approach is not used to override existing data when it is available from scientifically sound studies, but rather to fill modeling input data gaps when values are missing.

For many of the chemicals included in this proposed rule, biodegradation was judged to be the critical process controlling overall persistence in soil or water, but data were available for one or the other but not both media. Under these circumstances EPA assumed that half-lives for biodegradation are roughly comparable in the two compartments. This assumption is based on independently derived but consistent results reported by Boethling, et al. (Ref. XI) and Federle, et al. (Ref. XII). In the first study (Ref. XI), measured half-lives from existing literature data were collected for a wide variety of organic chemicals whose biodegradability had been tested using both soil and water/sediment grab samples (but not necessarily in the same study or by the same investigator). Mean ratios of half-life in water to half-life in surface soil were then calculated for the 20 study chemicals. These ratios varied widely but their overall mean was approximately one, which suggests that, in the absence of chemical-specific data, biodegradation in aerobic surface waters is about as fast as biodegradation in soil. Federle et al. (Ref. XII) compared biodegradation rates under various conditions in much the same fashion, but they utilized experimental data generated *de novo* in carefully controlled laboratory tests. Scaling factors (ratios of half-lives) for river water vs. soil varied widely as observed in the first study (Ref. XI), but the overall mean was again approximately one.

Comment: The commenter states that EPA registered pesticide active ingredients have some of the best available scientific data available for assessing effects on human health and the environment. FIFRA generated data should be used in the

assessment of PBT chemicals as well as EPA's risk assessment in the FIFRA process.

The commenter states that EPA acknowledges in the preamble that field studies, such as are often conducted to determine pesticide fate in the environment, are generally considered the most informative studies if properly conducted. The commenter agrees with this statement and urges EPA to use the data collected for FIFRA registration and the FIFRA risk assessment performed by EPA in its analyses of PBT pesticide materials. The commenter continues that FIFRA studies are performed under Good Laboratory Practices (GLP) and must follow protocols set in the Pesticide Assessment Guidelines. These studies provide far better scientific data when analyzed in total with a weight of evidence approach than any indicator can provide. The commenter contends that EPA has discounted the data that had been submitted, reviewed and collected by EPA under FIFRA because the reports were unpublished. The use of good scientific data is a goal of EPA and the commenter states that EPA should use the EPA reviewed FIFRA data in its analyses.

Response: EPA agrees that the best available data should be used in the evaluation of any chemical for the inclusion in the action proposed in this rule. In fact the Reregistration Eligibility Document for pendimethalin was carefully reviewed as were several of the key studies it cites. A more detailed discussion of the data reviewed and EPA findings on the persistence of pendimethalin in the context of this proposed rule has been addressed elsewhere in the response to comments.

The risk assessment EPA conducted on pendimethalin under FIFRA was based on its intended use as a pesticide. As noted above, the findings of the risk assessment are not related to, and do not impact on the determination of whether pendimethalin does or does not meet the persistence and bioaccumulation criteria set forth in the proposed rule.

References

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X) Webster, E., Mackay, D. and F Wania, F, "Evaluating Environmental Persistence." *Environ. Toxicol. Chem.*, in press (1998).

XI). Boethling, R.S., Howard, P.H., Beauman, J.A., and Larosche, M.E., "Factors for Intermedia Extrapolation in Biodegradability Assessment," *Chemosphere* v. 30, (1995), pp. 741-752.

XII). Federle, T.W., Gasier, S.D., and Nuck, B.A., "Extrapolating Mineralization Rates from the CO₂ Screening to Activated

Toxaphene. In the proposal, EPA preliminarily determined that toxaphene has persistence half-life values in soil of 11 to 1 years and a persistence half-life value in water of 5 to 1 years. EPA received no significant comments addressing toxaphene's persistence potential. EPA has reviewed information and all comments received from commenters on toxaphene's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that toxaphene persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule). In addition, toxaphene persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

Trifluralin. In the proposal, EPA preliminarily determined that trifluralin has persistence half-life values in soil of 394-99 days and a persistence half-life value in water of 37 to 5 days. EPA received no significant comments addressing trifluralin's persistence potential. EPA has reviewed information and all comments received from commenters on trifluralin's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that trifluralin persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 7 of the final rule).

Bioaccumulation Data for Pesticides.

Aldrin. In the proposal, EPA preliminarily determined that aldrin has a BCF value of 3,715. EPA received no significant comments addressing aldrin's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on aldrin's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that aldrin bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule).

Chlordane. In the proposal, EPA preliminarily determined that chlordane has a BCF value of 11,050. EPA received no significant comments addressing chlordane's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on chlordane's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that chlordane bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, chlordane bioaccumulates in the environment with a BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

Heptachlor. In the proposal, EPA preliminarily determined that heptachlor has a BCF value of 19,953. EPA received no significant comments addressing heptachlor's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on heptachlor's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that heptachlor bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, heptachlor bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

Isodrin. In the proposal, EPA preliminarily determined that isodrin has a BCF value of 20,180. EPA received no significant comments addressing isodrin's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on isodrin's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that isodrin bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, isodrin bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

Methoxychlor. In the proposal, EPA preliminarily determined that methoxychlor has a BCF value of 8,128. EPA received no significant comments addressing methoxychlor's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on methoxychlor's bioaccumulation characteristics. Taking into account this information,

as indicated in Table 3, EPA finds that methoxychlor bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule).

Pendimethalin. In the proposal, EPA preliminarily determined that pendimethalin has a BCF value of 1,944. EPA received no significant comments addressing pendimethalin's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on pendimethalin's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that pendimethalin bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule).

Toxaphene. In the proposal, EPA preliminarily determined that toxaphene has a BCF value of 34,050. EPA received no significant comments addressing toxaphene's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on toxaphene's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that toxaphene bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule). In addition, toxaphene bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

Trifluralin. In the proposal, EPA preliminarily determined that trifluralin has a BCF value of 5,674. EPA received no significant comments addressing trifluralin's bioaccumulation potential. EPA has reviewed information and all comments received from commenters on trifluralin's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that trifluralin bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule).

3.j. Tetrabromobisphenol A (CAS No. 79-94-7).

Toxicity Data for Tetrabromobisphenol A. EPA proposed to add tetrabromobisphenol A to EPCRA section 313 pursuant to EPCRA sections 313 (d)(2)(B) and (C).

Commenter List: C-1919

Comment: The commenter claims that the study cited by EPA in support of its conclusion that tetrabromobisphenol A (TBBPA) meets the EPCRA section 313(d)(2)(B) criteria for listing based on developmental toxicity was not a study on TBBPA.

Response: The study in question was submitted to EPA by ICI Americas Inc. with a cover letter identifying Saytex 111, the product tested, as being TBBPA. The product was identified as TBBPA by both name and CAS number. EPA has determined that the product tested was not TBBPA as claimed by the submitter but has been unable to determine why it was misidentified by the submitter. ICI Americas is now Zeneca at the Delaware location that submitted the study. A Zeneca staff member researched the submission and found that the report was originally from Ethyl Corporation and that no other report on TBBPA was submitted to EPA on that date. Without the misidentified developmental study, no adequate toxicology studies or other data were located by EPA that support the addition of TBBPA pursuant to EPCRA section 313(d)(2)(B). Thus, EPA is not adding TBBPA based on concerns for developmental toxicity or any other human health effects.

Commenter List: C-1919

Comment: The commenter states that TBBPA does not present a risk to human health. The commenter provided a review of the mammalian toxicity of TBBPA and concluded that TBBPA is not a "neurotoxin", reproductive "toxicant", or endocrine "disrupter." Based on the results of Ames tests, the commenter states TBBPA is unlikely to be a carcinogen.

Response: As EPA has stated above, EPA did not find data sufficient to support the listing of TBBPA under EPCRA section 313 based on human health concerns. However, EPA disagrees with the commenter's conclusion that the available data are adequate to determine TBBPA does not pose a potential risk to humans. In their review, the commenter provides no additional

relevant data or sources beyond the information on TBBPA previously reviewed and summarized by EPA in the its Support Document. Specifically, EPA disagrees with the commenter's statement, unsupported by any direct evidence in their review, that:

".... there is adequate evidence to conclude that TBBPA is not a neurotoxin or reproductive toxicant and it is unlikely to act as an endocrine disrupter; conclusions EPA has overlooked in its evaluation of TBBPA. Further, based upon a recent publication indicating the utility of the Ames test to predict noncarcinogens, there is a reasonable basis to conclude that TBBPA is unlikely to be a carcinogen."

In particular, as discussed in the Support Document, there were many data gaps in the limited information available that prevented evaluation of the potential human health hazard. No long-term or chronic studies, no studies of carcinogenicity, no studies of neurotoxicity, no reproductive toxicity, and only inadequate developmental toxicity studies were located by EPA. None of these data gaps are addressed by the commenter. EPA does not agree with the commenter's statement that based on a negative Ames test it can be concluded that any chemical is "not likely to be carcinogenic." EPA sees no evidence of studies of adequate quality or sensitivity to support commenter's statement that there was "ample opportunity" for neurological and reproductive effects to be observed in the few short-term and single 90-day rodent test, which did not specifically examine these critical endpoints. EPA also noted in the Support Document:

"However, there is some concern that TBBPA may have endocrine disruptor effects because the parent compound, Bisphenol A, has demonstrated estrogenic activity in rodents. Such subtle effects have not been captured in the available studies of TBBPA."

Therefore, while EPA is not listing TBBPA under EPCRA section 313 based on human health concerns, this determination should not be considered as an indication that TBBPA has no potential for adverse human health effects since so little data is available.

Commenter List: C-1919

Comment: The commenter attacks two introductory sentences in the background section of EPA's hazard assessment for TBBPA. The two sentences were:

Exposure of the general human population to TBBPA is thought to be limited. TBBPA, when found in the environment, is generally detected in the soil and sediments. TBBPA has also been detected in fish and shellfish that could be used as food.

The commenter states TBBPA was found only once in the U.S. in air. The commenter states TBBPA is not detected in fish and shellfish. The commenter also states that it is "inappropriate" for EPA to use data from sites outside the U.S.

Response: EPA disagrees with the commenters statements. The two hazard assessment introductory sentences from the human and ecological toxicity discussion were perhaps oversimplified by EPA, since the purpose of these two general statements was to put the toxicological data in perspective, not a thorough discussion of environmental fate and transport. However, EPA's conclusions remain the same since the information that the commenter objects to was not used to make any determinations regarding the listing of TBBPA under EPCRA section 313 or its classification as a PBT chemical.

Because the two sentences were just general background information, the WHO Environmental Health Criteria document from which the information was taken was not specifically cited by EPA. To clarify, EPA has expanded the two sentences:

Based on chemical and physical properties, TBBPA would be expected to partition to soils and sediments in the environment. TBBPA has been detected in these environmental media in Japan and Sweden, but no studies in the U.S. were available. It is believed methylated derivatives of TBBPA result from microbial biotransformation of TBBPA released to the environment. Methylated TBBPA has been detected in fish and shellfish samples in Japan. No studies of fish and shellfish in the U.S. were located (WHO, 1995). Therefore, it is possible that humans and ecological receptors could be exposed to TBBPA or its methylated derivatives, directly in soils and sediments and in fish or shellfish from contaminated areas used as food.

The commenter points out the lack of any data for the U.S. as if it were the same as evidence that TBBPA does not occur in the sediment, soil or biota here. Neither the commenter or any other source has conducted relevant tests in the U.S that EPA is

aware of. EPA does not believe it is significant that TBBPA was detected in the U.S. only in air samples because there is only one report with only one medium in the only time TBBPA was investigated. The commenter did not present reports of negative findings for sediments, soils and biota. Similarly, the lack of detection of TBBPA in fish and shellfish is a moot point given methylated derivatives were detected. EPA also believes that results from Japan and Sweden do have relevance to the U.S., since the physical and chemical properties of compounds that govern environmental fate and transport do not change with manmade national boundaries. Furthermore, Japan has diverse ecosystems similar to many areas of the U.S. from the Alpine north to the semi-tropical south.

Comment: The same commenter provides comments on the persistence and bioaccumulation of TBBPA and contends that there are insufficient data to conclude that TBBPA meets the listing criteria of EPCRA section 313(d)(2)(C)(ii) and 313(d)(2)(C)(iii).

Response: These two sections deal with EPA's authority to add a chemical based on its "toxicity and persistence in the environment" and its "toxicity and tendency to bioaccumulate in the environment" respectively. However, the commenter does not contend that TBBPA does not meet the listing criteria of EPCRA section 313(d)(2)(C)(i) which deals with EPA's authority to add a chemical base on its "toxicity" without consideration of persistence and bioaccumulation. As discussed elsewhere in these comment responses for TBBPA, EPA believes that TBBPA is persistent and bioaccumulative. However, EPA did not propose to added TBBPA to the EPCRA section 313 list of toxic chemicals based on its persistence or bioaccumulation data and neither of these properties were mentioned in the toxicity discussion of TBBPA in the proposed rule. Rather, EPA based its listing decision on the ecotoxicity data alone which indicated that TBBPA was highly toxic even without consideration of persistence or bioaccumulation.

Based the available toxicity data, EPA has concluded that TBBPA is toxic. It has the potential to kill fish, daphnid, and mysid shrimp, among other adverse effects, based on chemical and/or biological interactions. TBBPA can cause these toxic effects at relatively low concentrations. Aquatic acute toxicity calculated values for TBBPA include a fathead minnow 96-hour LC_{50} of 0.54 mg/L, a rainbow trout 96-hour LC_{50} of 0.40 mg/L, a bluegill sunfish 96-hour LC_{50} of 0.51 mg/L, and a daphnid 48-hour LC_{50} of 0.96 mg/L; mysid shrimp 96-hour LC_{50} values ranged from 0.86 to 1.2 mg/L depending on the age of the shrimp. Aquatic chronic toxicity calculated values from a daphnia 21- day study resulted in a Maximum Acceptable Toxicant Concentration (MATC) that was between 0.30 and 0.98 mg/L (geometric mean 0.54 mg/L) based on a significant reduction in reproduction rates; a fathead minnow 35-day study resulted in a MATC that was calculated to be between 0.16 and 0.31 mg/L (geometric mean 0.22 mg/L) based on adverse effects on embryo and larval survival.

TBBPA can cause its toxic effects at these relatively low concentrations, EPA considers it to be highly toxic. Since TBBPA is toxic at relatively low concentrations EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish, daphnid, and mysid shrimp kills, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

EPA reaffirms that there is sufficient evidence for listing TBBPA on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) based on the available ecotoxicity information for this chemical. Therefore, EPA is finalizing the addition of TBBPA on the EPCRA section 313 list.

Persistence Data for Tetrabromobisphenol A. In the proposal, EPA preliminarily determined that tetrabromobisphenol A has persistence half-life values in soil of 179 to 44 days and persistence half-life values in water of 84 to 48 days. EPA received several significant comments addressing tetrabromobisphenol A's persistence and discusses them below. EPA has reviewed information and all comments received from commenters on tetrabromobisphenol A's persistence characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that tetrabromobisphenol A persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. Additional discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking (Ref. 7 of the final rule).

Commenter List: C-1919

Comment: The commenter states that EPA's determination that Tetrabromobisphenol A (TBBPA) is persistent in the environment appears to be based upon a model which uses default data, that it is difficult to interpret EPA's methodology for applying its *EQC Model Output for Toxics Release Inventory PBT Rule Chemicals*, and it therefore is not clear how EPA arrived

at the conclusion that TBBPA is persistent.

Response: EPA disagrees that it is unclear how the EQC model was used in the assessment of chemical persistence and that EPA used only default data. EPA provided discussion on the conduct of the multimedia modeling in the document titled *EQC Model Output for Toxics Release Inventory PBT Rule Chemicals*. EPA used chemical specific input data (*i.e.*, half-lives in air, soil, water, and sediment and chemical properties) where available in all multimedia modeling runs. No default data were used in lieu of chemical specific inputs. All chemical specific inputs for each chemical were listed in this document. Further, EPA explained its use of the modified EQC model not only in the support document identified earlier, but also in the preamble to the proposed rule. In its description of the modeling EPA stated:

“Multimedia mass balance models offer the most convenient means to estimate overall environmental persistence from information on sources and loadings, chemical properties and transformation processes, and intermedia partitioning. For the chemicals included in this proposed rule EPA used the [modified] EQC model...to estimate overall environmental persistence. Overall persistence estimated in this way is used as an additional factor, in conjunction with reaction half-lives for individual media, bioaccumulation/ bioconcentration factors, etc., in justifying actions proposed in this rule.”

The EQC model is based on the fugacity approach first delineated by Mackay (Ref. 31 of final rule) and subsequently applied to numerous environmental processes (Ref. 32 of the final rule). It uses an “evaluative environment” in which environmental parameters such as bulk compartment dimensions and volumes (*e.g.*, total area, volume of soil and sediment) are standardized, so that overall persistence for chemicals with different properties and rates of transformation may be compared on an equal basis (Ref. 15 of the final rule). EPA used a version of the EQC level III model (Ref. 33 of final rule) which was modified to focus on net losses by deleting model terms for advective losses (movement out of the evaluative environment of air and water potentially containing a chemical) and sediment burial (Ref. 82 of the final rule). In this version of the model only irreversible transformation contributes to net loss of a chemical.

The overall persistence obtained from this model is calculated as the total amount in the evaluative environment when steady state is achieved, divided by the total loss rate. The results thus obtained are neither an overall environmental half-life nor a compartment (or transformation)-specific half-life; rather they are equivalent to an environmental residence time. When only irreversible transformation contributes to net loss--*i.e.*, under the conditions of this version of the EQC model--overall environmental persistence times can be converted to half-lives by multiplying the former by $\ln 2$ (*i.e.*, 0.693). The overall half-life calculated in this way is for dissipation in the environment as a whole and cannot be related directly to any individual compartment.

In the analysis EPA used the highest, lowest and mean values for the ranges of half-lives for soil, air and water as inputs to the model. These half-lives were collected from the literature from scientifically sound studies and were subject to data quality standards. The overall environmental persistence half-life for TBBPA calculated based on the EQC model was greater than 2 months but less than 6 months using the longest half-lives for air, soil, water and sediment. These results support EPA’s assertion that the persistence of TBBPA in the environment will meet the EPCRA section 313 persistence criteria.

The commenter believes that TBBPA does not meet the persistence criteria for air. To support this contention the commenter refers to a study cited in a World Health Organization (WHO) document (Ref. 83 of the final rule). Specifically the commenter cites photodegradation studies that demonstrated that the half-life of TBBPA adsorbed onto silica gel exposed to UV radiation was 0.12 day in air. In addition, the commenter contends that studies of the photolysis of TBBPA in the presence of UV light and hydroxyl radicals show that TBBPA was totally degraded within 5 to 6 days with an estimated 33 hour half-life. The commenter did not provide these studies or provide references to the original studies.

Further The same commenter cites WHO EHC 172 (Ref. 83 of the final rule) for data on photodegradation to support the claim that TBBPA does not meet the persistence criteria for air. A review of the citation provided by the commenter reveals that it is a secondary reference taken from unpublished data from Bayer (Ref. 10 of the final rule). EPA was unable to review the full unpublished study to determine the quality of the data, only the summary found in the WHO document was available. In the WHO summary of the Bayer study TBBPA adsorbed onto silica gel and was exposed to ultraviolet irradiation at the 254 nanometer (nm) wavelength. Eight metabolites were detected and a half - life value of 0.12 days obtained. WHO noted that “[i]t is difficult to derive environmental conclusions from the results of these experiments”.

EPA believes that the environmental relevance of the test results is doubtful. While the experiment may demonstrate

the potential for TBBPA to undergo photodegradation under laboratory conditions, the experimental conditions, to the extent they could be determined from the short summary provided, were not environmentally relevant.

In order for a molecule to undergo photochemical change it must absorb light. It is well known that only the transitions corresponding to ultraviolet/visible light absorption are inherently energetic enough to lead to chemical reactions. The wavelengths of importance for photochemical transformations is thus ultraviolet/visible light with a wavelength of 110 - 750 nm. When environmental photochemistry at or near the earth's surface is considered, the wavelengths of light of importance are further narrowed because the stratospheric ozone layer effectively prevents UV irradiation of less than 290 nm from reaching the earth's surface. Thus, only the light of the 290 - 750 nm wavelength absorbed by a molecule can potentially lead to photochemical changes of that molecule in the environment, near the earth's surface. EPA believes that because the subject study utilized UV irradiation at the 254 nm wavelength, a wavelength that does not reach the earth's surface due to mitigation by stratospheric ozone, the half-life derived is not relevant and, therefore, cannot be used to determine the persistence of TBBPA in air.

The commenter also refers to studies of the photolysis of TBBPA in the presence of UV light and hydroxyl radicals in which TBBPA was shown to totally degrade within 5 to 6 days with an estimated 33 hour half-life. No additional information or references were provided to enable EPA to evaluate these findings for use in the characterization of the atmospheric half-life TBBPA.

The commenter contends that TBBPA's molecular structure makes it inherently biodegradable. The hydroxyl moiety on the TBBPA molecule can be readily transformed by organisms in the environment. The parent TBBPA molecule is no longer present once this biotransformation takes place. Therefore, based on TBBPA's structure alone, the Agency should consider TBBPA as unlikely to be environmentally persistent.

EPA disagrees with the statement that based on structure alone, the Agency should consider TBBPA as unlikely to be environmentally persistent. While EPA generally believes that measured values from well conducted studies are preferable to structure activity relationships (SAR) as an indicator of persistence, the Agency believes that it is possible to make some general statements about the biodegradability of TBBPA based on its structure.

Current knowledge of structure biodegradability relationships suggests that the presence of multiple bromines on an aromatic molecule adversely effects biodegradation. In fact, when the biodegradability of TBBPA is assessed with EPA structure activity relationship tools for predicting biodegradation from structure, (Refs. 46 and 47 of the final rule) the presence of multiple aromatic bromines, a carbon with four single bonds, and the molecular weight of TBBPA are all structural features that reduce biodegradability. Therefore, even if EPA were to base its assessment of the persistence of TBBPA on its molecular structure, the Agency would conclude that it is not readily biodegradable.

The commenter contends that TBBPA will not meet the persistence criteria for water, soil and sediment because TBBPA will biodegrade in these media. The commenter cites the results of several biodegradation studies as demonstrating that TBBPA is not persistent in these media. The commenter states that even though degradation studies have shown that TBBPA is not "readily biodegradable" (*i.e.*, TBBPA is not mineralized to a significant extent by sewage sludge within 28 days) there are studies that indicate it is not persistent. Specifically, in studies submitted to EPA in 1989, TBBPA has been shown to be subject to biodegradation both in soil and sediment under aerobic or anaerobic conditions; TBBPA's estimated half-life derived from these studies is 50 days. In studies submitted by the Brominated Flame Retardants Industry Panel to EPA, TBBPA also was shown to undergo degradation in a sediment/water system with an estimated half-life of 48 to 84 days. (These data were reported under the Agency's TSCA Section 4 test rule.) The commenter argues that these data demonstrate that TBBPA does not meet most widely (and internationally) accepted criteria for persistence in soil or sediments (see the discussion of persistence criteria elsewhere in these comment responses) Therefore, TBBPA should not be considered to be persistent for purposes of EPCRA Section 313.

The commenter cites additional research conducted on the biodegradation of TBBPA under aerobic and anaerobic conditions in soil (Refs. 47 of the final rule) and asserts that the data indicate that "TBBPA does not meet the most widely and internationally accepted criteria." EPA discusses its assessment of the Springborn soil biodegradation studies elsewhere in the response to comments document (Ref. 69 of the final rule). As explained earlier, the international persistence criteria are not relevant to the classification of persistence under the criteria adopted by the Agency and EPA disagrees that TBBPA should not be considered persistent because it does not meet most widely (and internationally) accepted criteria.(see the discussion of persistence criteria elsewhere in these comment responses).

The commenter makes the argument that TBBPA has been shown to be subject to biodegradation in soil and sediment under aerobic and anaerobic conditions with “estimated” half-lives of 50 days. Although the commenter derived a biodegradation half-life, the method used to do so and the validity of the value could not be determined because no supporting information was provided. EPA, questions the validity of the 50 day half-lives estimated by the commenter on those grounds.

The commenter refers to two soil grab sample studies and a sediment/water microbial system study. These studies investigated the biodegradation of TBBPA in three different soil types in the presence (aerobic) and absence (anaerobic) of oxygen, and the biodegradation of TBBPA in a system containing sediment and river water in the presence of oxygen. In the aerobic soil studies less than 6% ultimate biodegradation (complete biodegradation to CO₂) was observed over the 64 day test period. The major portion of TBBPA remained in the soil. Analysis showed after 64 days 74 to 82% TBBPA remained in a Massachusetts sandy loam soil, 36 to 40% remained in an Arkansas silt loam, and 41 to 43% remained in a California clay loam soil. Over the course of the experiments TBBPA either remained in soil undegraded, underwent minor structural changes (primary biodegradation), or to a very small extent (<6%), underwent complete biodegradation to CO₂. Individual values for evolved CO₂ in each soil type over time were not reported and biodegradation half-life values were not calculated. If it is assumed in the absence of values for CO₂ evolution at sampling times spaced evenly over the test period reported data, that TBBPA underwent a steady rate of degradation over the duration of the experiments, approximate half-lives of 44 to 179 days can be estimated (Ref. 7 of the final rule).

Biodegradation half-lives from the aerobic soil biodegradation experiments can be approximated. The half life is defined as the amount of time necessary for the destruction of half of the chemical present in the medium. Given that the duration of the soil biodegradation test is 64 days (equivalent to greater than 2 months), a chemical that undergoes less than 50 % biodegradation by the end of the test period would have a half-life of greater than 2 months and meet the EPCRA 313 persistence criteria for soil. In one of the soils in which TBBPA was tested (a Massachusetts sandy loam soil) 74 to 82% of the original TBBPA applied remained in the soil unchanged at the end of the 64 day test period. Thus, in this study, TBBPA was shown to have a half-life in soil of greater than 2 months since less than 50% degradation of TBBPA occurred in 64 days.

The biodegradation of TBBPA in the same three soils as above under anaerobic conditions in a 64 day test has also been studied. The results showed that 44 to 57 % of the TBBPA applied to soil remained undegraded in the Massachusetts sandy loam soil after a 64 day test period, 53-65 % in an Arkansas silt loam soil, and 90% in a California clay loam soil. Less than 50% destruction of the test chemical occurred over a 64 day (> 2 month) test period in all soils tested. Thus, in this study, TBBPA was shown to have a half-life in soil of greater than 2 months since less than 50% degradation of TBBPA occurred in 64 days.

Aerobic sediment water microbial test systems containing natural sediments and river water were used to measure degradation half-lives for TBBPA in 56 day experiments. Half-lives calculated for the biodegradation of TBBPA ranged from 48 to 84 days. Researchers found an apparent correlation between half-lives and TBBPA concentration, and half-lives and microbial concentrations. Thus, in this study, TBBPA was shown to have a half-life in sediment water systems of greater than 2 months when either the larger value or the mean of the two values is considered.

Further, the commenter claims that abiotic degradation of TBBPA in water also is expected. The calculated half-life of decomposition of TBBPA by UV radiation in water was 10.2 days in spring, 6.6 in summer, 25.9 in autumn, and 80.7 days in winter. Therefore, TBBPA is not expected to be persistent in water. No other information was provided.

The commenter cites WHO EHC 172 (Ref. 83 of the final rule) for data on photodegradation to support the claim that TBBPA does not meet the persistence criteria for water. In its review of the literature to evaluate the persistence of TBBPA, EPA found no information on its photodegradation in water. A review of the citation provided by the commenter reveals that it is a secondary reference taken from unpublished data from Bayer (Ref. 10 of the final rule). EPA was unable to review the full unpublished study to determine the quality of the data. Only the summary found in the WHO document was available. The Bayer study on photodegradation in water yielded calculated half-lives ranging from 6.6 days to 80.7 days with the longest half-life calculated during the winter, when solar irradiation is least intense and the shortest half-life occurring in the summer, when the solar irradiation is most intense. The commenter did not include the fact that the effect of cloud cover lengthened the calculated half life by a factor of 2. Water depth was also found to influence the direct photodegradation of TBBPA. At the surface of a water body, solar irradiation is fairly uniform, however, as depth increases, both the water itself and materials in it can attenuate the transmission of solar energy through the water column. Irradiance has been shown to decrease by greater than 90 % for both ultraviolet and visible light at a depth of 5 meters in a eutrophic lake (Ref. 52 of the final rule). EPA disagrees

with the commenter's conclusion that TBBPA photodegradation in water will be sufficiently rapid that it will not meet the persistence criteria. Based on the study cited by the commenter which includes an 80 day (> 2 month) half-life for photodegradation of TBBPA in winter, and the mitigating effects of water depth and cloud cover on rates of photodegradation, EPA believes that a half-life of greater than 2 months in water is supported. EPA, therefore asserts that based on these findings, TBBPA meets the EPCRA section 313 persistence criteria of greater than 2 months in soil and water.

Bioaccumulation Data for Tetrabromobisphenol A. In the proposal, EPA preliminarily determined that TBBPA was found to have bioaccumulation BCF values of 780; 1,200; and 3,200. EPA received one significant comment addressing TBBPA's bioaccumulation which is discussed below. EPA has reviewed the comments and information received from commenters on TBBPA's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3 of the final rule, EPA finds that TBBPA bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's support documents for this rulemaking. (Ref. 71 of the final rule).

Commenter List: C-1919

Comment: The commenter contends that the available data on TBBPA do not support its classification as a PBT chemical. The commenter argues that the oyster BCF value of 780 does not support the proposed criterion of 1,000. The commenter also notes that EPA fails to consider that TBBPA is not retained in the body once dosing stops in a BCF test and that TBBPA is rapidly eliminated. The commenter states that rapid elimination limits any potential for biomagnification. The commenter notes that only the highest chironomid BCF value (3,200) was cited by EPA and not the fact that this is from a range of 650-3,200.

Response: EPA believes that the available data do support classification of TBBPA as a PBT chemical. Measured BCF values of 780, 1,200, and 3,200 were obtained from TSCA section 4 tests with oysters, fish and chironomids, respectively. The measured BCF values of 1,200 and 3,200 for fish and chironomids respectively, clearly satisfy the EPCRA section 313 bioaccumulation criterion of 1,000. EPA is aware that TBBPA will be eliminated from the body eventually once exposure to the chemical is halted, however, continuous or intermittent exposures of TBBPA to organisms may result in significant tissue residues depending on the exposure or release scenarios. The issue of biomagnification of TBBPA is not relevant to determining if TBBPA is a PBT chemical. As discussed in Unit VI.B.3., biomagnification is not required in order to have a concern for chemicals that bioaccumulate. The highest chironomid BCF value was listed because it is considered as a worst-case indication of bioaccumulation in sediment-dwelling invertebrates.

Comment: The commenter stated that certain BCF values for TBBPA were based on 14C-residues, and therefore represent the sum total of the parent compound, any retained metabolites and assimilated carbon. The commenter states that therefore, the BCF of the parent compound may be lower since a BCF based on total amount of radiolabeled material retained may not be comparable to the BCF derived for the parent compound only.

Response: A BCF based on total amount of radiolabeled material retained may not be comparable to the BCF derived for the parent compound only, but this does not matter. In measuring BCFs it is often not known whether the chemical in question remains in the organism as the original chemical or some metabolite. The chemical does not need to remain intact in the body in order for it to be considered bioaccumulated. BCFs that are calculated represents the total of whatever the organism has bioaccumulated (and is at steady state), whether it is unmodified parent compound, or metabolites, or degradation product(s). Since chemicals may exert their toxicity through metabolites or metabolites may be the result of expressed toxicity there is no reason to exclude them in a BCF determination.

Comment: The commenter stated that in two additional studies, TBBPA's BCF ranged from a low of 20 in edible tissue (blue gill sunfish, 28 day exposure to 9.8 ug/L) to a high of 485 (carp, 8 week exposure to 8 ug/L). The commenter states that taken as whole, these data indicate that TBBPA lacks bioaccumulation potential.

Response: The test data from blue gill and carp indicate that TBBPA bioaccumulates to a lesser degree in these species, in contrast to the fathead minnow and chironomid data. This is not surprising as there may be species to species differences in bioaccumulation potential (perhaps due to metabolic differences between organisms, etc.). If this BCF data is taken to conclude that TBBPA does not bioaccumulate, you are ignoring data that indicates it does bioaccumulate significantly (above 1000) in some species and you are therefore being under protective to species that may bioaccumulate the TBBPA to significant levels.

Comment: The commenter stated that the data suggest that bioconcentration of TBBPA appeared to be a function of the interstitial water concentration which, in turn, was a function of the sediment-bound TBBPA concentrations and the sediment's total organic carbon content. The commenter stated that in both high and medium organic carbon sediments, TBBPA's BCF at concentrations ranging from 13 to 100 mg/kg sediment were at or below 1000. The commenter state that in its review of this study, EPA cited only the highest value BCF (3200) found in one sediment type and the Agency neglected to mention that the BCF observations in this sediment study ranged from 650 to 3200. Further, in the low organic carbon sediment, TBBPA concentrations of 25 mg/kg sediment resulted in a BCF of < 1000. The commenter argues that therefore, a BCF > 1000 in chironomids only should be anticipated in low organic sediments that contain large amounts of TBBPA, 30-50 mg TBBPA/kg sediment and above. The commenter stated that given that the only reported environmental sediment values are < 0.2 mg TBBPA/kg dry weight (Japan), and that in the worst case of low organic carbon sediments, 25 mg TBBPA/kg sediment resulted in a BCF of < 1000, a conclusion that TBBPA is a bioconcentration hazard in this organism cannot be supported.

Response: The data suggest that bioconcentration of TBBPA appears to be a function of the interstitial water concentration which, in turn, was a function of the sediment-bound TBBPA concentrations and the sediment's total organic carbon content. This is what you would expect for chemicals like TBBPA that partition to sediments. There should be a direct relationship between bioaccumulation and the amount of organic carbon used in the sediments with the chironomids and for TBBPA there is. The highest bioaccumulation (BCF of 3200) occurred in the test using sediments with the lowest organic carbon content. The commenter confuses the issue by talking about the reported limited environmental sediment values. However, EPA cannot discount or ignore situations where there will be sediments with low amounts of organic carbon and if the TBBPA amounts are high enough there will be significant bioaccumulation. The issue of the concentration of TBBPA in sediments is an exposure consideration and does not impact a determination that TBBPA is bioaccumulative.

Comment: The commenter stated that to date, the only studies evaluating TBBPA uptake in fish have been performed by administration of TBBPA in water (i.e., through the gills). Studies evaluating the dietary uptake of TBBPA by fish have not been performed. However, based on rat pharmacokinetic studies, only low gastrointestinal uptake of TBBPA in fish would be expected. Rapid elimination of TBBPA also is expected based on the results of fish depuration studies and rat pharmacokinetic data. Therefore, bioaccumulation of TBBPA in fish consuming chironomids which have bioconcentrated TBBPA should not occur to any significant extent.

Response: In discussing consumption of chironomids with bioaccumulated TBBPA by fish, the commenter complicates the discussion unnecessarily. If fish (fathead minnows) and chironomids separately bioaccumulate TBBPA significantly (BCF 1000 or higher), this is enough to get an idea of bioaccumulation potential. One cannot say that fish consuming chironomids with TBBPA will not in turn bioaccumulate TBBPA to significant levels because studies to determine this have not been completed. It really depends on many factors, e.g., rate of consumption of chironomids, physicochemical conditions, condition of the fish, other sources of TBBPA, etc. The issue of "rapid" depuration has been addressed previously.

3.k. Lead and lead compounds

Commenter List: C-001, C-002, C-013, C-041, C-247, C-366, C-381, C-426, C-427, C-428, C-429, C-431, C-506, C-548, C-581, C-585, C-594, C-600, C-611, C-613, C-717, C-792, C-800, C-852, C-953, C-1353, C-1409, C-1439, C-1447, C-1451, C-1454, C-1804, C-1821, C-1864, C-2103, C-2104, C-2105, C-2131, C-2262 **[Plus many other post cards and letters from private citizens]**

Comments: An extremely large number of commenters requested that EPA include lead and lead compounds as PBT chemicals and lower the reporting thresholds. Commenters cited the fact the lead is highly toxic, especially to children, and that even if lead and lead compounds do not meet the bioaccumulation criteria they should be included based on their toxicity and persistence alone. Some commenters stated that EPA should not include lead and lead compounds as PBT chemicals under EPCRA section 313. Other commenters stated that, as a metal, the characteristics of persistence and bioaccumulation that apply to organic chemicals should not apply to lead or lead compounds and thus lead and lead compounds should not be classified as PBT chemicals.

Response: EPA is addressing issues associated with lowering the reporting thresholds for lead and lead compounds in a separate rulemaking activity. EPA will respond to comments specific to lead and lead compounds in that rulemaking.

3.I. Use of predicted toxicity values for chemicals being added.

Commenter List: C-1407

Comment: One commenter stated that if EPA is going to use Quantitative Structure Activity Relationship (QSAR) equations to determine if a chemical meets the EPCRA listing criteria, then EPA should include the equations in the proposed rulemaking for review and comment.

Response: EPA did provide access to the QSAR equations used for predicting the aquatic toxicity of certain chemicals proposed for addition. EPA used the equation for neutral organic chemicals and included in the docket for the proposed rule several references that discuss these equations and even provided information on how to download copies of the program that was used. The references made available included: (1) ECOSAR (Ecological Structure Activity Relationships). Factsheet. <http://www.epa.gov/opptintr/newchms/21ecosar.htm>, (2) Meylan, W.M. and Howard, P.H., "User's Guide for the ECOSAR Class Program" Syracuse Research Corporation. Prepared for Nabholz, J.V. and Cash, G., Risk Assessment Division, U.S. Environmental Protection Agency. November 1998, and (3) Gorsuch, J.W., et. al. (eds.), SAR/QSAR in the Office of Pollution Prevention and Toxics. In: Environmental Toxicology and Risk Assessment: 2nd Volume. STP 1216.

Commenter List: C-1423

Comment: The commenter cites statements EPA made in the proposed rule including: that EPA used toxicity prediction techniques where no or insufficient actual measured data exist upon which to make a decision and that EPA added that these techniques show a high correlation between predicted and measured toxicity values. The commenter stated that it is unclear how predicted values can highly correlate with measured values that either do not exist or are insufficient in number.

Response: The correlation that EPA was referring to is the correlation with measured data that was used to evaluate how well these predictive methods estimate aquatic toxicity. Predictive techniques often undergo an analysis in which chemicals that have measured values are subjected to the predictive technique in order to determine how close the predicted values are to measured values. EPA included the following reference in the proposed rule that includes discussions of such evaluations: Gorsuch, J.W., et. al. (eds.), SAR/QSAR in the Office of Pollution Prevention and Toxics. In: Environmental Toxicology and Risk Assessment: 2nd Volume. STP 1216.

4. COMMENTS RELATED TO THRESHOLDS

The issue most frequently raised by commenters was the Agency's choice of thresholds and the factors that EPA considered in lowering the thresholds. Many commenters contended that EPA should not consider burden in choosing thresholds. They believe that EPA should set a threshold of 10 pounds for PBT chemicals and 1 pound for that subset of PBT chemicals that are both highly persistent and highly bioaccumulative. Some commenters believe that EPA should set a threshold of 1 pound for all chemicals that are PBT chemicals. Numerous commenters believe that the threshold for reporting should be zero. Other commenters believe that burden should have been a greater consideration in EPA's choice of reporting thresholds. Many of these commenters believe that EPA should set thresholds based on some percentage of releases that would be reported.

EPA disagrees with these commenters. As explained in the proposal, the Agency considered a number of factors to determine the appropriate thresholds that should be established for these chemicals. EPA relied on the language of EPCRA sections 313(f)(2) and (h), and the legislative history to elicit the following principles to guide its exercise of discretion in lowering the thresholds, and in selecting the specific thresholds for PBT chemicals: (1) the purposes of EPCRA section 313; (2) the "verifiable, historical data" that convinces EPA of the need to lower the thresholds; (3) the chemical properties shared by the members of the class of toxic chemicals for which EPA is lowering the thresholds—*i.e.*, the degree of persistence and bioaccumulation; and (4) the reporting burden imposed by revised thresholds to the extent that such consideration would not deny the public significant information from a range of covered industry sectors. Further, EPA believes that in the language of EPCRA §313, and its legislative history, Congress provided direction on the appropriate weight to allocate to each of these considerations in implementing EPCRA section 313(f)(2). These considerations underlay the entire process by which EPA determined the appropriate thresholds. But, as noted below, the Agency's choice of revised thresholds was governed, and ultimately constrained, by EPCRA section 313's overriding purpose, which is to provide government agencies, researchers, and local communities, with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems.

In general, EPA's implementation of EPCRA section 313 is guided by the statutory purposes described by EPCRA section 313(h), which provides:

The release forms required under this section are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available...to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes.

In addition to section 313(h), EPA was also guided by several statements on the principles intended to guide EPA's implementation of EPCRA section 313 made by Representative Edgar, one of EPCRA section 313's principal architects, during debate on the Conference Report. *See, Legislative History* at 5313 - 16. In the course of his statement, Representative Edgar also articulated EPCRA section 313's overriding purpose, which is

to provide a *comprehensive view of toxic chemical exposure* and, hopefully, provide a basis for more sensible and effective local, State, and national policies.

Legislative History at 5316. (emphasis added).

Based on the existing reporting requirements, the Agency believes that there are still significant gaps in the picture the TRI data provides local communities, government agencies, and researchers. One of the most significant of these gaps is a comprehensive picture of the releases and potential exposure of PBT chemicals to humans and the environment. Currently, only a very limited picture of releases and other waste management of PBT chemicals is available from the TRI data, in part, as a result of the current thresholds. For example, under the current reporting thresholds, in 1997, EPA received only 29 reports on mercury and mercury compounds, and 6 reports on PCBs. This does not present a "comprehensive view of toxic chemical exposure." In addition, information on the releases and other waste management of PBT chemicals is particularly significant because these chemicals both persist and bioaccumulate. Individually, each of these attributes has the potential to pose increased exposures to humans and the environment. Toxic chemicals possessing both attributes have the potential to pose *significant* exposures to humans and ecosystems over a longer period of time; even small amounts of PBT chemicals that enter

the environment can accumulate to elevated concentrations in the environment and in organisms, and therefore have a greater potential to result in adverse effects on human health and the environment.

As a first step in addressing the significant gap of information on PBT chemical releases and waste management, EPA considered whether to lower the reporting thresholds for PBT chemicals. EPA then looked to section 313(f)(2) for further guidance on how to proceed. Since lowering the thresholds ensures that “all facilities subject to the requirements of [section 313]” will continue to report, the requirement in section 313(f)(2) that a revised threshold obtain a “substantial majority of total releases of each chemical at all facilities subject to the requirements of this section” can be met without the need for quantitative support. Consequently, EPA looked to other sources of Congressional direction in the statute and legislative history to guide its exercise of discretion in establishing revised thresholds.

Given that there is no guidance on implementing section 313(f)(2) in the Conference Report, EPA looked to the debate on the Conference Report. In this context, Representative Edgar, stated

It is also important to clarify the intent of Congress in establishing thresholds for reporting under this section....These thresholds were designed to obtain reporting on both a *substantial majority of the Nation's toxic chemical releases and to obtain reporting from a large number of firms*. These thresholds reflect Congress' judgement that such thresholds appropriately balance the need for information against the burden on facilities required to provide such information. The EPA is authorized to revise these thresholds, but only if such revised thresholds continue to obtain reporting on a substantial majority of total releases. Any determination by the EPA regarding the ability of revised thresholds to obtain reporting on a substantial majority of releases, especially if such revised thresholds raise the statutory levels, *must be based on verifiable, historical data which presents a convincing case that the statutory levels must be revised*.

Legislative History at 5313 (emphasis added). And during the House debate, Representative Swift noted that any revised threshold “should be *designed to improve the usefulness of the reports*. It must be structured to obtain reporting on a substantial majority of the *total nationwide releases* of the toxic chemical at *all facilities covered by section 313*.” *Id.* at 5338 (emphasis added).

In determining how to structure its threshold revisions, and particularly how it would improve the usefulness of the reports, EPA also consulted EPCRA's purposes, laid out in subsection (h). In this context, EPA also considered the statements made by Senator Stafford during debate on the Conference Report:

This section also requires the Administrator to computerize the data reported on the required forms and to make these data public by various means. Successful implementation of this requirement is vital to the basic purpose of the program. *The data should be managed in the computer in such a way as to allow a wide variety of analyses. For example, it should be possible to retrieve data, not only about individual facilities, but also aggregate data organized by type of chemical, type of effect, geographic location, company name, etc. as well as combinations of these parameters....*

Legislative History at 5186 (emphasis added).

Based on this Congressional guidance, EPA reached several conclusions. First, ample “verifiable, historical data” exists to support EPA's conclusions that PBT chemicals persist for long periods of time in the environment and bioaccumulate in organisms, including humans; that this persistence and bioaccumulation can result in higher exposures to humans and the environment; and that to “obtain a substantial majority of the Nation's toxic chemical releases,” lower thresholds for PBT chemicals are warranted. For example, PCBs have been found throughout the Great Lakes in sediments, water, and aquatic organisms. Multimedia analyses indicate that the majority (80-90%) of human exposure to chlorinated organic compounds, such as PCBs comes from the food pathway, a lesser amount (5-10%) from air, and minute amounts (less than 1%) from water. Most of the data available on human exposure to PCBs in the Great Lakes come from the analyses of contaminant levels in drinking water and sport fish. The consumption of contaminated sport fish and wildlife can significantly increase human exposure to the Great Lakes critical pollutants, such as PCBs. The sport fish are exposed to PCBs by consumption of sediments and through water. (Ref. 76). See also (Ref. 77 and 75).

Further, EPA strongly believes that increased reporting on PBT chemicals will improve the usefulness of the data on these chemicals. There are currently very few reports for some of the PBT chemicals, such as mercury, mercury compounds and PCBs. The currently available data provide a distorted picture of potential exposures to humans and the environment,

because at the current thresholds only a fraction of the releases from facilities otherwise subject to EPCRA section 313 are reported. This limited reporting results in a significant underestimation of the releases from the industry sectors covered by EPCRA section 313. As such, the current data are of limited use for evaluating the potential exposures to humans and the environment of toxic chemicals that persist and bioaccumulate. Expanding the picture of releases, and therefore potential exposures, will increase the utility of all the TRI data on these chemicals. See, e.g., Economic Analysis. Unit 6.4 (Ref. 67)

On these bases, EPA determined that revising the thresholds would be an important first step in closing the information gap on PBT chemicals. The Agency then began the process of determining the appropriate levels at which to establish the revised thresholds. For a number of technical and policy reasons, EPA chose an approach focused on two classes of PBT chemicals: (1) toxic chemicals that meet the EPCRA section 313 persistence and bioaccumulation criteria discussed in Unit VI.B., i.e., those toxic chemicals that have half-lives of 2 months or greater in water/sediment or soil and that have bioaccumulation or bioconcentration factors of 1,000 and (2) the subset of PBT chemicals that are highly persistent and highly bioaccumulative, i.e., those toxic chemicals that have half-lives of 6 months or greater in water/sediment or soil and that have bioaccumulation or bioconcentration factors of 5,000 or greater.

First, for the most persistent and bioaccumulative toxic chemicals any release will lead to elevated concentrations in the environment and in organisms. EPA believes that such highly persistent and highly bioaccumulative toxic chemicals are of international, as well as national concern, because of the extent of their persistence and bioaccumulation. As discussed elsewhere in this preamble, these facts have been widely recognized; there are a number of international agreements that ban, restrict, or phase out the manufacture, use and/or release of highly persistent and highly bioaccumulative toxic chemicals.

Similarly, toxic chemicals that are persistent and bioaccumulative are of national, regional, and local concern. As discussed elsewhere in this preamble, toxic chemicals that are persistent and bioaccumulative present a significant concern to many local communities due to the proximity of the communities to industrial sources. All other things being equal, a pollutant reaches nearby populations in less time than distant ones. Thus, toxic chemicals that persist and bioaccumulate can pose significant exposures to communities and ecosystems that immediately surround industrial sources as well as those communities that are subject to regional transport.

Given the international support for the extreme limitations on the use and release of toxic chemicals that are highly persistent and highly bioaccumulative, and the significant exposures that persistent and bioaccumulative toxic chemicals can pose to both local communities and broader regions of the United States and North America, EPA believes that it is appropriate to lower the reporting thresholds for *both* (1) persistent and bioaccumulative toxic chemicals and (2) for highly persistent and highly bioaccumulative toxic chemicals. In addition, EPA believes this information is important to the public, government agencies, and researchers; for example, the information reported by facilities under the lower thresholds will help these groups assess the loading of the PBT chemicals in both local and regional ecosystems, e.g., a small lake or river or a larger ecosystem such as the Great Lakes or the Chesapeake Bay. See *also*, Economic Analysis at 6-32 - 6-50 (Ref. 67) for examples of other uses of TRI data.

Second, EPA considered how the revised thresholds would provide the information on PBT chemicals needed to assist the public to obtain "a comprehensive view of toxic chemical exposure," as well as to assist government agencies, researchers, and other persons to conduct research and to establish appropriate regulations, guidelines and standards, in accordance with the directives laid out in subsection (h). EPA determined that providing greater information on two identifiable *classes* of chemicals best achieved these ends. It is consistent with the actions of a significant number of the groups that would use this information; for example, as discussed in Unit VI.B., UNEP is in the process of negotiating an international agreement on the class of persistent organic pollutants with half-lives of 6 months and BCF/BAF values of 5000. See *also* Economic Analysis at 6-46-48 for examples of how TRI data will be used (Ref. 67). Moreover, EPA determined that data on members within the same class are more easily comparable; the members of the classes EPA established in this rulemaking share a qualitatively comparable level of concern based on their potential for increased exposure. The Agency believed that creating two distinct classes of comparable chemicals would significantly enhance the ability of researchers, government agencies, and other similar persons, to use the reports. Establishing distinct classes of comparable chemicals normalizes the subsequent years' data, providing a baseline against which data users can ascertain trends over time. Consequently researchers can more easily distinguish, and therefore track, the releases and other waste management of highly PBT chemicals, to evaluate the efficacy and progress of the policy strategies intended to address the risks of PBT chemicals, such as the Binational Great Lakes Water Quality Initiative. Finally, administrative convenience argued for establishing a limited number of alternate thresholds. As a practical matter, it would be extremely burdensome for both the Agency and the regulated community to track a variety of individual thresholds for separate chemicals. In addition, because this was only the Agency's initial rulemaking to lower

thresholds for certain PBT chemicals, EPA intended that the revised thresholds establish a set of categories that would be generally applicable to future designated PBT chemicals. All of these considerations led the Agency to conclude that it should establish two sets of revised thresholds based on two classes of PBT chemicals.

Thus, having concluded it was appropriate to focus the rulemaking on two classes of chemicals, persistent and bioaccumulative toxic chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative, EPA began the process of determining the specific thresholds that would achieve the purposes of subsections (f)(2) and (h). The intrinsic properties of PBT chemicals argue for very low thresholds. The subset of PBT chemicals that are highly persistent and highly bioaccumulative warrant, in the absence of other considerations, a threshold approaching zero. Any release of these toxic chemicals is of global concern because they can persist for long periods of time, can maintain their identity even after undergoing long range transport, and can bioaccumulate to a significant degree. As discussed above, and at length in Unit VI.B of this document, the potential impacts that can result from any release of toxic chemicals that are highly persistent and highly bioaccumulative have been widely recognized. There are a number of international agreements that ban, restrict, or phase out the manufacture, use and/or release of the most persistent and bioaccumulative toxic chemicals.

However, EPA believes that a zero threshold would be impractical. Attempting to require facilities to determine if they manufacture, process, or otherwise use any amount whatsoever of these chemicals would be extremely burdensome and perhaps technically impossible. Without an actual numerical threshold, many facilities might report some amount of these chemicals in a misguided attempt to assure compliance. This could lead to misleading and inaccurate data on the actual sources of these chemicals. EPA believes that rather than setting a zero reporting threshold it would be better to set a very low threshold that provides facilities with a clear indicator of when they are required to report. In general for purposes of EPCRA section 313, one pound is the practical equivalent of 0 for these chemicals. EPA explained these considerations in the proposed rule (64 FR 712) and has received no information from commenters that convinces the Agency to pursue a different approach.

EPA then considered the relative degree of persistence and bioaccumulation between the two classes of chemicals. EPA wanted to establish two sets of revised thresholds with the same approximate relationship to each other, as the relative exposure potentials of PBT chemicals to that subset of highly persistent and highly bioaccumulative PBT chemicals. Simply stated, chemicals with half-lives of 6 months or greater and a BAF/BCF of 5,000 or greater have a higher exposure potential than chemicals with half-lives of 2 months or greater and a BAF/BCF of 1,000 or greater. However, although, as discussed below, EPA could establish a qualitative relationship, the Agency could not reliably quantify the relative exposure potential across the board for all of the members of both classes. Therefore, in attempting to translate the qualitative exposure potential of PBT chemicals to that subset of PBT chemicals that are highly persistent and highly bioaccumulative into a qualitative *threshold* relationship, EPA considered both the attributes of these chemicals and factors specific to thresholds.

The manufacture, process, and otherwise use thresholds are not equivalent to release thresholds although, in many cases, the quantity manufactured or otherwise used will be very similar to the quantity released. Thus, even if EPA were able to quantify the relative exposure potential of PBT chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative, based on their degrees of persistence and bioaccumulation, and their inter-relationship, the Agency would not rely solely on this to select a quantitative relative *threshold* relationship between these two classes of chemicals because 1) the manufacturing, processing, and otherwise use thresholds are not equivalent to release thresholds, and 2) the quantity released, not the quantity manufactured, processed or otherwise used, is a critical factor in determining exposure.

Nonetheless, EPA believes that the relative reporting thresholds should be based to some extent upon the qualitative differential between the potential exposures that may result from releases of PBT chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative.

There is not a direct quantifiable relationship between the potential exposures that can result from equivalent releases of a toxic chemical that persists in the environment with a half-life of 6 months and that has a bioaccumulation factor of 5,000 and releases of a toxic chemical that persists in the environment with a half-life of 2 months and that has a bioaccumulation factor of 1,000. The potential exposure to humans and the environment will depend upon a number of factors, including release patterns, environment variables such as soil type, surface water chemistry, the types and distribution of flora and fauna, and fish consumption patterns. However, EPA did consider the relative differences in the potential exposures between these two classes. For example, after one year, there will be more than 15 times as much of a highly persistent chemical that remains in the environment than of a persistent chemical, all other things being equal. Similarly, fish will accumulate more than 5 times as much of the highly bioaccumulative chemical than of the bioaccumulative chemical, all other things being equal. While EPA

believes that it can qualitatively describe the relative relationship of highly persistent chemicals to persistent chemicals and the relative relationship of highly bioaccumulative chemicals to bioaccumulative chemicals, the Agency cannot at the present time, define the relative relationship of persistence and bioaccumulation between the two classes of chemicals. This is in large part due to the many variables that must be considered in determining the potential exposures both due to the interaction of these chemical attributes and the large number of environmental factors that must be considered when evaluating persistence and bioaccumulation together.

Although EPA could not develop an exact quantitative threshold relationship between the two classes of chemicals, the Agency did consider the factors discussed above and did rely to some extent on the numerical relationships between the highly persistent and persistent chemicals and the highly bioaccumulative and bioaccumulative chemicals. Therefore, given that 1) highly bioaccumulative toxic chemicals will accumulate approximately 5 times greater than bioaccumulative toxic chemicals, 2) highly persistent toxic chemicals will remain in the environment after one year, at a level about 15 times greater than persistent toxic chemicals, 3) the fact that the EPCRA section 313 reporting thresholds are not release thresholds but that in some instances the quantities manufactured or otherwise used will be very similar to the quantity released, and 4) toxic chemicals that persist in the environment with half-lives of 2 months and bioaccumulation factors of 1,000 or greater can be of both local and regional concern, EPA believes that the threshold for PBT chemicals should be a factor of 10 greater than the threshold for that subset of PBT chemicals that are highly persistent and highly bioaccumulative. EPA believes that this ratio balances the uncertainties and factors, including numerical factors, that the Agency considered. Therefore, based on the chemicals' intrinsic characteristics, EPA would establish thresholds of one pound for that subset of PBT chemicals that are highly persistent and highly bioaccumulative and 10 pounds for PBT chemicals.

However, the legislative history of section 313(f)(2) indicates that in establishing the original thresholds, Congress recognized the burden imposed on the regulated community. Lowering thresholds necessarily will increase that burden. Therefore, EPA determined it would be reasonable to include some consideration of reporting burden in selecting thresholds for PBT chemicals. But EPA accorded less weight to burden than to the other considerations discussed above. First, neither section 313(f)(2), section 313(h), nor any other provision of EPCRA requires EPA to consider burden. Second, EPA was mindful of the fact that in several places in the legislative history Congress made clear it never intended impacts on reporting facilities to outweigh the public's right-to-know about their potential exposures to toxic chemicals. For example, although Representative Edgar recognized that Congress had considered burden in establishing the statutory thresholds, he did not include reporting burden as one of the general principles that should guide the Agency's implementation of EPCRA section 313 as a whole. Rather, he stated

This is a new Federal initiative, and I recognize the desire of some of my colleagues to move ahead cautiously to ensure that burdens imposed on industry are not excessive. Frankly, my concern rest with the families that live in the shadows of these chemical and manufacturing plants. I have put myself in their shoes and have fought for a program that looks after their needs. This legislation gets us will on the path to the full disclosure they deserve.

Legislative History at 5316. See also, *Legislative History* at 5185-86 (Senate debate on the Conference Report).

As noted in Unit VI.A, one of the major pieces of Congressional guidance on the establishment of alternate thresholds was to obtain a comprehensive picture of "total nationwide releases of the toxic chemical at all facilities covered by section 313." This language, plus other Congressional directives on implementing section 313 generally, such as section 313(h), reflect an interest in obtaining information from a broadly representative range of sources. Consequently, EPA determined that the Agency should consider burden only to the extent that it would not deny the public significant information from a range of covered industry sectors.

Therefore, EPA estimated the number of reports that would be submitted by each industry sector for four groups of thresholds, 1 and 10 pounds, 10 and 100 pounds, 100 and 1,000 pounds, and 1,000 pounds for both classes of chemicals. These options were selected for the following reasons. EPA needed a reasonable but finite number of options to evaluate, and the options described above represent a reasonable picture of the entire range of potential revised thresholds. Data limitations on the manufacturing, processing, and otherwise use of PBT chemicals in the numerous industries, processes, and uses covered by EPCRA section 313 constrained EPA's ability to make meaningful and reliable distinctions between threshold options that are less than an order of magnitude apart. For example, while EPA believes it can reliably estimate the difference in the number of reports from a 10 pound reporting threshold and a 100 pound reporting threshold, EPA believes that the data are insufficient to allow it to make a meaningful and reliable distinction in estimates of options that are closer than an order of magnitude such as 35 pounds and 50 pounds. EPA explained its data limitations in the proposal, and commenters provided no

information that would allow the Agency to increase the resolution of its analysis. Consequently, for the final rule, EPA analyzed options that were orders of magnitude apart from the two thresholds identified through its technical review: 1 pound for highly persistent and highly bioaccumulative chemicals, and 10 pounds for persistent and bioaccumulative chemicals.

Based on information provided in the Economic Analysis for this rulemaking, at the technical reporting thresholds EPA would obtain information from a broad range of facilities (Ref. 67). The analysis showed that at a threshold of one pound, the public would obtain information from all industry sectors that are currently subject to EPCRA section 313, and that have been identified as manufacturing, processing, or otherwise using those highly persistent highly bioaccumulative toxic chemicals that are part of this rulemaking (except dioxin and dioxin-like compounds which are discussed below). At a threshold of 10 pounds, the public would obtain information from all industry sectors that are currently subject to EPCRA section 313, and that have been identified as manufacturing, processing, or otherwise using those PBT chemicals that are part of this rulemaking. At the technical reporting thresholds, the estimated costs of the additional reports filed would have totaled \$355 million in the first year, and \$193 million in subsequent years (Ref. 67). EPA considered these costs, even though it cannot quantify the value of the information obtained or lost at the various thresholds, and cannot quantify the relationship between the reporting costs and the value of the information reported, or lost, at a particular threshold.

At thresholds of 10 pounds for highly persistent and highly bioaccumulative chemicals and 100 pounds for persistent and bioaccumulative chemicals, EPA is still able to obtain a significant amount of information on both classes of PBT chemicals from a wide range of industry sectors and sources. For example, no reporting on TBBPA would be lost from any sources or industry sectors at 100 pounds, and some information on octachlorostyrene would be potentially lost from only one industry sector, pesticide manufacturing facilities. At these thresholds, EPA does, however, lose information significant to local communities; for example, EPA loses considerable reporting on mercury and mercury compounds at 10 pounds, but the loss of information is localized in a limited number of industry sectors, and the public will still obtain some reporting from all of the currently covered industry sectors. For this threshold option, EPA estimated the total burden at these thresholds to be \$191 million for the first year, and \$105 million for subsequent years (Ref. 67).

At thresholds of 100 and 1,000 pounds and higher, EPA's analysis indicated that the public, government agencies, and researchers would lose information on many of the PBT chemicals from certain industry sectors and sources. For example, at a threshold of 100 pounds for toxic chemicals that are highly persistent and highly bioaccumulative, the Agency would not obtain reporting on mercury and mercury compounds generated in boilers in the manufacturing sector or information on octachlorostyrene from the primary metal industries. However, at these thresholds, EPA estimated the total first year costs to be \$99 million and \$55 million in subsequent years (Ref. 67).

These analyses led EPA to several conclusions. First, thresholds of 10 pounds for highly persistent and highly bioaccumulative chemicals and 100 pounds for persistent and bioaccumulative chemicals, achieve a significant reduction in reporting burden. Second, at these thresholds EPA obtains information from a broad distribution of industry sectors. Although EPA also loses information significant to local communities at these thresholds, it maintains the overall distribution of reporting from a broad range of industry sectors nationally. EPA could have attempted to compensate for the community-level loss of information on individual members of the classes of PBT chemicals, (*i.e.*, by establishing separate thresholds of 1 pound or 10 pounds for individual chemicals), but only by failing to take reporting burden into account for those individual chemicals. As explained previously, the availability of the data limited EPA's ability to distinguish meaningfully between thresholds separated by less than an order of magnitude. In addition, establishing separate thresholds would sacrifice many of the benefits of receiving information from comparable facilities using comparable chemicals, discussed earlier in this Unit. Thus greater information for local communities would be achieved at the expense of the increased utility of the reports for other purposes established under EPCRA section 313(h)--*e.g.*, assisting governmental agencies, researchers, agencies and other persons in the conduct of research and data gathering; and aiding in the development of appropriate regulations, guidelines, and standards. EPA believes that, to be consistent with the overriding policy directive in subsection (h), it must achieve a balance between improving the utility of the reports for all of the groups that rely on TRI data. Finally, as noted earlier in this Unit, administrative convenience argues against the establishment of individual thresholds. Among other issues, it would be burdensome on both EPA and the regulated community to track a variety of separate thresholds. Moreover, EPA intends the revised thresholds established in this rulemaking for the two classes of PBT chemicals to be generally applicable to future members of the two classes; absent a strong policy concern to the contrary, it would ultimately be inconsistent with the purposes of EPCRA section 313 for chemicals that share such common characteristics to have vastly different thresholds.

Therefore, EPA believes its selection of thresholds of 100 pounds for PBT chemicals and 10 pounds for that subset of PBT chemicals that are highly persistent and highly bioaccumulative, balances the purposes of EPCRA section 313 and the

Agency's desire to provide a comprehensive picture on releases and potential exposures of PBT chemicals, while factoring in an appropriate degree of the consequent impact on the regulated community.

Dioxin and dioxin-like compounds are highly persistent and highly bioaccumulative toxic chemicals. As discussed above, toxic chemicals that are highly persistent and highly bioaccumulative warrant, in the absence of other considerations, a threshold approaching zero. But, for the reasons discussed previously in this section, EPA does not believe that a zero threshold would be practical. However, because the dioxin and dioxin-like compounds are manufactured in extremely small amounts, EPA needed to select a threshold lower than that for the other highly persistent and highly bioaccumulative chemicals in order to obtain any reporting.

In choosing reporting thresholds for these chemicals, the Agency considered the extent of the information on dioxin and dioxin-like compounds that would be made available to the public, government agencies and researchers. EPA considered whether this level of information would provide them with "a comprehensive view of toxic chemical exposure," given the attributes of dioxin and dioxin-like compounds, and with "broad-based national information." At a threshold of 0.1 grams, the public would obtain information from all industry sectors that are subject to EPCRA section 313 and that have been identified in the Inventory of Sources of Dioxin in the United States (Ref. 3). EPA does not believe that a higher threshold, i.e., 1.0 grams, would provide the public with broad-based national information because there would be no information on the manufacture and release and other waste management of certain sectors. For example, at a higher threshold, EPA anticipates that there would be no reporting from pulp mills, paper mills, most ferrous foundry industries, and oil-fired utilities. At thresholds lower than 0.1 gram, there is greater coverage *within* certain industry sectors, with a concomitant significant increase in burden. EPA believes its selection of a threshold of 0.1 gram for dioxin and dioxin-like compounds balances the purposes of EPCRA section 313 and the Agency's desire to provide a comprehensive picture on releases and exposures of dioxin and dioxin-like compounds while factoring in an appropriate degree of the resultant impact on the regulated community.

4.b. Determination of Thresholds

1. EPA should set thresholds based on risk factors

C-1168, C-1419, C-1427; C-1421

Comment: Several commenters argued that EPA either should, or must, evaluate human health and environmental risks to support its revised reporting thresholds for PBT chemicals. These commenters offer a number of reasons for their argument. For example, one commenter stated that risk assessments were necessary to ensure that the public receives relevant data and to set the reporting thresholds for the dioxin and dioxin-like compound category at a level that will allow facilities to provide accurate and meaningful data. Another commenter states that any modification of the reporting thresholds established by Congress in EPCRA section 313 must be justified according to the overall purpose of the Act - to inform the public of known health risks posed by releases of toxic chemicals in their communities. EPA's proposal to require reporting of extremely low-level releases of PBT chemicals will not further this goal because EPA has not yet determined the relationship, if any, between releases of these PBT chemicals and human health. The commenter complains that the fact that a chemical persists or bioaccumulates does not, by itself, indicate a risk to human health, and cannot serve as the basis for increased reporting. Before lowering reporting thresholds, EPA must, at a minimum, identify the range of human exposures to a chemical and then convert those exposures to measures of health risk using either cancer potency factors or reference doses.

Response: EPA disagrees with commenters' claims that EPA should, or must, evaluate human health and environmental exposure and/or risks to support its revised reporting thresholds for PBT chemicals. As explained elsewhere in this response to comment document, EPCRA section 313 is not a risk-based reporting system, and that EPA believes that a risk-based approach to EPCRA section 313 reporting is at odds with the overriding policy of EPCRA section 313, which is to get information about the use, disposition, and management of toxic chemicals into the public domain, enabling users of this information to evaluate the information and draw their own conclusions about risk. Thus, not only does EPA disagree with commenters' focus on a risk-based system for EPCRA section 313 reporting, EPA also disagrees with commenters' misstatement of the overall purposes of EPCRA section 313.

EPA also believes that reporting on PBT chemicals without communicating risks relative to the reported quantities will not impact the accuracy of the data reported. Nor do commenters explain why establishing thresholds based on risk might increase the accuracy of the data reported. In contrast, as explained elsewhere, EPA does not believe that characterizing risks relative to quantities reported will increase the accuracy of information reported. Moreover, as explained elsewhere, EPA

disagrees with commenters' assumption that absent consideration of exposure or risk, the threshold levels chosen will result in the public being provided with information that is not meaningful. For example, one intent of EPCRA section 313 reporting is to move the determination of which risks are acceptable from the federal government to the communities in which the releases and other waste management occur.

2. EPA should consider releases in establishing thresholds

C-1353, C-1825, C-1836, C-1448; C- 419

Comment: Several commenters stated that EPA should establish revised thresholds based on capturing some percentage of estimated releases. One commenter stated that a methodology that considers release quantities would also be appropriate in determining thresholds for each PBT chemicals. The commenter believes EPA should examine release inventories that exist within EPA to make additional estimates for all PBT chemicals for affected industries. EPA could then determine an appropriate threshold for each PBT chemical, that would weigh quantity of chemical reported versus the burden of reporting. The commenter states that alternatively, if inventories/data do not exist, an overall methodology for development of estimated release data should be developed. Another commenter suggests that the methodology for setting reporting thresholds should be focused on the amount of additional emissions reported and consequent reductions likely to be achieved rather than the number of reports to be filed. One commenter also states that since EPA has found that "many of the PBT chemicals being addressed in today's action are manufactured as byproducts and the de minimis exemption does not apply to such chemicals," it would seem apparent that the Agency could set thresholds by utilizing TRI data for other chemicals already being reported which would be in the same streams.

Response: As explained elsewhere in response to comments, when lowering thresholds, EPA believes that the number of reports estimated to be filed under the lower reporting thresholds serves as an adequate surrogate for releases and is one consideration, among several others, that EPA used in determining the appropriate threshold levels for PBT chemicals and the subset of PBT chemicals that are highly persistent and highly bioaccumulative. There are a number of reasons EPA believes it is appropriate to use the number of reports and distribution of reporting, rather than estimating the quantity of releases, to aid in the selection of threshold levels. First, as explained in its proposal and elsewhere in this response to comment document, the statutory requirement to ensure that revisions to thresholds obtain reporting on "a substantial majority of total releases of the chemical at all facilities subject to the requirements" of section 313 can be met without the need for quantitative support about release quantities. Second, given that lowering thresholds will capture information not currently being reported, attempting to estimate releases that might be reported to guide the threshold levels chosen is impractical and not informative. As EPA explains in its proposed rule, it has not attempted to calculate total national releases to all media using any methodology, such as use of throughput data and emissions factors, because there is insufficient information currently available for these chemicals, and insufficient information on the numerous processes employed by all the sectors involved, to calculate a comprehensive and accurate release estimate for each sector. 64 FR at 718. Likewise, because there is insufficient information to estimate releases under any particular threshold, there is insufficient information to estimate the source reduction that might be achieved to address any releases that occur below existing thresholds. It is because there is a lack of facility-specific information relating to releases for these PBT chemicals under TRI and other reporting programs that EPA is lowering thresholds for PBT chemicals. EPA requested comment on whether there is a methodology that would allow the Agency to reliably calculate release estimates at the facility level. The commenters' suggestion does nothing more than restate EPA's request for comment as a policy recommendation.

In addition, EPA does not agree that it could or should set thresholds by utilizing TRI data for other chemicals already being reported which would be in the same process streams. Industries report releases as one whole number and do not distinguish releases that are the consequence of any particular activity. Thus, releases reported by facilities with multiple processes could not be traced to a particular process stream to extrapolate from one process for one chemical to the same process for a different chemical. Second, there is no necessary relationship between releases and threshold activities; stated another way, there is no general relationship between the amounts reported as released and the throughput of the chemical. Thus, it is not necessarily possible to extrapolate between releases of one chemical and throughput of another chemical. Third, because of existing thresholds or exemptions, many chemicals will not be reported. In this case, there would be no TRI data from which to extrapolate. Similarly, if the PBT chemical is by-product of a process for a chemical that is not listed, there would be no TRI data for that chemical. In sum, it would not prove useful to set thresholds using the commenter's suggested methodology.

Finally, EPA also disagrees that it should weigh the quantity of the chemical estimated to be reported versus the burden of

reporting to determine the appropriate thresholds. EPA believes that the commenter's suggestion inherently assumes that the amount reported as released for any individual facility serves as the primary benefit against which to weigh the burden of reporting. As explained elsewhere in this response to comment document and in the Economic Analysis supporting this rule, the benefits of the reporting contemplated by this rule are not measured by the quantity of PBT chemicals reported as released. Rather, EPA considers the benefits of reporting under this rule to be primarily reflected by the purposes served by reporting of information under EPCRA section 313.

C-1407

Comment: Commenters suggest that prior to finalizing any lower thresholds, EPA should "test" the feasibility of these thresholds being measurable when back calculated to typical generating processes and expected throughput volumes. For example, in order to quantify 10 pounds of polycyclic aromatic compounds incidentally manufactured in combustion gas, based on a representative amount of coal burned at typical facility, between 0.5 and 1 PPBv would need to be detected.

Response: Commenters appears to request that EPA should compare the thresholds chosen with the detectability of chemicals in streams managed at a typical facility to determine whether facilities can feasibly report information under the revised thresholds. EPA disagrees with this recommendation. There are a variety of activities through which a threshold might be triggered. That one activity does not trigger reporting or that a chemical is managed below what might be detectable limits in a single process should not control the threshold levels chosen. EPCRA section 313 covers a wide range of facilities and activities and it would be inconsistent with the purposes of reporting under EPCRA section 313 to allow a particular activity at a particular kind of facility to determine what an appropriate threshold might be for all facilities subject to reporting.

Moreover, commenter's example is not relevant because, as noted in the Economic Analysis, concentration of PACs are substantially higher in fuels than in combustion gases. Many facilities can readily determine that they exceed thresholds based on fuel consumption regardless of the amount of the toxic chemical that is coincidentally manufactured during combustion of the fuel.

C-1424; C-1421; C-1459

Comment: Several commenters state that, according to the Agency's "Economic Analysis" for this rulemaking (December 1998), no change in the PCB thresholds is needed to capture the great majority of the compound's releases to the environment.

A commenter states that the Analysis finds (at p. K-5) that 95% of all U.S. PCB emissions to air (in 1990) came from municipal, medical or hazardous waste incineration facilities. It also finds (at page K-20) that, to the extent such facilities fall within the SIC Codes subject to TRI reporting, 28 waste incineration facilities should report under the current thresholds-and only an additional 11 such facilities would report if the threshold were reduced from its current 10,000 to the proposed 10 pounds (even a further reduction to 1 pound would produce no additional reporters). Accordingly, commenters state that the great majority of PCB releases are subject to TRI reporting without any change in the reporting thresholds. If further information is needed, it should be achieved through SIC Code revisions to capture all emitters-not by threshold revisions.

Response: EPA disagrees with the commenters' conclusion that no change is needed to the PCB threshold because a "great majority" of PCB releases are already reported. First, the estimates quoted by the commenter only address air releases. Air releases are only a fraction of the data that is reported to TRI, and EPA does not believe that it is appropriate to determine thresholds based solely on air release data. Second, the air release estimates cited by the commenters are top-down estimates that were extrapolated from a limited number of studies. As EPA has discussed elsewhere in this response to comments document, there are inherent uncertainties in such estimates, and they are not appropriate for setting EPCRA section 313 thresholds. Nor does such data serve as an adequate substitute for information collected under EPCRA section 313. Finally, as addressed elsewhere in this response to comment document, EPA is revising thresholds for PBT chemicals because the existing information is insufficient given the persistent and bioaccumulative nature of these chemicals. Even information on small quantities of releases and other waste management are important for PBT chemicals.

EPA agrees that there are facilities that are not covered by EPCRA section 313 that are likely to release and manage PBT chemicals. EPA also agrees that it may be appropriate at some later date to add facilities that are not currently covered to capture additional information on PBT chemicals. However, EPA disagrees that it must or should add these facilities before lowering thresholds for PBT chemicals. As explained throughout the response to comment document, EPA believes it is appropriate to lower the existing statutory thresholds for PBT chemicals given the persistent and bioaccumulative nature of these chemicals.

Comment: In addition to lacking the scientific basis for singling out this group of chemicals for lowered thresholds, EPA lacks a sound policy basis for any proposed lowering of reporting thresholds. Another commenter states that if EPA is going to set a new policy precedent by attempting to lower the thresholds specified in the statute, then at a minimum the Agency must enumerate the criteria it will use to determine under what circumstances it believes it can lower a TRI threshold. EPA has not enumerated any general conditions for modifying a TRI threshold. Any changes EPA makes to the TRI program should be intended to improve the TRI program itself, not simply to use the program as a tool to advance a different, specific EPA effort. For example, reducing the reporting threshold for mercury is listed as one of 10 "key mercury action items" in EPA's Action Plan for Mercury. This sets an inappropriate policy precedent of using goals from outside the TRI context and framework to change the TRI program itself. TRI was not intended to be an "action item" or tool for targeting specific chemicals. Misusing the program in this way has the potential to cause long-term damage to the program.

Response: EPA disagrees with commenters statement that it lacks a basis choosing the chemicals it has chosen as an initial list of chemicals subject to these revised thresholds. EPA's basis for choosing these particular chemicals is discussed elsewhere in this response to comment document.

EPA also disagrees with commenters statement that EPA has no a sound policy basis for any proposed lowering of reporting thresholds for these chemicals. As explained throughout this response to comment document, EPA is lowering thresholds for PBT chemicals to address one of hte most significant gaps in the information currently reported under EPCRA section 313 – information on releases and other waste management practices relating to PBT chemicals. Addressing this gap will improve the usefulness of the range of data on these chemicals and will provide the public, government agencies, and researchers with access to critical information on PBT chemicals that can be used for many purposes, including, for example, to track the progress of national and international efforts addressing concerns about PBT chemcials. Contrary to commenters claim, it is completely appropriate and consistent with the purposes of EPCRA section 313 to revise thresholds to achieve the goals of EPA media programs and to inform other efforts relating to PBT chemicals.

EPA addresses commenters concerns regarding criteria for revising thresholds elsewhere in this response to comment.

C1860: Shouldn't this be somewhere else??

Comment: There is no discussion in the administrative record concerning the reason that substances with two-month half-lives should be considered so persistent as to require a dramatically lower TRI reporting threshold. By definition, a substance with a two month half-life has its concentration reduced to 0.02% of its original concentration through biodegradation alone after two years. In fact, the preamble seems to confuse the use of much longer half-lives as screening tools for testing to justify the use of the two-month half-life for risk management purposes. This definition defies the common sense definition of "persistent."

4.a Three-tier approach for thresholds

Commenter List: C-1407; C-1409; C-1822; C-1845; C-1855; C-1929; C-835; C-22; C-41; C-792; C-848; C-1351; C-1355; C-1409; C-1415; C-1451; C-1454; C-1823; C-1871

Comment: Several commenters suggest that EPA should establish one threshold system rather than two or three for PBT chemicals. Some commenters generally believe that the one threshold should be established for chemicals meeting the 2 month persistence and 1,000 BAF/BCF criterion while others believe that the one threshold should be established for chemicals of greater persistence and potential for bioaccumulation. Some commenters are concerned that a multi-tiered threshold approach for PBT chemicals will increase complexity, obscure and confuse the meaning of the data, and dilute attention from addressing the most important PBT issues. Numerous commenters support a two threshold approach that is based on thresholds of 1 and 10.

Response: EPA disagrees with commenters' suggestions to establish a one rather than a two threshold approach for PBT chemicals. As explained elsewhere in this Response to Comment document, EPA believes that a two threshold approach appropriately distinguishes between those toxic chemicals that are persistent and bioaccumulative and the subset of those toxic

chemicals that are highly persistent and highly bioaccumulative. This two threshold approach recognizes that the members of each class share a qualitatively comparable level of concern based on their potential for increased exposure and allows comparisons within each class of chemicals, and from year to year. EPA believes it is appropriate to establish different threshold classes for chemicals with differing levels of concern. This, among other things, enhances the ability of researchers, government agencies, and other similar persons to use the information reported to ascertain, for example, trends for similarly situated chemicals.

EPA also chose a two threshold approach rather than establishing individual thresholds for separate chemicals to avoid unduly burdensome requirements and increased complexities. As a practical matter, it would be burdensome for both the Agency and the regulated community to track a variety of individual thresholds for separate PBT chemicals. However, EPA does not believe this is the case for a two threshold approach for PBT chemicals. Any incremental potential burden or complexity that might be caused by establishing two rather than one threshold for PBT chemicals would certainly be relatively minor compared to setting separate thresholds for PBT chemicals. Moreover, EPA believes that any potential incremental burden or complexity that might be created by a two threshold approach is justified in light of the relative persistence and bioaccumulation of the chemicals within each class.

EPA disagrees with commenters concerns that this two threshold approach approach will cause confusion or dilute attention from the most important PBT issues. In fact, EPA believes that its two threshold approach will increase the utility of information generally on PBT chemicals, in part, because it will allow the data users to distinguish between the two classes of chemicals and as noted above, make trend comparisons among chemicals within the same class. In addition, it will obviously allow the data user to focus on only that subset of PBT chemicals that are highly persistent and highly bioaccumulative.

Comment: One commenter contends that EPA should not have two thresholds for PBT chemicals because there is uncertainty in the persistence and bioaccumulation data available to EPA and there is a lack of persistence and bioaccumulation data. In addition, they contend that a two tier system is a problem for chemicals such as trifluralin. Because the soil half-life data for trifluralin range from 99 to 394 days, the commenter contends that it is a difficult scientific question to determine which of the two tiers to place such chemicals.

Response: The commenter implies that the resolution of the half-lives determined from persistence data is not finer than 4 months, i.e., the uncertainty in the data does not allow a distinction between a half-life of 2 months and a half-life of 6 months. EPA disagrees with the commenter. Uncertainty always exists but does not by itself preclude or render invalid reasonable judgments based on weight-of-evidence. There are many environmental factors that can affect a substance's half-life, including but not limited to, for example, temperature, pH, sunlight intensity, hydroxyl radical concentration, and microbial activity. Which environmental characteristics are most important for a given substance largely depends on which transformation processes are most important for that substance. The net result is that there is substantial variability in environmental half-lives in both space and time, and this variability is reflected in available measured half-lives.

This complexity led the authors of a popular series of handbooks of environmental data to conclude "...it is impossible (and misleading) to document a single reliable half-life." These authors further concluded that "the best that can be done is to suggest a semi-quantitative classification of half-lives into groups, assuming average environmental conditions to apply." However, there is no such thing as average environmental conditions, nor is it possible to meaningfully compare qualitative or semi-quantitative judgments about half-lives to numerical persistence criteria. It is for this reason that EPA used an approach similar to the one used in Howard et al. [1], a handbook that is cited as the source for much of the data contained in the Mackay handbooks. The EPA approach, summarized in the proposed rule and described in more detail in the support document available in the public docket [2], requires collecting and reviewing all or sufficient relevant persistence data to characterize quantitatively a range of half-lives for each medium and substance, which fairly represents the range of actual values seen in existing data. This "reasonable range" of half-lives (language in the proposed rule) represents the balance of the preponderance of evidence ("weight of evidence") and is the method EPA used to characterize persistence.

Further, the commenter contends that this is a problem for trifluralin because the half-lives for trifluralin range from 2 months or greater but less than 6 months to 6 months or greater. Given that EPA does not agree with the commenter's conclusions regarding the resolution of the half-lives determined from persistence data, EPA cannot agree that the Agency cannot determine whether the half-life of a chemical in a medium is 2 months or greater but less than 6 months or if the half-life is 6 months or greater. Nor, as discussed in the preamble to the proposed rule (64 FR 705-6), does EPA believe that it is problematic that there is a range of half-lives. When EPA assesses the persistence of a toxic chemical, the Agency considers the type of studies conducted, assesses the quality of the studies, multimedia modeling. The Agency uses these factors to determine

which data and half-life or narrow range of half-lives best represent the persistence of the chemical. This analysis is conducted regardless of the range of half-lives observed in the various studies. EPA believes that this analysis is no less supportable if the range of half-lives bracket the 2 month criterion or the 6 month factor.

References

1. Howard PH, RS Boethling, WF Jarvis, WM Meylan and EM Michalenko. 1991. *Handbook of Environmental Degradation Rates*. Chelsea, MI: Lewis.
2. Aronson D, H Printup, K Shuler and P Howard. 1998. Chemical Fate Half-Lives for Toxics Release Inventory (TRI) Chemicals. Syracuse Research Corporation report SRC TR 98-008, prepared under U.S. EPA contract 68-D5-0012, 30 July 98.

4.c. Comments on EPA's Specific Threshold Options

Comment supporting 1 and 10 lb option

C-22, C-41,C-537, C-554,C-792, C-848, C-1351, C-1355, C-1409, C-1415, C-1451, C-1454, C-1823, C-1871, C-1899, C-1932.

Comment: Several commenters stated their support for the 1 and 10 pound reporting thresholds. One commenter stated that the one and ten pound reporting threshold in Option 1 would capture twice as many facilities, and thousands of pounds of chemicals, that would have gone unreported under the other options. This threshold would maximize the public's access to information. If EPA and states are truly convinced that PBT chemicals are of concern and that small quantities of such chemicals are also of concern, then we need to take the necessary steps to document these releases, the affected populations, and their environment. Another commenter stated that Option 1 would assure that small quantity releases of PBT chemicals from covered facilities are disclosed to surrounding communities. Decreasing reporting burden is insufficient grounds for not having lower thresholds for chemicals of extreme concern than were proposed. Another reason that EPA should adopt the lower reporting thresholds for the persistent and highly persistent chemical categories is due to the uncertainty in the calculations for persistence and bioaccumulation. These calculations are based on broad generalizations and predictive equations and the lower reporting threshold number could be used as a margin of safety to help compensate for the uncertainty in the modeling. Although it may be true that the proposed thresholds would capture a greater percentage of the releases than is currently possible, the health of the environment and the health of the people of this country need to be the priorities. Due to the persistent and bioaccumulative nature of these chemicals, and the fact that chemical contamination is found in what are considered pristine areas of the Chesapeake Bay, it is imperative that the sources of these chemicals be identified.

Response: As discussed elsewhere in this Response to Comments document, for all of the reasons outlined by the commenter, it was EPA's technical judgement that these chemicals warrant thresholds of 1 and 10 pounds. However, EPA concluded that in this rulemaking it would be reasonable to include some consideration of burden. Consequently, the Agency determined that thresholds of 100 pounds for PBT chemicals and 10 pounds for that subset of PBT chemicals that are highly persistent and highly bioaccumulative, balances the purposes of EPCRA section 313 and the Agency's desire to provide a comprehensive picture on releases and potential exposures to PBT chemicals, while factoring in an appropriate degree of the consequent impact on the regulated community.

C1409

Whether they currently report to TRI or not, all facilities that have these PBTs on site will have to determine if threshold levels are met before submitting reports. When thresholds were 25,000 or 10,000 pounds, it might have been possible to know at a glance that a facility did not meet the criteria. However, even with a threshold of 100 pounds, this will likely not be the case. Industry representatives on EPA's NACEPT Toxics Data Reporting Committee have indicated that the record keeping necessary to decide if thresholds are met is often the most significant cost to a facility, rather than completing an actual TRI form. And even facilities that don't meet the thresholds will have to keep sufficient documentation to assure regulators and surrounding communities that they are in compliance with reporting requirements. It is thus extremely unlikely that the extra cost to industry created by the one and 10 pound threshold option is significantly greater than the 10 and 100 pound thresholds, and there is no reason not to implement the lower thresholds.

Response: EPA disagrees that the burden for reporting thresholds of 1 and 10 pounds is not significantly larger than the burden at 10 and 100 pounds. As shown in the economic assessment for this rule, the burden for complying with EPCRA section 313 is not due solely to compliance determinations and filling out the form. In addition to those two activities, the facility must calculate their on-site releases to the air, water, land, and underground injection, determine the quantities that they otherwise managed as waste on-site, determine the quantities that they sent off-site for recycling, energy recovery, treatment, and disposal, determine the releases due to catastrophic events, determine source reduction activities, determine the maximum on-site, and the management of on-site waste streams. There are a significant number of facilities that will not be required to make these determinations once they have determined that they do not exceed the reporting threshold.

C537:

Comment: The commenter supports the one pound/10 pound option for a number of reasons. First, the vast number of fish advisories issued due to the contamination of our fisheries with persistent and/or bioaccumulative chemicals, especially PCBs, mercury, and dioxin, points to the fact that the EPA's current programs have failed to prevent widespread environmental

contamination and loss of natural resources. So, at this point, EPA's actions must be directed not only at prevention, but at restoring America's waters. This can only be done by tracking and eventually eliminating the sources of PBTs while at the same time cleaning up existing contamination. Second, EPA does not know the relative significance of the many smaller sources of PBTs as compared to the fewer large sources of PBTs. Certainly in the case of smog, a combination of controls upon large point sources such as polluting industry as well as control of the multitude of automobiles has been necessary to reduce levels in many areas. The Agency has recently permitted boilers and other industrial furnaces to burn PCBs for disposal, a practice which will only increase the number of smaller facilities contributing to the PBT burden to the environment and to human health. By collecting information from facilities which release large and small amounts, the Agency and the public will be better able to gauge what additional pollution prevention measures would be most practical and effective. Third, PBT chemicals are pernicious and we have failed to pay sufficient attention to the danger posed by these chemicals. Because these persistent chemicals accumulate in living tissue and move through the food chain, they are able to function in the environment as ecological toxins, essentially poisoning entire ecosystems rather than creating the usual chemical damage which, while severe, is more limited in scope. Thus, much smaller reporting quantities are justified due to the chemical characteristics of these pollutants as well as their potential to cause major damage to ecological system

Response: As discussed elsewhere in this response to comments document, for all of the reasons outlined by the commenter, it was EPA's technical judgement that these chemicals warrant thresholds of 1 and 10 pounds. However, EPA concluded that in this rulemaking it would be reasonable to include some consideration of burden. Consequently, the Agency determined that thresholds of 100 pounds for PBT chemicals and 10 pounds for that subset of PBT chemicals that are highly persistent and highly bioaccumulative, balances the purposes of EPCRA section 313 and the Agency's desire to provide a comprehensive picture on releases and potential exposures to PBT chemicals, while factoring in an appropriate degree of the consequent impact on the regulated community

Comments on EPA's preferred option

C-1447, C-1869, C-2233

Comment: The commenters note their support for the following: (1) Requiring dioxin releases and other waste management activities greater than 100 micrograms to be reported; (2) lowering the reporting thresholds to 100 pounds for PBTs with persistence half-lives of 2-6 months and bioaccumulative factors of 1000-5000; and (3) lowering the reporting thresholds to 10 pounds for PBTs with persistence factors of greater than 6 months and bioaccumulative factors of over 5000.

Response: As discussed at length in its previous responses, EPA agrees that thresholds of 100 pounds for PBTs with persistence greater than 2 months and bioaccumulation values greater than 1000; and 10 pounds for that subset of PBTs with persistence of greater than 6 months and bioaccumulative values of over 5000 balances the purposes of EPCRA section 313 and the Agency's desire to provide a comprehensive picture on releases and potential exposures of PBT chemicals, while factoring in an appropriate degree of the consequent impact on the regulated community. EPA has therefore adopted this option in the final rule.

C-311

Comment: EPA's proposed two-tiered reporting threshold of 10/100 pounds seems reasonable, since less hazardous chemicals should have less stringent reporting requirements. However, EPA should consider a single threshold of 10 pounds, since the persistence and toxicity data seem to support even a 10 pound threshold and a two-tiered reporting scheme is likely to cause confusion for those reporting and using the data.

Response: EPA disagrees with commenters' suggestions to establish a one rather than a two threshold approach for PBT chemicals. As explained elsewhere in this Response to Comment document, EPA believes that a two threshold approach appropriately distinguishes between those toxic chemicals that are persistent and bioaccumulative and the subset of those toxic chemicals that are highly persistent and highly bioaccumulative. This two threshold approach recognizes that the members of each class share a qualitatively comparable level of concern based on their potential for increased exposure and allows comparisons within each class of chemicals, and from year to year. EPA believes it is appropriate to establish different threshold classes for chemicals with differing levels of concern. This, among other things, enhances the ability of researchers, government agencies, and other similar persons to use the information reported to ascertain, for example, trends for similarly situated chemicals.

C-1843

Comment: A commenter asserts that the proposed rule does not adequately support the selection of the 100 pounds/10 pounds annual reporting threshold rather than some other amount. Given other sources of chemicals, such as emissions from manmade activities not subject to the TRI program, EPA is seeking to impose a level of reporting precision on TRI-reporting facilities that would not have any practical utility. Moreover, limitations on the accuracy of estimation and analytical techniques would make it very difficult for facilities to establish whether a 10 pound or even a 100 pound threshold was exceeded or to calculate release estimates.

Response: EPA disagrees with the implication by the commenters that simply because EPCRA section 313 may not capture all the sources of releases of PBT chemicals, EPA should not attempt to capture more information from the facilities that do report under EPCRA section 313. This comment has been voiced in every major rulemaking under EPCRA section 313 but, as EPA has stated in the past, this is not an argument that EPA believes should restrict any efforts to collect additional data under EPCRA section 313. The mere fact that for some chemicals significant release sources are not captured does not in any way diminish the importance of the information or decrease the utility of the information that can be provided by those facilities that are required to report under EPCRA section 313. The TRI data base consists of the most comprehensive data base of release information available in the US. However, Congress never envisioned that TRI would capture all releases -- for example, volatile organic chemicals (VOCs) cause the formation of tropospheric ozone which causes adverse respiratory effects, including asthma. EPA has made determinations pursuant to EPCRA section 313(d)(2)(B) and (C) that these chemicals meet the statutory toxicity criteria. EPA realizes that significant releases of VOC are from mobile sources including cars and trucks. These emissions are not covered by EPCRA section 313. However, EPA believes that the public has a right to know about releases of these chemicals from factories. The fact that cars are not subject to EPCRA section 313 does not diminish the value of the information reported by facilities. For those chemicals that do have large release sources not captured under EPCRA section 313, EPA will use whatever additional data it has to assist the Agency in actions that might be taken under the Agency's PBT strategy or other EPA PBT related programs and will not rely solely on the data collected under EPCRA section 313. In addition, if there are significant sources of PBT chemicals that are not reported under EPCRA section 313, EPA will attempt to let the public know that some sources are not captured. In fact, in the most recent TRI data release documents, EPA has been providing information to the public on other sources of releases for certain EPCRA section 313 chemicals.

EPA disagrees that facilities will not be able to make threshold determinations at 10 and 100 pounds or make release and other waste management estimates. To comply with EPCRA section 313, section 313 (g)(2) states that:

[i]n order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation.

Therefore, EPCRA section 313 is clear that covered facilities that exceed the applicable thresholds must comply with the reporting requirements. They may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved." EPCRA section 313 does not, however, provide any exemption from the practice of using readily available data to comply with the reporting requirements of EPCRA section 313.

EPA believes that the information available to the typical EPCRA section 313 reporter is generally greater and/or more accessible than it was 10 years ago. With the improved estimation techniques and tools that are available to the current EPCRA section 313 reporter, EPA believes that facilities will be able to accurately estimate releases and other waste management amounts of EPCRA section 313 PBT chemicals. As discussed elsewhere in more detail, facilities have a variety of sources available to help them comply with these reporting requirements. These include the EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and other industry guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletin 1000, *NCASI's Handbook of Chemical Specific Information for SARA Title Section 313 Form R Reporting*), improved estimation techniques and emissions factors, e.g., EPA's Office of Air and Radiation estimation techniques and emissions factors such as AP-42.

Comments for all PBTs

Comments: C-1419, C-1433, C-1815, C-1825, C-1841, C-1845

Comment: Several commenters propose that EPA adopt a threshold of 100 pounds for "priority PBTs" only, and retain existing

thresholds for PBTs of lower priority. These commenters state that they oppose the creation of another, separate class of "semi-PBT" chemicals based on internationally unrecognized criteria of persistence half-life of 2 months or more and bioaccumulation factor of 1000 or more. Another commenter set a reporting threshold of 100 pounds for only those substances that: (1) Are considered highly PBT (i.e., have BAFs or BCFs of 5000 or greater and meet the 6 months persistence criterion), and (2) are not on the list of chemicals considered not bioaccumulative under the Great Lakes Water Quality Guidance. In support of this option the commenter asserts that, by focusing on the priority PBT releases, at thresholds of 100 pounds EPA will still obtain a significant number of TRI reports. Two commenters suggest that the EPA establish a threshold of at least 100 pounds for all PBT chemicals except dioxins, because they believe it represents a balance between reporting burden and the public's right to know. One commenter stated that a reporting threshold of 100 pounds, with a *de minimis* concentration of 50 ppm, is more appropriate than EPA's proposed thresholds, while still protective of the environment.

Response: EPA disagrees that a single threshold of 100 pounds for only highly PBT chemicals represents an appropriate balance between reporting burden and the public's right to know, or that it would achieve the purposes of this rulemaking. As discussed in Unit IV.A of the final rule and elsewhere in this response to comments document, for a number of reasons, EPA believes that it is appropriate in this rulemaking to lower the thresholds for both persistent and bioaccumulative chemicals, and the subset of highly persistent and highly bioaccumulative chemicals. EPA has determined that chemicals meeting EPA's criteria for both persistence and bioaccumulation warrant lowered thresholds because chemicals possessing both attributes have the potential to pose *significant* exposures to humans and ecosystems over a longer period of time; even small amounts of PBT chemicals that enter the environment can accumulate to elevated concentrations in the environment and in organisms, and therefore have a greater potential to result in adverse effects on human health and the environment. In addition, EPA determined that providing greater information on two identifiable *classes* of chemicals best achieved the purposes of EPCRA section 313.

Further, as discussed in detail elsewhere in this document, EPA believes that it would be inappropriate to adopt one threshold for PBT chemicals and to limit the PBT chemicals for which there are lower thresholds to those which meet the criteria for persistence and bioaccumulation for the international programs cited because the purposes of TRI are different the purposes of the cited international programs. The TRI was established by Congress under EPCRA section 313 in response to public demand for information on toxic chemicals being released in their communities. The TRI is national in scope, but the overriding goal is to provide information on releases to communities so that they can determine if the releases result in potential risks and to reduce risk for communities as a whole. The entire concept of TRI, and indeed other, similar pollutant release and transfer registries (PRTRs) since established in several nations, is founded on the belief that the public has the right to know about chemical usage and release in the areas in which they live, as well as the hazards that may be associated with these chemicals. This emphasis is fundamentally different from the global focus of the UNEP negotiation and residual risk. It is EPA's position that the domestic, community-based focus of TRI has important implications with regard to the criteria used to identify toxic chemicals as persistent and/or bioaccumulative, as well as the methods and models used to evaluate persistence and/or bioaccumulation.

In contrast to EPCRA section 313 which is an information collection and dissemination program, the international agreements cited by the commenters are intended to ban, restrict, or phase-out the manufacture, use and/or release of a limited set of persistent organic pollutants and certain heavy metals that are highly persistent and highly bioaccumulative. Descriptions of the purposes of the Protocol on Persistent Organic Pollutants (POPs); Convention on Long-Range Transboundary Air Pollution (LRTAP), United Nations Economic Commission for Europe (UNECE), United Nations Environmental Programme on POPs, North American Commission for Environmental Cooperation's Sound Management of Chemicals (NACEC SMOC), as well as the International Council of Chemical Associations' position on POPs are presented below. The following quotes clearly illustrate that the intent of the international agreements is narrowly focused on that subset of toxic chemicals which are of regional (e.g., North America, Europe) or global concern.

Further, EPA determined that a 100 pound threshold for the subset of highly persistent and highly bioaccumulative chemicals would not be consistent with the purposes of EPCRA section 313 because the public, government agencies and researchers would not obtain information on many of the PBT chemicals from several industry sectors and sources. For example, at a threshold of 100 pounds for toxic chemicals that are highly persistent and highly bioaccumulative, the Agency would not obtain reporting on mercury and mercury compounds generated in boilers in the manufacturing sector or information on octachlorostyrene from the primary metal industries. See also Economic Analysis, Appendices A-J and Supplemental Information on Distribution of Additional Reporting From SIC codes.

C-1168, C-1419, C-1423, C-1427, C-1861, C-1867,

Comment: Several commenters argued that EPA should raise the thresholds to 100 pounds based on the assertion that some percentage of the emissions of an individual chemical from a particular industry sector would be captured at those thresholds. For example, a commenter supported a threshold of 100 pounds for all PBTs, and noted that all mercury cell chlor-alkali facilities would be required to report mercury releases if the threshold is set at 100 pounds, which is 100 times lower than the current 10,000 pound threshold. The commenter states its belief that this is a sufficient reduction for reporting mercury releases. If after such data are collected and evaluated, a determination can be made whether further threshold reductions are appropriate. Another commenter states that a threshold of 100 pounds per year would capture over 95% of the mass emitted, yet omit the reporting burden on about 30% of U.S. power plants. The commenter states that EPA has not provided a technical, risk-based justification for the lower reporting threshold for mercury that it is proposing. Since the purpose of the TRI reporting threshold is to capture a substantial majority of the (mass of) mercury (or other substance) released (rather than a majority of sources in a category being required to report), the 10 pound per year lower limit is unnecessary. For utility plants, at a minimum, a lower reporting limit of 100 pounds per year is sufficient for public information.

Response: EPA disagrees with the commenter's methodology for selecting thresholds, and with the specific thresholds suggested. As discussed in Unit I.E. and Unit VII.A of this response to comments document, EPA did not select its thresholds by estimating releases from a particular industry sector, and then selecting the thresholds estimated to capture some specific percentage of those projected releases. As discussed at length in Unit VII.A., EPA did not have the information or methodology that would allow it to reliably estimate releases. In addition, as noted elsewhere in this response to comments document, for a number of technical and policy reasons, EPA chose not to establish separate thresholds for individual PBT chemicals, but chose to create two classes of revised thresholds that would be generally applicable for the class of PBT chemicals and that subset of highly persistent and highly bioaccumulative chemicals. Consequently, EPA does not believe it would be appropriate to rely on the impact of a particular threshold on emissions of a single chemical from one industry sector to identify and support a particular threshold.

Comment: One commenter asserts that thresholds of 10 pounds per year are not likely to result in better information to the public, but will more likely lead to misinformation and overestimation of the actual presence of PBT chemicals in particular communities because many companies will likely report, regardless of whether there is any direct evidence that PBT chemicals are in a particular product or process, in order to avoid potential enforcement by EPA. The commenter states that such potential over-reporting cannot reliably inform the public regarding the presence of the release of toxic chemicals in their communities, nor help states and other regulatory agencies to direct resources and efforts at reducing and/or elimination real risks associated with the presence of PBT chemicals in wastestreams. To avoid this conundrum, EPA should instead establish thresholds of 100 pounds for the listed PBT chemicals (except dioxin as listed in the preamble), which will provide adequate information to the public and regulators to establish priorities for reducing waste streams, while avoiding unnecessary, burdensome reporting of insignificant sources of PBT chemicals.

Response: EPA disagrees with the commenters assertion that covered facilities will or should overestimate and misreport the quantities of chemicals present to protect themselves from liability. Overestimating releases and other waste management quantities will result in information that is as misleading as information based on underestimating releases and other waste management quantities. For ten years, the TRI database has been a key tool in providing information to the public on release and other waste management quantities of toxic chemicals. Further, based on their best readily available information, facilities should report what they believe to be most accurate amounts of releases and other waste management. As EPA has explained in guidance, facilities are instructed to document their reasoning and calculations when making estimates for threshold determinations and release and other waste management calculations. (See Q&As 470 and 472-474 in the 1998 "EPCRA Section 313 Questions and Answers" document (EPA 745-B-98-004)) These records are what EPA inspectors review for enforcement actions. Just as inspectors may enforce against facilities that deliberately under-report, they may also enforce against facilities that deliberately over-report. Therefore, given that facilities should report as accurately as possible and that facilities are increasingly encouraged to reduce their release and other waste management quantities, EPA does not believe that liability concerns provide a real incentive to covered facilities to over-report these quantities.

Support for higher thresholds

C-1815, 1843

Comment: One commenters states that if EPA insists on expanding the category beyond the high priority PBTs, EPA should adopt Option 4, and establish a 1000 pound threshold for all PBTs except dioxins. Another commenter alleges that a single

annual reporting threshold for PBTs of 1,000 pounds would avoid unnecessary reporting and significantly reduce the regulatory burden (by a factor of five according to EPA's analysis), while still providing the public with an appropriate amount of information on routine releases of PBTs.

Response: EPA disagrees that a 1000 pound threshold for PBT chemicals would achieve an acceptable balance between the purposes of EPCRA section 313, the Agency's desire to provide a comprehensive picture on releases and potential exposures of PBT chemicals, while factoring in an appropriate degree of the consequent impact on the regulated community. For example, at a 1000 pound threshold, EPA would receive no reports on benzo(g, h, i)perylene from any industry sector; no reports on octachlorostyrene or hexachlorobenzene from primary metal industries, and no mercury reports from solvent recovery systems.

C-1815, C-1819, C-1832, C-1833, C-1837, C-1838

Comment: Several commenters stated that lowering the thresholds to 10 and 100 pounds, regardless of use, constitutes a three and four order of magnitude reduction in the reporting threshold, respectively, and appears extreme. The commenters suggest that a more reasonable approach might be to maintain the 10,000 pound threshold for the first reporting year for PBT's, and then lower the reporting threshold by an order of magnitude the following year if the data collected are not sufficient.

Response: EPA assumes that the commenters' request is focused primarily on the newly added chemicals; for the chemicals that are currently listed, the Agency has already effectively conducted whatever analyses the commenters appear to contemplate, in determining that it would be appropriate to lower the thresholds for the chemicals, and it is unclear what further information would be obtained from an additional year of reporting. EPA disagrees that a year of reporting for the newly added chemicals would yield information that would convince the Agency that the public did not need information on small quantities of PBT chemicals. And for the reasons discussed elsewhere in this response to comments document, EPA disagrees that a threshold of 1,000 pounds would be appropriate.

C1865

Comment: The commenter alleges that, upon examination of the results of EPA's economic analysis, EPA's rationale for its proposed thresholds is without merit. EPA's "Summary of Options Considered" table does not even include the current thresholds, but only alternative thresholds from 1 to 1,000 pounds. There is an absence of analysis of the results that EPA presents. For example, there is no explanation of why EPA considers 17,329 reports (10/100 option) "significantly more information" than 10,854 reports (100/1000 option), but does not judge 31,739 reports (1/10 option) significantly more information" than 17,329 reports. Furthermore, many of the reports are likely to be "zero reports" and thus may not provide information on releases.

Response: While the "Summary of Options Considered" table does not include the current thresholds, the economic analysis did include information on reporting at current thresholds, estimates of the reporting that would occur at current thresholds for chemicals not currently listed, or the information necessary to calculate such estimates. (This is explained in detail elsewhere in this response to comments document.) EPA has explained elsewhere that retaining the existing thresholds for PBT chemicals would exclude significant information, as many facilities would not exceed the current reporting thresholds for PBT chemicals.

EPA believes that it is obvious that the 17,329 reports predicted for the 10/100 pound option provide significantly more information than the 10,854 reports predicted for the 100/1000 pound option. However, contrary to the commenter's assertion, EPA did not conclude that the 31,739 reports predicted at the 1/10 pound option do not provide significantly more information than the 17,329 reports at the 10/100 pound option. EPA does believe that the 1/10 pound option would provide more information than the 10/100 pound option. The 1/10 pound option was EPA's preference based on technical reasons. However EPA chose to promulgate the 10/100 pound option in order to balance the additional information that would be provided as the threshold is lowered with the concomitant increase in burden. Finally, EPA has described elsewhere in this response to comments document why it gives no credence to the comments that have been submitted that many of the reports are likely to be "zero reports". While some of the reports may be on relatively small amounts, even small amounts of PBT chemicals are of concern. EPA believes that the record for the rule provides detailed explanations of EPA's data and rationale for the rule.

C-1168, C1423:

Comment: The commenter states that EPA should raise its threshold for mercury to at least 500 pounds. The commenter states that a 10 lb threshold is not necessary to capture a "substantial majority" of all mercury releases from reporting facilities and imposes an unnecessarily high burden on the regulated community. The commenter asserts a threshold as high as 500 pounds per year would capture more than 66% of all mercury releases from electric generating facilities in the country. The commenter also alleges that a threshold of 100 pounds would capture as much as 96% of the total mercury releases. Either of these alternative thresholds would relieve the regulatory burden on a significant number of electric generating facilities that have minuscule annual releases of mercury.

Response: EPA disagrees with the commenter's methodology for selecting thresholds, and with the specific thresholds suggested. As discussed in Unit I.E. and Unit VII.A of this response to comments document, EPA did not select its thresholds by estimating facilities' releases, and then selecting the thresholds estimated to capture some percentage of projected releases.

As noted elsewhere in this response to comments document, for a number of technical and policy reasons, EPA chose not to establish separate thresholds for individual PBT chemicals, but chose to create two classes of revised thresholds that would be generally applicable for the class of PBT chemicals and that subset of highly persistent and highly bioaccumulative chemicals. Consequently, EPA does not believe it would be appropriate to rely on the impact of a particular threshold on emissions of a single chemical from one industry sector to identify and support a particular threshold.

C-1421, C-1820

Comment: The commenter's stated that lower TRI thresholds for PCBs are not warranted because additional TRI reports would not provide useful data, and lower reporting thresholds would serve no risk-reduction purpose. Moreover, the level of toxicity of PCBs does not support targeting them for lower thresholds, and testing is not required for PCBs in fuel oil. As the comments of the Utility Solid Waste Activities Group explain, EPA's proposal to reduce the threshold for PCBs to 10 pounds would add as many as 9300 new facility reports on PCBs. Yet these new sources, in total, contribute at most 0.1% of all PCB releases to air. The vast majority of PCB releases are already subject to TRI reporting at existing thresholds. Thus, little additional release information will be produced by lowering the PCB, yet the burdens on industry will be substantial. The current PCB threshold should not be revised.

Response: EPA disagrees. As discussed in Unit VI.F. of the final rule and elsewhere in this response to comments, EPA does not believe that, in general, determinations under EPCRA section 313 should be made based on risk. Further, as discussed in Unit VI.B. of the final rule and elsewhere in this document, EPA does not believe that an additional toxicity criterion should be applied to EPCRA section 313 listed toxic chemicals, such as PCBs.

EPA does not believe that it should not lower the thresholds for PCBs based on the commenter's assertion that the additional reporting will "contribute at most 0.1% of all PCB releases to air." First, EPA cannot determine the actual TRI release quantities. Second TRI releases are not limited to air releases; TRI releases include releases to land, water, and underground injection. Third, TRI data are not limited to releases, but also include other waste management quantities. Finally, even if the majority of releases were subject to TRI, given the degree of persistence and bioaccumulation of PCBs, and the documentation showing that PCBs are distributed throughout the environment and have accumulated in fish and other organisms, EPA believes that the public has a right to know about even small quantities of PCBs. ⁶

⁶PCBs have been found throughout the Great Lakes in sediments, water, and aquatic organisms. Multimedia analyses indicate that the majority (80-90%) of human exposure to chlorinated organic compounds, such as PCBs comes from the food pathway, a lesser amount (5-10%) from air, and minute amounts (less than 1%) from water. Most of the data available on human exposure to PCBs in the Great Lakes come from the analyses of contaminant levels in drinking water and sport fish. The consumption of contaminated sport fish and wildlife can significantly increase human exposure to the Great Lakes critical pollutants, such as PCBs. The sport fish are exposed to PCBs by consumption of sediments and through water. (Ref. 76 in the final rule).

Comment: The commenter asserts that EPA's 10 lb mercury threshold meets neither the requirements of EPCRA section 313(f)(2), nor the criteria that EPA established in the proposed rule. The commenter characterizes EPA's proposal as creating the standard that an appropriate revised threshold captures "significantly" more information about PBT chemicals than current thresholds without imposing undue burdens on private industry. The commenter contends that EPA's proposed ten-pound threshold for mercury (l) goes far beyond what is needed to obtain significant information about mercury releases, and (2) is unnecessarily burdensome to electric utilities, one category of facilities potentially subject to mercury reporting. The commenter provided the following analysis to support these contentions: a reporting threshold of 500 pounds per year would account for 67.9% of mercury releases from utilities, more than the substantial majority required by EPCRA, while imposing reporting burdens on only 108 out of 404 such facilities. Likewise, a reporting threshold of 100 pounds per year would account for 96.3% of mercury emissions, or nearly all, while imposing reporting burdens on only 287 electric utility facilities. The commenter states that, in contrast, EPA's proposed reporting threshold of ten pounds would add information on only an additional 3.7% of mercury releases while requiring an additional 109 electric utility facilities to report. Relying on this analyses, the commenter states that a reporting threshold of 500 or 100 pounds would capture a substantial or even overwhelming majority of mercury release information while excepting significant numbers of facilities with low release levels from the onerous burdens of TRI reporting.

Response: EPA disagrees that its revised thresholds fail to meet the requirements of EPCRA section 313(f)(2). As discussed in more detail in Unit I.E, EPA interprets section 313(f)(2) to require that any revised threshold obtain a substantial majority of the total releases from facilities that are currently reporting. Because the universe of facilities under a lower threshold can logically be no smaller than the universe of facilities currently reporting, EPA's threshold meets the statutory standard. Nor does EPCRA state that a revised threshold can obtain *only* a substantial majority of total releases, and no more, which appears to be the commenter's interpretation.

Even if the commenter's numbers are correct, EPA does not believe that they would justify establishing a threshold of 500 pounds for either the class of highly persistent and highly bioaccumulative chemicals, or establishing an individual threshold of 100 for mercury. As discussed elsewhere in this response to comments document, EPA decided for a number of reasons that establishing two classes of revised thresholds for PBT chemicals would best achieve the purposes of this rulemaking and EPCRA section 313. Neither the impact on a single industry sector, nor the percent of the releases of a single chemical from a single industry sector, is in itself, sufficient to justify revising the thresholds for an entire class of chemicals. Nor, given that EPA's consideration of burden was constrained by EPCRA's overriding purposes, does the impact on the utility sector equate to the considerations that led EPA to establish a separate threshold for dioxin and dioxin-like compounds, and justify the establishment of a separate threshold for mercury. As discussed in more detail elsewhere in this response to comments document, EPA believes that there are significant quantities of mercury, and other PBTs that would not be reported at the 100 pound threshold, and therefore rejected that option.

C-1440; C-1861

Comment: Two commenters stated that the proposed threshold of 10 pounds per year for mercury is unreasonably low. The commenter stated that releases of mercury at levels as high as 890 pounds per year have not been shown to cause adverse health impacts. The commenter stated that further study is likely to prove that even higher levels of mercury do not cause adverse health impacts, and recommends that EPA adopt a threshold of 1,000 pounds.

Response: EPA disagrees. The comment is premised on the notion that EPA should set thresholds based on the level at which the releases would present a risk. The commenter appears to misunderstand that the EPCRA section 313 thresholds are activity thresholds, rather than release thresholds. EPA has not based its revised thresholds on some level of releases because there is not a clear correlation between manufacture, process, and otherwise use thresholds and a facility's releases, although, in many cases, the quantity manufactured or otherwise used will be very similar to the quantity released. The commenter provided no information to support the relationship between its 890 pound per year calculation, and its suggested 1,000 pound activity threshold. Further, as noted elsewhere in this response to comments document, as a general matter, EPA does not believe it would be consistent with the purposes of EPCRA section 313 to consider "risk" in its implementation of the statute. And even if it were, it is not clear how EPA would factor such considerations into the specific thresholds, because the quantity released, not the quantity manufactured, processed or otherwise used, is a critical factor in determining exposure, and therefore risks. Releases can vary significantly between facilities.

Finally, as discussed elsewhere in this response to comments document, EPA disagrees that with the commenter's assertion that 890 pounds per year of mercury releases would not cause adverse health impacts.

4.d. Consideration of Burden

Commenter List: C-22, C-41, C-792, C-848, C-1351, C-1355, C-1409, C-1415, C-1451, C-1454, C-1810, C-1823, C-1871, C-011, C-033, C-056, C-072, C-073, C-100, C-109, C-141, C-1892, C-2235, C-2262, C-262, C-369, C-484, C-490, C-502, C-520, C-605, C-362, C-039, C-64, C-70, C-79, C-80, C-82, C-83, C-86, C-87, C-88, C-91, C-92, C-95, C-96, C-97, C-99, C-101, C-102, C-104, C-163, C-177, C-180, C-182, C-194, C-254, C-286, C-298, C-302, C-303, C-332, C-341, C-344, C-346, C-365, C-378, C-390, C-392, C-419, C-565, C-1585, C-1588, C-1592, C-1792, C-1946, C-1947, C-1948, C-1949, C-1950, C-1951, C-1952, C-1953, C-1954, C-1955, C-1956, C-1957, C-1958, C-1959, C-1960, C-1961, C-1962, C-1963, C-1964, C-1965, C-1966, C-1967, C-1968, C-1969, C-1970, C-1971, C-1972, C-1973, C-1974, C-1975, C-1976, C-1977, C-1978, C-1979, C-1980, C-1981, C-1982, C-1983, C-1984, C-1985, C-1986, C-1987, C-1988, C-1990, C-1991, C-1992, C-1993, C-1994.

Comment: Several commenters opposed EPA's consideration of burden in selecting revised thresholds in this rulemaking, stating that EPA should select thresholds of 1 and 10 pounds, or zero. One commenter suggests that if EPA is concerned about the burden that reporting might have on small businesses and facilities, it should explicitly provide limited exemptions for the smallest facilities.

Response: EPA disagrees with the commenters. As noted in the final rule and in earlier responses, EPA believes that it is reasonable to include some consideration of burden. In selecting the specific thresholds, EPA relied heavily on the Congressional guidance in EPCRA's legislative history, and the legislative history of section 313(f)(2) indicates that in establishing the original thresholds, Congress recognized the burden imposed on the regulated community. Lowering thresholds necessarily will increase that burden. However, EPA's consideration of burden was constrained by competing Congressional guidance that EPCRA's authors never intended burden to outweigh the public's need for access to information, and by EPCRA section 313's overriding purposes, which is to provide government agencies, researchers, and local communities, with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems. Therefore, EPA only considered burden to the extent that it would not deny the public significant information from a range of covered industry sectors.

EPA's concerns are not specific to small businesses; as EPA has repeatedly stated, it is genuinely interested in achieving EPCRA's policy objectives in a manner that will not unduly burden the regulated community. With respect to the commenter's specific suggestion, as noted elsewhere in this document, EPA has limited authority to craft exemptions to EPCRA's reporting requirements.

C-1168, C-1423, C-1812, C-1405, C-1419, C-1812, C-1825, C-1869, C-1867, C-1845, C-1865, C-1817.

Comment: Several commenters supported EPA's decision to include some consideration of burden in selecting its revised thresholds. Numerous commenters urged the agency to raise its proposed reporting thresholds to a level that minimizes the impact on an individual industry sector, on the grounds that it will remove unnecessary administrative burden without resulting in detrimental environmental effects or depriving the public of meaningful information from the individual sector. One commenter also stated that it is appropriate to lower the thresholds in a way that would not be unduly burdensome on industry because the Agency must recognize that both government and regulated community resources are finite. The commenter states that neither party has the resources to chase down every molecule of every compound that could be considered a PBT. The commenter further states that methods for estimating these very low levels are subject to significant inaccuracy, and analytical testing at these concentrations is extremely expensive. Therefore, as a matter of public policy, it is prudent to consider the burden on industry as one factor when setting the reporting thresholds; burden should not be the only factor used to set reporting thresholds, but it must be one of the factors considered.

Response: EPA agrees that in this rulemaking it is appropriate to consider burden in a limited fashion as one of several factors in establishing its revised thresholds. EPA also agrees that both government and regulated community resources are finite, and has focused this rulemaking accordingly in a number of ways. But, as discussed above, and in several other responses in this document, EPA only considered burden to the extent that it would not deny the public significant information from a range of covered industry sectors. However, as further discussed in Unit VI.B. and C, EPA disagrees that it should base its selection of the specific thresholds applicable to a class of PBT chemicals, manufactured, processed, and otherwise used by a wide variety

of industry sectors, on the impact on an individual industry sector. Rather EPA estimated the total number of reports that would be filed at each threshold and weighed the associated costs in light of the information that would be obtained or lost at a particular set of threshold options. EPA considered these costs, even though it cannot quantify the value of the information obtained or lost at the various thresholds, and cannot quantify the relationship between the reporting costs and the value of the information reported, or lost, at a particular threshold.

C-1428, C-1438, C-1815, C-1825, C-1841, C-1843, C-1846.

Comment: Several commenters believe that EPA is required to consider the burden to industry resulting from lowered thresholds, and provide the following citations to support that assertion: (1) various citations to EPCRA's legislative history; (2) the Paperwork Reduction Act; (3) Executive Order 12, 866; and (4) EPA's Strategic Plan. One commenter provides a summary of the requirements of the Regulatory Flexibility Act and notes that it affirmatively directs EPA to consider and adopt less burdensome alternatives when appropriate for small businesses. Another commenter believes that EPA mistakenly cited to legislative history discussing burden in the context of EPCRA 311 and 312, not EPCRA 313, and that EPA's rationale for not considering the burden is therefore incorrect. Another commenter states that the Agency has a definite responsibility to consider the burden on industry because of the rule's costs. The commenter states that the bottom line is that this proposal significantly increases the upward trend of TRI reporting costs, and EPA has an obligation to consider alternatives that would reduce burden to the regulated community.

Response: EPA disagrees with the commenters' conclusions. It is accurate to state that EPA is required by various statutes, executive orders, and internal policies, to assess or analyze the burden of its actions; thus, to that extent, the commenters are correct that the Agency must "consider" burden under TRI. However, this does not mean that any of the above-cited statutes or policies amend EPCRA, or as a matter of law require EPA in this rulemaking to necessarily adopt a particular threshold option simply because it imposes a lower reporting burden. Neither EPCRA section 313(f)(2), nor any other provision, imposes a legal requirement on EPA to select a revised threshold based on a cost-benefit assessment, or otherwise establishes the weight that EPA must afford to the potential impacts on the regulated community in implementing EPCRA section 313. Ultimately, although EPA's interpretation of EPCRA section 313's provisions is guided by the legislative history, the legislative history cannot override the statutory language.

Specifically, as discussed above, EPA considered all of EPCRA section 313's legislative history, rather than merely the excerpts the commenters selectively quote, and believes that its interpretation reflects all of the Congressional guidance. For example, although Representative Edgar recognized that Congress had considered burden in establishing the statutory thresholds, he did not include reporting burden as one of the general principles that should guide the Agency's implementation of EPCRA section 313 as a whole. Rather, he stated

This is a new Federal initiative, and I recognize the desire of some of my colleagues to move ahead cautiously to ensure that burdens imposed on industry are not excessive. Frankly, my concern rests with the families that live in the shadows of these chemical and manufacturing plants. I have put myself in their shoes and have fought for a program that looks after their needs. This legislation gets us well on the path to the full disclosure they deserve.

Legislative History at 5316. See also, *Legislative History* at 5185-86 (Senate debate on the Conference Report). In addition, the commenter's allegation that EPA's interpretation is based on legislative history on EPCRA sections 311 and 312 is mistaken; the discussion to which EPA cited in the proposed rule follows immediately from a discussion of EPCRA sections 311 and 312, but pertains specifically to EPCRA section 313.

All of the specific legal instruments cited by the commenters do not so constrain EPA's discretion in implementing EPCRA's as to require the Agency to include costs as a necessary factor in its decisions. The PRA requires, that in order to obtain OMB approval for an information collection request, EPA demonstrate that its information collection is the least burdensome necessary for the proper performance of the agency function, that will comply with legal requirements and that will achieve programmatic objectives.

The analytical requirements of sections 603 and 604 of the RFA apply only in specified circumstances, which are not applicable to this particular rulemaking. As discussed elsewhere in this document and the final rule, EPA certified that this rule would not have a significant impact on a substantial number of small entities, and therefore the RFA's specific analytical requirements are not applicable. But in any event, the RFA does not mandate that an agency adopt the least burdensome option. In addition, sections 603-604 specifically restricts the alternatives that EPA must consider to those that are "consistent

with the stated objectives of applicable statutes.”

EO 12,866 specifically provides that the principles on which the commenters rely, only apply “to the extent permitted by law, and where applicable.” In addition, the executive order explicitly states that its direction on cost-benefit assessments do not apply when “a statute requires another regulatory approach,” and that “[e]ach agency shall tailor its regulations to impose the least burden on society, individuals, businesses of different sizes, and other entities (including small communities and governmental entities), *consistent with obtaining the regulatory objectives...*” (emphasis added).

Goal seven of EPA's Strategic Plan commits EPA to expand American's Right to Know About their Environment, and one of the enumerated strategies for accomplishing this goal is to “[c]ontinue to expand the coverage of pollutants, pollution sources, and data elements in EPA's Toxics Release Inventory.” Similarly, another section of EPA's Strategic Plan notes “PBTs are of great concern regardless of how they are managed. Reducing the presence of these chemicals will lead to safer chemical substitutions and manufacturing processes, eliminate some occupational exposures to certain chemicals of concern, and, in general, result in safer communities....EPA will reduce the toxicity of waste by focusing on reductions in persistent, bioaccumulative and toxic chemicals (PBTs).” EPA believes its actions in this rulemaking are fully consistent with its Strategic Plan, and that reading the Strategic Plan as a whole, EPA's discretion on the extent to which it is appropriate to consider burden is not foreclosed.

However, as discussed elsewhere, for a number of reasons, including the Congressional guidance contained in EPCRA's legislative history, EPA believes it has discretion to consider burden in implementing EPCRA section 313, and that it is reasonable to do so in this rulemaking, in a limited fashion as one factor in establishing its revised thresholds.

C1843, C1846

Comment: Two commenters assert that the Agency has previously considered burden in implementing the TRI program, and therefore EPA must consider burden in selecting its revised thresholds. One commenter suggests that EPA must consider burden in this rulemaking because the Agency has consistently taken account of reporting burdens as a key factor in its prior section 313 rulemakings: EPA established higher reporting thresholds for gasoline and diesel fuel at retail stations to “provide relief from annual reporting” and to “strike a balance between the value of information generated ... and the burden of generating that information;” EPA's economic analysis caused it to omit three industry sectors from its proposed rule to expand Section 313 coverage. EPA issued its rule to establish an alternate threshold for reporting in part “to offset the increased burden” of the Section 313 chemical expansion rule and the then-prospective industry sector expansion; and EPA based its initial establishment of the *de minimis* thresholds under section 313 on “the information development burden both on the part of the user and the supplier.” Another commenter questions why EPA has “shifted its position” on whether it should consider burden in the TRI program, stating that they are “unaware of any changes to the law that would support EPA's shift in position on burden.” The commenter further states that departure from a long-standing position, absent a change in law or fact, has been repeatedly viewed by the U. S. Supreme Court as legally suspect and calls into question an agency's decision. See *Motor Vehicle Manufacturers Association v. State Farm Mutual*, 463 U.S. 41 - 42 (1988).

Response: EPA disagrees with the commenter's characterization of some of its past actions. The first action referenced by the commenter was a rulemaking under EPCRA sections 311 and 312, not section 313. The commenter is similarly mistaken about the role burden played in EPA's rulemaking to add additional facilities in certain industry sectors. As EPA explained in the proposal, it did not specifically exclude three industry sectors simply because of the estimated reporting burdens on these sectors. Although EPA acknowledged that the economic analysis preliminarily identified that these industry groups could be adversely affected at a disproportionately high rate, EPA also noted its concern that “based on a preliminary review, the projected value of reporting for these industry groups is questionable. EPA continues to refine this information and explore alternatives for these industry groups.” (61 Fed. Reg. 33592). Finally, as discussed in detail elsewhere in this response to comments document, EPA disagrees with the commenter that its sole reason for promulgating the *de minimis* exemption was burden. In addition to reducing burden, the Agency adopted the *de minimis* exemption because: 1) it believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; 2) the Agency did not believe that the quantities from these low concentrations would significantly contribute to threshold determinations and release calculations at the facility; and 3) the exemption was consistent with information mandated by the OSHA hazard communication standard (HCS).

EPA also disagrees that the fact that it considered burden to some extent in prior rulemakings, necessarily compels the Agency, as a matter of law, to consider it in all rulemakings. As discussed above, and in Unit I.E., EPCRA section 313

does not compel the Agency to consider burden in its implementation of the TRI program. In individual past rulemakings, EPA considered whether it was reasonable to allow the reporting burden to influence its decision, but EPA's discretion is not therefore constrained in every subsequent rulemaking to adopt an identical decision. Even where the agency has a long-standing policy, where that Agency has a valid rationale for varying from that policy, it may do so. Notwithstanding the commenter's citation, the Court's decision in *State Farm* supports EPA's interpretation. The Supreme Court specifically held in that case that an agency may change its view "either with or without a change in circumstances," but in such cases the agency "must supply a reasoned analysis." 463 US 29, 57 (1983). Nonetheless, as discussed elsewhere in this response to comments document, EPA has included some limited consideration of burden in this rulemaking, and is consistent with the

4.e. Lower thresholds based on persistence or bioaccumulation

Commenter Number: FORM C: Individual Citizen (C0025); Blue Ridge Environmental Defense League (C0035); FORM A: Ohio BASS Chapter Federation (C0041); Blue Ridge Environmental Defense League (C0035); Coalition Against Toxics (C0118); Citizen Action (C428); FORM E: Individual Citizen (C521); Sierra Club (C537); FORM F: New Mexico State House of Representatives (C575); City Councilman, Las Vegas Nevada (C585); Gulf Restoration Network (C594); Southeast Environmental Task Force (Chicago) (C616); League of Women Voters of Louisiana (C619); US-Citizens Aviation Watch Association (C629); Tennessee Scenic Rivers Association (C631); Minnesota Office of Environmental Assistance (MOEA) (802); Grand Calumet Task Force (C1351); Ohio Environmental Council (C1355); National Environmental Trust (C1409); Cold Mountain Cold Rivers (C1415); Atlantic States Legal Fund (C1451); Ecology Center (C1454); Center for Neighborhood Technology (C1573); Save the Prairie Society (C1580); Illinois Environmental Council (C1589); Illinois Maternal and Child Health Coalition (C1590); Champaign County Health Care Consumers (C1591); US-Citizens Aviation Watch Association (C1631); Lake Michigan Federation (C1804); 22 Interest Groups (Alaska Clean Air Coalition, Alaska Center for the Environment, Environmental Working Group, Natural Resources Defense Council, Legal Environmental Assistance Foundation, Inc. (LEAF), Florida Consumer Action Network, Physicians for Social Responsibility/Atlanta, Campaign for a Prosperous Georgia, Center for Neighborhood Technology, Natural Resources Council of Maine, American Lung Association of Michigan, Michigan Environmental Council, Minnesota Center for Environmental Advocacy, Izaak Walton League of America, NJ Environmental Watch, Environmental Advocates, Ohio Environmental Council, The Oregon Clearinghouse for Pollution Reduction, Tennessee Valley Energy Reform Coalition (TVERC), Southern Environmental Law Center, VPIRG, Pollution Probe) (C1823); Bring Urban Recycling to Nashville Today (C1828); Save Our Cumberland Mountains (C1830); EDF (C1855); Chesapeake Bay Foundation (C1871); North Dakota House of Representatives (C1872); Florida Clean Power Coalition (C1899); Louisiana Labor-Neighbor Project (C1910); 20/20 Vision (C1911); American Lung Association of Tennessee (C1914); Jewish Council for Public Affairs (C1921); Physicians for Social Responsibility (C1932); numerous individual citizens.

IBM (C446); Department of Energy (C1353); RJ Reynolds (C1356); GM Worldwide Facilities Group Environmental Services (C1406); General Electric (C1421); Pentachlorophenol Task Force (C1430); Chrome Coalition (C1431); SSINA (C1431a); Copper and Brass Fabricators Council, Inc. (C1435); Chemical Specialties Manufacturers Association (C1455); Chemical Manufacturers Association (C1815); Rohm and Hass Company (1825); Eastman Chemical Company (C1841); ASARCO (C1850); Steel Manufacturers Association (C1858); American Iron and Steel Institute (C1864); American Petroleum Institute (C1865); Kodak (C1869); Brominated Flame Retardant Industry Panel of CMA (C1919);

Comment: Many commenters contend that EPA should lower the reporting thresholds in this rulemaking for toxic chemicals that are toxic and persistent or toxic and bioaccumulative. The persistence of a chemical impacts its frequency of contact with an organism through its environmental residence time and concentration in the environment. The bioaccumulative potential of a chemical represents its likelihood to concentrate in an organism, thereby increasing the level and duration of exposure. Frequency, level, duration, and timing are each important exposure parameters that deserve independent and special attention. The commenters contend that EPA does not recognize the importance of each of these chemical characteristics and that they act in different ways to increase the adverse impact of toxic chemicals. They contend that by not recognizing the importance of each of these chemical characteristics, numerous persistent toxic chemicals or bioaccumulative toxic chemicals are not included since high persistence, low bioaccumulation chemicals and high bioaccumulation, low persistence chemicals do not meet the proposal's criteria for persistence and bioaccumulation.

Other commenters contend that EPA should not lower the reporting thresholds for toxic chemicals that are persistent but not bioaccumulative or bioaccumulative but not persistent because these chemicals are unlikely to be problematic from a public health perspective.

Response: For purposes of this rulemaking, EPA is choosing to focus on certain toxic chemicals that are both persistent and bioaccumulative. However, EPA does not agree with the comment that only toxic chemicals that are both persistent and bioaccumulative are of concern. EPA agrees with those commenters who state that toxic chemicals that are persistent and those toxic chemicals that are bioaccumulative warrant lower reporting thresholds. EPA plans to address these chemicals in a future rulemaking.

4.f. Choice of threshold for the dioxin and dioxin-like compounds category

Commenter list: C-450, C-538, C-792, C-1168, C-1221, C-1354, C-1352, C-1405, C-1406, C-1407, C-1422, C-1425, C-1420, C-1427, C-1428, C-1433, C-1435, C-1436, C-1440, C-1442, C-1443, C-1453, C-1457, C-1458, C-1809, C-1812, C-1814, C-1815, C-1841, C-1843, C-1844, C-1853, C-1845, C-1856, C-1858, C-1861, C-1865, C-1868, C-2102,

Comment: Many of the commenters object to the 0.1 gram reporting threshold for dioxin because they believe that it is set too low. The commenters believe that at this level the data will be inaccurate, filled with errors, and that reporting will result in questionable data that will be misleading. The commenters also stated that a threshold at this level will result in overestimations and thus over-reporting. Two commenters argued that the 0.1 gram threshold is so low that most if not all reported release values will be hypothetical rather than real. While most commenters agreed with EPA's determination that a zero threshold would be problematic, many commenters contend that a 0.1 gram threshold is essentially a zero threshold. Some commenters contend that facilities will report some value just to make sure that they are in compliance to avoid liability. Most commenters requested that EPA set a higher reporting threshold that will allow facilities to accurately estimate their manufacture and release of chemicals in this category. Of the commenters that requested a higher threshold, most commenters did not specify what level would be appropriate. Of those commenters that did propose a higher level, most suggested that the threshold be raised to 1.0 gram or the equivalent amount in pounds. Other thresholds mentioned ranged from 100 grams to 10 pounds.

Some commenters suggested that the threshold should be based on some level of release to the environment. Several comments provided examples of how raising the reporting threshold to 1.0 gram would capture 80-90% of the releases from certain industry sectors while significantly reducing the number of facilities that would be required to report (for example, from 31 to 6). One commenter stated that it is apparent from the preamble that some method was applied to threshold determinations for other PBT chemicals and that a similar method should be applied to dioxin and dioxin-like compounds.

Another commenter states that if EPA sets the reporting threshold for the dioxin and dioxin-like compounds category at greater than 1 gram, it may still capture a substantial majority of releases from facilities subject to EPCRA section 313 reporting even though fewer reports will be submitted than if the threshold is set at 0.1 gram for this category. However, they assert, because EPA has not performed a threshold analysis on the volumes that will be reported, it is impossible to determine whether a substantial majority of the dioxin releases at a 1 gram standard would be captured.

Another commenter believes that inasmuch as the Agency's long-overdue draft report on dioxin has not yet been released, it is inappropriate to set such low thresholds of 0.1 gram at this time. One commenter questioned the scientific basis for the threshold.

Response: EPA disagrees with the commenters and believes that the 0.1 gram reporting threshold for dioxin and dioxin-like compounds is an appropriate threshold for this category. Also, contrary to one commenter's statement, EPA did apply a method to threshold selection as discussed below.

Dioxin and dioxin-like compounds are highly persistent and highly bioaccumulative toxic chemicals. As discussed above, toxic chemicals that are highly persistent and highly bioaccumulative warrant, in the absence of other considerations, a threshold approaching zero. But, for the reasons discussed in the proposed and final rules as well as elsewhere in these comment responses, EPA does not believe that a zero threshold would be practical. However, because the dioxin and dioxin-like compounds are manufactured in extremely small amounts, EPA needed to select a threshold lower than that for the other highly persistent and highly bioaccumulative chemicals in order to obtain any reporting.

In choosing reporting thresholds for these chemicals, the Agency considered the extent of the information on dioxin and dioxin-like compounds that would be made available to the public, government agencies and researchers. EPA considered whether this level of information would provide them with "a comprehensive view of toxic chemical exposure," given the attributes of dioxin and dioxin-like compounds, and with "broad-based national information." At a threshold of 0.1 grams, the public would

obtain information from all industry sectors that are subject to EPCRA section 313 and that have been identified in the Inventory of Sources of Dioxin in the United States (Ref. 3 of the final rule). EPA does not believe that a higher threshold, i.e., 1.0 grams, would provide the public with broad-based national information because there would be no information on the manufacture and release and other waste management of certain sectors. For example, at a higher threshold, EPA anticipates that there would be no reporting from pulp mills, paper mills, most ferrous foundry industries, and oil-fired utilities. At thresholds lower than 0.1 gram, there is greater coverage *within* certain industry sectors, with a concomitant significant increase in burden. EPA believes its selection of a threshold of 0.1 gram for dioxin and dioxin-like compounds balances the purposes of EPCRA section 313 and the Agency's desire to provide a comprehensive picture on releases and exposures of dioxin and dioxin-like compounds while factoring in an appropriate degree of the resultant impact on the regulated community.

The examples that certain commenters provided as to how a higher threshold would still capture a significant percentage of the releases from their industry sector may be true for a particular industry group or sector but, as explained above, this is not true for all industry sectors. As discussed above, even a 1.0 gram higher reporting threshold would result in the loss of data from entire industry sectors.

Elsewhere in the comment response for dioxin and dioxin-like compounds, EPA addresses the issues of the quality of the data, the ability to estimate releases and other waste management quantities, as well as the fact that a higher reporting threshold will not improve the accuracy of the data since it will still be based on the same measurements and estimation techniques. As discussed elsewhere in these comment responses, capturing a substantial majority of releases does not impact the selection of a lower reporting threshold.

As to the commenter that suggested that thresholds for dioxin and dioxin-like compounds not be lowered until the Agency has completed its reassessment of these chemicals, this is not necessary. As discussed elsewhere in the comment responses in this Part and in Part 2 of this document, there is nothing in the reassessment that affects the determination that these chemicals meet the EPCRA section 313 listing criteria or that would impact the lowering of the reporting thresholds.

EPA disagrees with the commenters assertion that covered facilities will or should overestimate and misreport the quantities of chemicals present to protect themselves from liability. Overestimating releases and other waste management quantities will result in information that is as misleading as information based on underestimating releases and other waste management quantities. For ten years, the TRI database has been a key tool in providing information to the public on release and other waste management quantities of toxic chemicals. Further, based on their best readily available information, facilities should report what they believe to be the most accurate amounts of releases and other waste management. As EPA has explained in guidance, facilities are instructed to document their reasoning and calculations when making estimates for threshold determinations and release and other waste management calculations. (See Q&As 470 and 472-474 in the 1998 "EPCRA Section 313 Questions and Answers" document (EPA 745-B-98-004)) These records are what EPA inspectors review for enforcement actions. Just as inspectors may enforce against facilities that deliberately under-report, they may also enforce against facilities that deliberately over-report. Therefore, given that facilities should report as accurately as possible and that facilities are increasingly encouraged to reduce their release and other waste management quantities, EPA does not believe that liability concerns provide a real incentive to covered facilities to over-report these quantities.

Commenter Number: C1443, C-1457, C-403, C-1354, C-1408, C-1419, C-1420, C-1425, C-1428, C-1436, C-1440, C-1442, C-1448, C-1450, C-1457, C-1814, C-1822, C-1836, C-1844, C-1845, C-1853, C-1856, C-1865, C-1434, C-1443

Comment: The commenters requested that the reporting thresholds for the dioxin and dioxin-like compounds category be established in terms of toxic equivalents (TEQs). Some commenters simply requested that the proposed 0.1 gram absolute weight threshold be changed to a 0.1 gram TEQ threshold. The most common suggestion commenters provided was to establish a 1.0 gram TEQ threshold, but values of 0.001 pound TEQ, 0.002 pounds TEQ and 0.00022 pounds TEQ were also suggested. Other commenters equate use of TEQ as bad data, underestimating the total amount (mass) of dioxin releases.

Response: As discussed in detail elsewhere in this response to comment document, EPA does not believe it is appropriate to establish a TEQ-based reporting threshold under EPCRA section 313. In addition, compared to the 0.1 absolute gram reporting threshold, all of the TEQ based thresholds are actually higher reporting thresholds when considered on a absolute mass basis. As discussed in the previous response, EPA does not believe that it would be appropriate to establish a higher reporting thresholds for dioxin and dioxin-like compounds.

Commenter Number: C-1420

The commenter recommends that the final rule only include those categories of facilities that have been targeted through other EPA programs as significant sources of dioxin be required to report under EPCRA section 313. They argue that EPA has invested substantial resources to identify categories of facilities that have dioxin emissions and that the TRI program should leverage that investment and limit the applicability of the EPCRA section 313 reporting requirements to those types of facilities only. Those facilities have dioxin data that will allow them to accurately report their emissions. They believe that this approach will ensure that the information that is reported under EPCRA section 313 represents actual emissions of dioxin rather than industry guesses.

Response: As discussed in more detail elsewhere in these comment responses, EPA does not believe that the reporting of dioxin and dioxin-like compounds should be limited to subset of facilities covered under EPCRA section 313 that EPA has identified as potential sources of dioxin. For one thing, this subset may not be complete, other covered facilities may be sources of dioxin. Indeed, new sources may be found as a result of the EPCRA section 313 reporting requirements, but if the only certain facilities were subject to reporting then new sources may not be found.

Commenter Number: C-1439, C-1409, C-403, C-1405, C-1419 and C-1442

Comment: One commenter (C-1442) urges EPA to clearly define the criteria for determining the reporting threshold for dioxin and dioxin-like compounds. They contend that if the rationale for the threshold is based on the possibility of adverse health effects, as the proposed rule seems to imply, then EPA should provide the supporting documentation for this position. They assert that the reportable quantity threshold for dioxin should be linked to some defined criteria, such as the likelihood of releases to cause adverse health outcomes. Otherwise, they contend, a decision to set one number for the reportable quantity threshold is as good as any other number. The commenters argue that EPA should set a much lower threshold than 0.1 gram for dioxin and dioxin-like compounds. Another commenter (C-1419) argues that the lack of a demonstrated risk basis for the proposed reporting levels is matched by the great uncertainty inherent in reporting of the very small levels of dioxins and furans to be required.

One commenter (C-1439) asserts the reporting threshold for dioxin of 0.1 grams is between 5.5 million and 600 million times higher than the acceptable human intake level established by ATSDR. Thus, if the dioxin from a single release of .099 grams were distributed evenly over the population in the Western Hemisphere, between 5,500,000 and 600,000,000 people would be exposed to unacceptable health risks from that release. Yet, they argue, under the EPA proposed rule, no one would know - because the facility would not have to report the release. The commenter contends that the harm caused by dioxins and other PBTs at such low quantities requires a reporting threshold of zero. To further support their assertion, they argue that EPA has an obligation to implement the U.S. commitments to zero discharge and virtual elimination of persistent bioaccumulative toxic compounds, dioxins are extremely potent birth defect-causing chemicals produced by incineration of PVC plastics and in certain manufacturing processes, research has shown that extremely low concentrations - 60 parts per trillion in tissue - can kill 50 percent of young lake trout, and the International Agency for Research on Cancer (IARC) recently classified the most toxic dioxin compound (2,3,7,8-TCDD) as a known human carcinogen.

Another commenter (C-1409) contends that although EPA states that it believes that the 0.1 gram threshold will capture the "majority of releases" as required under EPCRA, no documentation for this particular claim is provided. They argue that since there is no requirement under EPCRA section 313 to monitor for dioxins, many reports from facilities with throughputs greater than 0.1 gram will be estimates, subject to the same sort of guesswork for facilities with less than 0.1 gram of throughput. Actual monitoring for dioxins nationwide is sketchy at best, and EPA needs to consider that TRI will likely become the primary source of information on industrial emissions of dioxins. They believe that there is no reason to think that a facility that calculates its throughput at 0.04 gram won't have sufficient uncertainty in its calculations to make it impossible to decide what the actual number really is -- especially if the calculation is based on emission factors. Yet 0.04 gram does not round up to 0.1 gram, so this facility would not submit a Form R for dioxins. The commenter argues that a realistic approach to setting a non-zero threshold is to compare it to the smallest release value that should be *i.e.*, 0.0001 gram. This level yields a ratio of threshold to minimum release quantity of 1,000. However, it has been suggested that dioxin emissions as low as one picogram are significant, as is the case for dioxins in the United Kingdom's permit system, and as daily input of dioxins is often measured at that same level. The commenter asserts that one can assume that one picogram is a level of sufficient importance to be reported, then using the same ratio of threshold to release level of 1,000 suggests that the threshold for dioxins should be set at 1,000 picograms -- eight orders of magnitude lower than the 0.1 gram level specified by the Agency.

One commenter (C-403) asserts that at 0.1 g too much dioxin goes unreported (high cancer effects at that level) and that

the production of 99 mg of dioxin compounds would miss the reporting threshold, but the amount generated is nearly 1000 fold greater than the 100 µg (0.0001 g) release level "which EPA's proposal deems significant." They argue that this quantity will accumulate annually posing a nationwide risk to people at this toxic level, insufficiently informing and protecting the public. They further argue that the 0.1 g level is inconsistent with stated objectives. EPA has previously stated that "any release is a concern.", 64 Fed. Reg. 712. Further, industry burdens should never outweigh the need to provide this public health information, 64 Fed. Reg. 693.

Response: The basic argument that these commenters are making is that EPA must consider risk in selecting thresholds. As EPA has stated elsewhere in this response to comments document, EPA disagrees with the commenters' assertion that evidence of risk is required prior to lowering the threshold for any EPCRA section 313 chemical. Section 313(f)(2) addresses revisions to the reporting thresholds. It does not require EPA to establish prior to the lowering of reporting thresholds that releases at a particular threshold will result in specific quantitative risks. That section expressly provides that the Administrator may establish a threshold amount for a toxic chemical different from the 25,000 pound threshold for manufacturing and processing activities and the 10,000 pound threshold for otherwise use activities. The only requirement for revising the reporting threshold for a toxic chemical is that the revised threshold must obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to reporting. By lowering the threshold for PBTs, EPA meets this requirement because under the lower threshold, a substantial majority of releases currently being reported will continue to be reported. Moreover, as is evident from the estimates in the economic analysis of the number of reports at the various threshold amounts considered, a 0.1 gram reporting threshold will capture a majority of releases at covered facilities. EPA therefore did not believe that setting a lower threshold justified the burden that it would impose on the regulated community.

Commenter Number: C043, C1220, C1262, C1274, C1279, C1309, C1310, C1311, C1312, C1315, C1351, C1432, C1451, C1451, C1464, C1467, C1573, C1872, C1910, C1914, C1932, C1932, C2028, C2095, C403a, C426, C428, C429, C517, C521, C537, C671, C740, C751, C754
(Plus a very large number of comments from private citizens)

Comment: The commenters assert that EPA should establish a zero threshold for dioxin and dioxin-like compounds. Some commenters argue that the reporting threshold for dioxin is still too high and will miss a multitude of facilities releasing dioxin. One commenter (C-043) asserts that they agree with EPA that dioxin quantities below detection levels are of concern and that EPA has routinely cited "negative" or zero detection of dioxins at half the level of detection for both statistical and protective policy reasons. They argue that these assumptions are based upon the ultra high biomagnification that dioxin is capable of, dioxin's long-term persistence in the environment, as well as the complexity in measuring and calculating the toxicity of samples that may contain any combination of hundreds of dioxin and dioxin-like compounds. They contend that dioxins have never been found in quantities approaching any current EPCRA section 313 threshold levels, however, their super toxic potency at minute levels is infamous and their ubiquity in human tissue, the food chain, and the environment represents an unprecedented environmental crisis. Various EPA emission estimates for dioxins in the entire U.S. range from 3,300 to 50,000 grams from all sources. Therefore, emissions from individual facilities will hopefully never approach pounds, let alone tons. They assert that although dioxins are almost never produced intentionally, except for laboratory uses, they are almost certain to be found as an accidental by-product of all industrial processes involving chlorine compounds (production and waste treatment of PVC, pulp & paper bleaching, solvents, pesticides, etc.). The commenter therefore recommends that there be no threshold for dioxins or a zero threshold for the purposes of satisfying statutory language for TRI reporting requirements for facilities who produce, use or dispose of chlorinated substances.

Response: As discussed elsewhere in these comment responses, EPA believes that a zero threshold would be impractical. Attempting to require facilities to determine if they manufacture, process, or otherwise use any amount whatsoever of these chemicals would be extremely burdensome and perhaps technically impossible. Without an actual numerical threshold, many facilities might report some amount of these chemicals in a misguided attempt to assure compliance. This could lead to misleading and inaccurate data on the actual sources of these chemicals. EPA believes that rather than setting a zero reporting threshold it would be better to set a very low threshold that provides facilities with a clear indicator of when they are required to report. In general for purposes of EPCRA section 313, one pound is the practical equivalent of zero for these chemicals. EPA explained these considerations in the proposed rule (64 FR 712) and has received no information from commenters that convinces the Agency to pursue a different approach.

5. COMMENTS ON CHANGES TO EXISTING REPORTING REQUIREMENTS

5.a. Change to de minimis level

Comments indicating that there is no need to amend the exemption or that the rationale for the de minimis exemption is still valid

Commenter List: C-1820; (New Century Services); C-1836 (National Petroleum & Refiners Association); C-1421 (General Electric); C-1843 (SOCMA); C-1850 (ASARCO); C-1865 (American Petroleum Institute); C-1441 (Chevron); C-1422 (CPMA); C-1863 (NMA); C-1826 (NWMA)

Comment: The commenters assert that EPA has not justified why the *de minimis* exemption is no longer valid. Some commenters (C- 1843; SOCMA and C-1421; General Electric) argue that the need to be consistent with the OSHA HCS that EPA cited in the 1988 final rule continues to be relevant with regards to the burden associated with collecting these small quantities. Another commenter (C-1422; CPMA) argues that analysis and reporting have not gotten any less expensive while the resources needed for these endeavors have increased. Yet another commenter (C-1863; NMA) asserts that EPA offers little but speculation as support to eliminate the exemption for PBT chemicals.

Response: EPA disagrees. As originally explained in the 1988 final rule implementing the reporting provisions of EPCRA section 313, and subsequently discussed in the 1997 final rule adding seven new industry sectors and in the proposal to add PBT chemicals, EPA promulgated the *de minimis* exemption for several reasons. In addition to reducing burden, the Agency adopted the *de minimis* exemption because: 1) it believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; 2) the Agency did not believe that the quantities from these low concentrations would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509); and 3) the exemption was consistent with information mandated by the Occupational Safety and Health Administration's (OSHA) hazard communication standard (HCS).

The Agency does not believe, however, that the factual findings it made in 1988 can be equally applied to PBT chemicals. First, given ten years of experience with the program, the Agency believes there are many sources of information, in addition to MSDSs, available to reporters to use in making EPCRA section 313 determinations. Some of these sources of information include EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). In addition, relevant information has become much more accessible to covered facilities over the past ten years. For example, although the United States Geological Survey's U.S. Coal Quality Database has been in existence since the mid 1970s, only more recently has it been made available on the Internet. (<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>). Further, the Agency believes that it underestimated how much information covered facilities had available to them in 1988 regarding small concentrations of toxic chemicals in mixtures.

In addition, the purpose of the PBT rulemaking is to capture significantly smaller quantities of releases and other waste management activities associated with these chemicals. In 1988, EPA believed that the quantities of a toxic chemical imported, processed, otherwise used, or manufactured as an impurity in a mixture or trade name product at *de minimis* concentrations would not contribute significantly to the thresholds of 25,000 and 10,000 pounds. However, because most of the PBT chemicals addressed in this rulemaking have been shown to persist and bioaccumulate, EPA has lowered substantially the thresholds for these chemicals. At these lower thresholds, the importing, processing and otherwise use of mixtures containing below *de minimis* levels of PBT chemicals can reasonably be anticipated to significantly contribute to these lower threshold determinations. Moreover, as explained at length in the proposal at 710-14, even small releases of PBT chemicals have the potential to pose human health and environmental risks over a long period of time. The Agency, therefore, believes that there will be significant releases and other waste management of PBT chemicals resulting from the processing or otherwise use of mixtures containing PBT chemicals below the *de minimis* levels.

Finally, as explained in the 1983 final rule, OSHA chose the 1.0 and 0.1 percent concentration limits based on comments that these levels seemed to be sufficiently protective of workers and were considered to be reasonable by a number of commenters. (November 25, 1983; 48 FR 53280; at 53290) Persistence and bioaccumulation were not considered as part of the OSHA rulemaking. The HCS is designed to ensure the protection of employees exposed to mixtures containing hazardous chemicals whereas the purpose of the PBT rulemaking is to provide the public with relevant information on toxic chemicals that persist and

bioaccumulate in the environment. EPA has additional environmental considerations for the PBT rulemaking that were not considered during the promulgation of the HCS. Further, EPA disagrees that there is a need to be consistent with OSHA to reduce burden for the PBT rule. EPA is not required to be consistent with the HCS. In 1988, EPA chose to be consistent with the OSHA HCS because the Agency expected facilities to be familiar with these levels and thought that covered facilities might only have access to MSDSs for information on the content and percentage composition of toxic chemicals in mixtures. (See 53 FR 4509) However, given ten years of experience with the program, the Agency believes that facilities have other sources of information, in addition to MSDSs, available to them. Further, EPA has never instructed facilities to confine their considerations of compliance with EPCRA section 313 to MSDSs. Rather, EPA has consistently instructed facilities to use their best readily available data in determining compliance with the statute. Therefore, if a facility has better information than an MSDS regarding the concentration of a toxic chemical in a mixture, for example, product specifications indicating that the chemical is above the *de minimis* level, the facility should be using that information to comply with EPCRA section 313. Consistency with the OSHA HCS, then, does not necessarily reduce burden.

In addition, under the OSHA standard, if an employer has reason to believe that a permissible exposure limit for a component may be exceeded under the mixture's normal circumstances of use, the HCS also requires employers to list chemicals that are below the 1.0% and 0.1% thresholds. Therefore, OSHA adopted exceptions to the 1.0% and 0.1% limits under the HCS. Similarly, PBT chemicals are different from other toxic chemicals in that they may pose a more significant concern to the environment in much smaller quantities than other toxic chemicals.

Therefore, given that: 1) covered facilities have additional sources of information available to them regarding the concentration of PBT chemicals in mixtures; 2) even minimal releases of persistent bioaccumulative toxic chemicals may result in significant adverse effects and can reasonably be expected to significantly contribute to the proposed lower thresholds; and 3) the concentration levels chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to PBT chemicals.

In light of these facts, as EPA explained in the preamble to the proposed rule, the Agency lacks the authority to retain the *de minimis* exemption for PBT chemicals. EPA's legal authority for promulgating the *de minimis* exemption was the *de minimis* principle, which recognizes that most regulatory statutes permit the "implication" that an agency has the authority to craft exemptions "when the burdens of regulation yield a gain of trivial or no value". E.g., Alabama Power Co. v. Costle, 636 F.2d 323 (D.C. Cir. 1979). Courts have consistently held that this doctrine is to be narrowly construed, and that Agencies bear the burden of demonstrating the factual basis for such an exemption. Id. Accord, EDF v. EPA, 82 F.3d 451, 466-67 (D.C. Cir. 1996); Les v. Reilly,(9th Cir. 1991).

Comment List - C-1843

Comment: The commenter assert that the *de minimis* exemption was not merely a transition provision. They argue that EPA's statements in the preamble language of the PBT proposal that states that the primary reason for the *de minimis* thresholds was to ease reporting "for the first two years of reporting" or "to facilities newly affected by EPCRA Section 313" (64 FR 714) are disingenuous and that neither the record from the 1988 rulemaking nor the consistent use of the thresholds in the decade since, support the notion that the exemption was intended merely as a transition provision. They argue that the rationales for initial implementation of the *de minimis* thresholds - that they are necessary to avoid a heavy reporting burden and that little meaningful information would be lost, particularly in view of the limited available information about trace constituents - continue to apply.

Response: EPA disagrees. When using the phrases cited by the commenter, the Agency was being consistent with previous EPA discussions on this topic. For example, in one instance, the Agency was referring to 1988 preamble language in the final rule implementing the EPCRA section 313 program that states:

“for the first two years of reporting, users of these mixtures are only likely to be able to rely on the product MSDS for information about the content and percentage composition of covered toxic chemicals in these products” (53 FR 4509) (emphasis added).

In addition, when the Agency discussed the adoption of the *de minimis* exemption in the 1988 final rule, the discussion clearly was limited to facilities newly regulated in 1988. However, the Agency also states in that rule that:

EPA plans to review this *de minimis* policy and the assumptions upon which it is based in light of data that will be collected under this rule. (53 FR 4509)

Therefore, although the Agency may not have stated that the *de minimis* exemption was intended to be a transition provision, even in 1988, EPA was not convinced that the *de minimis* exemption would remain as it was originally adopted.

Further, in the 1997 final rule adding seven new industries to the list of industries covered by EPCRA section 313, the Agency again states that:

“EPA plans to review the *de minimis* exemption and the assumptions upon which it is based, in light of data that will be collected under this rule, and the additional facilities' experiences in reporting. Subject to the results of its review, EPA may elect to initiate rulemaking to modify the exemption.” (62 FR 23846)

In addition, the Agency never indicated that the information lost from the *de minimis* exemption would be meaningless. Rather EPA did not believe that the quantities listed toxic chemicals in mixtures or trade name products at *de minimis* concentration levels would contribute significantly to the threshold determinations and release calculations at the existing thresholds. As originally explained in the 1988 final rule implementing the reporting provisions of EPCRA section 313, and subsequently discussed in the 1997 final rule adding seven new industry sectors and in the proposal to add PBT chemicals, EPA promulgated the *de minimis* exemption for several reasons. The Agency adopted the *de minimis* exemption because: 1) it believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; 2) the Agency did not believe that the quantities from these low concentrations would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509); and 3) the exemption was consistent with information mandated by the Occupational Safety and Health Administration's (OSHA) hazard communication standard (HCS). However, as explained in more depth in other responses to comment, EPA believes that: 1) covered facilities have additional sources of information available to them regarding the concentration of PBT chemicals in mixtures; 2) the small quantities of PBT chemicals from these low concentrations would be much more likely to contribute to the lower thresholds proposed; and 3) the concentration levels chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals. Therefore, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to PBT chemicals and is eliminating the exemption for these toxic chemicals.

Commenter List: C- 1851 (Cyprus Amax Minerals Company)

Comment: The commenter asserts that the original rationale of the *de minimis* exemption was not limited only to burden reduction. Further, they argue that inherent in the *de minimis* exemption is its relationship to risk. They argue that the *de minimis* levels were established pursuant to OSHA's HCS, where that agency determined it considered protective of workers who are in daily contact with the substances, which the commenter equates to an evaluation of risk. In addition, they argue that EPA adopted these levels for its *de minimis* exemption, based on concentration levels (1) below which the substance does not present a significant risk, and (2) warranting exclusion of information on thresholds or releases of the substance at or below this concentration as such information would not contribute significantly to providing meaningful data to the public to evaluate potential risks of releases. They argue that burden reduction was a consequence of this determination, not a rationale.

Response: EPA disagrees that the Agency's intent in providing the *de minimis* exemption was risk-based. As originally explained in the 1988 final rule implementing the reporting provisions of EPCRA section 313 and reiterated in several previous responses, EPA promulgated the *de minimis* exemption for several reasons. None of these reasons included any assessment of potential risks or whether the information lost would be insignificant or not meaningful. In addition to reducing burden, the Agency adopted the *de minimis* exemption because: 1) it believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; 2) the Agency did not believe that the quantities from these low concentrations would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509); and 3) the exemption was consistent with information mandated by the OSHA HCS. The Agency did not consider, however, risk when adopting this exemption. EPA believes that the two considerations to which the commenter seems to refer, consistency with the OSHA HCS and the expected contribution from these chemicals to threshold and release calculations are misrepresented by the commenter.

EPA did not adopt the 1.0% and 0.1% concentrations because it believed that below these concentrations the toxic chemical does not present a significant risk. Rather, in 1988, EPA chose to be consistent with the OSHA HCS because the Agency

expected facilities to be familiar with these levels and thought that covered facilities might only have access to MSDSs for information on the content and percentage composition of toxic chemicals in mixtures. EPA has additional environmental considerations for the PBT rulemaking, however, that were not considered with the promulgation of the HCS, nor in the 1988 rulemaking. The HCS is designed to ensure the protection of employees exposed to mixtures containing hazardous chemicals, whereas the purpose of the PBT rulemaking is to provide the public with relevant information on toxic chemicals that persist and bioaccumulate in the environment. The Agency believes that these levels are not appropriate for PBT chemicals in mixtures.

Further, the Agency did not believe that toxic chemicals in mixtures below 1.0% and 0.1% concentrations would not contribute significantly to providing meaningful data to the public to evaluate potential risks of releases. Rather, as EPA explains in the PBT proposal, in 1988, the Agency did not expect that toxic chemicals below the 1.0% and 0.1% concentrations in mixtures would significantly contribute to the thresholds finalized in the rule (*i.e.*, 10,000 and 25,000 lbs/year) and release calculations. However, the purpose of the PBT rulemaking is different from past rulemakings in that it is intended to capture significantly smaller quantities of releases and other waste management associated with these chemicals. Many of the PBT chemicals addressed in the proposal have been shown to cause adverse effects at concentrations far less than the *de minimis* levels. For example, the LOAEL for aldrin is 0.25 mg/kg/day. The Agency, therefore, believes that there may be significant releases and other waste management of PBT chemicals resulting from the processing or otherwise use of mixtures containing PBT chemicals below the *de minimis* levels. Therefore, given that covered facilities have additional sources of information available to them regarding the concentration of PBT chemicals in mixtures, that even minimal releases of persistent and bioaccumulative toxic chemicals may result in significant adverse effects even in low concentrations will likely contribute significantly to the proposed lower thresholds for PBT chemicals, and that the concentration levels chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA believes that the reasons underlying the *de minimis* exemption do not apply to PBT chemicals.

Finally, EPA believes that the commenter misunderstands the concept of risk. If the Agency believed that all small concentrations of toxic chemicals did not pose a risk, it would not have limited the *de minimis* exemption as it did. The commenter appears to believe that release from processing will not present a risk while releases resulting from coincidental manufacturing of byproducts will present a risk. The Agency is not aware of any information that would support that belief, nor has the commenter provided any support for it. Further, determining whether a toxic chemical poses a risk is dependent upon a number of factors including toxicity of the chemical, release patterns, environmental fate, route of exposure, *etc.* It is improbable that one or two concentration cut-offs would protect all populations under all scenarios.

Commenter list: C-1864 (American Iron and Steel Institute); C1843 (SOCMA); C-1850 (ASARCO); C-1865 (American Petroleum Institute)

Comment: The commenters assert that the *de minimis* levels are well understood and were originally chosen to be consistent with OSHA HCS and therefore should be retained. One commenter (C-1864; American Iron and Steel Institute) argues that because these levels are believed to be protective of workers who might be exposed to hazardous and carcinogenic constituents, the levels should also be protective of the potentially exposed community and therefore the *de minimis* exemption should remain for PBT chemicals. Another commenter (C-1850; ASARCO) argues that there is no reason to make the standard more stringent than OSHA's HCS.

Response: EPA disagrees that the need to be consistent with OSHA to reduce burden is sufficient to justify retaining the *de minimis* exemption for PBT chemicals. EPA is not required to be consistent with the OSHA HCS. In 1988, EPA chose to be consistent with the OSHA HCS as part of its rationale for the exemption, because the Agency expected facilities to be familiar with these levels and thought that covered facilities might only have access to MSDSs for information on the content and percentage composition of toxic chemicals in mixtures. (See 53 FR 4509) However, EPA has never instructed facilities to stop looking if information concerning a toxic chemical is not on an MSDS. Rather, EPA has consistently instructed facilities to use their best readily available data in determining compliance with EPCRA section 313. As EPA explained earlier, given 10 years of experience with the program, the Agency believes that facilities may have other sources of information, in addition to MSDSs, available to them. Therefore, if a facility has better information regarding the concentration of a toxic chemical in a mixture, for example, that the chemical is above the *de minimis* level, the facility should be using that information to comply with EPCRA section 313. Further, under the OSHA HCS, if an employer has reason to believe that a permissible exposure limit for a component may be exceeded under the mixture's normal circumstances of use, the HCS also requires employers to list chemicals that are below the 1.0% and 0.1% thresholds. Therefore, OSHA adopted exceptions to the 1.0% and 0.1% limits under the HCS. Similarly, PBT chemicals are different from other toxic chemicals in that they may pose a more significant

concern to the environment in much smaller quantities than other toxic chemicals. Furthermore, contrary to the commenters statement, the small concentrations subject to the *de minimis* exemption are not necessarily small quantities and may contribute significantly to exceeding the lowered reporting thresholds.

Comment List: C- 1836 (National Petroleum Refiners, Inc.); C-1846 (Independence Mining Co., Inc.); C-1865 (API)

Comment: The commenters assert that the rationale for adopting the *de minimis* exemption does not disappear simply because now EPA believes a lower threshold is needed for PBT chemicals. One commenter (C-1836; National Petroleum Refiners, Inc.) argues that the notion that *de minimis* levels of impurities in raw materials will become significant because of the extremely low thresholds proposed by the agency only underscores the absurdity of the proposed thresholds.

Response: EPA disagrees. As explained previously, releases of PBT chemicals are a significant concern even in very small quantities. For example, mercury releases from the combustion of fuels is of particular concern for the Great Lakes area. As explained in the EPA/Environment Canada document entitled "Background Information on Mercury Sources and Regulations" for the Binational Great Lakes Toxics Strategy:

...mercury is a potent neurotoxin, capable of impairing neurological development in fetuses and young children and damaging the central nervous system of adults. Mercury does not degrade and is not destroyed by combustion. When released to the environment, even in small quantities, it bioaccumulates, reaching dangerous levels in fish at the top of the aquatic food chain. Fish consumption advisories throughout Great Lakes waterbodies are testament to the health risks caused by mercury present in the Great Lakes ecosystem.

The paper also discusses the sources of mercury releases stating that:

Mercury emitted into the air by combustion, incineration, or manufacturing processes may later be deposited in lakes. Mercury emission also come from natural sources including marine and aquatic environments, as well as volcanic and geothermal activity. However recent studies suggest that anthropogenic sources contribute to the majority of mercury releases.

At the current thresholds of 10,000 and 25,000 pounds/year, many significant releases of this chemical are going unreported to the TRI database. The lowering of the threshold for this very toxic chemical without a concomitant change in the *de minimis* exemption could result in very limited reporting. For example, mercury can be found at very low concentrations in steel. A resmelting facility could process and release more than 100 pounds of mercury a year from its resmelting activities. However, although this total quantity is greater than the 10 pound threshold for mercury, if the concentration of mercury in the steel is less than the *de minimis* limit, none of the mercury would be reportable if the *de minimis* level were retained for PBT chemicals. The elimination of the *de minimis* exemption coupled with the lowering of the threshold for mercury will make much more information on the releases and other waste management of this very toxic chemical available to the public.

Further, the *de minimis* exemption is an exemption for toxic chemicals that are present in low concentrations in mixtures that are imported, processed, otherwise used, or manufactured as an impurity. EPA believed in 1988 that the quantities imported, processed, otherwise used, or manufactured as an impurity of a toxic chemical in a mixture at *de minimis* levels would not contribute significantly to the thresholds of 25,000 and 10,000 pounds. This does not mean that quantities less than 25,000 or 10,000 pounds are significant to the communities in which they are released or otherwise managed as waste, nor that such quantities do not have the potential to present a hazard when released. At the low thresholds proposed for PBT chemicals, the thresholds can more easily be exceeded for chemicals present below the *de minimis* concentration level.

Commenter List: C-1825 (Rohm and Haas)

Comment: The commenter asserts that EPA should only make changes to the *de minimis* exemption in cases where there is an absolute need to disrupt the current evaluation protocol.

Response: EPA believes that this is a case where there is an "absolute need" to make changes to the *de minimis* exemption. EPA believes that PBT chemicals are different from other toxic chemicals covered under EPCRA section 313 in that even minimal releases of these chemicals may have significant adverse impacts. As previously explained, EPA believes that the reasons for the *de minimis* exemption that the Agency expressed in previous rulemakings do not apply to PBT chemicals.

Given that covered facilities have additional sources of information available to them regarding the concentration of PBT chemicals in mixtures, that even minimal releases of persistent bioaccumulative chemicals may result in significant adverse effects and may significantly contribute to the proposed lower thresholds, and because the concentration levels chosen to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA believes that there is a need to “disrupt the current protocol.”

Further, even in 1988, the Agency was not convinced that the *de minimis* exemption would remain as it was originally intended. As stated in the final rule:

EPA plans to review this *de minimis* policy and the assumption upon which it is based in light of data that will be collected under this rule. (53 FR 4509)

Therefore, because the Agency does not agree that the reasons originally considered in adopting the *de minimis* exemption are appropriate for this rulemaking, EPA is eliminating the *de minimis* exemption for PBT chemicals.

Meaningful data issues

Comment List: C-1843 (SOCMA); C-1422 (CPMA); C-798 (Iron Mining Association of Minnesota)

Comment: The commenters assert that the only valid case for dropping the *de minimis* exemption would be for those processes where a PBT chemical is present in the process stream in trace amounts and is concentrated in the waste stream. Some commenters assert that in virtually all cases the releases to air and water typically will contain far lower concentrations of PBT chemicals than the process streams. In addition, through dilution, attenuation and other effects, environmental concentrations will be far lower still. Further they argue that EPA has presented no evidence to support the belief that releases of *de minimis* quantities of PBT chemicals has led to elevated levels in the environment.

Response: EPA disagrees that the *de minimis* exemption should only be eliminated for PBT chemicals that are concentrated above the *de minimis* level in the wastestream. The commenter has presented no rationale for its assertion, and the Agency is aware of no facts that would support it for PBT chemicals. Even relatively small releases of PBT chemicals have the potential to accumulate over time and cause adverse health and environmental effects. Further, EPA is aware of no information that would support distinguishing between chemicals in the process stream and the same chemicals in the waste stream, nor has the commenter submitted any with its comments. The *de minimis* exemption applies to toxic chemicals that are manufactured as impurities, imported, processed or otherwise used in mixtures or trade name products. If the concentration of the toxic chemical remains below the *de minimis* level throughout the threshold activity, releases and other waste management associated with that activity are eligible for the exemption. The applicability of the exemption, therefore, is based on the concentration of the toxic chemical during the threshold activities, not during the release and other waste management activities. Simply removing the exemption for PBT chemicals that are concentrated above the *de minimis* level in wastestreams is unworkable because it would be inconsistent with the applicability mechanics of the exemption.

In addition, the Agency believes that there many instances in which toxic chemicals found in concentrations below the current *de minimis* levels during processing are concentrated to above those levels in the waste stream. For example, mercury can be found at very low concentrations in steel. A resmelting facility could process and release more than 100 pounds of mercury a year from its resmelting activities. Therefore, EPA believes that there is evidence regarding the concentrations of toxic chemicals being concentrated in releases from process streams and that release of *de minimis* PBT chemicals has led to elevated levels in the environment.

Comment List: C-1843 (SOCMA); C-1431 (Chrome Coalition)

Comment: The commenters assert that the elimination of the *de minimis* thresholds would not yield meaningful additional information. One commenter (C-1843; SOCMA) argues that the proposed rule vastly overstates the significance of TRI data and therefore incorrectly concludes that the *de minimis* thresholds would "deprive communities of important information on PBT chemicals." (64 FR 714) Instead, they argue, TRI data only provide a snapshot view of releases from the chemical industry and the few other industry sectors subject to TRI reporting and that many potential release sources are not subject to TRI reporting. These sources overwhelm the limited additional information that would be reported were the *de minimis* thresholds eliminated. By failing to recognize these circumstances, the proposed rule seeks to impose an excessive, unduly precise degree of TRI reporting for PBT chemicals that would have no practical utility. In addition, one commenter (C-1431; Chrome Coalition) asserts

that the *de minimis* exemption should remain intact in order to ensure that only meaningful amounts of substances are reported under EPCRA section 313.

Response: EPA disagrees that the proposed rule vastly overstates the significance of the TRI data. The public, all levels of government and the regulated community have come to rely on TRI data in improving decision making, measuring pollution prevention, and understanding the environmental and health consequences of toxic chemical releases and other waste management activities. Although the Toxics Release Inventory does not contain a complete inventory of every release, EPA believes it does provide one of the most comprehensive and accessible sources of release and other waste management information available. EPA also disagrees with the commenter's assertion that the data base only contains information from the chemical industry and a few others. In fact, all 20 manufacturing industry groups as well as an additional 7 other industries including metal and coal mining facilities and hazardous waste management facilities are subject to EPCRA section 313. Further, with the addition of these 7 newly covered industries, EPA expects over 27,500 facilities to submit over 110,000 reports on more than 630 toxic chemicals to the TRI for the 1998 reporting year. Currently no other sources of information can provide releases and information on other waste management quantities and qualitative source reduction data with the scope, level of detail, and chemical coverage as data currently included in TRI.

Further, as EPA has previously explained, PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues. Even relatively small releases of such chemicals have the potential to accumulate over time and cause significant adverse impacts on human health and the environment. Therefore, EPA believes it is particularly important to gather and disseminate to the public relevant information on even relatively small amounts of releases and other waste management of PBT chemicals. Under the 10,000 and 25,000 pound/year reporting thresholds, a significant amount of the releases and other waste management activities involving PBT chemicals are not being captured and thus the public does not have the information needed to determine if these chemicals are present in their communities at levels that may pose a significant risk.

Commenter List: C-1847 (American Portland Cement Alliance)

Comment: The commenter argues that in the absence of an exemption for *de minimis* levels of compounds found in mixtures, many facilities will be responsible for reporting based upon throughput of materials. In these cases, the release reported will often be zero. They argue that the plethora of zero-release reports will provide a burden for reporting facilities and EPA while only confusing the public and providing no relevant reductions in releases.

Response: EPA disagrees. EPA believes that reports indicating that a facility exceeds a threshold but has no releases or other quantities of the PBT chemical managed as waste does provide the public with information on PBT chemicals in their community. Just as knowing that facilities in a given community are releasing or otherwise managing PBT chemicals as waste, EPA believes that the public should also know when facilities exceed an activity threshold for a given chemical but have no waste management activities associated with it. The fact that a facility has developed a process with no associated releases or other waste management is extremely valuable information for both the local community in which the facility is located but also to other communities, as the facility with zero releases can serve as a model to other similar facilities. Further, in addition to providing release and other waste management information, facilities report an indication of how the chemical is used and the maximum amount of the chemical on-site during the reporting year. This information may also be important to the community for emergency planning purposes.

Comment List: C-1407 (Delphi); C1356 (RJ Reynolds); C-1420 (Reynolds Metal Co); C-1421 (General Electric); C-1863 (National Mining Association); C-1826 (Northwest Mining Association); C-1865 (American Petroleum Institute); C-1843 (SOCMA)

Comment: The commenters argue that the *de minimis* exemption already does not apply to the manufacture of a toxic chemical unless the toxic chemical is manufactured as an impurity or is imported. Therefore, any incidental manufacturing of a PBT as a byproduct would not be eligible for the *de minimis* exemption and would be subject to reporting. They argue that the elimination of the exemption will provide little additional information and would not be value-added. One commenter (C-1421; GE) asserts that because the current *de minimis* exemption does not apply to quantities of toxic chemicals manufactured as individual chemicals or as by-products, the main manufacturers potentially contributing to environmental loading of chemicals are already required to consider *de minimis* quantities. Thus, they argue, the existing exemption is appropriate and sufficiently conservative and should be retained for PBT chemicals.

Response: The commenters are correct in stating that there are instances where PBT chemicals are manufactured as by-products and would, therefore, not be affected by the elimination of the *de minimis* exemption. However, as EPA explained in the PBT proposal, there are also many instances where a PBT chemical may exist in a mixture or trade name product at a concentration below the 1% or 0.1% *de minimis* limit but where the processing or otherwise use of the PBT chemical in that mixture would otherwise contribute significantly to or in itself exceed the reporting thresholds (at 64 FR 714). For example, mercury can be found at very low concentrations in steel. A resmelting facility could process and release more than 100 pounds of mercury a year from its resmelting activities. However, although this total quantity is greater than the 10 pound proposed threshold for mercury, if the concentration of mercury in the steel is less than the *de minimis* limit, none of the mercury would be reportable if the *de minimis* level is retained for PBT chemicals. Releases and other waste management associated with these exempt activities would be absent from the TRI data base. Because even minimal releases of PBT chemicals may result in elevated concentrations in the environment or in an organism and can have the potential to cause an adverse effect, EPA believes that all releases of these chemicals are of concern and that such information is significant and of value to the public.

With respect to the commenter asserting that, even if the *de minimis* exemption were retained, the main manufacturers potentially contributing to environmental loading are already required to consider *de minimis* quantities, EPA notes that, because it lacks the data to estimate the releases from facilities, it cannot determine with any accuracy, the extent to which retention of the *de minimis* exemption would ensure reporting of the “significant” releases and other waste management. As noted above, the analyses/rationale upon which the Agency had previously justified the exemption/made such a determination is inapplicable to PBT chemicals. Nor has the commenter provided any information that would allow the Agency to determine the accuracy of its assertion.

Burden Issues

Commenter List: C-1168 (Duquesne Light), C-1352 (Borden Chemicals and Plastics), C-1353 (Department of Energy); C1356 (RJ Reynolds); C1405 (NASA - Ames Research Center); C-1407 (Delphi); C-1423 (Edison Electric Institute); C-1853 (Vinyl Institute); C-1859 (Phelps Dodge); C-1836 (National Petroleum Refiners, Inc.); C-1847 (American Portland Cement Alliance); C-1863 (National Mining Association); C-1826 (NW Mining Association)

Comment: Several commenters assert that the initial reason for the *de minimis* exemption was to alleviate undue burden on reporting facilities and that the elimination of the *de minimis* exemption will significantly increase the reporting burden. One commenter (C1356; RJ Reynolds) asserts that reviewing each MSDS, when a facility may have many MSDSs for chemicals used on-site to see if it includes trace quantities of PBT chemicals will be very time consuming. This commenter also reminds EPA that once a PBT chemical is identified on an MSDS, the facility will have to estimate annual releases based on usage and then aggregate the releases for the same PBT chemical shown on MSDSs found elsewhere at the facility. One commenter asserts that they do not have the manpower to track products on an individual basis looking for trace quantities of PBT chemicals. (C-1353; Department of Energy)

Response: EPA disagrees with the commenters’ contention that the initial reasons for adopting the *de minimis* exemption are valid for PBT chemicals. As originally explained in the 1988 final rule implementing the reporting provisions of EPCRA section 313, reiterated in the 1997 final rule adding seven new industry sectors, and discussed in the proposal to add PBT chemicals, EPA promulgated the *de minimis* exemption for several reasons, of which burden was only one. In addition to burden reduction, EPA promulgated the *de minimis* exemption because: (1) the Agency believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; (2) the Agency did not believe that these low concentrations would result in quantities that would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509); and 3) the exemption was consistent with information collected by the Occupational Safety and Health Administration’s (OSHA) Hazard Communication Standard (HCS). If EPA had adopted the exemption only to reduce burden, the exemption would have covered all uses of *de minimis* quantities of the toxic chemical in mixtures. The exemption, however, includes only limited uses of the toxic chemical in mixtures (*i.e.*, importing, processing, otherwise use, and manufacturing impurities) that were roughly tailored to whether EPA expected that facilities were reasonably likely to have information that would allow them to determine thresholds and make release calculations.

The purpose of the PBT rulemaking, however, is different from past rulemakings in that it is intended to capture information on significantly smaller quantities of releases and other waste management associated with these chemicals. Most of the PBT chemicals addressed in this rule have been shown to cause adverse effects at concentrations far less than the *de*

minimis levels. For example, dioxins have been shown to cause adverse effects at levels in the parts per trillion. In addition, after 10 years of experience with the program, the Agency believes there are many sources of information in addition to material safety data sheets (MSDSs), readily available to reporters to use in making EPCRA section 313 determinations. Some of these sources of information include EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Section 313 Form R Reporting*). In addition, relevant information has become much more accessible to covered facilities over the past ten years. For example, although the United States Geological Survey's U.S. Coal Quality Database has been in existence since the mid 1970s, only more recently has it been made available on the Internet.

(<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>). Further, the Agency believes that it underestimated how much information covered facilities had available to them in 1988 regarding small concentrations of toxic chemicals in mixtures.

Therefore, given that: (1) Covered facilities have additional sources of information available to them regarding the concentration of PBT chemicals in mixtures; (2) even minimal releases of persistent bioaccumulative chemicals may result in significant adverse effects and these small quantities can reasonably be expected to significantly contribute to the proposed lower thresholds; and (3) the concentration levels originally chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to PBT chemicals.

Commenter List: C1356 (RJ Reynolds); C-1421 (General Electric); C-1422(CPMA); C-1820(New Century Service); C-1423 (EEI); C-1440 (Tenn. Valley Authority); C-1420 (Reynolds Metals Co.); C-1825 (Rohm and Haas); C-1836 (National Petroleum & Refiners Association); C-1868 (International Paper); C-0446 (IBM); C-1919 (Brominated Flame Retardant Industry Panel of CMA); C-1843 (SOCMA); C-1457 (Dow); C-1858 (CMA); C-1441 (Chevron); C-1865 (American Petroleum Institute)

Comment: The commenters' concern with the PBT proposal is the lack of benefit and substantial additional release information it would provide in light of the burden that would be placed on facilities to track and report on chemicals. One commenter (C-1820; New Century Services) insists that requiring sources to undertake threshold calculations for *de minimis* substances in the fuel they burn poses an unnecessary burden with no benefit. Another commenter (C-1440; TVA) is specifically concerned with the added burden for the electric utility industry and does not believe that the elimination of the *de minimis* exemption for PBT chemicals would be prudent or cost effective. They assert that many minor, insignificant releases (fugitive coal dust emissions, for example) that are not currently reported because of the *de minimis* exemption would be reportable and would require many man-hours of work to estimate in order to comply with the reporting requirements. Another commenter (C-1836; National Petroleum Refiners, Inc.) indicates that the removal of the exemption will result in a significant increase in the reporting burden for petroleum refineries, petrochemical plants, and petroleum bulk storage facilities, with no probable benefit. Another commenter (C-1868; International Paper) argues that if the *de minimis* exemption is deleted, many covered facilities which maintain hundreds of Material Safety Data Sheets (MSDS), will have to evaluate materials to determine if there is a potential for PBT chemical presence in order to determine if the very low reporting threshold is exceeded, even where the levels are well below any analytical detection limit. This review will add many hours of effort to each chemical reviewed -- nearly all of which will be of little or know value.

Response: EPA disagrees that the elimination of the *de minimis* exemption will result in the reporting of no beneficial information. The commenters do not substantiate their claim. The availability of information on PBT chemicals is a critical component of a community's right-to-know. Existing data leads EPA to believe that, as a general matter, releases of toxic chemicals that persist and bioaccumulate are of greater concern than the release of toxic chemicals that do not persist or bioaccumulate. Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. Therefore, it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals. Thus, for PBT chemicals, releases and other waste management activities even in relatively small amounts are of concern. By eliminating the *de minimis* exemption for PBT chemicals, EPA will provide communities across the nation with access to data that may help them in making this determination. EPA also expects this information to be used by various government agencies to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment.

As explained in the 1988 final rule, reiterated in the 1997 industry expansion final rule and discussed in the proposal to add PBT chemicals, EPA adopted the *de minimis* exemption for several reasons. EPA did not solely consider burden in adopting this exemption. Among other considerations, such as consistency with the OSHA HCS, the Agency believed that facilities newly

covered by EPCRA section 313 would have limited access to information regarding small quantities of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities. However, after ten years experience with the program, EPA believes that covered facilities now have additional sources of information available to them, in addition to monitoring data, that they may consider in making threshold determinations and release and other waste management calculations. Some of these sources of information include EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). In addition, relevant information has become much more accessible to covered facilities over the past ten years. For example, although the United States Geological Survey's U.S. Coal Quality Database has been in existence since the mid 1970s, only more recently has it been made available on the Internet. (<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>). Further, the Agency believes that it underestimated how much information covered facilities had available to them in 1988 regarding small concentrations of toxic chemicals in mixtures.

Because the Agency believes that many covered facilities will have the necessary information to make threshold determinations and release and other waste management calculations for PBT chemicals, and because the Agency believes that releases of even very small amounts of PBT chemicals may be of concern, EPA is eliminating the *de minimis* exemption for PBT chemicals.

Further, EPA disagrees that maintaining the *de minimis* exemption will "ensure that only meaningful amounts of substances" are reported. The *de minimis* exemption is based on a concentration not an absolute amount. Facilities may process or otherwise use low concentrations of a chemical but because they process large quantities of a mixture containing the toxic chemical, this may result in large amounts of the toxic chemical released. Certainly a facility can easily exceed the lowered thresholds even if the chemical is present in low concentrations (e.g., mercury in steel). In addition, because the chemicals are known to persist, even very small quantities, over time, will accumulate to greater quantities in the environment.

Commenter List: C-1434 (Association of International Automobile Manufacturers); C-1431 (Chrome Coalition); C-1444 (ATMI)

Comment: The commenters are concerned that if the *de minimis* exemption is eliminated for PBT chemicals, there will be a lack of benefit and substantial additional release information in light of the burden that would be placed on facilities to track and report on chemicals which are present at levels below detection by analytical equipment or at trace levels.

Response: The Agency disagrees with the comment that small quantities of PBT chemicals will not produce a benefit to the community. The availability of information on PBT chemicals is a critical component of a community's right-to-know. Further, existing data leads EPA to believe that, as a general matter, releases of toxic chemicals that persist and bioaccumulate are of greater concern than the release of toxic chemicals that do not persist or bioaccumulate. Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. Therefore, it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals. Thus, for PBT chemicals, releases and other waste management activities even in relatively small amounts may be of concern. By eliminating the *de minimis* exemption for PBT chemicals, EPA will provide communities across the nation with access to data that may help them in making this determination. EPA also expects this information to be used by various government agencies to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment.

As explained in the 1988 final rule, reiterated in the 1997 industry expansion final rule and discussed in the proposal to add PBT chemicals, EPA adopted the *de minimis* exemption for several reasons. EPA did not solely consider burden in adopting this exemption. Among other considerations, such as consistency with the OSHA HCS, the Agency believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities. However, after ten years experience with the program, EPA believes that covered facilities now have many sources of information available to them in addition to monitoring data, that they may consider in making threshold determinations and release and other waste management calculations. Some of these sources of information include EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). In addition, relevant information has become much more accessible to covered facilities over the past ten years. For example, although the United States Geological Survey's U.S. Coal Quality Database has been in existence since the mid 1970s, only more recently has it been made available on the Internet.

(<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>). Further, the Agency believes that it underestimated how much information covered facilities had available to them in 1988 regarding small concentrations of toxic chemicals in mixtures.

In addition, as EPA explained in the 1988 final rule, if a covered facility has no information on the concentration of the toxic chemical in the mixture, including no reasonable estimates or other information reasonably known, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations. The Agency believes that allowing facilities to continue to take the *de minimis* exemption for PBT chemicals simply because monitoring technology in use at a covered facility is not capable of detecting small amounts of a PBT chemical, when facilities have other sources of information available to them, would unnecessarily deprive the public of important information on PBT chemicals being released in their community. Because the Agency believes that many covered facilities will have the necessary information to make threshold determinations and release and other waste management calculations for PBT chemicals and because the Agency believes that releases of even very small amounts of PBT chemicals may be of concern, EPA is eliminating the *de minimis* exemption for PBT chemicals.

Commenter List: C-1847 (American Portland Cement Alliance); C-1862 (Fort James); C-1844 (Oxychem); C-798 (Iron Mining Association of MN); C-1842 (United Technologies); C-1860 (Rubber Manufacturers Association); C-1843 (SOCMA); C-1440 (TVA); C-1868 (International Paper); C-1428 (American Forestry and Paper)

Comment: The commenters assert that requiring facilities to make threshold determinations at any amount is extremely time consuming and burdensome. They also argue that a facility should not be required to determine if a PBT chemical exists in a mixture simply because it is theoretically possible or because the materials contain background levels of PBT chemicals. One commenter (C-1847; American Portland Cement Alliance) asserts that with compounds such as mercury, such quantification could be extremely difficult, particularly given the chemical inconsistencies of quarried raw materials such as those used in cement manufacturing. They argue that companies making an effort to calculate their releases based on the contents of raw materials and other factors will be frustrated by attempts to discern minute quantities. They argue that this is precisely why the *de minimis* exemption was devised. Another commenter (C-1862; Fort James) asserts that eliminating the *de minimis* exemption for regulated industries that either process, otherwise use, or manufacture PBT chemicals would create a needless inventory, recordkeeping, and reporting burden for which data may not be available. Another commenter (C-1843; SOCMA) argues that the primary burdens of EPCRA section 313 arise from the identification and evaluation of process streams and that the elimination of the *de minimis* exemption would vastly increase the extent of the required effort. Another commenter (C-1842; United Technologies) asserts that it is possible that a false positive result from a laboratory such as mercury found at the limit of detection in wastewater, could launch an on-going tracking and analysis program.

Response: EPA disagrees. EPA adopted the *de minimis* exemption for several reasons. In part, the Agency expected that for the first two years of the program, covered facilities would rely mainly on MSDSs which do not include hazardous chemicals in mixtures if their concentrations are below 1.0 % or 0.1 % for carcinogens. The Agency believed that covered facilities would have difficulty determining the concentrations of toxic chemicals in mixtures below those concentrations if the concentration was not listed on the MSDS. (February 16, 1988; 53 FR 4511) However, given ten years of experience with the program, EPA now believes there are many sources of information, in addition to MSDSs, available to facilities concerning concentrations of toxic chemicals in their raw materials. Some of these sources of information include EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). In addition, relevant information has become much more accessible to covered facilities over the past ten years. For example, although the United States Geological Survey's U.S. Coal Quality Database has been in existence since the mid 1970s, only more recently has it been made available on the Internet. (<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>). Further, the Agency believes that it underestimated how much information covered facilities had available to them in 1988 regarding small concentrations of toxic chemicals in mixtures.

In addition, EPCRA section 313 does not require facilities to test or monitor for toxic chemicals but rather it requires that covered facilities make reasonable estimates using their best readily available data. Further, as EPA explained in the 1988 final rule, if a covered facility has no information, including no reasonable estimates or other information reasonably known, on the concentration of the toxic chemical in the mixture, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations. (February 16, 1988; 53 FR 4511) In addition, from the comment, it is unclear why requiring facilities to identify and evaluate process streams containing relatively small quantities of PBT chemicals is more burdensome than for larger quantities of these chemicals, given that: 1) in many cases covered facilities

do have the information needed to make reasonable estimates regarding the concentration of PBT chemicals in mixtures; and 2) facilities need not consider toxic chemicals in mixtures for threshold and release and other waste management calculations if the facility has no information on the concentration of the toxic chemical in the mixture. The additional burden is that facilities would have to include information they are not currently required to use. In addition, although EPA agrees that the primary burdens of EPCRA section 313 arise from the identification and evaluation of process streams, EPA disagrees that the elimination of the *de minimis* exemption would vastly increase the extent of this required effort. Covered facilities will need to identify and evaluate process streams when considering a toxic chemical in concentrations below the *de minimis* level just as they already do for toxic chemicals found in process streams in concentrations above the *de minimis* level.

Further, EPA disagrees that eliminating the *de minimis* exemption will create a needless inventory. The toxics release inventory has been very successful in providing important data to the public on toxic chemicals released or otherwise managed as waste in their communities, encouraging the reduction of releases, and promoting pollution prevention efforts. As EPA has previously explained, small quantities of PBT chemicals can pose a significant concern to the environment. Therefore, eliminating the *de minimis* exemption for PBT chemicals will further the goals of the EPCRA section 313 program in providing relevant information about these chemicals to the public.

In addition, EPA does not believe that a false positive result from a laboratory, such as mercury found at the limit of detection in wastewater, should launch an extensive on-going tracking and analysis program. As EPA has explained in guidance, facilities should document their reasoning and calculations when making estimates for threshold determinations and release and other waste management calculations. If a facility receives a false positive test result but has no other reason to believe that the chemical is in the waste or mixture, the facility should simply document why they believe the PBT chemical is not present.

Consistency with the OSHA HCS

Commenter List: C-1862 (Fort James); C-798 (Iron Mining Association of MN)

Comment: The commenter asserts that if future modifications to the *de minimis* exemption are considered, EPA should ensure consistency between the Community Right-to-Know standard and any planned revisions to the Employee Right-to-Know standard (*i.e.*, the OSHA HCS).

Response: EPA will attempt to be consistent with the Employee Right-to-Know standard wherever possible if it is appropriate to be consistent. However, the intent of EPCRA section 313 and section 6607 of the PPA is to collect and disseminate to the public information regarding releases and other waste management of toxic chemicals. Specifically, PBT chemicals are a concern for the environment as well as for human health. The OSHA HCS, however, has the very different intent of ensuring the protection of employees exposed to mixtures. In this case, because even in very small concentrations PBT chemicals are of concern for the environment as well as human health, EPA believes that the *de minimis* exemption is inappropriate for the EPCRA section 313 program for PBT chemicals. There may, however, be different concerns concerning these chemicals in the workplace. Therefore, given the different mandates between the OSHA HCS and EPCRA section 313, EPA believes that it will not always be advisable to ensure consistency between the two programs.

Impurities

Commenter List: C- 1836 (National Petroleum Refiners, Inc)

Comment: The commenter asserts that the *de minimis* exemption should be retained specifically for PBT chemicals manufactured as an impurity or imported.

Response: The commenter does not explain why the *de minimis* exemption should be retained for PBT chemicals manufactured as impurities or imported. Nor does the commenter discuss why these activities are different from other processing and otherwise use activities which would otherwise be eligible for the *de minimis* exemption under this rule. As previously explained, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to PBT chemicals. Given that covered facilities have additional sources of information available to them regarding the concentration of PBT chemicals in mixtures, that even minimal releases of PBT chemicals may result in significant adverse effects, and because the concentration levels chosen to be consistent with the OSHA HCS are inappropriate for PBT chemicals because quantities of PBT chemicals in mixtures present below the *de minimis* levels can be manufactured, processed or otherwise used in excess of the thresholds. Thus these are not *de minimis* quantities of PBT chemicals which persist in the

environment and bioaccumulate. EPA believes that the *de minimis* exemption is inappropriate for PBT chemicals manufactured as impurities or imported and therefore, is eliminating the exemption for these activities.

Commenter List: C-1455 (Chemical Specialties Manufacturers Association)

Comment: The commenter asserts that the *de minimis* exemption for PBT chemicals present as impurities must be retained. They argue that the nature and extent of the information on PBT chemical concentration is questionable. According to this commenter, any fair reading of the EPCRA statute indicates that EPCRA section 313 was not designed to gather information at this level of detail.

Response: The commenter does not explain what they mean when they state that the information on PBT chemical concentration is questionable nor why they believe that EPCRA section 313 was not designed to gather detailed information. Congress did not include any type of *de minimis* exemption in the EPCRA statute. Nor does any part of the statute indicate that Congress believed information on small quantities of toxic chemicals is less valuable. Rather, the *de minimis* exemption for the EPCRA section 313 program, in addition to most of the exemptions to reporting, was adopted by EPA through rulemaking. (40 CFR § 372.38(a)) As originally explained in the 1988 final rule implementing the reporting provisions of EPCRA section 313, and subsequently discussed in the 1997 final rule adding seven new industry sectors and in the proposal to add PBT chemicals, EPA promulgated the *de minimis* exemption for several reasons. Specifically, the Agency adopted the *de minimis* exemption because: 1) it believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; 2) the Agency did not believe that the quantities from these low concentrations would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509); and 3) the exemption was consistent with information mandated by the OSHA HCS. However, as explained in more depth in other responses to comment, EPA believes that covered facilities have several sources of information available to them regarding the concentration of PBT chemicals in mixtures, that even minimal releases of persistent bioaccumulative chemicals may result in significant adverse effects and may significantly contribute to the proposed lower thresholds, and that the *de minimis* concentration levels chosen, in part, to be consistent with the OSHA HCS, are inappropriately high for PBT chemicals. Therefore, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to PBT chemicals and is eliminating the exemption for these toxic chemicals.

Commenter list: C- 1841 (Eastman Chemical Co); C-1457 (Dow); C-1815 (CMA); C-1428 (American Forestry and Paper Association)

Comment: The commenters assert that EPA should maintain the *de minimis* exemption for PBT chemicals present as impurities. They argue that PBT chemicals present as impurities are not readily available, and that obtaining the relevant data or even conducting the initial reviews to determine what information is available and identifying data gaps would impose a huge burden on industry. They argue that even developing estimates with any accuracy entails a significant amount of time. In the instance of impurities, they assert that the absence of data and the difficulty in developing estimates will result in a heavy burden with little information of value being reported. Some commenters argue that the practical effect of eliminating the *de minimis* exemption is to vastly increase the reporting burden for covered facilities. They believe that the elimination of the *de minimis* level is a requirement to provide new data and can find no evidence in the record that the burden of eliminating the *de minimis* exemption has been outlined in detail.

Response: EPA disagrees with these commenters. Although there are burdens associated with obtaining relevant data, determining available information and identifying data gaps, EPA disagrees that the elimination of the *de minimis* exemption for PBT chemicals present as impurities would vastly increase the extent of this required effort. From the comment, it is unclear why requiring facilities to identify and evaluate process streams containing small quantities of PBT chemicals as impurities is more burdensome than for larger quantities of these chemicals manufactured, processed or otherwise used at a covered facility in excess of the activity thresholds. For example, a facility monitors for chemical A at a concentration of greater than 0.001% and monitors for chemical B at a concentration of greater than 1.5%. The monitoring is done for the same wastestream and the same frequency. There is no differential in effort or burden. Currently, the only difference is that facilities can ignore available data.

As explained previously, EPA believes that in many cases covered facilities have the information needed to make reasonable estimates regarding the concentration of PBT chemicals in mixtures. Many covered facilities are required to comply with other

environmental laws that require the facility to perform monitoring on listed toxic chemicals. For example, under the Resource Conservation and Recovery Act (RCRA), hazardous waste treatment, storage and disposal facilities are required to obtain detailed chemical and physical analysis of a representative sample of any hazardous wastes prior to any treatment storage or disposal and to develop written waste analysis plans that specify the frequency of sampling. In addition, EPA considers production records, monitoring or analytical data, EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)), trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*) and reasonable judgement on the part of the facility's management all to be readily available data that covered facilities may use to make their calculations. Covered facilities should use similar sources of information regardless of the concentration of the toxic chemical in the mixtures. As EPA explained in the 1988 final rule, if a covered facility does have information regarding the concentration of a toxic chemical in a mixture or trade name product, it must consider all non-exempted sources of the chemical for threshold determinations. If an activity threshold is exceeded for the chemical, they must then calculate release and other waste management quantities. The same process involving gathering relevant data for PBT chemicals present as impurities would apply regardless of the concentration of the PBT in the mixture. Therefore given that facilities: 1) are not required to perform additional monitoring; 2) are not required to consider concentrations of toxic chemicals for which they have no information; and 3) need only consider readily available data, EPA disagrees that the elimination of the *de minimis* exemption for PBT chemicals present as impurities would vastly increase the extent of this required effort. In addition, EPCRA section 313 (g)(2) requires that facilities use readily available information. EPCRA does not require that a facility conduct additional monitoring. Thus, the commenter is incorrect that eliminating the *de minimis* exemption will require facilities to provide new data.

Further, EPA believes that data concerning small concentrations of PBT chemicals present as impurities in mixtures and in the wastestreams that result from the manufacturing, processing, or otherwise use of these mixtures is valuable information. The availability of information on PBT chemicals is a critical component of a community's right-to-know. Existing data leads EPA to believe that, as a general matter, all things being equal, releases of toxic chemicals that persist and bioaccumulate are of greater concern than the release of toxic chemicals that do not persist or bioaccumulate. Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. Thus, for PBT chemicals, releases and other waste management activities even in relatively small amounts are of concern. Given that covered facilities have several sources of information available to them regarding the concentration of PBT chemicals in mixtures and that even minimal releases of persistent and bioaccumulative toxic chemicals may result in significant adverse effects, EPA believes that the *de minimis* exemption is inappropriate for PBT chemicals present as impurities and is therefore eliminating the exemption for these activities.

Comment List: C-1443 (Pioneer)

Comment: The commenter asserts that EPA does not address toxic chemicals that are manufactured as impurities in its discussion of the *de minimis* exemption. The commenter argues that most of unintentionally produced toxic chemicals remain as a tiny percentage of the product stream and are not separated and thus are impurities and not byproducts as they believe EPA considers them. Further, they argue that removing the *de minimis* exemption for these chemicals would have a much greater effect than EPA claims in the proposed rule because EPA did not consider the effect of removing the *de minimis* exemption for PBT chemicals manufactured as impurities.

Response: The commenter is confused. Since the inception of the EPCRA section 313 program, toxic chemicals manufactured as impurities have been eligible for the *de minimis* exemption. As EPA explains in the PBT proposal:

The *de minimis* exemption allows facilities to disregard certain concentrations in mixtures or other trade name products they import, process or otherwise use in making threshold calculations and release and other waste management determinations for section 313 reporting. The *de minimis* exemption does not apply to the manufacture of a toxic chemical *unless the toxic chemical is manufactured as an impurity* or is imported. (emphasis added) (64 FR 713)

EPA makes the distinction between toxic chemicals that are impurities, *i.e.*, they remain with the product distributed in commerce, and toxic chemicals that manufactured byproducts, *i.e.*, they are removed before the final product is distributed. Therefore, EPA certainly considered the manufacturing of impurities when it proposed to eliminate the *de minimis* exemption for PBT chemicals.

EPA disagrees that the elimination of the *de minimis* exemption for PBT chemicals present as impurities would vastly increase the extent of this required effort of complying with EPCRA section 313. From the comment, it is unclear why requiring facilities to identify and evaluate process streams containing small quantities of PBT chemicals as impurities is more burdensome than for larger quantities of these chemicals. Covered facilities will need to identify and evaluate process streams when considering PBT chemicals as impurities in concentrations below the *de minimis* level just as they already do for toxic chemicals found in process streams in concentrations above the *de minimis* level. Given that facilities: 1) are not required to perform additional monitoring, 2) are not required to consider concentrations of toxic chemicals for which they have no information; and 3) need only consider readily available data, EPA disagrees that the elimination of the *de minimis* exemption for PBT chemicals present as impurities would vastly increase the extent of this required effort.

Further, EPA believes that data concerning small concentrations of PBT chemicals present as impurities is valuable information that would be lost if the *de minimis* exemption were retained for these chemicals. The availability of information on PBT chemicals is a critical component of a community's right-to-know. Existing data leads EPA to believe that, as a general matter, releases of toxic chemicals that persist and bioaccumulate are of greater concern than the release of toxic chemicals that do not persist or bioaccumulate. Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. Thus, for PBT chemicals, releases and other waste management activities even in relatively small amounts are of concern. Given that covered facilities have several sources of information available to them regarding the concentration of PBT chemicals in mixtures and that even minimal releases of persistent bioaccumulative chemicals may result in significant adverse effects EPA believes that the *de minimis* exemption is inappropriate for PBT chemicals present as impurities and is therefore eliminating the exemption for these activities.

Applicability of de minimis exemption

Comment List: C1356 (RJ Reynolds)

Comment: The commenter refutes, in part, EPA's statement that "because many of the PBT chemicals addressed in today's action are manufactured as byproducts and the *de minimis* exemption does not apply to such chemicals eliminating it would have no effect on the reporting of those chemicals." The commenter asserts that if the manufactured by-product subsequently goes into a formulation for a product that is distributed in commerce, the receiving facility would account for the PBT present in the material received as either "processed" or "otherwise used" and would be subject to release and other waste management reporting.

Response: EPA agrees that if the *de minimis* exemption remained for PBT chemicals, these chemicals processed or otherwise used might be eligible for the *de minimis* exemption. However, when EPA originally adopted the *de minimis* exemption it only covered limited uses of the toxic chemical. Specifically EPA chose processing, otherwise using, importing and manufacturing toxic chemicals impurities as eligible for the exemption. The Agency did not include, however, manufactured byproducts. As stated in the 1988 final rule:

This final rule does not adopt a *de minimis* concentration limitation in connection with the production of a byproduct. EPA believes that the facility should be able to quantify the annual aggregate pounds of production of a byproduct which is not an impurity because the substance is separated from the production stream and used, sold, or disposed of, unlike an impurity which remains in the product. (53 FR 4504)

nade this distinction because in 1988, the Agency believed that facilities might not know the concentrations of toxic chemicals processed or otherwise used in mixtures below the levels required to be included on MSDSs under the OSHA Hazard Communication Standard. In 1988, the Agency did not expect facilities to know the quantities of toxic chemicals manufactured as impurities that are subsequently used in commerce because there may be no tracking of these chemicals. The Agency did expect, however, facilities to have information regarding toxic chemicals manufactured on-site and then separated from the product. The commenter argues that the elimination of the *de minimis* exemption would now require the inclusion of toxic chemicals manufactured in byproducts that are subsequently processed or otherwise used. However, the Agency believes that facilities would already have the information needed in considering threshold determinations and release and other waste management calculations for these toxic chemicals because the chemicals were initially manufactured as byproducts. Therefore, in these situations, the reason for distinguishing between these activities is lost. EPA believes, therefore, that in the future, especially, it would be inappropriate, given the nature of PBT chemicals, to maintain the *de minimis* exemption.

lition, EPA believes that in many cases the receivers of the manufactured by-product that has been subsequently processed by the ating facility have the information needed to make reasonable estimates regarding the concentration of PBT chemicals in mixtures. E lders production records, monitoring or analytical data, EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Elec rating Facilities* (EPA 745-B-99-003)), trade association guidance documents (e.g., National Council of the Paper Industry for Air and n Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 I orting*), and reasonable judgement on the part of the facility's management all to be readily available data that covered facilities may u their calculations. However, as EPA explained in the 1988 final rule, if a covered facility does not have any information regarding the ntration of a toxic chemical in a mixture or trade name product, including no reasonable estimates and any other information reasonal y, it need not consider these quantities when making threshold determinations and release and other waste management calculations.

ional Monitoring Concerns

Commenter List: C-1168 (Duquesne Light), C-1352 (Borden Chemicals and Plastics), C-1434 (Association of International Automobile Manufacturers); C-1444 (ATMI); C-1844 (Oxychem); C1837 (Babcock and Wilcox); C-1833 (J. Ray McDermott, Inc.); C-1838 (Diamond Power International, Inc.); C-1819 (McDermott International, Inc.); C-1832 (BWX Technologies, Inc.); C-1453 (Equiva Services, LLC); C-1842 (United Technologies); C-1851 (Cyprus Amax Minerals Co.)

Comment: Some commenters assert that facilities will have to begin monitoring for trace quantities of chemicals in mixtures if the *de minimis* exemption is eliminated for PBT chemicals. One commenter (C-1434; AIAM) argues that the only way facilities would be able to estimate the levels of dioxin in combustion products and wastewater treatment "would be to undertake the costly burden of monitoring what comes off at a series of concentrations and temperatures." Another commenter (C-1444; ATMI) asserts that if the *de minimis* level is eliminated, industry would be subject to increased enforcement action because exhaustive testing may be insufficient to detect the chemicals. Furthermore, the increased testing requirements would place a significant cost burden on industry. In addition, one commenter (C-1842; United Technologies) asserts that with the elimination of the *de minimis* exemption for PBT chemicals would require industry could to analyze and track many PAH compounds generated in fuel burning sources.

Response: EPA disagrees. As stated in EPCRA section 313 (g)(2):

[i]n order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. *Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation. ...* (emphasis added)

Therefore, under EPCRA section 313, facilities are not required to perform any additional monitoring or analysis of production, process or use other than that already collected under other requirements. However, if a facility is required to monitor toxic chemicals under another statute, this data must be considered in determining thresholds and release and other waste management calculations under EPCRA section 313. EPCRA section 313(g) requires that facilities use readily available data, or in absence of such data, facilities are required to use reasonable estimates. If no monitoring data are available, the facility should use other readily available information in making threshold determinations and release and other waste management calculations. Further, if the facility believes that it has other, more representative data than its monitoring data, the facility should use that instead.

As to specifically tracking PBT chemicals in wastewater, the commenter is unclear as to whether the toxic chemicals discussed in the comment are manufactured as by-products or are processed or otherwise used. As discussed above, the *de minimis* exemption does not apply to toxic chemicals manufactured as by-products. Therefore, if PBT chemicals are coincidentally manufactured during on-site wastewater treatment, covered facilities are required to consider those toxic chemicals for threshold determinations and release and other waste management calculations even if the *de minimis* exemption were retained for PBT chemicals. Similarly, PBT chemicals manufactured as a result of burning fuel would not be exempt even if the *de minimis* exemption were retained because manufactured by-products are not eligible for this exemption. PBT chemicals in below *de minimis* concentrations in mixtures that are imported, processed, or otherwise used will be affected by the elimination of the *de minimis* exemption. Covered facilities will need to consider these quantities towards threshold determinations and release and other waste management calculations. These calculations would include the amounts

contained in combustion by-products and wastewater treatment units. Additional monitoring of these quantities, however, would not be required under EPCRA section 313. Finally, EPA has limited the dioxin listing with the qualifier "manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical." Therefore, not all processing or otherwise use activities of the dioxin and dioxin-like compounds must be considered towards the facility's threshold determinations.

Readily Available Data Issues

Comment List: C-1407 (Delphi); C-1421 (General Electric); C-1842 (United Technologies); C-1851 (Cyprus Amax Minerals, Co.); C-1863 (NMA); C-1826 (NWMA); C-1850 (ASARCO); C-1843 (SOCMA); C-1865 (API)

Comment: The commenters assert that the elimination of the *de minimis* exemption would conflict with the condition that reporters obtain data from readily available sources. They argue that AP-42 guidance, Air CHIEF CD-ROM, TANKS, CHEMDAT8 and WATER8 would provide additional assistance in estimating the amount of a PBT incidentally manufactured in wastestreams or released, however, these tools will not help quantify the amount of chemical in materials which are distributed in commerce or used as feedstock. One commenter (C-1421;GE) argues that information generally available to covered facilities is no greater than it was 10 years ago because basic OSHA rules for MSDS information have not changed.

Response: The Agency believes that since reporting first began in 1988, new sources of information have become available to covered facilities to determine concentrations of toxic chemicals in mixtures. In addition to the data bases and information sources cited by the commenter, EPA believes there are other sources of data that can and should be used in making threshold determinations and release and management calculations for PBT chemicals. Examples of these sources of information include EPA guidance documents (e.g., *EPA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade association guidance documents (e.g., National Association of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Section 313 Form R Reporting*). In addition, relevant information has become much more accessible to covered facilities in the past ten years. For example, the United States Geological Survey's U.S. Coal Quality Database has been in existence since the 1970s, but only more recently has it been made available on the Internet. (<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>) EPA believes that these tools, in addition to the ones cited by the commenter, will help covered facilities quantify the amount of chemical in materials which are distributed in commerce or used as feedstock and will allow covered facilities to make reasonable calculations to comply with EPCRA section 313. Further, the Agency believes that it underestimated how much information covered facilities had available to them regarding small concentrations of toxic chemicals in mixtures. Therefore, EPA believes that facilities have sufficient information to make threshold determinations and release and other waste management calculations for PBT chemicals below *de minimis* concentrations. However, as explained above, if a covered facility has no information, including no reasonable estimates, or other information reasonably known about the concentration of the toxic chemical in the mixture, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations (at 53 FR 4511). Therefore if the *only* source of information on a toxic chemical in a mixture is an MSDS, and the MSDS does not indicate if the chemical is contained in the mixture, the facility is not required to consider the chemical towards threshold determinations or release and other waste management calculations.

EPA believes that some facilities covered under EPCRA section 313 have more extensive information available to them than they did in 1988 or EPA underestimated how much information they had available in 1988, and because these facilities are not required to report if they have no information on the concentration of the toxic chemical, the Agency believes that in these cases retention of the *de minimis* exemption would allow facilities to avoid reporting when information is available to them that would otherwise permit them to report.

Commenter List: C-1353 (Department of Energy), C-1356 (RJ Reynolds); C1405 (NASA - Ames Research Center); C-1421 (General Electric); C-1427 (Babcock and Wilcox); C-1833 (J. Ray McDermott, Inc.); C-1838 (Diamond Power International, Inc.); C-1819 (McDermott International); C-1832 (BWX Technologies, Inc.); C-1453 (Equiva Services, LLC); C-1862 (Fort James); C-1865 (American Petroleum Institute); C-1421 (American Forestry and Paper); C-0446 (IBM); C-1850 (ASARCO)

Comment: Commenters are concerned about the proposal to eliminate the *de minimis* exemption for PBT chemicals because MSDSs are a primary source of information for products used or processed that contain toxic chemicals. Because concentrations below 1% (and lower for carcinogens) are not required on MSDSs, the commenters believe that reporters will no longer be able to use MSDSs to screen for products containing below these concentrations for PBT chemicals. They assert that there does not seem to be another consistent source of information on whether a product contains a PBT chemical below *de minimis* levels. They also assert that the elimination of the *de minimis* exemption will cause additional burden for the regulated community because covered facilities will struggle with how to comply in the absence of a consistent source of information.

ation, but it will produce negligible information because data on *de minimis* quantities generally will not be found. Commenters also a with the lower reporting thresholds for most PBT chemicals of 10 or 100 pounds per year, there will be a greater likelihood that products ning PBT chemicals will go undetected and, thus, unreported.

Response: EPA disagrees. The Agency believes that since reporting first began in 1988, many new sources of information, in addition to MSDSs, have become available to covered facilities to use to determine concentrations of toxic chemicals in mixtures. Some of these sources of information include EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). In addition, relevant information has become much more accessible to covered facilities over the past ten years. For example, although the United States Geological Survey's U.S. Coal Quality Database has been in existence since the mid 1970s, only more recently has it been made available on the Internet. (<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>). Further, the Agency believes that it underestimated how much information covered facilities had available to them in 1988 regarding small concentrations of toxic chemicals in mixtures. In fact, at least one commenter (C-1353; Department of Energy) implied that they had other sources of information by indicating that MSDSs were one of its principle sources of information. However, as EPA explained in the preamble to the final rule:

“[i]n the event that the person does not know the specific concentration or the upper bound concentration than the person is not required to further estimate or otherwise factor that chemical in that mixture or product into threshold or release calculations.” (February 16, 1988; 53 FR 4511)

Therefore if the *only* source of information on a toxic chemical in a mixture is from an MSDS, and the MSDS does not indicate if the chemical is contained in the mixture, the facility is not required to consider the toxic chemical towards threshold determinations or release and other waste management calculations.

Because facilities covered by EPCRA section 313 have more extensive information available to them than they did in 1988 and because these facilities are not required to report if they have no information on the concentration of the toxic chemical including no reasonable estimates or other information reasonably, the Agency believes that in these cases the *de minimis* exemption will allow facilities to avoid reporting when information is available to them that would permit them to report.

Requests to retain *de minimis* for a specific mixture or industry

Commenter List: C-1842 (United Technologies)

Comment: The commenter asserts that EPA should not remove the *de minimis* exemption for PBT chemicals at facilities that burn fuel for heat or power because they believe that EPA can more efficiently obtain information on the impact of fuel burning from sources other than reports by every individual user.

Response: EPA disagrees. The commenter does not suggest any other data sources from which EPA can more efficiently obtain information on the impact of fuel burning. In the past, EPA has carefully analyzed existing sources of release information and has consistently found that these, either separately or taken together, can adequately substitute for the TRI program. As explained in the 1997 final rule that requires seven new industries to report under EPCRA section 313:

EPA maintains several other data bases that are designed to support the enforcement and compliance efforts of the Agency's major program offices. Existing data sources include the Aerometric Information Retrieval System (AIRS), the Permit Compliance System (PCS), the Biennial Reporting System (BRS), and the Tier I and II reports submitted under sections 311 and 312. However, these alternate data sources do not provide an adequate substitute for the information reported to TRI, nor do they create the same incentives to implement pollution prevention measures that TRI does. Currently available non-TRI sources of information cannot provide release and transfer, inventory, or pollution prevention data with the scope, level of detail, and chemical coverage as data currently included in TRI. (62 FR 23833; at 23881)

Therefore, EPA does not believe there is another source from which to obtain this release and other waste management of toxic chemicals burning.

Commenter List: C-1168 (Duquesne Light); C-1423 (EEI); C-1842 (United Technologies); C-1861 (Indianapolis Power and Light); C-1820 (Energy Services)

ment: Some commenters assert that to avoid unnecessary and undue burden, EPA should retain the *de minimis* exemption for polycyclic aromatic hydrocarbons (PAHs) present in fuel that are destroyed during combustion. They state that PAHs often are present in fuel oil below *de minimis* concentrations and that most, if not all, PAHs are destroyed during the combustion process. Further they assert that even if the release threshold is exceeded, no releases of the PAHs would be reported on the Form R. They insist that requiring facilities to conduct release calculations for PAHs in the fuel oil they burn would impose an unnecessary burden on industry with no corresponding benefit. However, they argue that facilities are not likely to know the quantity of PAHs in their fuel oil if the substances are present below *de minimis* concentrations because such information is exempt under supplier notification regulations. Therefore, they assert that the elimination of the *de minimis* exemption for PAHs in fuel oil will not generate additional TRI reports. One commenter (C-1820 New Century Services) seems to argue that PAHs created and destroyed in fuel are exempt because they are otherwise used and thus eligible for the *de minimis* exemption.

Response: EPA disagrees with the commenters' assertions. The commenters imply that a chemical should be exempt from reporting under EPCRA Section 313 if it is not released. This is inconsistent with the statute. Specifically, EPCRA Section 313 (a) states:

[t]he owner or operator of a facility subject to the requirements of this section shall complete a toxic chemical release form as published under subsection (g) for each toxic chemical listed under subsection (c) that was manufactured, processed, or otherwise used in quantities exceeding the toxic chemical threshold quantity established by subsection (f) during the preceding calendar year at such facility. Such form shall be submitted to the Administrator and to an official or officials of the State designated by the Governor on or before July 1, 1988, and annually thereafter on July 1 and shall contain data reflecting releases during the preceding calendar year.

EPCRA criteria for determining whether a facility reports under EPCRA section 313 are not based on quantities released but rather on quantities of toxic chemicals manufactured, processed, and otherwise used at the facility. Whether the toxic chemical is eventually released or consumed is irrelevant in terms of threshold determinations. Further, Congress required the maximum quantity of the toxic chemical on-site to be reported which clearly indicates that Congress did not intend for the TRI database to be limited to releases.

In addition, the commenters assert that facilities are not likely to know the quantity of the PAHs in their fuel oil if they are below *de minimis* concentrations because these quantities are exempt from supplier notification. However, EPA believes covered facilities have other sources of information available to them in making their threshold determinations and release and other waste management calculations. Some sources include production records, monitoring or analytical data, EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electric Generating Facilities* (EPA 745-B-99-003)), trade association guidance documents (e.g., National Council of the Paper Industry for Air and Environmental Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Section 313 Form R Reporting*), and reasonable judgement on the part of the facility's management. In addition, as EPA explained in the 1988 final rule, if a facility has no information on the concentration of the toxic chemical in the mixture, including no reasonable estimates or other information reasonably known, they need not consider the chemical in that mixture for threshold determinations and release and other waste management activities.

Further, EPA believes that reports indicating that a facility exceeds a threshold but has no releases or other quantities of the PBT chemical reported as waste does provide the public with information on PBT chemicals in their community. Just as knowing that facilities in a given community are releasing or otherwise managing PBT chemicals as waste, EPA believes that the public should also know when facilities exceed the release threshold for a given chemical but have no waste management activities associated with it. Further, in addition to providing release and other waste management information, facilities report an indication of how the chemical is used and the maximum amount of the chemical released during the reporting year. This information may also be important to the community for emergency planning purposes. Further, EPA is required to obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements of this EPCRA section 313. (EPCRA section 313 (f)(2)) Reports indicating zero releases would give an indication of whether or not the Agency is obtaining a substantial majority of releases.

This commenter's assertion that all PAHs are destroyed during the combustion of fuel is contradicted by another commenter (C-1418; SCANA/SCE&G), who, based on existing information performed an evaluation and estimates releases at 20 pounds of PAHs from the burning of fuel. In addition, the commenters interested in retaining the *de minimis* exemption for PAHs in fuels, do not explain if they are only interested in maintaining the *de minimis* exemption for the PAHs that are actually destroyed during combustion and eliminating the exemption for other chemicals covered by the PAH chemical category, or if the commenter wants to maintain the *de minimis* exemption for all PAHs covered by the PAH chemical category that are combusted in fuel. In either instance, the *de minimis* exemption is based, in part, on whether toxic chemicals are contained in mixtures in such small quantities such that they are not expected to significantly contribute to threshold determinations, as well as release calculations. However, as explained in previous comments, since PBT chemicals can remain in the environment for

a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. Therefore, it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals. Thus, for PBT chemicals, releases and other waste management activities that occur at facilities that manufacture, process, or otherwise use such chemicals in relatively small amounts are of concern.

Commenter list: C- 1438 (International Carbon Black Association)

Comment: The commenters assert that the *de minimis* exemption should be retained for PACs in carbon black because the PAC content of is very low, varies widely and cannot be easily estimated based on data that is currently available or that can be developed without great effort. They argue that the burden of estimating and reporting PAC releases on carbon black is disproportionately high because there is no guidance available for estimating releases of PACs from the carbon black manufacturing process. In fact, without extensive testing, they argue, there is no reliable method for estimating PAC releases on carbon black from the manufacturing process. Further, they assert that the information that exists is not of the quantity and quality necessary to meaningfully estimate releases. They believe that the existing data consists of too few samples and the results are too variable to provide a meaningful basis for estimating PAC releases. Even if the carbon black industry were to sponsor the extensive testing required, it could face substantial difficulty. No consensus method for measurement of the PACs exists. Further, laboratory standards for all of the PACs are not readily available to all member companies and/or outside laboratories. In addition, because the concentrations and identities of PACs contained on carbon black are highly variable from process to process, from raw material to raw material, and even from batch to batch, it is extremely difficult to develop any meaningful generalizations for use in estimating PAC releases.

Response: EPA disagrees that the burden of estimating and reporting PAC releases on carbon black is disproportionately high. As explained in EPCRA section 313 (g)(2), facilities are not required to perform any additional monitoring or analysis of production, process or use other than that already collected under other requirements. Therefore, EPA does not require extensive testing to comply with EPCRA section 313. However, EPA believes that in many cases covered facilities already have the information needed to make reasonable estimates regarding the concentration of PBT chemicals in mixtures. For example, concentrations of benzo(a)pyrene (BaP) in carbon black were reported in the article entitled “Effect of Carbon Black on Worker Health in the Rubber Industry” (Page 4, Table 2) as found in “Dangerous Properties of Industrial Materials Report” (January/February 1985). In this article, carbon black N375 was shown to have 1 ppm BaP and N762 to have 8 ppm.

In addition, from the comment it seems that some carbon black facilities have produced samples. Many covered facilities that successfully comply with EPCRA section 313 do not even have samples or monitoring data on which to base estimates. If however, as EPA has stated in guidance documents, a facility does not believe that its available data is representative and reasonable estimates would provide more accurate release information facilities should use that. (See, for example, Q&A # 469 in the 1998 “EPCRA Section 313 Questions and Answers” document.) Some sources of information EPA believes covered facilities have available to them in making their calculations include production records, monitoring or analytical data, EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)), trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI’s *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*), and reasonable judgement on the part of the facility’s management. In addition, as EPA explained in the 1988 final rule, if a covered facility has no information on the concentration of the toxic chemical in the mixture, including no reasonable estimates or other information reasonably known, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations. If a covered facility does have information regarding the concentration of a toxic chemical in a mixture or trade name product, they must consider all non-exempted sources of the chemical for threshold determinations. If an activity threshold is exceeded for the chemical, they must then calculate release and other waste management quantities. The same process involving gathering relevant data for PBT chemicals contained in mixtures or other trade name products in very small quantities would apply regardless of the concentration of the PBT chemical in the mixture. Therefore given that facilities are not required to perform additional monitoring, are not required to consider concentrations of toxic chemicals for which they have no information, and need only consider readily available data, EPA disagrees that identifying and evaluating carbon black for PACs will be more costly than toxic chemicals found in other mixtures. In addition, carbon black facilities should not be relying solely on generalizations made across the industry to comply with EPCRA section 313. These facilities should be considering site specific information in conjunction with models and guidance documents and other more general information to make threshold determinations and release and other waste management calculations.

In addition, EPA believes that many facilities will be able to accurately estimate releases and other waste management of PBT chemicals in very small quantities. Although it may be true that some facilities will be better able to make those estimates than others, EPA does not believe this justifies not collecting accurate information on small quantities from those facilities that can provide it. Further, facilities are required, for each release or other waste management amount reported, to indicate the principal method used to determine the amount of release reported. There are codes which allow the facility to indicate whether the estimate is based on monitoring data, mass balance calculations, published emission factors, or other approaches such as engineering calculations or best engineering judgement. The statute requires that facilities use readily available data collected at the facility to meet other regulatory requirements or as part of routine plant operations. EPA does not require that additional monitoring or sampling be done in order to comply with EPCRA section 313. By looking at the information provided through the use of these codes, users of the data can gain an understanding of the degree of accuracy or uncertainty in particular numbers reported by a facility.

Comment List: C-1863 (National Mining Association); C-1826 (NW Mining Association)

Comment: The commenters assert that by eliminating the *de minimis* exemption for all PBT chemicals because the ones currently considered are commonly byproducts, all future PBT chemicals would be denied the *de minimis* exemption whether or not they are byproducts. Specifically, the commenters are concerned that EPA may in some future rulemaking add other naturally occurring metal compounds to the list of PBT chemicals covered by EPCRA section 313 that would otherwise be eligible for the *de minimis* exemption.

Response: The commenters are confused; EPA did not eliminate the *de minimis* exemption because the PBT chemicals in this rulemaking are commonly considered byproducts. As explained in the 1988 final rule implementing EPCRA section 313, the Agency adopted the *de minimis* exemption because: 1) it believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; 2) the Agency did not believe that the quantities from these low concentrations would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509); and 3) the exemption was consistent with information mandated by the OSHA HCS.

The Agency agrees that there are instances where PBT chemicals are manufactured as byproducts and would therefore not be affected by the elimination of the *de minimis* exemption. However, as EPA explained in the PBT proposal, the Agency also believes that there are many instances in which a PBT chemical may exist in a mixture at a concentration below the 1% or 0.1% *de minimis* limit (e.g., mercury found in steel) but where the processing, otherwise use, importation or manufacture as an impurity of the PBT chemical in that mixture would otherwise contribute significantly to or exceed the reporting thresholds proposed. (64 FR 714) Releases and other waste management associated with these exempt activities, however, would have been eligible for the *de minimis* exemption. Moreover, as explained in more depth in other responses to comment, EPA believes that covered facilities have several sources of information available to them regarding the concentration of PBT chemicals in mixtures, that the small quantities of PBT chemicals would be much more likely to contribute to the lower thresholds proposed, and that the concentration levels chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals. Therefore, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to chemicals that persist and bioaccumulate and is eliminating the exemption for these toxic chemicals. If the Agency determines that additional toxic chemicals meet the EPCRA section 313 persistence and bioaccumulation criteria, EPA would not allow the *de minimis* exemption to be taken for these chemicals.

Commenter List: C- 1851 (Cyprus Amax Minerals Company)

Comment: The commenter asserts that the *de minimis* exemption should be retained for PBT chemicals present at mining facilities. They argue that the burden upon the mining industry is even greater in the context of the low thresholds proposed for PBT chemicals. Further, they assert that although EPCRA does not require covered facilities to conduct tests concerning the amount of listed chemicals processed, most reporters rely upon their knowledge of their manufacturing processes and raw materials to produce meaningful data for EPCRA section 313 reporting purposes. This is not true of the mining industry. Due to the volume of materials moved in the extraction process and the heterogeneous nature of the materials mined, process knowledge often is inadequate to produce a meaningful picture of the minute levels of PBT chemicals that may be present in mining operations. They assert that inadequate process knowledge combined with the enormous expense of constantly testing the processed materials makes the elimination of the *de minimis* exemption for PBT chemicals unworkable as applied to mining operations.

Response: EPA disagrees with the commenter. As the commenter points out, under EPCRA section 313(g)(2), facilities are not required to perform any additional monitoring or analysis of production, process, or use other than that already collected under other statutory or regulatory requirements. Therefore, there should be no added cost due to testing to comply with EPCRA section 313. However, EPA believes that in many cases mining facilities have the information needed to make reasonable estimates regarding small concentrations of PBT chemicals in the ores mined. In addition, as EPA explained in the 1988 final rule, if a covered facility has no information on the concentration of the toxic chemical in the mixture, including no reasonable estimates, the facility need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations. If a mining facility does have information regarding the concentration of a toxic chemical in a mixture or trade name product, the facility must consider all non-exempted sources of the chemical for threshold determinations. If an activity threshold is exceeded for the chemical, the facility must then calculate release and other waste management quantities. Covered mining facilities will need to identify and evaluate process streams when considering a PBT chemical in concentrations below the *de minimis* level just as they already do for toxic chemicals found in process streams in concentrations above the *de minimis* level. Therefore, given that covered facilities: (1) Are not required to perform additional monitoring; (2) are not required to consider concentrations of toxic chemicals for which they have no information; and (3) need only consider readily available data, EPA disagrees that identifying and evaluating mining activities involving mixtures containing less than 1.0% or 0.1% concentrations of PBT chemicals will be more burdensome than for larger quantities of these chemicals manufactured, processed, or otherwise used at a mining facility in excess of the activity thresholds.

Commenter list: C- 1846 (Independence Mining Co., Inc.); C-1859 (Phelps Dodge Corporation)

Comment: The commenters argue that the *de minimis* exemption should be retained for naturally occurring materials. One commenter (C-1859; Phelps Dodge) believes the *de minimis* exemption should specifically be maintained for naturally occurring metals and metal compounds that may in the future be added to the EPCRA section 313 list of toxic chemicals.

Response: EPA disagrees. The commenters provide no rationale as to why the *de minimis* exemption should be maintained specifically for naturally occurring PBT chemicals. Many chemicals that occur in nature are quite toxic; for example, mercury is sometimes naturally found in coal and oil. However, releases of mercury from the combustion of fuels is of particular concern for the Great Lakes area. Without further reasoning or basis, EPA is not persuaded that the releases and other waste management of toxic chemicals found naturally occurring that are processed or otherwise used by covered facilities should be exempted from reporting to the TRI. Because of the potential adverse effects on the environment from PBT chemicals, EPA believes that the elimination of the *de minimis* exemption for these chemicals is necessary to make the most information on the releases and other waste management activities associated with the human manipulation of these chemicals available to the public.

Concerns regarding inconsistency within the PBT proposal

Commenter list: C-1859 (Phelps Dodge Corporation)

Comment: The commenter asserts that EPA's reasoning on the *de minimis* exemption is inconsistent within the text of the PBT proposal preamble. The commenter argues that at one point the Agency explains that many PBT chemicals are manufactured byproducts and the exemption does not apply to manufactured byproducts and therefore the elimination of the exemption would not affect these chemicals but elsewhere explains that "there will be significant numbers of activities that occur for which the *de minimis* exemption could otherwise be taken."

Response: EPA disagrees that the text of the PBT proposal preamble is inconsistent concerning the elimination of the *de minimis* exemption for PBT chemicals. Although many PBT chemicals are manufactured byproducts and are therefore currently ineligible for the *de minimis* exemption, EPA believes that there are yet many other instances in which activities involving PBT chemicals are otherwise currently eligible for the exemption. For example, PBT chemicals manufactured as the result of waste treatment and disposed are not currently eligible for the exemption. However, PBT chemicals found in fuels below *de minimis* concentrations that are combusted on-site currently are eligible for the *de minimis* exemption for the otherwise use activity of combustion. However, because the Agency can no longer rely on its original bases for the *de minimis* exemption to justify retention of the exemption for PBT chemicals, and lacks a new basis, the Agency is eliminating the *de minimis* exemption for all uses of these toxic chemicals. Further, the removal of the *de minimis* exemption will help to ensure that the revised thresholds capture a "substantial majority of total releases".

Concerns that EPA has provided no evidence of significant releases

Commenter List: C-1421 (General Electric); C-1457 (Dow); C-1815 (CMA); C-1428 (American Forestry and Paper); C-1863 (National Mining Association); C-1826 (NW Mining Association); C-1859 (Phelps Dodge); C-1851 (Cyprus Amax); C-1850 (ASARCO)

Comment: The commenters argue that EPA presents no information to support its assertion that there are many instances where a PBT chemical may exist in a *de minimis* concentration in a mixture but the manufacture, process, or otherwise use of the chemical in the mixture would contribute significantly to exceeding the proposed low thresholds for PBT chemicals. They also assert that the Agency has provided no evidence that *de minimis* quantities of PBT chemicals in mixtures are resulting in significant releases of the chemicals or environmental loads. One commenter (C1428; AF&P) argues that in order to justify removing the *de minimis* exemption, the Agency should provide some form of quantification of the releases that are allegedly not being reported as a result of the *de minimis* exemption. Otherwise, the commenter asserts, EPA's proposed removal of the *de minimis* exemption is a pure policy decision without any scientific basis. Another commenter (C-1863; NMA) asserts that the Agency speculates about the existence of chemicals and then speculates on the ramifications of that chemical's speculative existence. They assert that the single example of dioxin does not provide the reasoned basis necessary for the agency's conclusory leap that other PBT chemicals can cause adverse effects at levels below *de minimis*, nor does a conclusion as to dioxin support abolition of the *de minimis* principle for all PBT chemicals.

Response: EPA disagrees that the Agency needs to show that PBT chemicals below *de minimis* levels result in "significant releases" because the statute bases a reporting determination on thresholds and not releases. However, even if there were a need, releases of mercury from the resmelting of steel, for example, could contribute significantly. For example, mercury can be found at very low concentrations in steel. A resmelting facility could process and release more than 100 pounds of mercury a year from its resmelting activities. However, although this total quantity is greater than the 10 pound proposed threshold for mercury, if the concentration of mercury in the steel is less than the *de minimis* limit, none of the mercury would be reportable if the *de minimis* level is retained for PBT chemicals. Releases and other waste management associated with these exempt activities would be absent from the TRI data base. Because even minimal releases of PBT chemicals may result in elevated concentrations in the environment or in an organism and can have the potential to cause an adverse effect, EPA believes that all releases of these chemicals are of concern and that such information is significant and of value to the public.

Further, EPA does not believe that it needs to meet any quantification criteria based on releases to justify the removal of the *de minimis* exemption because the original exemption was not a small quantity exemption, but rather an MSDS exemption. The exemption was based on the assumption that for the first few years of reporting, covered facilities would likely only have MSDSs on which to make threshold determinations and because there was an OSHA *de minimis* exemption these facilities would not have concentration information. As explained previously, however, the Agency now believes that covered facilities have numerous sources from which to draw to make threshold determinations, as well as release and other waste management calculations. In addition, the commenter has presented no rationale for its assertion, and the Agency is aware of no facts that would support it for PBT chemicals. Even relatively small releases of PBT chemicals have the potential to accumulate over time and cause adverse health and environmental effects. Further, EPA is aware of no information that would support distinguishing between chemicals in the process stream and the same chemicals in the waste stream, nor has the commenter submitted any with their comments.

Finally, whether or not to remove the *de minimis* exemption is not a science decision as the commenter asserts. The commenter misuses the term science. The decision is based on: 1) information regarding whether threshold quantities can be exceeded; 2) there is no legal or policy reason for the *de minimis* exemption given that thresholds will be exceeded; and 3) we know there is information available on many mixtures manufactured, processed or otherwise used at covered facilities (e.g., coal, oil, pesticide production, TSD profiles).

Commenter List: C- 1815 (CMA); C-1457 (Dow)

Comment: The commenters are concerned that eliminating the *de minimis* exemption will require many very small sources to report under the TRI. They argue that at a minimum, many small sources will need to be reviewed as potential sources and that data gaps found to exist will be extremely costly to assess. They assert that it is unrealistic for EPA to assume that the industry will report only on what they know, without making an effort to fill the gaps. They also argue that although there is no current history for enforcement actions that could arise from reports based on what is known to a facility, the possibility of expanding the grounds for enforcement are an area of genuine concern to facilities reporting under EPCRA section 313.

Response: EPA disagrees. From the comment, it is unclear why requiring facilities to identify and evaluate process streams containing low concentrations of PBT chemicals will be more burdensome than for larger concentrations of these chemicals in mixtures that are manufactured, processed or otherwise used at a covered facility in excess of the activity thresholds. As stated in EPCRA section 313 (g)(2), under EPCRA section 313, facilities are not required to perform any additional monitoring or analysis of production, process or use other than that already collected under other requirements or already available. Production records, monitoring or analytical data, EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)), trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*), and reasonable judgement on the part of the facility's management are all sources of information available to covered facilities in making their calculations. In addition, many covered facilities are required to comply with other environmental laws that require the facility to perform monitoring on listed toxic chemicals. For example, under the Resource Conservation and Recovery Act (RCRA), hazardous waste treatment, storage and disposal facilities are required to obtain detailed chemical and physical analysis of a representative sample of any hazardous wastes prior to any treatment storage or disposal and to develop written waste analysis plans that specify the frequency of sampling. Further, as EPA explained in the 1988 final rule, if a covered facility has no information on the concentration of the toxic chemical in the mixture, including reasonable estimates, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations. However, if a covered facility does have information regarding the concentration of a toxic chemical in a mixture or trade name product, they must consider all non-exempted sources of the chemical for threshold determinations. If an activity threshold is exceeded for the chemical, they must then calculate release and other waste management quantities. Covered facilities will need to identify and evaluate process streams when considering a toxic chemical in concentrations below the *de minimis* level just as they already do for toxic chemicals found in process streams in concentrations above the *de minimis* level. Therefore given that facilities: 1) are not required to perform additional monitoring; 2) are not required to consider concentrations of toxic chemicals for which they have no information; and 3) need only consider readily available data, EPA disagrees that identifying and evaluating process streams containing less than 1.0% or 0.1% concentrations of PBT chemicals will be more costly than for larger quantities of these chemicals manufactured, processed or otherwise used at a covered facility in excess of the activity thresholds.

Further, regarding increased enforcement, based on the above discussion, covered facilities are expected to have reasonable knowledge of the toxic chemicals present at their site and should document their considerations concerning threshold determinations and release and other waste management considerations. Because there is a statutory provision limiting monitoring requirements under EPCRA section 313 and there is regulatory language concerning reporting toxic chemicals for which the facility has no knowledge it is unlikely that facilities will have additional enforcement concerns.

Comment List: C-1424 (Chemical Manufacturers Association PCB Panel); C1405 (NASA - Ames Research Center)

Comment: The commenters assert that by eliminating the *de minimis* exemption, facilities that have previously been exempt would now have to report. They indicate that potentially a large number of facilities process chemicals containing trace level PCBs that, albeit at very low levels, are ubiquitous in the environment. The commenters assert that although the number of reports may be large, the likelihood of other than truly *de minimis* PCB releases is very low and these releases will be dwarfed by the waste incineration releases that EPA already covers under EPCRA section 313.

Response: The commenters confuse the *de minimis* exemption with *de minimis* quantities. The *de minimis* exemption is an exemption for toxic chemicals that are present in low concentrations in mixtures that are imported, processed, otherwise used, or manufactured as an impurity. EPA believed in 1988 that the quantities imported, processed, otherwise used, or manufactured as an impurity of a toxic chemical in a mixture in low concentrations would not contribute significantly to the thresholds of 25,000 and 10,000 pounds. This does not mean that quantities less than 25,000 or 10,000 pounds are *de minimis* quantities. Further at the new threshold of 10 pounds for PCBs, the threshold can easily be exceeded for chemicals present below the *de minimis* concentration level.

While individually these additional releases may be dwarfed by the waste incineration releases, the smaller releases will still provide beneficial information to communities because even very small releases can have significant impacts. For example, PCBs persist in soil for 0.91 to 7.25 years and bioaccumulate at a factor greater than 200,000. This clearly shows that even very small releases have the potential for large exposure impacts. Further, the commenter contends that because PCBs are ubiquitous in the environment, small quantities should not be reported. EPA believes, however, that an additional reason that small PCB releases should be reported is because they constitute additional loadings on environments such as the Great

Lakes.

In addition, with regards to facilities previously exempt now needing to report, EPA has accounted for these facilities in the economic analysis for this rulemaking. The commenter does not explain why they believe these estimates are invalid or inaccurate. Because EPA has already considered these new facilities, it is unclear how this now should be considered for maintaining the *de minimis* exemption.

Concerns that the rule will result in inconsistent reporting

Commenter List: C- 0446 (IBM); C-798 (Iron Mining Association of Minnesota); C-1865 (American Petroleum Institute)

Comment: The commenters argue that removing the *de minimis* exemption would lead to inconsistent reporting and would create a deterrent for facilities to conduct their own sampling programs. They assert that environmentally proactive facilities would report information because they have monitored for these chemicals whereas facilities without any information would not be required to report. One commenter (C- 0446; IBM) asserts that over-reporting by facilities just to ensure compliance would produce potentially significantly misleading and inaccurate data which, they argue, will divert the Agency and the public's attention from where real action is needed. They assert that this undermines the very purpose of the PBT strategy which is to focus limited resources where the risk is greatest. Additionally, they argue, it would unfairly expose facilities that over report out of caution to potentially negative publicity. They further assert that the reasoning EPA used for reporting dioxin in the PBT proposed rule, is also applicable to the elimination of the *de minimis* exemption. Specifically they cite:

"Attempting to require facilities to determine if they manufacture, process, or otherwise use any amount whatsoever of these chemicals would be extremely burdensome and perhaps technically impossible. Without an actual numerical threshold, many facilities might report some amount of these chemicals just to make sure that they are in compliance. This could lead to misleading and inaccurate data on the actual sources of these chemicals as well as imposing increased burden on reporting facilities." (64 FR 712)

Another commenter (C-1865; API) asserts that because EPA wants to use TRI data as a tool to target certain chemicals, EPA is proposing thresholds so low that they might be met solely due to *de minimis* quantities of chemicals in mixtures. They argue that eliminating the *de minimis* exemption will compound data inconsistencies and may result in gross distortions in TRI data with the potential to mislead the public, if releases for PBT chemicals appear artificially high relative to other chemicals and relative to past years.

Response: EPA disagrees that removing the *de minimis* exemption for PBT chemicals will introduce a "deterrent for facilities to conduct their own sampling programs." If there is such a deterrent, it is already in place because EPCRA section 313 (g)(2) only requires that facilities use readily available information. Facilities are not required to perform any additional monitoring or analysis of production, process or use other than that already required under other environmental and health statutes. In addition, if a covered facility does not have information regarding the concentration of a toxic chemical in a mixture or trade name product, they need not consider that quantity of the chemical for threshold determinations and release and other waste management calculations. Since the beginning of the EPCRA section 313 reporting program, there have been differing levels of information underlying individual Form Rs. Further, EPA believes that the information available to the typical EPCRA section 313 reporter is generally greater than it was 10 years ago. Because of this improved information availability, EPA believes that many facilities will be able to accurately estimate releases and other waste management of PBT chemicals in very small quantities. Although it may be true that some facilities will be better able to make those estimates than others, EPA does not believe this justifies not collecting accurate information on small quantities from those facilities that can provide it. Further, facilities are required, for each release or other off-site waste management quantity reported, to indicate the principal method used to determine the amount of release reported. There are codes which allow the facility to indicate whether the estimate is based on monitoring data, mass balance calculations, published emission factors, or other approaches such as engineering calculations or best engineering judgement. By looking at the information provided through the use of these codes, users of the data can gain an understanding of the degree of accuracy or uncertainty in a particular number reported by a facility. In addition, EPA will present the releases and other waste management of PBT chemicals in context with the other toxic chemicals in the Public Data Release. Therefore, the Agency disagrees that the removal *de minimis* exemption will distort the data and make releases of PBT chemicals appear artificially high relative to other chemicals in previous years.

Further, over reporting "out of caution" is not more acceptable than under reporting TRI data. Both underestimates and

overestimates provide misleading data to the public. EPA believes that the public should be provided with data as accurate as possible given the constraints of the statute.

Risk Issues

Commenter List: C-1820; (New Century Services); C-1836 (National Petroleum & Refiners Association); C- 1440 (Tenn. Valley Authority); C-1847 (American Portland Cement Alliance)

Comment: Some commenters argue that the Agency has not justified why the exemption will result in increased health risk to the public or the environment. One commenter (C- 1440; TVA) argues that given the extremely low levels of these PBT chemicals in coal, the risk to the general public from these releases, which they believe is the original purpose of the legislation, is not apparent. Another commenter (C-1836; National Petroleum & Refiners Association) asserts that EPA must demonstrate that removal of the exemption for specific PBT chemicals will have a public health or environmental benefit. Another commenter (C-1847; American Portland Cement Alliance) argues that the level of reportable compounds contained in mixtures is irrelevant to public health concerns when the compounds of concern remain chemically bound within benign compounds.

Response: EPA strongly disagrees with those commenters who indicated that EPA must consider risk to the general public when determining whether to eliminate the *de minimis* exemption. The purpose of TRI is to provide data on the releases (and other waste management activities) of listed toxic chemicals to communities so that they may use these data in conjunction with toxicity information for the chemical and site-specific information to determine if releases present a potential risk. They can also use TRI data in other ways. For example, an individual can use TRI data as a factor in choosing a neighborhood in which to live. The purpose of TRI, however, is not to make a national determination of risk, nor did EPA consider risk in its original adoption of the *de minimis* exemption under EPCRA section 313.

Moreover, as previously explained, EPA originally promulgated the *de minimis* exemption based on several considerations that are inapplicable to PBT chemicals. Where, as here, the rationale and factual bases underlying an exemption no longer exist with respect to a particular class, the Agency believes it cannot justify retaining the exemption for that class. Further, the Agency has received no information from any commenters that contradicts the Agency's factual and legal conclusions, or that would otherwise present a basis for retention of the *de minimis* exemption.

EPA also disagrees with the comment that because there are very low levels of PBT chemicals (e.g., mercury) in coal that the risk to the general public is not apparent. EPA believes that the commenter misunderstands the concept of risk. Because a chemical is in a low concentration in coal does not in itself control the level of risk that can result when coal is combusted. For example, mercury compounds are found in very low concentrations in coal. When coal is combusted, mercury compounds are either converted into mercury chloride or reduced to elemental mercury. Some of the mercury/mercury chloride is released to air and some remains in the bottom ash. The concentration of the mercury/mercury chloride in the air wastestream will not be the same as the concentration originally present in the coal. Once the mercury/mercury chloride is released, it will be carried varying distances before it is deposited. Mercury can be transported over large distances, while mercury chloride may be deposited relatively rapidly by wet and dry deposition processes. The amount of mercury in a community or ecosystem will depend upon sources both local and distant. Once mercury has been deposited, it will bioaccumulate in organisms and will also persist in the environment as a sink for exposure and bioaccumulation. The amount of mercury that a human, animal, or plant will be exposed to is related more closely to exposure pathways and the quantity that is present in an ecosystem rather than the concentration in the coal that is combusted. Thus, EPA believes that the commenter is incorrect.

Commenter List: C- 1851 (Cyprus Amax Minerals Company)

Comment: The commenter asserts that EPA's statement in the PBT proposal:

"[T]he intent of the *de minimis* exemption was primarily burden reduction. The *de minimis* exemption was not intended to be a general small quantity exemption, but rather an exemption based on the limited information likely to be readily available to facilities newly affected by EPCRA section 313." (64 FR 714)

is a mischaracterization and an attempt to dodge the inherent risk issue. They assert that, because the regulations already provide an exclusion for facilities that know the identity of the toxic chemical but not the specific concentration of the chemical in the mixture (40 CFR 372.30(b)(3)(iii)), limited information was not the principal reason for the exemption. They assert that the *de minimis* exemption, which applies even where a facility has full information, but the information does not lead to reporting

of meaningful data.

Response: EPA disagrees. There were several reasons EPA adopted the *de minimis* exemption. Burden reduction was clearly one of these reasons. As EPA explains in the 1988 final rule promulgating the *de minimis* exemption:

[b]ased on the comments received, EPA has determined that it is reasonable and appropriate to adopt a *de minimis* concentration limitation for toxic chemicals in mixtures under section 313. EPA believes that it is necessary to provide a *de minimis* limitation to help reduce the information development burden both on the part of the user and the supplier of such products.

In addition, EPA promulgated the *de minimis* exemption because: 1) the Agency believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding small concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; 2) the Agency did not believe that the quantities that result from these low concentrations in mixtures would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509); and 3) the exemption was consistent with information mandated by OSHA HCS.

Risk, however, clearly was not a consideration in adopting the *de minimis* exemption. The *de minimis* exemption can be taken only in certain circumstances that are related to whether a facility would have access to or would generate an MSDS. Certainly whether a facility has or generates an MSDS has no bearing on whether releases are particularly risky. If the Agency believed that small concentrations of any chemical would not result in risks, the Agency simply would have excluded all small concentrations of chemicals. The Agency did not do this. In addition, if EPA were to believe that small concentrations could be excluded because they pose minimal risk, the Agency does not believe that only one or two concentration cut-offs for all of the chemicals on the EPCRA section 313 list could be used. Further, determining whether a toxic chemical poses a risk is dependent upon a number of factors including toxicity of the chemical, release patterns, environmental fate, route of exposure, etc. It is improbable that one or two concentration cut-offs would protect all populations under all scenarios.

As explained previously, given that covered facilities have several sources of information available to them regarding the concentration of PBT chemicals in mixtures, that even minimal releases of persistent bioaccumulative chemicals may result in significant adverse effects, and that the concentration levels chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to PBT chemicals.

Further, EPA disagrees with the comment that the *de minimis* exemption was adopted because the information would not lead to reporting of meaningful data. EPA did not consider whether the information reported without the *de minimis* exemption would be meaningful. Rather the Agency considered whether or not toxic chemicals contained in mixtures or trade name products below the 1.0% and 0.1% concentrations would significantly contribute to threshold determinations and release calculations. However, at the current thresholds of 10,000 and 25,000 pounds/year, many significant releases of PBT chemicals are going unreported to the TRI database. The lowering of the threshold for PBT chemicals without a concomitant change in the *de minimis* exemption could result in very limited reporting. For example, mercury can be found at very low concentrations in steel. A resmelting facility could process and release more than 100 pounds of mercury a year from its resmelting activities. However, although this total quantity is greater than the 10 pound proposed threshold for mercury, if the concentration of mercury in the steel is less than the *de minimis* limit, none of the mercury would be reportable if the *de minimis* level is retained for PBT chemicals. Releases and other waste management associated with these exempt activities would be absent from the TRI data base.

Information Will Lack Consistency/Will Not Be Complete

Commenter list: C- 1817 (Koch Specialty Chemical Co)

Comment: The commenter asserts that the *de minimis* exemption allows for more accurate comparisons because it is a common value to all reports and, they assert, focuses attention where it most needs it. They argue that because no monitoring or analysis is required and no analytical methods are specified by EPCRA section 313, the quality of information that is reported on the TRI, is already highly variable. Further, they assert that if the reporting thresholds are lowered as proposed and the *de minimis* exemption is removed, the task of analysis may be technically impossible. They argue that with 602,200,000,000,000,000,000,000 molecules in a gram-mole of any chemical, the probability is that there is at least one

molecule of each and every chemical used by humans in every sample and analytical methods simply cannot determine these exceeding low concentrations.

Response: EPA disagrees that this is a common value to all reports. As explained previously, the *de minimis* exemption is not an across the board small quantity exemption. Rather, it is based on the concentration of the toxic chemical in a mixture or trade name product. Facilities that manufacture as an impurity, import, process or otherwise use the toxic chemical below certain concentration levels may be eligible for this exemption. However, if a facility manufactures the toxic chemical as a byproduct, this activity is not eligible for the exemption regardless of its concentration in the mixture. Therefore, the database does not contain information on only those chemicals present in process streams above 1.0 or 0.1%. Information on the toxic chemical in the wastestream is provided in section 7a of the Form R. If users of the data wanted to focus on concentrations of the chemical in the wastestream, they would focus on section 7a. In addition, if the commenter is suggesting that the *de minimis* exemption allows the user to focus on quantities of concern - he/she is incorrect because large quantities may be excluded from reporting while small quantities may be included (e.g., from coincidental manufacturing).

As explained previously, the *de minimis* exemption was adopted for a variety of reasons which focused on an expected lack of readily available data and whether or not low concentrations of toxic chemicals found in mixtures and other trade name products would contribute significantly to the finalized thresholds and release calculations. The Agency did not, however, consider the accuracy of comparisons across facilities. EPA believes that the information available to the typical EPCRA section 313 reporter is generally greater than it was 10 years ago. Because of this improved information availability, EPA believes that many facilities will be able to accurately estimate releases and other waste management of PBT chemicals in very small quantities. Although it may be true that some facilities will be better able to make those estimates than others, EPA does not believe this justifies not collecting accurate information on small quantities from those facilities that can provide it. Further, facilities are required, for each release or other waste management amount, to indicate the principal method used to determine the amount of release reported. There are codes which allow the facility to indicate whether the estimate is based on monitoring data, mass balance calculations, published emission factors, or other approaches such as engineering calculations or best engineering judgement. The statute requires that facilities use readily available data collected at the facility to meet other regulatory requirements or as part of routine plant operations. EPA does not require that additional monitoring or sampling be done in order to comply with EPCRA section 313. By looking at the information provided through the use of these codes, users of the data can gain an understanding of the degree of accuracy or uncertainty in any particular number reported by a facility.

The commenter states that there is a molecule of each and every chemical in each sample and this will make analysis impossible. The first part of this assertion is irrelevant and EPA disagrees with the second part. Under EPCRA section 313, facilities are only required to rely on readily available information; monitoring data if available, and if not, then only "reasonable estimates of the amounts involved." EPCRA section 313(g)(2). This would preclude the commenter's concern that facilities would need to account for each potential molecule of a listed toxic chemical. As previously explained, if a facility does not have any information regarding the concentration of a toxic chemical in a mixture or a trade name product, the facility is not required to consider that quantity of the toxic chemical when making threshold determinations or release and other waste management calculations. Further, if a facility believes a toxic chemical is in a mixture or trade name product but is below detection limits, facilities are instructed to report half of the detection quantity as explained in EPA guidance (See Q&A #497 in the 1998 "EPCRA Section 313 Questions and Answers" document).

In addition, EPA disagrees that attention to PBT chemicals should be focused on larger quantities of PBT chemicals. As explained previously, PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues. Even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. Thus, for PBT chemicals, releases and other waste management activities even in relatively small amounts are of concern.

Comment List: C-1843 (SOCMA)

Comment: The commenter asserts that EPA should not remove the *de minimis* exemption because the information can never truly be complete. Even Congress, in enacting Section 313, they argue, recognized that the reported information would not be complete. They argue that EPCRA Section 313(f)(2) authorizes EPA to revise the reporting thresholds provided that a "substantial majority" of aggregate releases are subject to reporting and the legislative history further observes that Section 313 "would not necessarily require reporting from each facility." H.R. Conf. Rep. No. 962, 99th Cong., 2d Sess. 296 (1986); 132 Cong. Rec. H9607 (daily ed. Oct. 8, 1986) (statement of Rep. Swift) ("[r]eporting from all facilities will not necessarily be required"). EPCRA Section 313(f)(2) and the legislative history also show that the case law citations^{3/} offered by EPA in

support of its proposed approach are inapposite. The concentration thresholds are not based on EPA's inherent authority to establish, through regulation, *de minimis* exemptions from statutory provisions. Rather, Congress specifically granted EPA the flexibility to craft regulations excluding some (albeit a minority) of releases and some facilities. The proposed rule fails to present any data showing that elimination of the long-established *de minimis* thresholds would be necessary for PBT chemicals in order to satisfy Section 313.

Response: EPA disagrees. First, the commenter is incorrect as a matter of fact; EPA relied on the *de minimis* principle for its legal authority to create its regulatory *de minimis* exemption. In the authority section of its 1988 rulemaking, EPA did not cite to EPCRA section 313(f)(2), or make the findings required to exercise authority under that section of the statute. Nor did the Agency amend the manufacture, processing, and otherwise use thresholds; as has been explained in previous responses, the *de minimis* exemption is not an across-the-board small quantities exemption, but an exemption based on the availability of information and on the recognition that EPCRA section 313 does not require monitoring.

Second, if the commenter was merely trying to offer the Agency another theory on which to promulgate or retain the *de minimis* exemption, the Agency does not believe that reliance on EPCRA section 313(f)(2) is adequate for several reasons. The most significant is that, while EPCRA section 313(f)(2) permits EPA to modify thresholds, it does not authorize EPA to modify the reporting requirement in EPCRA section 313(g) that facilities must report “[t]he annual quantity of the toxic chemical entering each environmental medium.”

Commenter List: C1405 (NASA - Ames Research Center)

Comment: The commenter asserts that the elimination of the *de minimis* exemption will eliminate a uniform set of values to which the regulated community is held.

Response: EPA disagrees. Because there have been many significant changes to the EPCRA section 313 program over the past ten years, EPA believes that it is incorrect to state that there has been a “uniform set of values to which the regulated community has been held.” For example, in 1994 EPA began allowing facilities that meet certain criteria to file the Form A, a substantially abbreviated form (59 FR 61488). Under this regulation, facilities that release or otherwise manage as waste less than 500 pounds of a listed toxic chemical and that manufacture, process or otherwise use less than one million pounds of the chemical during a reporting year may submit a form that simply certifies that the facility meets these criteria. Companies eligible to file the Form A still meet all of the criteria for reporting but do not have to report their amounts of the toxic chemical released or otherwise managed as waste. Other significant changes to the program include changes to the list of toxic chemicals as a result of the addition of several new industries to those covered by EPCRA section 313 (November 30, 1994; 59 FR 61488).

As stated previously, EPA does not believe that the reasons the Agency originally adopted the *de minimis* exemption apply to this rulemaking. The purpose of the PBT rulemaking is significantly different from past rulemakings in that it is intended to capture significantly smaller quantities of releases and other waste management associated with these chemicals. Many of the PBT chemicals addressed in the proposal have been shown to cause adverse effects at concentrations far less than the *de minimis* levels. For example, dioxins have been shown to cause adverse effects at levels in the parts per trillion. In addition, after ten years of experience with the program, the Agency believes there are many sources of information, in addition to MSDSs, available to reporters to use in making EPCRA section 313 determinations. Some of these sources of information include EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). Further, even in 1988, the Agency was not convinced that the *de minimis* exemption would remain as it was originally intended. As stated in the final rule:

EPA plans to review this *de minimis* policy and the assumption upon which it is based in light of data that will be collected under this rule. (53 FR 4509)

Therefore, because the program has undergone many significant changes, and because the Agency does not agree that the reasons originally considered in adopting the *de minimis* exemption are appropriate for this rulemaking, EPA does not believe that the elimination of the *de minimis* exemption will remove a uniform set of values to which the regulated community is held.

Requests for Guidance on PBT chemicals

Commenter List: C-1353 (Department of Energy); C-1842 (United Technologies)

Comment: If the *de minimis* exemption is eliminated, the commenters request that EPA provide information on those products that will have PBT chemicals below *de minimis* levels. Specifically, one commenter (C-1842; United Technologies) argues that EPA should develop a database designed to provide PBT chemical reporting information.

Response: EPA may at some point in the future, develop additional information such as a source guide for PBT chemicals expected to be in mixtures below the current *de minimis* levels

Comments in Support of Eliminating the *de minimis* Exemption

Commenter List: C-849 and C-403 (Communities for a Better Environment); FORM A: C041 (Ohio BASS Chapter Federation); C-1351 (Grand Calumet Task Force); C1355 (Ohio Environmental Council); C-1409 (National Environmental Trust); C1415 (Cold Mountain Cold Rivers); C-1899 (Florida Clean Power Coalition); C-1825 (Rohm and Haas); C-1454 (Ecology Center; C-1447 (Oregon DEQ); C-1449 (RESTORE); C-1451 (Atlantic States Legal Fund); C-553 (Individual Citizen); C-311 (NJ DEP); C-1823 (22 Interested Parties); C-1871 (Chesapeake Bay Foundation); C-0792 (Mass. DEP); C-0802 (Minnesota OEA); C-1855 (Environmental Defense Fund); C- 1932 (Physicians for Social Responsibility); C-0836 (Individual Citizen), C-311

Comment: Several commenters support EPA's proposal to eliminate the *de minimis* exemption for PBT chemicals. They argue that the *de minimis* exemption would undermine the proposed changes to the reporting threshold and would allow an unnecessary loophole from reporting. They assert that proposal does not require any additional testing for impurities and that the only additional reporting would be for those facilities that use sufficient quantities of mixtures or trade name products containing PBT chemicals as impurities. Therefore, they assert, the additional burden would be for reporting only, not any new analyses. One commenter (C-1825; Rohm and Haas) believes that the *de minimis* exemption may be appropriate specifically for dioxins. Another commenter (C-403; Communities for a Better Environment) provided several examples of information that would be lost if the *de minimis* exemption were to be retained. One example included dioxin-like chemicals found in diesel fuel and motor oil as products from a refinery are roughly 0.000000005% of the product, far below the 0.1% *de minimis* concentration level based on the commenter's analysis of data from UC Riverside (1998). Another commenter (C-1855; Environmental Defense Fund) asserts that the original rationale for the *de minimis* exemption levels, *i.e.*, based on Occupational Safety and Health Administration Hazard Communication Standard (HCS) thresholds of 1.0% for hazardous chemicals in mixtures and 0.1% for carcinogens in mixtures, does not apply to raw materials that are not manufactured chemicals, such as crude oil, coal, mining inputs, etc. (which all commonly contain toxic chemical impurities).

Response: EPA agrees with these commenters and is eliminating the *de minimis* exemption for PBT chemicals. As discussed above, the reasons EPA indicated for originally adopting the *de minimis* exemption are not applicable to PBT chemicals. In addition, EPA received no compelling arguments from commenters to extend the *de minimis* exemption to PBT chemicals. Because the purpose of the PBT rulemaking is different from past rulemakings in that it is intended to capture information on significantly smaller quantities of releases and other waste management associated with these chemicals, the *de minimis* exemption could significantly limit the amount of reporting on PBT chemicals. Therefore, given that: (1) covered facilities have several sources of information available to them regarding the concentration of PBT chemicals in mixtures; (2) even minimal releases of persistent bioaccumulative chemicals may result in significant adverse effects and can reasonably be expected to significantly contribute to the proposed lower thresholds; and (3) the concentration levels chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to PBT chemicals. EPA is therefore eliminating the *de minimis* exemption for PBT chemicals.

PCB and TSCA issues

Commenter List: C1405 (NASA - Ames Research Center)

Comment: The commenter asserts that since the Toxic Substances Control Act (TSCA) does not require the tracking of items below 50 parts per million, the elimination of any *de minimis* concentration would increase the burden to facilities to identify and track any material which contains PCBs at any concentration at the facility.

Response: While the commenter is correct that removal of the *de minimis* will increase burden, as explained previously, EPA did not adopt the *de minimis* exemption solely to reduce burden. As explained in the PBT proposal and in this document, the

nature of PBT chemicals make the *de minimis* exemption in appropriate for these chemicals. EPA believes that facilities now have additional sources of information available to them to determine the concentrations of PBT chemicals in a variety of mixtures and trade name products. Although TSCA does not require the tracking of chemicals below 50 parts per million, EPA believes that there are other sources of information such as process knowledge available to covered facilities in making threshold determinations and release and other waste management calculations for small quantities of PCBs. In addition, it is unclear from the comment, why tracking PCBs is more burdensome than for other chemicals that TSCA does not require facilities to track which are manufactured, processed or otherwise used at a covered facility in excess of the activity thresholds. Covered facilities must consider all sources of releases and other waste management for each non-exempt toxic chemical for which an activity threshold has been exceeded.

Supplier Notification

Commenter List: C-1844 (Oxychem); C-1919 (Brominated Flame Retardant Industry Panel of CMA)

Comment: The commenters argue that removing the *de minimis* exemption changes the supplier notification requirements. This change would also increase the burden on reporting facilities, as they will be required to track minuscule amounts of PBT chemicals through their processes. At a minimum, the facility must make threshold determinations. Additional burden is imposed because TRI reports become more complex when trace amounts are included.

Response: The commenters are confused. As explained in the PBT proposal, EPA did not propose to modify the applicability of the *de minimis* exemption for supplier notification of PBT chemicals because the Agency believes that there is sufficient information available on PBT chemicals to covered facilities. The requirement of additional information under the supplier notification requirements in this case would result in redundancies.

Commenter List: C-1433 (Chlorobenzene Producers Association)

Comment: The commenter supports the current proposal to continue the *de minimis* exemption for purposes of Subpart C Supplier Notification Requirements under 40 C.F.R. § 372.45(d)(1).

Response: EPA agrees. As explained in the PBT proposal, the Agency believes there is sufficient information available on PBT chemicals to covered facilities. The requirement of additional information would result in redundancies under the supplier notification requirements.

Commenter List: C-1868 (International Paper)

Comment: The commenter asserts that raw material suppliers will be required to assess their products and chemical formulations and to notify customers of PBT chemicals potentially present in raw materials. If the *de minimis* exemption is removed, manufacturers will be put in the impossible position of having to determine chemical quantities at and below PBT analytical detection limits. To protect themselves from liability, they likely will over estimate and inaccurately report the quantities of PBT chemicals present. The cost to suppliers and manufacturers of this analytical and administrative burden is not considered in the proposed rule's economic analysis and should be added.

Response: The commenter is confused. EPA did not propose to modify the *de minimis* exemption for supplier notification of PBT chemicals because the Agency believes that there is sufficient information available on PBT chemicals for covered facilities. Therefore, suppliers will not be required to alert their customers if PBT chemicals are contained in their raw materials.

EPA disagrees with the commenter's assertion that manufacturers will be in an impossible position when determining thresholds and release and other waste management calculations for PBT chemicals known to be present but that exist below detection limits. Although no monitoring is required specifically under EPCRA section 313, EPA believes that covered facilities generally have the information necessary to make reasonable estimates concerning the concentrations of PBT chemicals in mixtures and trade name products they use on-site. There are many sources of information available to covered facilities to help them make this determination. Specifically, some of these sources of information include production records, monitoring or analytical data, EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)), trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream

Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*) and reasonable judgement on the part of the facility's management. EPA believes that these tools will allow covered facilities to quantify the amount of PBT chemicals in materials which are distributed in commerce or used as feedstock and will allow covered facilities to make reasonable calculations in order to comply with EPCRA section 313. As explained in EPA guidance, (See Q&A #497 in the 1998 *EPCRA Section 313 Questions and Answers* document), if a facility believes a toxic chemical is in a mixture or trade name product but is below detection limits, facilities are instructed to report half of the detection quantity. Therefore, EPA believes that facilities have sufficient information to make threshold determinations and release and other waste management calculations for PBT chemicals below *de minimis* concentrations.

Further, some covered facilities may not have a detection limit to serve as an upper limit. As EPA explained in the 1988 final rule if a covered facility has no information on the concentration of the toxic chemical in the mixture, including reasonable estimates, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations. In addition, it is unclear from the comment, why tracking PBT chemicals in small quantities is more burdensome than for other chemicals which are manufactured, processed or otherwise used at a covered facility in excess of the activity thresholds. Covered facilities will need to identify and evaluate process streams when considering a toxic chemical in concentrations below the *de minimis* level just as they already do for toxic chemicals found in process streams in concentrations above the *de minimis* level.

EPA disagrees with the commenters assertion that covered facilities will or should overestimate and misreport the quantities of chemicals present to protect themselves from liability. Overestimating releases and other waste management quantities will result in information that is as misleading as information based on underestimating releases and other waste management quantities. For ten years, the TRI database has been a key tool in providing information to the public on release and other waste management quantities of toxic chemicals. Further, based on their best readily available information, facilities should report what they believe to be most accurate amounts of releases and other waste management. As EPA has explained in guidance, facilities are instructed to document their reasoning and calculations when making estimates for threshold determinations and release and other waste management calculations. (See Q&As 470 and 472-474 in the 1998 "EPCRA Section 313 Questions and Answers" document (EPA 745-B-98-004)) These records are what EPA inspectors review for enforcement actions. Just as inspectors may enforce against facilities that deliberately under-report, they may also enforce against facilities that deliberately over-report. Therefore, given that facilities should report as accurately as possible and that facilities are increasingly encouraged to reduce their release and other waste management quantities, EPA does not believe that liability concerns provide a real incentive to covered facilities to over-report these quantities.

5.a.i. Establish a lower *de minimis* level for PBT chemicals

Commenter List: C-1352 (Borden Chemicals and Plastics)

Comment: The commenter requests EPA to consider a *de minimis* level that approaches a realistic level of detection for a particular stream.

Response: As explained in previous comments, EPA adopted the *de minimis* exemption for several reasons including the desire to be consistent with information previously mandated by the Occupational Safety and Health Administration's (OSHA) hazard communication standard (HCS). This OSHA standard requires the listing of hazardous chemicals on material safety data sheets (MSDSs) but allows chemical suppliers to omit from the MSDSs hazardous chemicals that are below certain concentrations. Specifically, EPA adopted the *de minimis* concentration levels of 0.1% for carcinogens and 1.0 percent for non-carcinogens based on the OSHA standard because the Agency believed that facilities newly covered under EPCRA sections 313 would already be familiar with the HCS. EPA adopted the *de minimis* levels under EPCRA section 313, then, not based on detection limits but rather on an expected familiarity with the OSHA standard.

In addition, the commenter does not explain what they mean by a realistic level of detection for a particular stream. There are numerous analytical methods used to detect PBT chemicals. EPA believes that to establish different *de minimis* levels based not only for each toxic but also on the different process streams used by covered facilities, would not only be inconsistent with the reasons for the adoption of the current concentration levels, but that it would also be impractical. Whereas one of the reasons for adopting the *de minimis* exemption was to reduce burden for the reporting facility, the Agency believes that establishing a complicated schedule of *de minimis* concentrations for different chemicals and process streams would more likely significantly increase the reporter's burden. Further, as explained in previous comments, even minimal releases of PBT chemicals may result in elevated concentrations in the environment or in an organism and can reasonably be anticipated to

result in significant adverse effects. For these reasons, EPA is not persuaded that revised *de minimis* concentrations that are specific to the various detection levels of PBT chemicals is appropriate for this rulemaking.

Finally, because EPA did not propose to amend the *de minimis* exemption for PBT chemicals but rather to eliminate this exemption for these chemicals entirely, EPA could not, at this time, legally finalized an amendment of this exemption.

Comment List: C-1845 (PPG Industries); C-1443 (Pioneer Chloralkali); C-1814 (Chlorine Chemistry Council); C-1438 (International Carbon Black Association); C-1448 (Mercatus Center at George Mason)

Comment: The commenters argue that in lieu of eliminating the *de minimis* exemption for PBT chemicals, it would make more sense to change the level for the *de minimis* exemption for these chemicals. Some commenters argue that a more appropriate threshold would be to compare the current thresholds and the current *de minimis* levels and use the same ratio to the lowered PBT chemical thresholds. Therefore, they argue, the existing level is 1% for a threshold of 10,000 pounds, so a logical reduction of the *de minimis* level would be 0.01% for the new proposed threshold of 100 pounds and 0.001% for the new proposed threshold of 10 pounds per year and 1 ppb for dioxins. One commenter, (C-1814; Chlorine Chemistry Council) argues that the current *de minimis* level of 0.1% for known or suspected carcinogens is not appropriate for dioxins. They suggest that EPA lower the *de minimis* exemption for dioxins proportionally to the lower reporting threshold EPA sets in the final rule. A reporting threshold for dioxins of 0.002 pounds TEQ, (not the threshold proposed in the PBT proposal) is approximately seven orders of magnitude less than the current 10,000-pound threshold, they assert. Therefore, the 0.1% *de minimis* exemption should be lowered proportionally to 1×10^{-8} %. This translates into a concentration of 100 parts per trillion.

Response: EPA disagrees with these commenters. As explained previously, EPA adopted the *de minimis* exemption for several reasons including the desire to be consistent with information mandated by the OSHA HCS. This OSHA standard requires the listing of hazardous chemicals on MSDSs but allows chemical suppliers to omit from the MSDSs hazardous chemicals that are below certain concentrations. Specifically, EPA adopted the *de minimis* concentration levels of 0.1% and 1.0% for non-carcinogens based on the OSHA standard. The rationale for the OSHA HCS *de minimis* exemption is not relevant to PBT chemicals. As explained in the 1983 final rule, OSHA chose the 1.0% concentration limit based on comments that this level seemed to be sufficiently protective of workers and was considered to be reasonable by a number of commenters (48 FR 53280, at 53290, November 25, 1983). OSHA was also persuaded by comments that in some instances the 1.0% cut-off levels may not be protective enough with respect to certain health hazards and adopted the 0.1% level for carcinogens. (48 FR 53292) Specifically PBT chemicals are of concern because they persist and bioaccumulate in the environment. Persistence and bioaccumulation were not considered as a part of the OSHA rulemaking. Rather, the OSHA HCS, has the very different intent of ensuring the protection of employees exposed to mixtures. In addition, there are no reasons for extrapolating new *de minimis* levels based on the proposed thresholds. Therefore, given the different intents between the OSHA HCS and EPCRA section 313, EPA does not believe that basing alternative *de minimis* levels for PBT chemicals based on a ratio between the lowered threshold and the OSHA HCS levels is appropriate.

Commenter List: C- 1851 (Cyprus Amax Minerals Company)

Comment: - The commenter argues that if, in specific cases for specific substances, the *de minimis* level is determined as not appropriate, EPA should perform an individual evaluation, using sound scientific principles and risk analysis, to determine what an appropriate *de minimis* level should be for that specific substance. Although it may mean more work and time, they assert that addressing substances individually will engender better analysis and more relevant and useful comments as to EPA's approach, and ultimately result in more meaningful data to the public. They further argue that grouping PBT chemicals together for evaluation and analysis is not appropriate, as they are not similar for a variety of reasons.

Response: EPA disagrees that risk analyses should be involved when considering the application of the *de minimis* exemption. Both EPCRA section 313 and PPA section 6607 require that facilities that meet certain thresholds report on their releases and other waste management quantities. Specifically, EPCRA Section 313 (a) states:

[t]he owner or operator of a facility subject to the requirements of this section shall complete a toxic chemical release form as published under subsection (g) for each toxic chemical listed under subsection (c) that was manufactured, processed, or otherwise used in quantities exceeding the toxic chemical threshold quantity established by subsection (f) during the preceding calendar year at such facility. Such form shall be submitted to the Administrator and to an official or officials of the State designated by the Governor on or before July 1, 1988, and annually thereafter on July 1 and shall contain data reflecting releases during the preceding calendar year.

Section 6607 of the PPA states that:

Each owner or operator of a facility required to file an annual toxic chemical release form under section 313 of the Superfund Amendments and Reauthorization Act of 1986 ("SARA") for any toxic chemical shall include with each such annual filing a toxic chemical source reduction and recycling report for the preceding calendar year.

Neither statute requires that EPA make risk determinations. EPA believes that regulatory exemptions cannot be applied if it will result in excluding reporting on releases and other waste management of chemicals that meet reporting thresholds. Further, EPA believes that it would be absurd to allow reporting required by statute only after a risk assessment is performed.

Commenter List: C-1438 (ICBA)

Comment: The commenter argues that EPA should retain the *de minimis* exemption specifically for chemicals that are not bioavailable. They argue that because they are not bioavailable, they do not pose the same risk as the other PBT chemicals.

Response: Chemicals that meet the PBT criteria are PBT chemicals independent of whether they are contained in any other material. The commenter contends that PBT chemicals contained certain materials (*i.e.*, substances or matrices) are not bioavailable and thus there should be a mechanism for exempting the reporting of PBT chemicals when contained in such materials. EPA believes that all of the PBT chemicals identified in this rulemaking are bioavailable. However, such a mechanism already exists under EPCRA section 313. If the commenter believes that a PBT chemical is contained in a material from which it cannot become available then the commenter can submit a petition pursuant to EPCRA section 313(e)(1) to delete that PBT chemical from reporting when contained in such materials. EPA would address such a petition in a manner similar to the Agency's stated policy and guidance concerning petitions to delist individual members of the metal compounds categories (May 23, 1991, 56 FR 23703). Under the metals policy EPA considers whether the metal from a metal compound can become bioavailable under abiotic or biotic conditions. An assessment of the bioavailability of a PBT chemical contained in certain materials would include processes such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformation (both abiotic and biotic); bioavailability when the material is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs); and bioavailability when the material is inhaled (solubilization in and/or absorption from lungs, especially taking into account the likelihood that the material will lodge in the lungs and be converted to soluble forms by the lung's defense mechanism).

5.b. Change to the use of the alternate threshold and Form A

Commenter list: C-1168, C-1433, C -1431A, C -1435, C-1858

Comment: One issue raised by commenters relates to EPA's proposal to exclude all PBT chemicals from the alternate threshold of 1 million pounds for PBT chemicals. Several commenters argue that EPA should retain the alternate threshold of 1 million pounds for PBT chemicals. Commenters state that most, if not all, PACs in fuel are destroyed during combustion. Therefore, commenters believe that a facility that exceeds the otherwise use threshold for these PACs will have no releases to report. Commenters further state that because these facilities use well under 1 million pounds of PACs per year, they are entitled under the current rule to use the reduced reporting option of Form A. Commenters assert that elimination of the alternate threshold option would require the facilities to prepare the lengthy Form R report that ultimately will contain no more information than that provided in the Form A. Commenter further asserts that the burdens on the regulated entities would far outweigh any benefit obtained from such reports.

In addition, several commenters support SBA's (Letter from Kevin Bromberg to Christine Augustyniak, et al. (Dec. 21, 1998)) suggesting retention for PBT chemicals of the Form A alternative reporting option, in order to ensure that only meaningful amounts of substances are reported under TRI. Commenters assert that EPA's proposed elimination of these options will significantly exacerbate the reporting burdens imposed by the lower thresholds while failing to provide for the collection of substantial additional release information.

Response: EPA disagrees. As stated in detail in the proposal, EPA believes that use of the existing alternate threshold and reportable quantity for Form A would be inconsistent with the intent of expanded PBT chemical reporting.

A commenter states that because PACs in fuel are destroyed during combustion, EPA should retain the alternate threshold or provide a new alternate. First, the commenter did not provide any information to support the contention that PACs in fuel are destroyed during combustion. And, to the contrary, EPA believes that, even if some or all of the PACs in fuel are destroyed during combustion, additional PACs may be created during the combustion process. Consequently, absent the information needed to support such an exemption or the need for an alternate threshold, EPA does not believe it would be appropriate at this time to grant such an exemption or provide a new alternate Form A threshold. The Agency believes that it is appropriate to collect and analyze several years worth of data at the lowered thresholds before EPA considers developing a new alternate threshold and reportable quantity appropriate for PBT chemicals.

In addition, the commenter also appears to be raising a broader issue than just the destruction of PACs during combustion. The commenter implies that when a facility estimates its releases to be zero, the facility should be eligible to use the Form A. The commenter appears to misunderstand how to calculate the amounts required to be reported on the Form A. Facilities may use the Form A provided that they do not exceed 500 pounds for the total annual reportable amount for a chemical, and that their amounts manufactured or processed or otherwise used do not exceed one-million pounds. The annual reportable amount is equal to the combined total quantities released at the facility, disposed within the facility, treated at the facility, recovered at the facility as a result of recycle operations, combusted for the purpose of energy recovery at the facility, and amounts transferred from the facility to off-site locations for the purpose of recycle, energy recovery, treatment, and/or disposal. The commenter only appears to consider their releases as reportable amounts and does not appear to consider quantities generated from their other waste management activities as reportable amounts. This additional waste management information on PBT chemicals is very important to communities because it helps them understand the quantities of EPCRA section 313 chemicals that are being transported through their communities, the destination of these EPCRA section 313 chemicals, as well as the reported waste management activity at the receiving facility. In conclusion, EPA has not proposed to disregard this waste management information in calculating the annual reportable amount, therefore the commenter's approach is not consistent with current reporting under Form A or appropriate as an approach for reporting on PBT chemicals.

The commenter also states that the alternate threshold should be retained in order to ensure that only meaningful amounts of substances are reported under EPCRA section 313. EPA disagrees that retention of the alternate threshold would ensure that only meaningful information is reported under EPCRA section 313. The 500 pound waste threshold category could be interpreted by some users, as a worst-case, to mean that greater than 500 pounds of the chemical has been released into the environment (i.e., 500 pounds of production-related waste as release and some quantity of catastrophic release). Other users may assume that the facility had no catastrophic releases and all of the toxic chemical in waste was managed in a manner other than as release, e.g., the toxic chemical in waste was recycled. For PBT chemicals where any release could be cause for a concern, an uncertainty level of 500 pounds may result in data that is virtually unusable. As a result, EPA does not agree with the commenter that the alternate threshold will ensure that only meaningful amounts of substances will be reported under EPCRA section 313.

In addition, the commenter argues that elimination of the alternate threshold for PBT chemicals will cause reporting burdens to increase while failing to provide for the collection of substantial additional release information. EPA's economic analysis used reporting costs for the Form R to estimate the costs to those facilities that would not be able to use the alternate threshold as well as the benefits of the collection of additional release and other waste management of PBT chemicals. The commenter does not dispute those estimates. As a result, EPA sees no compelling argument presented by the commenter to dispute EPA's decision to exclude all PBT chemicals from the alternate threshold of 1 million pounds.

Commenter list: C-041, C-802, C -1351, C-1355, C-1409, C-1415, C-1449, C-1454, C-1845, C-1855, C-1871, C-1899

Comment: Commenters argue that EPA should eliminate the alternate threshold of 1 million pounds for all PBT chemicals on the EPCRA section 313 list.

One commenter asserts that in light of the relatively small quantities of concern for PBT chemicals, particularly those with no deliberate commercial manufacture, it makes little sense to retain the Form A. The commenter further states that they believe that a modified Form A would be inappropriate due to the concern over releases of these chemicals at low levels.

Another commenter adds that the Form A is clearly inappropriate for chemicals that will now have thresholds significantly lower than the 500 pound waste generation level. They further contend that it is not appropriate for EPA to set a new Form A threshold for PBT chemicals, given the need to collect more information on these substances.

A commenter states that EPA should impose a limitation to the use of Form A certifications concerning PBT chemicals because Form A information is insufficient for conducting analyses on PBT chemicals and would be virtually useless to communities and the DEQ for assessing risk from releases of PBT chemicals.

Response: EPA agrees with the commenters that all PBT chemicals should be excluded from the alternate threshold of 1 million pounds. As stated in detail in the proposal, EPA believes that use of the existing alternate threshold and reportable quantity for Form A would be inconsistent with the intent of expanded PBT chemical reporting. The general information provided in the Form A on the quantities of the chemical that the facility releases and otherwise manages as waste is insufficient for conducting meaningful analyses on PBT chemicals and would be virtually useless for communities interested in assessing risk from releases and other waste management of PBT chemicals.

EPA also agrees that a new alternate threshold for PBT chemicals would be inappropriate due to the concern over releases and other waste management of these chemicals at low levels. As stated in the proposal, even small quantities of persistent bioaccumulative chemicals may cause elevated concentrations in the environment and organisms that may cause significant adverse effects. Given the persistent and bioaccumulative nature of these chemicals and the need for communities to have information about these PBT chemicals, EPA believes it would be inappropriate to allow an option that would exclude information on some releases and other waste management of these chemicals.

5.b.i. Develop a modified Form A for PBT chemicals

Commenter list: C-1848

Comment: In response to EPA's proposal to exclude all PBT chemicals from the alternative threshold of 1 million pounds, commenter argues that EPA should consider establishing a different alternate reporting threshold for these chemicals. Commenter states that, at a minimum, an alternate reporting threshold of 10 to 100 pounds would be consistent with the throughput-reporting threshold proposed for all PBT chemicals except dioxins. Commenter further states that the Small Business Administration's analysis suggests significant reductions in burden associated with alternate reporting thresholds of 50 pounds for PBT chemicals. Commenter states that, based on an SBA study commissioned of petroleum bulk plants, which it estimates will be the largest group of reporters under this proposal, it finds that most of the reports avoided by this alternate threshold would reflect zero releases.

Response: EPA disagrees with the comment suggesting that a new alternate threshold be established for PBT chemicals. As stated in the proposal, even small quantities of persistent bioaccumulative chemicals may cause elevated concentrations in the environment and organisms that may cause significant adverse effects. Given the persistent and bioaccumulative nature of these chemicals and the need for communities to have information about these PBT chemicals, EPA believes it would be inappropriate at this time to allow an option that would exclude information on some releases and other waste management of these chemicals. The general information provided in the Form A on the quantities of the chemical that the facility manages as waste is insufficient for conducting meaningful analyses on PBT chemicals. Therefore, EPA does not agree that a new alternate threshold for PBT chemicals should be established.

The commenter suggests that reporting burdens will increase while failing to provide for the collection of substantial additional release information. EPA's economic analysis used reporting costs for the Form R to estimate the costs to those facilities that would not be able to use the alternate threshold as well as the benefits of the collection of additional release and other waste management of PBT chemicals. The commenter does not dispute those estimates. As a result, EPA sees no compelling argument presented by the commenter to dispute EPA's decision to exclude all PBT chemicals from the alternate threshold of 1 million pounds.

Commenter list: C-1845, C-1855, C-836

Comment: Commenters argue that EPA should eliminate the alternate threshold of 1 million pounds. Another commenter supports EPA's proposal to exclude all PBT chemicals from use of the Form A (the alternate reporting threshold of 1 million pounds). The commenter states that in light of the relatively small quantities of concern for PBT chemicals, particularly those with no deliberate commercial manufacture, it makes little sense to retain the Form. One commenter further states that they believe that a modified Form A would be inappropriate due to the concern over releases of these chemicals at low levels.

Another commenter agrees with EPA that it is premature at this time to consider a modified Form A for these chemicals.

Response: EPA agrees with the commenters that a new alternate threshold for PBT chemicals would be inappropriate due to the concern over releases and other waste management of these chemicals at low levels. EPA also agrees that it is premature to consider a new alternate threshold for PBT chemicals. As stated in the proposal, even small quantities of persistent bioaccumulative chemicals may cause elevated concentrations in the environment and organisms that may cause significant adverse effects. Given the persistent and bioaccumulative nature of these chemicals and the need for communities to have information about these PBT chemicals, EPA believes it would be inappropriate to allow an option that would exclude information on some releases and other waste management of these chemicals. The general information provided in the Form A on the quantities of the chemical that the facility releases and otherwise manages as waste is insufficient for conducting meaningful analyses on PBT chemicals. In addition, the Agency believes that it is appropriate to collect and analyze several years worth of data at the lowered thresholds before EPA considers developing a new threshold and reportable quantity appropriate for PBT chemicals. Therefore, EPA agrees with the commenters that the Agency should exclude all PBT chemicals from the alternate threshold of 1 million pounds and that no new alternate threshold for PBT chemicals should be established at this time.

5.c. Changes to the use of range reporting

Commenter list: C-1352, C-1420, C-1421, C-1431/1431A, C-1435, C-1458, C-1824, C-1842, C-1845, C-1847, C-1850, C-1858, C-1861, C-1863, C-1864, C-1865

Comment: One issue raised by commenters relates to EPA's proposal to require that facilities report numerical values, not ranges, for all PBT chemicals. The commenters argue that EPA should maintain range reporting for PBT chemicals. The commenters argue that the following factors listed below support their contention.

- 1) Applying different reporting conventions for PBT chemicals would complicate TRI reporting, cause compliance difficulty, and introduce data inconsistencies (i.e., ranges for some chemicals but not for others). Commenters also argue that eliminating the use of range reporting for PBT chemicals has the potential to mislead the public and divert attention from actual risks.
- 2) Reporting numerical values for PBT chemicals assumes a level of accuracy that generally does not exist in the measurement of releases. In addition, commenter states that estimating numerical values would require the use of material balances, which are difficult to apply and essentially inaccurate for chemicals used in low concentrations. The commenter contends that, especially where reports are estimates, ranges may in fact provide more information than point estimates. Commenters argue that, for these reasons, elimination of range reporting will result in inaccurate estimates. Commenters also state that eliminating the use of range reporting for PBT chemicals would give the false impression of precise data, where uncertainty inherently exists.
- 3) Eliminating the use of range reporting for PBT chemicals would be extremely burdensome to facilities.
- 4) Eliminating the use of range reporting for PBT chemicals could result in an increase in threat to confidential information and a possible increase in trade secret claims.
- 5) Eliminating the use of range reporting for PBT chemicals will not result in the collection of substantial additional release information.

Response: EPA disagrees with those commenters suggesting that EPA should maintain range reporting for PBT chemicals.

- 1) **Applying different reporting conventions for PBT chemicals would complicate TRI reporting, cause compliance difficulty, and introduce data inconsistencies (i.e., ranges for some chemicals but not for others). Commenters also argue that eliminating the use of range reporting for PBT chemicals has the potential to mislead the public and divert attention from actual risks.**

EPA disagrees that the elimination of the use of range reporting for PBT chemicals will unduly complicate EPCRA section 313 reporting and cause compliance difficulties and data inconsistencies. There are already many different industries that report to EPA for 643 chemicals. EPA provides numerous guidance documents and training opportunities to reporting industries. With

the finalization of the PBT rule, EPA will provide updated guidance documents, will prepare and provide, in those cases where it is appropriate, chemical specific guidance documents, and will continue to offer training in order to assist facilities in reporting under EPCRA section 313. EPA also believes that the Agency will be able to adequately explain to the public the different reporting requirements for PBT chemicals so that they are put in context of other TRI data. EPA currently does this for other types of chemicals on the EPCRA Section 313 list such as metals and pesticides.

Additionally, EPA believes that the elimination of the use of range reporting is a critical part of this rulemaking, of which the ultimate goal is to provide useful information on PBT chemicals to assist communities in determining if PBT chemicals are present in their communities at levels that may pose an unacceptable risk. This information on PBT chemicals can also be used by other government agencies and others to identify problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Consequently, the information collected about these PBT chemicals will inform the public rather than mislead the public and will actually assist the public in determining the risk of PBT chemicals in their communities.

- 2) **Reporting numerical values for PBT chemicals assumes a level of accuracy that generally does not exist in the measurement of releases. In addition, commenters state that estimating numerical values would require the use of material balances, which are difficult to apply and essentially inaccurate for chemicals used in low concentrations. Commenters contend that, especially where reports are estimates, ranges may in fact provide more information than point estimates. Commenters argue that, for these reasons, elimination of range reporting will result in inaccurate estimates. Commenters also state that eliminating the use of range reporting for PBT chemicals would give the false impression of precise data, where uncertainty inherently exists.**

As stated in the proposal, EPA believes that the use of ranges could misrepresent data accuracy because the low or the high end range numbers may not really be that close to the estimated value, even taking into account its inherent error (i.e., error in measurements and developing estimates). The user of the data must make a determination on whether to use the low end of the range, the mid-point, or the upper end. For example, a release of 501 pounds could be misinterpreted as 999 pounds if reported as a range of 500-999. This represents a nearly 100 percent error. This uncertainty severely limits the applicability of release information where the majority of releases, particularly for PBT chemicals, are expected to be within the amounts eligible for range reporting. The utility of these data would be severely limited given the uncertainty associated with data reported using ranges. Therefore, due to this uncertainty, EPA believes that facilities should report numerical values, not ranges, for PBT chemicals.

In addition, EPA believes that the information available to the typical EPCRA section 313 reporter is generally greater and more accessible than it was 10 years ago. Because of this improved information availability, EPA believes that many facilities will be able to more accurately estimate releases and off-site transfers for further waste management of PBT chemicals in quantities of less than 1,000 pounds without the use of range codes. Although it may be true that some facilities will be better able to make those estimates than others, EPA does not believe this justifies not collecting the more specific and useful information from those facilities that can provide it.

Further, the Form R and Instructions and annual TRI data release provide information on the methods used to generate information reported and characterize many of the limitations that may apply to the data. This aids the data user in understanding the overall nature of the information available to it under EPCRA section 313. Facilities are required, for each release or transfer amount, to indicate the principal method used to determine the amount of release reported. There are codes which allow the facility to indicate whether the estimate is based on monitoring data, mass balance calculations, published emission factors, or other approaches such as engineering calculations or best engineering judgement. By looking at the information provided through the use of these codes, users of the data can gain an understanding of the degree of accuracy or uncertainty in any particular number reported by a facility. Thus, EPA believes that false impressions will not be communicated to the data user about the accuracy of the information filed.

Finally, EPCRA permits facilities to use reasonable estimates in the absence of readily available data to calculate thresholds and reportable amounts. Compliance with EPCRA section 313 does not require that additional monitoring or sampling be done. Thus, the statute contemplates some level of imprecision in the data that may be filed, yet, by authorizing reporting based on reasonable estimates, affirms the community right-to-know purposes relative to information based on such reasonable estimates. Reporting of releases of low volumes of PBT chemicals based on such reasonable estimates is no different than reporting on other toxic chemicals based on the same kind of information; in either case, the reporter may be relying on

estimates to report quantities of the toxic chemical. The TRI data that has been reported since 1987 is a blend of estimates based on monitoring data, mass balance calculations, published emissions factors and engineering calculations or engineering judgement.

3) Eliminating the use of range reporting for PBT chemicals would be extremely burdensome to facilities.

The original intent of providing the range reporting option was primarily as a burden reducing measure focused on small businesses. (53 FR 4524 and 4514) In past expansion activities, EPA has tried to retain burden reducing options wherever feasible. However, EPA does not expect the elimination of range reporting to significantly affect the unit cost of reporting because many facilities that could use range reporting are not choosing to do so. An analysis of the 1997 data reported under EPCRA section 313 reveals that the number of instances in which a range code was used for reporting quantities in sections 5 and 6 of the Form R was 37,168. These 37,168 instances included 7,605,305 pounds of releases and transfers using the median of the range code reported. However, there were 66,842 instances in which range reporting could have been used (i.e., the amounts reported were below 1,000 pounds) but the reporting facility chose instead to report a number rather than a range.

These 66,842 instances included 13,662,758 pounds of releases and transfers. Thus, in 64% of the instances where range reporting could have been used facilities reported a number instead. The fact that in a majority of the instances in which range reporting could have been used facilities opted to report specific numbers would appear to indicate that the elimination of range reporting for PBT chemicals is unlikely to impose any significant additional burden on facilities. Therefore, EPA does not expect the elimination of range reporting to have any significant effect on unit reporting costs.

4) Eliminating the use of range reporting for PBT chemicals could result in an increase in threat to confidential information and a possible increase in trade secret claims.

The commenter argues that the elimination of the use of range reporting for PBT chemicals could result in an increase in threat to confidential information and a possible increase in trade secret claims. Commenter maintains that Congress considered the need to protect trade secret information in the discussion of reporting chemical use and presence in ranges for EPCRA section 313:

The conference substitute provides for reporting categories of use and ranges of chemicals present because the exact use of an identified chemical at a facility or the exact amount present may disclose secret processes. In some circumstances, this information may need to be reported in terms of broad 43 categories of use or amount ranges...(U.S. House of Representatives (1986). Superfund Amendments and Reauthorization Act of 1986: Conference Report, Report 99-962, 298)

However, EPA believes that the conference report language cited by the commenter clearly refers only to the use of range reporting for the data element entitled "maximum amount of the toxic chemical on-site at any time during the calendar year." EPA is not precluding range reporting for maximum amounts on-site. Contrary to the notion expressed by the commenter, Congress did not expressly direct EPA to allow range reporting for the reporting of releases and transfers off-site for further waste management. Moreover, in the statute, Congress specifically intended the means and mechanism for facilities to protect information often claimed as confidential through the statute's trade secret provisions. If the commenter believes that any report filed might reveal trade secret information as protected by EPCRA section 322, the commenter may file a trade secret claim by following the procedures as outlined in 40 CFR Subpart 350. In addition, the statute is clear that only trade secret claims may be made for the specific chemical identity. Therefore, EPA believes that Congress adequately provided procedures for the protection of CBI and that a possible increase in CBI claims does not outweigh the need for increased information on releases and other waste management of PBT chemicals.

5) Eliminating the use of range reporting for PBT chemicals will not result in the collection of substantial additional release information.

EPA disagrees. The issue of range reporting is closely tied to the lowering of the reporting thresholds for PBT chemicals. As EPA noted in the proposal,

Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment.

EPA also noted in the proposal that,

Under current reporting thresholds, a significant amount of the releases and other waste management activities involving PBT chemicals are not being captured and thus the public does not have the information needed to determine if PBT chemicals are present in their communities and at levels that may pose a significant risk.

Therefore, by the lowering of reporting thresholds, EPA will receive important information on the quantities of PBT chemicals being released or otherwise managed as waste. Given the lowering of the reporting thresholds, continued use of ranges could misrepresent data accuracy because the low or the high end range numbers may not really be that close to the estimated value, even taking into account its inherent error (i.e., errors in measurements and developing estimates). The user of the data must make a determination on whether to use the low end of the range, the mid-point, or the upper end. For example, a release of 501 pounds could be misinterpreted as 999 pounds if reported as a range of 500-999. This represents a nearly 100 percent error. This uncertainty severely limits the applicability of release information where the majority of releases, particularly for PBT chemicals, are expected to be within the amounts eligible for range reporting. Given that the large uncertainty would be part of these data and would severely limit their utility, EPA has concluded that facilities must report numerical values, not ranges, for PBT chemicals.

Commenter list: C-1420, C-1824, C-1845, C-1864

Comment: Several commenters recommend the use of multiple ranges rather than total elimination of ranges just for PBT chemicals. One commenter generally agrees with EPA's position that reporting ranges "B" (11 to 499 pounds) and "C" (500 to 999 pounds), as they currently exist, may be too broad to provide meaningful information for PBT chemicals. Because the proposal does not impose any new obligation to measure or test beyond what is currently required, however, the commenter believes it is still appropriate to retain the "A" reporting range of 1 to 10 pounds for PBT chemicals. The commenter contends that the use of a specific number conveys a sense of precision that may not actually exist. Commenter argues that the retention of the "A" reporting range in its current form, coupled with the new reporting range of "greater than zero, but less than 1 pound", will provide meaningful and valuable information to the public on PBT chemical transfers or releases.

Another commenter agrees with the purpose underlying the EPA's proposal to prohibit the use of range reporting for PBT chemicals and believes the ranges authorized under the current rules are too broad to be useful for PBT chemicals. However, the commenter believes that EPA should recognize that reporting in ranges is often necessary because uncertainty makes the selection of a single number arbitrary.

Another commenter argues that EPA should retain range reporting for PBT chemicals, even if the ranges are lower than those allowed for non-PBT chemicals. Commenter further contends that they believe that range reporting helps to correct some of the error introduced to EPCRA section 313 reporting through the use of estimates.

Response: EPA disagrees that the Agency should retain the "A" reporting range of 1 to 10 pounds for PBT chemicals or that the Agency should retain some form of range reporting for PBT chemicals. As stated in the proposal, EPA believes that the use of ranges could misrepresent data accuracy because the low or the high end range numbers may not really be that close to the estimated value, even taking into account any potential inherent error (i.e., error in measurements and developing estimates). The user of the data must make a determination on whether to use the low end of the range, the mid-point, or the upper end. For example, a release of 501 pounds could be misinterpreted as 999 pounds if reported as a range of 500-999. This represents a nearly 100 percent error. Even with a lower range such as 1 to 10 pounds, the uncertainty associated with range reporting could severely limit the applicability of release information for PBT chemicals. Numerical values are particularly important since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues. This means that even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause adverse impacts on the environment and organisms. The utility of these data would be limited given the uncertainty associated with data reported using ranges. Therefore, due to this uncertainty, EPA is requiring that facilities report numerical values, not ranges, for PBT chemicals.

In addition, EPA believes that the information available to the typical EPCRA section 313 reporter is generally greater and more accessible than it was 10 years ago. Because more of this improved information availability, EPA believes that many facilities will be able to accurately estimate releases and off-site transfers for further waste management of PBT chemicals in quantities of less than 1,000 pounds without the use of range codes. Although it may be true that some facilities will be better able to make those estimates than others, EPA does not believe this justifies not collecting the more specific and useful information

from those facilities that can provide it. Further, in the Form R, facilities are required, for each release or transfer amount, to indicate the principal method used to determine the amount of release reported. There are codes which allow the facility to indicate whether the estimate is based on monitoring data, mass balance calculations, published emission factors, or other approaches such as engineering calculations or best engineering judgement. By looking at the information provided through the use of these codes, users of the data can gain an understanding of the degree of accuracy or uncertainty in any particular number reported by a facility. Thus, EPA does not believe that false impressions will be communicated to the data user about the accuracy of the information filed.

Finally, EPCRA permits facilities to use reasonable estimates in the absence of readily available data to calculate thresholds and reportable amounts. EPCRA does not require that additional monitoring or sampling be done in order to report. Thus, the statute contemplates some level of imprecision in the data that may be filed, yet, by authorizing reporting based on reasonable estimates, affirms the community right-to-know purposes relative to information based on such reasonable estimates. Reporting of releases of low volumes of PBT chemicals based on such reasonable estimates is no different than reporting on other toxic chemicals based on the same kind of information; in either case, the reporter may be relying on estimates to report releases. The TRI data that has been reported since 1987 is a blend of estimates based on monitoring data, mass balance calculations, published emissions factors and engineering calculations or engineering judgement.

Commenter list: C-041, C-311, C-403a, C-553, C-802, C-836, C -1351, C-1355, C-1409, C-1415, C-1454, C-1823, C-1855, C-1871, C-1899

Comment: A number of commenters state that EPA should eliminate range reporting for all PBT chemicals on the EPCRA section 313 list.

One commenter also states that currently, facilities that release less than 1,000 pounds of a chemical are allowed to report their releases by means of range codes. Commenter further state that these ranges can severely over- or underestimate the amounts of actual releases, and would not be appropriate for chemicals such as PBTs. The commenter goes on to say that the entire purpose of lowering the thresholds is to provide data currently not available -- it is important that these data reflect actual amounts, at least within the two significant digits for reporting.

Another commenter adds that it is important to report numerical values, not ranges, of dioxin releases. The commenter states that few or none of the facilities producing dioxin would report dioxin releases within the existing ranges. The commenter asserts that EPA could not ensure that a substantial majority of releases is reported. The commenter believes that the largest releases could not be distinguished from facilities near zero discharge, and the Inventory would be useless for aiding dioxin pollution prevention. Therefore, the commenter believes that the alternative to EPA's numerical reporting proposal would result in failure to meet the right to know goals of EPCRA.

Response: EPA agrees that range reporting should be eliminated for PBT chemicals. As stated in the proposal, EPA believes that the use of ranges could misrepresent data accuracy because the low or the high end range numbers may not really be that close to the estimated value, even taking into account any potential inherent error (i.e., error in measurements and developing estimates). The user of the data must make a determination on whether to use the low end of the range, the mid-point, or the upper end. For example, a release of 501 pounds could be misinterpreted as 999 pounds if reported as a range of 500-999. This represents a nearly 100 percent error. This uncertainty severely limits the applicability of release information where the majority of releases, particularly for PBT chemicals, are expected to be within the amounts eligible for range reporting. Numerical values are particularly important since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues. This means that even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. The utility of these data would be severely limited given the uncertainty associated with data reported using ranges. Therefore, due to this uncertainty, EPA believes that facilities should report numerical values, not ranges, for PBT chemicals.

One commenter appeared to request that EPA eliminate range reporting for all chemicals. EPA's proposal only addressed the issue of range reporting for PBT chemicals. At this time, EPA intends to retain range reporting for all other chemicals listed under EPCRA section 313.

5.d. Changes to the use of the half-pound rule and whole numbers

Commenter List: C-1407, C-1421, C-1423, C-1440, C-1457, C-1458, C-1815, C-1825, C-1845, C-1847, C-1850, C-1861, C-1863, C-1864, C-1865

Comment: One issue raised by commenters relates to EPA's proposal that, other than for the dioxin and dioxin-like compounds category, all non-zero releases of PBT chemicals greater than one tenth of a pound be reported. EPA also proposed that for quantities less than 10 pounds, fractional quantities, e.g., 6.2 pounds, rather than whole numbers would be required, provided the accuracy in the underlying data on which the estimate is based supports this level of precision. In addition, EPA proposed that all non-zero releases of dioxin and dioxin-like compounds greater than 100 micrograms be reported. The commenters are opposed to these provisions of the proposal for several reasons outlined below.

- 1) Commenters argue that the expectation that an annual quantity of a chemical release or transfer can be quantified to a fraction of a pound is totally unrealistic. Commenters believe that not only would such minute amounts be impossible to quantify (again, EPA needs to consider average throughput volumes and quantification limits), but also misrepresent the accuracy of the reported releases or transfers. Further, commenters argue that even with the use of empirical concentration data, when scaled up to average output volumes of millions of gallons of water or hundreds of thousands of pounds of coal burned per year, the best data which can be reported would still need to be whole numbers. In addition, commenters state that the proposal to report quantities less than 10 pounds using fractional quantities assumes a greater accuracy for measuring releases than exists in reality. Another commenter adds that nowhere in the proposed rule does EPA demonstrate that such knowledge is readily available to a reporting facility. Also, another commenter states that when the "estimated" data is blended with the "measured" data, the summarized information is really no better than the weakest estimate used in the summary. The commenter does not believe that any of the releases or waste management quantities should be reported to two significant digits (when reporting under 10 pounds) if not all can be reported to two significant digits because this weakens the entire data set.
- 2) Commenters state that forcing industry to apply different rules for different chemicals would introduce confusion and compliance difficulty. Commenters further state that reporting different chemicals under different conventions would introduce data inconsistencies in the TRI database.
- 3) Commenters argue that EPA's economic analysis does not include the costs of eliminating existing rules for rounding and whole numbers.
- 4) Commenters oppose this action because they believe that to require all facilities to calculate their values with such precision can create an undue burden on those facilities that do not have readily available data to provide such precise reports. Commenters argue that EPA's proposal places those facilities in an impossible position with no feasible alternatives. Commenters contend that EPA's proposal would eliminate a number of reporting options that were designed to alleviate the burden on facilities subject to EPCRA 313. Another commenter adds that eliminating these methods greatly increases the reporting burden, while providing no more substantive and useful information to the public.
- 5) Commenters argue that EPA should add a new reporting range of "greater than zero, but less than one (1) pound" for the case of low, but not zero, releases or transfers.
- 6) A commenter states that EPA doesn't have the legal authority to prohibit facilities from reporting on the basis of "reasonable estimates" when Congress has explicitly provided for such reporting. The commenter argues that EPA, by requiring facilities to report more information on smaller quantities, is in essence demanding the use of "material balances." The commenter states that the smaller the quantities and concentrations, the more difficult it becomes to apply a mass balance approach. The commenter implies that the Agency may be attempting, via this proposed rule, to "backdoor" a form of the Phase III TRI expansion.

Response: EPA disagrees with the comments above. EPA proposed this very important change in the reporting of PBT chemicals because the current combination of requiring the reporting of whole numbers and allowing rounding to zero would result in a significant number of facilities reporting their releases of some PBT chemicals, notably dioxins, as zero.

- 1) **Commenters argue that the expectation that an annual quantity of a chemical release or transfer can be quantified to a fraction of a pound is totally unrealistic. Commenters believe that not only would**

such minute amounts be impossible to quantify (again, EPA needs to consider average throughput volumes and quantification limits), but also misrepresent the accuracy of the reported releases or transfers. Further, commenters argue that even with the use of empirical concentration data, when scaled up to average output volumes of millions of gallons of water or hundreds of thousands of coal burned per year, the best data which can be reported would still need to be whole numbers. In addition, commenters state that the proposal to report quantities less than 10 pounds using fractional quantities assumes a greater accuracy for measuring releases than exists in reality. Another commenter adds that nowhere in the proposed rule does EPA demonstrate that such knowledge is readily available to a reporting facility. Also, another commenter states that when the "estimated" data is blended with the "measured" data, the summarized information is really no better than the weakest estimate used in the summary. The commenter does not believe that any of the releases or waste management quantities should be reported to two significant digits (when reporting under 10 pounds) if not all can be reported to two significant digits because this weakens the entire data set.

EPA proposed to require reporting of all releases and other waste management quantities of PBT chemicals (except dioxin) that are greater than a tenth of a pound, provided that the accuracy in the underlying data on which the estimate is based supports this level of precision. EPA further stated that releases and other waste management quantities would continue to be reported to two significant digits. In addition, EPA stated that for quantities of 10 pounds or greater, only whole numbers would be required to be reported. For the category of dioxin and dioxin-like compounds, which have a proposed reporting threshold of 0.1 gram, EPA proposed that facilities report all releases and other waste management activities greater than 100 micrograms (i.e., 0.0001 gram).

After reviewing all comments on this issue, EPA is modifying its approach on the level of precision covered facilities should use to report their releases and other waste management quantities of PBT chemicals. Facilities should continue to report releases and other waste management amounts greater than a tenth of a pound (except dioxin), at a level of precision supported by the accuracy of the underlying data and the estimation techniques on which the estimate is based.

This approach is consistent with the statutory reporting requirements when estimating reportable amounts. The statute requires facilities to, among other things, report "[t]he annual quantity of the toxic chemical entering each environmental medium." 42 U.S.C. § 11023(g)(1)(C)(iv). To determine this "annual quantity," the statute directs facilities to use readily available data (including monitoring data). When such data are not readily available, the statute directs facilities to use reasonable estimates. 42 U.S.C. section 11023(g)(2). However, while the statute allows some level of imprecision regarding reportable amounts, it does not create an exemption or exception that would allow facilities to report less precisely than provided for by their data or estimation techniques. Therefore, facilities should report PBT chemicals as precisely as their estimation techniques or readily available data allow. If a facility's release or other waste management calculations support reporting an amount that is more precise than two significant digits, then the facility should report that more precise amount.

EPA also disagrees that the requirement to report in fractional amounts will misrepresent the accuracy of the reported releases or transfers. The Form R and Instructions and annual TRI data release provide information on the methods used to generate information reported and characterize many of the limitations that may apply to the data. This aids the data user in understanding the overall nature of the information available under EPCRA section 313. For example, in the Form R, facilities are required, for each release or transfer amount, to indicate the principal method used to determine the amount of release reported. There are codes which allow the facility to indicate whether the estimate is based on monitoring data, mass balance calculations, published emission factors, or other approaches such as engineering calculations or best engineering judgement. By looking at the information provided through the use of these codes, users of the data can gain an understanding of the degree of accuracy or uncertainty in any particular number reported by a facility. Therefore, EPA does not believe the requirement to report in fractional amounts will convey false impressions to the data user about the accuracy of the information filed.

Additionally, EPCRA permits facilities to use reasonable estimates in the absence of readily available data to calculate thresholds and reportable amounts. EPCRA does not require that additional monitoring or sampling be done in order to report. Thus, the statute contemplates some level of imprecision in the data that may be filed, yet, by authorizing reporting based on reasonable estimates, affirms the community right-to-know purposes relative to information based on such reasonable estimates. Reporting of releases of low volumes of PBT chemicals based on such reasonable estimates is no different than reporting on other toxic chemicals based on the same kind of information; in either case, the reporter may be relying on estimates to report quantities. The TRI data that has been reported since 1987 is a blend of estimates based on monitoring

data, mass balance calculations, published emissions factors and engineering calculations or engineering judgement. The current proposal is really no different than TRI reporting practices have been since the program began.

EPA also disagrees with the commenter's contentions (1) that when the "estimated" data is blended with the "measured" data, the summarized information is really no better than the weakest estimate used in the summary and (2) that no release or waste management quantities should be reported to two significant digits (when reporting under 10 pounds) if not all can be reported to two significant digits because this weakens the entire data set. First, it is not clear, when the commenter refers to "summarized information" that is a blend of "estimated" and "measured" data, whether the commenter means information reported on individual Form Rs or aggregate information in the national TRI data base. If the commenter is referring to information on individual Form Rs, many Form Rs currently are based upon a mix of monitoring data and estimated data. It is the nature of the program. EPCRA permits facilities to use reasonable estimates in the absence of readily available data to calculate thresholds and reportable amounts. Indeed, EPCRA prohibits EPA from requiring facilities to conduct any additional monitoring to comply with the statute's reporting requirements. Thus, EPA does not have the option to require use of only monitoring or "measuring" data if a facility does not already have it readily available. Rather, a facility must use readily available information or reasonable estimates to calculate reportable amounts. One way a facility could derive its best "reasonable estimate" is to rely on partial monitoring data to estimate annual reportable amounts. In fact, "mixing" "measured data" and "estimated data" could strengthen, not weaken, a reasonable estimate reported on a Form R.

If the commenter is referring to aggregate information in the national data base, again, the TRI data that has been reported since 1987 is a blend of estimates based on monitoring data, mass balance calculations, published emissions factors and engineering calculations or engineering judgement. Indeed, Congress contemplated this blend and still thought the TRI database would be useful. The current proposal to have facilities report using fractional quantities for PBT chemicals, provided the underlying data supports this level of precision, is really no different than TRI reporting practices have been since the program began. And most would argue that TRI has proved a very valuable tool since that time. TRI has been an important tool in empowering the Federal government, State governments, industry, environmental groups, and the general public, to fully participate in an informed dialogue about the environmental and human health impacts of toxic chemical releases and other waste management activities.

In addition, the TRI system has given the public, government, and the regulated community a significantly improved ability to understand the magnitude of chemical emissions in the United States; to compare chemical releases among facilities and transfers of chemical wastes among States, industries, and facilities; and perhaps most importantly, to assess the need to reduce and where possible, eliminate these releases and other waste management activities.

Also, EPA believes that the Agency will be able to adequately explain to the public the different reporting requirements for PBT chemicals so that they are put in context of other TRI data. EPA currently does this for other types of chemicals on the EPCRA Section 313 list such as metals and pesticides. Furthermore, at the facility level, individuals can review a facility's Form R to determine the principal method used to calculate the amount of release reported. Therefore, EPA does not agree with the commenter's contention that when "estimated" data is blended with "measured" data, the summarized information is really no better than the weakest estimate used in the summary.

Finally, requiring reporting to two significant figures when accuracy of the underlying data support such precision does not weaken the data set. Rather, it strengthens it. The data is more precise. The commenter is basically saying that if some of the data is imprecise it should all be imprecise. Although it may be true that some facilities will be better able to make these precise estimates than others, EPA does not believe this justifies not collecting the more precise information from those facilities that can provide it. Indeed, as discussed above, to ensure that the most precise information for PBT chemicals is reported, facilities should report to more than two significant digits when a facility's best readily available information or reasonable estimates allow greater accuracy.

2) **Commenters state that forcing industry to apply different rules for different chemicals would introduce confusion and compliance difficulty. Commenters further state that reporting different chemicals under different conventions would introduce data inconsistencies in the TRI database.**

EPA disagrees. There are already many different industries that report to EPA for 643 chemicals. EPA provides numerous guidance documents and training opportunities to reporting industries. With the finalization of the PBT rule, EPA will provide updated guidance documents and will continue to offer training in order to assist facilities in reporting to TRI. As noted in an earlier response on this issue, the Form R and Instructions and annual TRI data release provide information on the methods used to generate information reported and characterize many of the limitations that may apply to the data. This aids the data user in understanding the overall nature of the information available under EPCRA section 313. EPA also believes that the

Agency will be able to adequately explain to the public the different reporting requirements for PBT chemicals so that they are put in context of other TRI data. EPA currently does this for other types of chemicals on the EPCRA Section 313 list such as metals and pesticides.

Additionally, where facilities have information permitting them to report with greater accuracy, EPA believes that the elimination of the use of the half-pound rule and whole numbers are a critical part of this rulemaking, of which one goal is to provide useful information on PBT chemicals to assist communities in determining if PBT chemicals are present in their communities at levels that may pose a significant risk. This information on PBT chemicals can also be used by other government agencies and others to identify problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Consequently, the information collected about these PBT chemicals will inform the public rather than confuse the public and will actually assist the public in determining the risk of PBT chemicals in their communities.

3) Commenters argue that EPA's economic analysis does not include the costs of eliminating existing rules for rounding and whole numbers.

EPA disagrees. EPA did not change the unit cost of reporting because it does not expect the changes to the existing rules for rounding and whole numbers to significantly affect the unit cost of reporting.

The use of rounding and whole numbers is related to how information is *presented* on the reporting form rather than how it is *calculated*. EPA is proposing that all releases or other waste management quantities of greater than a tenth of a pound of PBT chemicals be reported, provided that the appropriate activity threshold has been exceeded. And, as discussed above, to ensure that the most precise information for PBT chemicals is reported, facilities should report to more than two significant digits when a facility's best readily available information or reasonable estimates allow greater accuracy. As an issue of presentation rather than estimation, this action is not expected to have any significant effect on unit reporting costs.

4) Commenters oppose this action because they believe that to require all facilities to calculate their values with such precision can create an undue burden on those facilities that do not have readily available data to provide such precise reports. Commenters argue that EPA's proposal places those facilities in an impossible position with no feasible alternatives. Commenters contend that EPA's proposal would eliminate a number of reporting options that were designed to alleviate the burden on facilities subject to EPCRA 313. Another commenter adds that eliminating these methods greatly increases the reporting burden, while providing no more substantive and useful information to the public.

As discussed above, EPA is modifying its approach on the level of precision covered facilities should use to report their releases and other waste management quantities of PBT chemicals. Facilities should continue to report releases and other waste management amounts greater than a tenth of a pound (except dioxin), provided that the accuracy in the underlying data on which the estimate is based supports this level of precision. Rather than automatically reporting to two significant digits, if a facility's release or other waste management calculations support reporting an amount that is more precise than two significant digits, then the facility should report that more precise amount. The Agency believes that, particularly for PBT chemicals, facilities may be able to calculate their estimates of releases and other waste management quantities to a tenth of a pound. If a facility has such precise information, it should report it. If the data and/or estimation techniques do not support this degree of accuracy, then the facility's estimates are not required to be reported to a greater accuracy than is supportable. Indeed, a facility may report one significant digit if its estimation techniques do not support two digit accuracy. Likewise, if a facility's readily available data or estimation techniques support reporting of fractional amounts 10 pounds or above, then the facility should report in fractional amounts 10 pounds or above. Therefore, neither the argument that EPA is creating an undue burden on facilities or the argument that these facilities have no feasible alternative to reporting using fractional quantities is true. Consequently, the commenter's contention that EPA's proposal would eliminate a burden reducing option is based on a misunderstanding and incorrect.

EPA also disagrees that burden is increased while providing no more substantive and useful information to the public. Because PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in the environment, even relatively small releases of PBT chemicals from individual facilities have the potential to accumulate over time to higher levels and may cause significant impacts on human health and the environment. As EPA noted in the proposal,

Under current reporting thresholds, a significant amount of the releases and other waste management activities involving PBT chemicals are not being captured and thus the public does not have the information needed to determine if PBT chemicals are present in their communities and at levels that may pose a significant risk.

Therefore, by the lowering of reporting thresholds, EPA will receive important information on the quantities of PBT chemicals being released or otherwise managed as waste. Given the lowering of the reporting thresholds, continued use of the reporting to two significant figures when data supports more precise information and allowing rounding to zero could result in the public and others being deprived of information on significant amounts of PBT chemicals being released or otherwise managed in their communities. The more precise information collected as a result of these changes will actually provide more substantive and useful information, not less, to the public.

5) Commenters argue that EPA should add a new reporting range of "greater than zero, but less than one (1) pound" for the case of low, but not zero, releases or transfers.

EPA disagrees that the Agency should establish a new reporting range of "greater than zero, but less than 1 pound" to address the case of low, but not zero, releases or transfers. As stated elsewhere in this document and in the proposal, EPA believes that the use of ranges, even a range of greater than zero, but less than one pound, could lead to misinterpretation of the data because the low or the high end range numbers may not really be that close to the estimated value, even taking into account any potential inherent error (i.e., error in measurements and developing estimates). The user of the data must make a determination on whether to use the low end of the range, the mid-point, or the upper end. For example, a release of 0.1 pounds could be misinterpreted as 0.9 pounds if reported as a range of 0.1-0.9. This means that the data user could be assuming that the reported release is actually almost ten times greater than it was in actuality. In addition, these values are particularly important since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in the environment. This means that even relatively small releases, such as releases under one pound, of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant impacts on human health and the environment. The utility of these data could be severely limited even for a new range such as was suggested by the commenter. Therefore, due to this uncertainty and the potential for loss of information about even low levels of PBT chemicals, particularly dioxins, EPA does not believe that a new reporting range of "greater than zero, but less than one pound" should be established.

6) Commenter states that EPA doesn't have the legal authority to prohibit facilities from reporting on the basis of "reasonable estimates" when Congress has explicitly provided for such reporting. Commenter argues that EPA, by requiring facilities to report more information on smaller quantities, is in essence demanding the use of "material balances." Commenter states that the smaller the quantities and concentrations, the more difficult it becomes to apply a mass balance approach. Commenter implies that the Agency may be attempting, via this proposed rule, to "backdoor" a form of the Phase III TRI expansion.

EPA is not prohibiting facilities from reporting on the basis of "reasonable estimates" or demanding the use of "material balances" as the commenter asserts. As discussed above, EPA is modifying its guidance on the level of precision covered facilities should use to report their releases and other waste management quantities of PBT chemicals. Facilities should continue to report releases and other waste management amounts greater than a tenth of a pound (except dioxin), provided that the accuracy in the underlying data on which the estimate is based supports this level of precision. Rather than reporting to two significant digits, if a facility's release or other waste management calculations support reporting an amount that is more precise than two significant digits, then the facility should report that more precise amount. The Agency believes that, particularly for PBT chemicals, facilities may be able to calculate their estimates of releases and other waste management quantities to a tenth of a pound. If a facility has such precise information, it should report it. However, as stated above, if the data and/or estimation techniques do not support this degree of accuracy, then the facility's estimates are not required to be reported to a greater accuracy than is available. Indeed, a facility may report one significant digit if its estimation techniques do not support two digit accuracy. Likewise, if a facility's readily available data or estimation techniques support reporting of fractional amounts 10 pounds or above, then the facility should report in fractional amounts 10 pounds or above. Therefore, the assertions made by commenters above are based on a misunderstanding because EPA is not prohibiting the use of "reasonable estimates" or asking facilities to report to a greater degree of accuracy than is supported by their data and/or estimation techniques. Consequently, the materials accounting implication that EPA is attempting to "backdoor" a form of the Phase III TRI expansion is unfounded and inaccurate.

Commenter List: C-1354, C-1447, C-1855

Comment: Commenters agree with EPA's proposal that, other than for the dioxin and dioxin-like compounds category, all non-zero releases of PBT chemicals greater than one tenth of a pound should be reported. EPA also proposed that for quantities less than 10 pounds, fractional quantities, e.g., 6.2 pounds, rather than whole numbers would be required. In addition, EPA proposed that all non-zero releases of dioxin and dioxin-like compounds greater than 100 micrograms be reported. Commenters also agreed with these provisions of the proposal.

Response: EPA agrees with the commenters that, other than for the dioxin and dioxin-like compounds category, all non-zero releases of PBT chemicals greater than one tenth of a pound be reported. In addition, as discussed above, to ensure the most precise information for PBT chemicals is reported, facilities should report to more than two significant digits when a facility's best readily available information or reasonable estimates allow greater accuracy.

5.e. Reporting Limitation of Alloys

Commenter list: C-1407, C-1421, C-1431, C-1435, C-1811, C-1813, C-1826, C-1827, C-1850, C-1854, C-1858, C-1863, C-1864, and C-1865

Comments: The commenters support EPA's determination to defer the reporting of vanadium when contained in alloys. Commenters suggest that the Agency adopt a reporting limitation for the other metals such as chromium, copper, manganese, and nickel which are commonly found in alloys. The commenters state that alloys have significantly different bioavailability, bioaccumulation, and toxicity characteristics than other forms of metals, and thus should be treated separately. The commenters argued that alloys are inherently more stable than unalloyed materials, do not enter the environment as readily as unalloyed materials and hence do not interact as greatly with organisms, and should be considered safer from an environmental and human health perspective. The commenters suggested that alloys should be treated separately not only for threshold changes, but also for EPCRA section 313 listings in general and recommend excluding alloys from general EPCRA section 313 listings for metals.

Commenter states in regard to the reporting of metals in alloys that it makes little or no sense to require the reporting of such "useless" information, since the information does not serve the purpose of informing the community. Commenter states that expanding the alloys exemption would help to achieve EPCRA section 313's underlying purpose, *i.e.*, to provide the public with meaningful information, while at the same time reducing the burden on reporting facilities. Commenter states that they believe that the proposed alloys exemption correctly recognizes that metals in alloys are not generally available for exposure or for toxic effects. Commenter states that expansion of the exemption would improve the TRI data base by reporting only releases that may pose risks to human health and the environment, thereby providing the public with more meaningful data.

Commenters state that in 1992 the metals industry groups petitioned EPA to revise the EPCRA Section 313 listings for chromium, copper, manganese, and nickel as constituents of metal alloys by adding the reporting qualifier of "fumes, dust or fines" -- the so-called "alloys exemption." Commenters state that over the past six-and-a-half years the industry has addressed a variety of issues raised by EPA with respect to the alloys exemption and submitted extensive analysis to the Agency demonstrating that the exemption is logical and appropriate for the aforementioned metals (and possibly other metals). Commenters state that: 1) Scrap alloys that contain chromium, nickel, manganese, and copper are safely managed as valuable commodities and recycled so that there is no release of any toxic metals; 2) the processing, use, or recycling of stainless steel and other alloys does not pose environmental or health risks, including from leaching or corrosion; and 3) limiting TRI reporting to "fumes, dust, or fines" for these metals when present in alloys is a "win-win scenario," where the public is not burdened with misleading data, industry is not burdened by collecting such data, and EPA may achieve its goals of "cleaner, cheaper, smarter" environmental regulation.

Commenters state that the definition of vanadium alloys should be expanded to include "fused alloy slag" in the qualifier as well. The commenters contend that the state of the vanadium in a ferroalloy form is one of intimate chemical combination on the atomic level, not a simple mixture of individual components and it is inherently stable and cannot be dissociated by ordinary means. The commenters argued that likewise, the fused alloy slag formed represents an intimate chemical combination of materials as a result of the smelting operation. Commenters state that these elemental materials may include various components such as gangue or ore, ash of fuel, refractory lining, or other stable oxides with the ultimate characterization resting upon the chemical stability of the resultant fused alloy bearing slag. Thus, the commenters argue, vanadium contained in either alloy or alloy slag form is fused in a stable compound and therefore, no releases of vanadium into the environment would occur from either substance. Commenters state that the true environmental issue to consider in the formulation of an activity qualifier

is the leachability of the material in that state, and since in both of the aforementioned cases the vanadium is in a stable compound, leaching would not be expected. The commenters asserted that without allowing an exemption for fused alloy slag, large volumes of steelmaking and ferroalloy slag will unnecessarily fall under this reporting requirement. Commenters request that EPA reconsider its position and expanded the definition of alloy to include both vanadium alloys and vanadium alloy slags.

Response: EPA agrees with those commenters that support EPA's belief that it would be inappropriate, at this time, to change the status quo regarding reporting vanadium when contained in an alloys. As EPA stated in the proposed rule, the Agency is reviewing the issue of whether there should be any changes to the reporting requirements for metals contained in alloys. EPA is not lowering the reporting threshold for cobalt and cobalt compounds, and therefore the Agency is taking no action with respect to a reporting limitation for cobalt when contained in alloys.

EPA did not state, and did not intend to imply that EPA considers alloys to be "safe," or as some commenters suggested, that EPA had "correctly" recognized that metals in alloys are not generally available for exposure or to express their toxic effects. EPA has not completed its review of the alloys issue and has made no conclusions regarding whether there should or should not be any type of limitation or exemption for any metals contained in alloys. EPA's proposal merely recognized that while this issue was under review it would not be appropriate to change the status quo regarding the reporting requirements for vanadium when contained in alloys at this time. The commenters contend that alloys have significantly different bioavailability, bioaccumulation, toxicity characteristics than other forms of metals and are inherently more stable than unalloyed materials and do not enter the environment as readily as unalloyed materials. EPA believes that the issue with alloys is primarily bioavailability, *i.e.*, do the metals contained in alloys become available. This issue is the focus of EPA's current review. At this point in time, while EPA is in the process of a scientific review of the issues pertinent to alloys, the Agency is not prepared to make a final determination on whether vanadium in vanadium alloys meets the EPCRA section 313(d)(2) toxicity criteria.

Some commenters suggested that EPA create an the alloys reporting limitation for all metals contained in alloys. However, as EPA has stated, the review of whether any kind of exemption or reporting limitation should be granted for certain metals in alloys is still under review and until the Agency has thoroughly reviewed the available data, EPA is not prepared to extend the reporting limitation to any other metals. With regard to the extension of the reporting limitation to vanadium contained in fused alloy slags, the commenters did not provide any data to support their contentions concerning the availability of vanadium from such slags. The Agency does not believe that a metal compound in a slag necessarily will be environmentally unavailable, rather, the Agency's experience with a previous EPCRA section 313(d) review of manganese slags, indicates that at least in some cases the metal will be available. EPA suggests that if the commenters want EPA to review data on specific forms of slags, and to consider a reporting limitation for such slags, that the commenters submit a petition along with the appropriate supporting data to show that vanadium is not available from fused alloy slags (see, e.g., 60 FR 44000, August 24, 1995 petition to delist certain manganese slags).

Some commenters referred to EPA's ongoing review of the alloys issue and stated that over the last six-and-a-half years the industry has addressed a variety of issues raised by EPA, submitted extensive analysis to the Agency demonstrating that it is logical and appropriate to establish an alloys exemption, and provided a number of reasons that they believe alloys do not pose environmental or health risks. Commenters also stated that the information reported on metals in alloys is useless information that does not serve the purpose of informing the communities about toxic chemicals. The issue of whether metals contained in alloys meet the listing criteria of EPCRA section 313 and therefore should remain on the list is very complex, and the limited data provided by industry to date has been insufficient for EPA to make a final decision. As stated, the Agency is reviewing all of the information that has been provided as well as additional information that has been found during an extensive review of the available literature on alloys and the corrosion that can result in metals being released from certain alloys. EPA has prepared a draft report on the corrosion of these alloys and this report is currently undergoing internal and external review. Based on the results of this report EPA will decide whether there is sufficient information to support some kind of reporting limitation or exemption for certain metals contained in alloys. Until EPA can make such a determination the Agency does not consider the information currently reported to be useless to communities since, at a minimum, the data identifies which facilities have the potential to release toxic metals.

Commenter: C-1855

Comment: Commenter states that for reasons of consistency – which helps ensure data quality – with existing EPCRA Section 313 metal compound categories, they opposes adding the qualifier "except when contained in an alloy" in any new listing for vanadium.

Response: EPA has not completed its review of the alloys issue and has made no conclusions regarding whether there should or should not be any type of limitation or exemption for any metals contained in alloys. EPA's proposal merely recognized that while this issue was under review it would not be appropriate to increase the reporting requirements for those facilities that must submit reports for vanadium contained in alloys. Therefore, EPA has expanded the EPCRA section 313 listing for vanadium by removing the "fume or dust" qualifier for vanadium, but has not expanded the listing for vanadium to include vanadium when contained in an alloy in this final rule. Until EPA has the opportunity to fully evaluate the available data, and pending internal and external review of the report EPA is having prepared on this subject, the Agency is unprepared to make a final determination on whether vanadium contained in alloys meets the EPCRA section 313(d)(2) listing criteria and is therefore subject to the EPCRA section 313 reporting requirements. EPA believes that consistency, in this context, does not provide a sufficient basis to require reporting of vanadium contained in alloys.

6.A. Use of other factors in identifying PBT chemicals and setting thresholds

Commenter Number: C-1407

Comment: The commenter asserts that the thresholds for the PBT rulemaking should be lowered only for chemicals for which EPA can demonstrate that TRI facilities are the primary source of environmental loading. It argues that Agency would then be able to clearly demonstrate that it has met the intent of capturing the majority of releases through TRI reporting, as set forth in the statutory requirements at 42 U.S.C. 11023. The commenter support their argument by asserting that a key consideration of the Canada's BNS implementation, the Toxic Substances Management Policy (TSMP) is whether a chemical is "predominantly anthropogenic" or naturally occurring. This factor is used to determine if a chemical is considered for virtual elimination (Track 1/Level 1) or life cycle management (Track 2/Level 2). Elements and naturally occurring substances are not candidates for Track 1 under Canada's policy. These substances can be targeted for management under Track 2 if human activity has been found to be a significant contributing factor to the presence of the chemical in the environment, for example the group polynuclear aromatic hydrocarbons (PAHs). However, where a Track 1 substance results from the degradation or transformation of a parent substance in the environment, the parent substance may also be considered for Track 1, for example mercury and mercury compounds. They recommend that EPA also include anthropogenic considerations as part of the determination for designating any EPCRA chemicals as PBT chemicals.

Response: One of the purposes of EPCRA section 313 is to provide the public with reporting on releases of toxic chemicals into the environment that result from human activities. The purpose of the TRI program is to provide information both at the community level and at the national level. EPA does not believe that the statute requires nor does the Agency believe that there is a compelling policy reason to include as a criterion in selecting thresholds, whether releases are primarily due to anthropogenic sources. First, there are not sufficient data that would allow the Agency to determine whether the majority of releases are anthropogenic; release data is not currently available as discussed elsewhere in the document, EPA cannot generate reliable release estimates. The purpose of TRI is to provide release data. Second, while at a national level, the majority of releases may not be due to anthropogenic sources, the majority of releases in many communities may be primarily due to anthropogenic sources. Even if there were such a test, for each of the chemicals in this rulemaking there is at least a significant fraction of the releases that enter the environment from human industrial activities. Further, EPA does not believe that the Canadian systems cited by the commenter have the same community-based mandate as EPCRA section 313.

Commenter Number: C-1932

Comment: The commenter supports EPA's approach to including PBT chemicals into the TRI program. However, they argue that while persistence and bioaccumulative characteristics are certainly important in making regulatory decisions, these are not the only factors that should be considered. The commenter urges the Agency to include factors related to toxicity, environmental presence, and others in making this determination. They believe that the special susceptibility of certain populations, such as children, should be included as a criterion for inclusion.

Response: As discussed elsewhere in this document, EPA believes that it is appropriate to revise the reporting thresholds for PBT chemicals based on the degree of persistence and bioaccumulation. EPCRA section 313(f)(2) does not require that EPA consider toxicity or risk in revising thresholds. A fuller discussion can be found in Units VI.B and VI.F of the final rule and elsewhere in this document.

6.b. Degree of toxicity, environmental presence, biomagnification, etc.

Commenter Number: C-1407, C-1436

Comment: The commenter believes that EPA's statement in the proposal:

The availability of [EPCRA 313 data on PBTs] can allow all parties to identify and track releases of PBT chemicals and monitor the progress of the programs designed to reduce the amount of PBT chemicals entering the environment

is only partially true. They argue that PBT chemicals are defined as toxic chemicals that partition to water, sediment, or soil and are not removed at rates adequate to prevent their bioaccumulation in aquatic or terrestrial species. In order to provide useful information to the public, EPA should provide information as to the degree of partitioning to the various media for each chemical when finalizing the rule. Without this baseline, it will be impossible to utilize reported data to assess progress. EPA

should also provide in the final rule, a more substantial foundation to demonstrate how the additional information will, in fact, provide adequate data to make such assessments.

Environmental partitioning and bioavailability must be given more weight in determining real bioaccumulation potential when such scientific information is available.

Response: EPA used multi-media modeling to determine if each toxic chemical partitioned, at least to a minimum extent into any compartment for which the compartmental half-life criterion for persistence was met for that chemical. As clearly stated in the proposed rule, EPA used the multi-media modeling “as an additional factor, in conjunction with reaction half-lives for individual media, bioaccumulation/bioconcentration factors, etc., in justifying [the] actions proposed.” In considering the results of the multi-media in the assessment of whether the chemical meets the persistence criteria, EPA is in fact making a determination that a sufficient extent of partitioning to a medium where a chemical is persistent occurs.

As to the use of partitioning and bioavailability in determining bioaccumulation, bioavailability is addressed elsewhere in this document; bioaccumulation is discussed below. Bioaccumulation is a process by which organisms may accumulate certain chemicals in their bodies. The term refers to both uptake of chemicals from water and from ingested food and sediments. Bioaccumulation is not defined to include partitioning. Further, because environmental conditions vary, partitioning will vary depending upon the specific conditions. Thus, EPA believes that it is inappropriate to consider partitioning as a component of bioaccumulation.

Commenter Number: C-1421, C-1865,

Comment: Two commenters (C-1421 and C-1865) argue that EPA should establish a toxicity criterion that identifies a subset of the most toxic chemicals as PBT. They argue that the list of EPCRA section 313 toxic chemicals consists of chemicals that vary widely in their ability to produce toxic effects. They contend that many chemicals on the current list were included directly by statute, absent toxicity analysis and that more than half of the chemicals and chemical categories for which EPA proposed lower thresholds were on the original statutory list. They contend that EPA has announced its intention to review chemicals on the original EPCRA section 313 list to determine whether data for those chemicals conform with the statutory criteria for listing of chemicals on TRI. The commenter believes it is premature to apply special designations such as PBT or to attempt to lower thresholds before establishing the relative degree of toxicity of the chemicals on the TRI list. They further argue that consideration of degree of toxicity is also necessary for legal reasons. They assert that all of the EPCRA section 313(d)(2) criteria for additions involve consideration of toxicity. Sections 313(d)(2)(A) and (B) discuss human health effects. Section 313(d)(2)(C) allows a listing when a chemical is known to cause or can reasonably be anticipated to cause environmental effects because of its toxicity, toxicity and persistence, or toxicity and bioaccumulation.

Response: EPA disagrees with the commenters that because EPA has not completed its review of the original list of toxic chemical that it should lower the reporting thresholds for the chemicals that are the subject of today's action. The commenter believes EPA should postpone today's action because the toxic chemicals that are the subject of today's action have varying levels of toxicity. The commenter does not state that these chemicals do not meet the EPCRA section 313(d)(2) criteria. Rather the commenter believes that toxic chemicals should not be considered to be PBT chemicals until their *relative* toxicities have been established. The commenter implies that there should be separate toxicity criteria for PBT chemicals. As EPA has discussed elsewhere in this document, EPA is not establish

6.c. Change reporting frequency (require reporting every other year, etc.)

Commenter Number: FORM A: Ohio BASS Chapter Federation (C041); Communities For A Better Environment (C403a); Ohio Environmental Council (C1355); Cold Mountain Cold Rivers (C1415); Oregon DEQ (C1447); Atlantic States Legal Fund (C1451); Ecology Center (C1454); 22 Interest Groups (Alaska Clean Air Coalition, Alaska Center for the Environment, Environmental Working Group, Natural Resources Defense Council, Legal Environmental Assistance Foundation, Inc. (LEAF), Florida Consumer Action Network, Physicians for Social Responsibility/Atlanta, Campaign for a Prosperous Georgia, Center for Neighborhood Technology, Natural Resources Council of Maine, American Lung Association of Michigan, Michigan Environmental Council, Minnesota Center for Environmental Advocacy, Izaak Walton League of America, NJ Environmental Watch, Environmental Advocates, Ohio Environmental Council, The Oregon Clearinghouse for Pollution Reduction, Tennessee Valley Energy Reform Coalition (TVERC), Southern Environmental Law Center, VPIRG, Pollution Probe) (C1823);

Comment: The majority of commenters contend that modulating thresholds for reporting so that lower reporting thresholds are used every other year (with current thresholds used in alternate years) would introduce confusion for the regulated community and data users and would not significantly reduce burden. Further it could discourage facilities from establishing common standard procedures for data collection. Modulation will also result in data gaps, undermining data consistency and tracking. Many commenters believe that time-series reporting is a fundamental attribute of TRI. One commenter contends that EPA should adopt alternating reporting thresholds because the TRI data do not substantively change from year to year.

Response: EPA agrees that modulating the reporting thresholds would introduce confusion for both the regulated community and data users. For data users, EPA believes that modulating the reporting thresholds would limit the usefulness of the TRI data because there would be poor data consistency and poorer data quality. For the regulated community, EPA believes that the burden reduction would not be significant and would possibly be offset by the confusion that would be introduced by different thresholds in alternate years.

Further, EPA does not agree that there are not substantive yearly changes. The commenter states that “estimation technique changes” and “other factors” accounted for 82 percent of the increases reported between 1989 and 1990, and 67 percent of the 1989 to 1990 decreases. EPA, “1991 Toxics Release Inventory – Public Data Release.” 1991, p. 163. The commenter misrepresents what was presented in the “1991 Toxics Release Inventory – Public Data Release.” “Other factors” account for more of the net change than any other reason assessed. “Other factors” include changes in “reporting guidance, changes in facility interpretation and application of that guidance, reporting errors, accidental and one-time releases, increased recycling.” The commenter fails to note that a significant portion of the reporting guidance change and application of the guidance focused on ammonia and ammonium sulfate. The commenter also does not point out that “estimation technique changes” account for 3% of the net changes from 1989 to 1990. Nor does the commenter support his contention by pointing to changes in more recent data, i.e., 1992 - 1997 data. Therefore, EPA disagrees with the commenter that recent year to year changes in the TRI are primarily due to “estimation technique changes.”

6.d. Modification of laboratory exemption and other exemptions for PBT chemicals

Commenter List: C-0446, C-802, C-1168, C-1353, C-1356, C-1420, C-1421, C-1423, C-1424, C-1425, C-1426, C-1428, C-1430, C-1440, C-1443, C-1447, C-1455, C-1457, C-1458, C-1815, C-1817, C-1819, C-1820, C-1824, C-1825, C-1827, C-1832, C-1833, C-1837, C-1838, C-1841, C-1842, C-1843, C-1845, C-1846, C-1861, C-1863, C-1864, C-1865

Comment: Commenters argue that it is inappropriate for EPA to eliminate the otherwise use exemptions for PBT chemicals. The commenters believe that EPA should maintain the otherwise use exemptions for PBT chemicals. The commenters argue that the following factors listed below support their contention.

1) The commenter believes it is inappropriate for EPA to eliminate the otherwise use exemptions for PBT chemicals because these exemptions apply to activities that are ancillary to the primary purpose of the facility and over which the facility may have little or no control. Commenters argue that EPCRA §313 was enacted for the purpose of collecting data on releases related to manufacturing activities. They state that TRI was not intended to capture reports on non-industrial activities simply because they happen to occur within the facility boundary of an industrial facility. Commenters add that requiring reporting for such ancillary activities would not further the purposes of EPCRA §313 nor would this reporting add to the public's right-to-know.

2) Commenters argue that eliminating the otherwise use exemptions could significantly increase the reporting burden of all reporters within the TRI program by subjecting facilities to reporting simply by virtue of the presence of PBT chemicals in these ancillary activities. Commenters state that, with respect to most of these exempted uses, the amounts in question are relatively small, and the reporting facility is not likely to have the information necessary to calculate thresholds or releases. Commenters believe that without the exemptions, facilities would be faced with the burdens of undertaking the analysis of whether they meet the applicable thresholds or whether they even have the necessary data or methodology to estimate thresholds and releases. Additionally, commenters argue that the rationale for the otherwise use exemptions was not solely based on the de minimis principle, but rather was contemplated by EPA as a means of placing some reasonable limitations on the concept of “otherwise use” of TRI chemicals and to avoid imposing an unnecessary reporting burden on many facilities. Several commenters cite specific examples to illustrate the burden that would be imposed on facilities if EPA eliminates the

intake air and water exemption, the personal use exemption, or the laboratory exemption. Finally, commenters believe that the information in any reports that would be submitted would be insignificant compared to the reports submitted on industrial-type activities.

3) Commenters argue that the elimination of one specific otherwise use exemption, the intake air and water exemption, would require reporting of PBTs in intake air and water and would produce extremely inaccurate and misleading information. Commenters claim that this change would be misleading in that it would suggest that the reporting facilities are somehow responsible for the presence of TRI substances in the environment, which is not the case. Commenters add that it would also be inaccurate because it would require facilities to report substances that already have been released into the environment, resulting in multiple counting. The commenters believe that this would yield a gross overstatement of the amount of the substance to which the public is exposed. Commenters also argue that nothing in EPCRA suggests that Congress intended facilities to report as "releases" chemicals present in their intake air or water. They state that Section 313 of EPCRA focuses on providing the public with accurate, meaningful data on releases from facilities, so that members of the public can use that information to understand the risks presented by such releases, and set goals for and measure progress towards reduction of those risks where necessary. The commenters believe that requiring reporting on intake pollutants would accomplish neither objective. The commenters add that this change would not produce an accurate picture of the risks presented by releases, because it would grossly overstate the amount of the substance released to the environment, and it would not give the public any idea of which sources actually are responsible for the initial release. They conclude that the change would not provide a basis for setting and measuring progress towards risk reduction goals, because the sources reporting the "releases" are not responsible for or in control of the activity which caused the substance to be present in the environment in the first instance. Additionally, one commenter states that having facilities subject to EPCRA section 313 reporting compile and report release data on these generally insignificant activities, while not addressing similar releases from the thousands of facilities not subject to such reporting, does not present an accurate or complete picture to the community.

4) Several commenters discuss the article exemption and urge EPA not to eliminate this exemption or lower the threshold quantity (i.e., 0.5 pounds) which must be met to qualify for the exemption.

5) One commenter argues that EPA should eliminate the laboratory exemption and the otherwise use exemptions, such as the structural component exemption, the routine janitorial or facility grounds maintenance exemption and the motor vehicle maintenance exemption for PBT chemicals. Commenter believes that the accumulation potential shown by PBT chemicals and the fact that some PBT chemicals have been shown to cause adverse effects at the part per trillion level justifies denying the laboratory exemption from being extended to reporting facilities. Commenter states that laboratory activities are conducted in a controlled environment where data collection is already a substantial part of the work conditions, so the reporting burden should not be terribly significant. In addition, commenter argues that the otherwise use exemptions, such as, use as a structural component of the facility, use in routine janitorial or grounds maintenance, or use for the purpose of maintaining motor vehicles operated by the facility, are all activities that are conducted under the facility manager's control and simple good housekeeping practices should provide the necessary data to estimate release and waste management totals.

Response: In the proposed rule, EPA requested comments on whether the Agency should modify the exemptions at 40 C.F.R. § 372.38 (C). At this time, EPA is not modifying any of these exemptions; therefore, the Agency is not addressing comments on this issue. Any changes to these exemptions would require additional rulemaking, and any comments submitted to EPA during this rulemaking will be considered as part of EPA's evaluation of these exemptions.

Several commenters urged EPA to retain the article exemption, including the threshold quantity (i.e., 0.5 pounds) which must be met to qualify for the exemption. EPA did not request comments on or discuss the article exemption in the proposed rule, therefore, the Agency is not taking action on this issue at this time. Any comments submitted to EPA during this rulemaking will be considered as part of EPA's continued evaluation of these exemptions.

EPA recently created an exemption for quantities of EPCRA section 313 chemicals manufactured, processed or otherwise used in coal extraction activities. (40 CFR 372.38(g)) This exemption allows covered facilities in SIC code 12 to exclude from threshold determinations and release and other waste management calculations toxic chemicals used in these activities. EPA exempted these quantities because, as the Agency stated in the industry expansion final rule, it believed that "...facilities that extract coal for distribution in commerce would be able to take the *de minimis* exemption for the listed toxic chemicals in the coal" (at 62 FR 23862). However, the Agency further stated that "...EPA may reconsider this exemption at a later date in light of additional information" (at 62 FR 23862).

In addition, EPA excludes EPCRA section 313 chemicals found in metal mining overburden from threshold determinations and release and other waste management calculations under EPCRA section 313 (40 CFR 372.38(h)). Although the Agency believed that EPCRA section 313 chemicals may be present in overburden, EPA exempted these quantities because the Agency believes that overburden contains EPCRA section 313 chemicals in negligible amounts (at 62 FR 23859). However, because coal extraction materials and overburden may contain PBT chemicals, and as explained elsewhere in this document, even small amounts of PBT chemicals may be of concern, this exemption may not be suitable for PBT chemicals. The Agency is currently making any changes to these exemptions, any possible future changes would require additional rulemaking.

7. COMMENTS ON THE ECONOMIC ANALYSIS

7.a. EPA should predict releases, instead of relying on number of reports

Commenter list: C-1353, C-1421, C-1428, C-1431, C-1431b, C-1432, C-1435, C-1448, C-1825, C-1836, C-1850, C-1858, C-1860, C-1863, C-1865, C-1866

Comment: The commenters note that EPA did not predict the amount of PBT chemicals expected to be reported at the lower reporting thresholds. Although one commenter (C-1825) mentions various categories of reported information, most commenters express a particular interest in an estimate of the quantity of PBT chemical *releases* that would be reported, as well as a comparison of this quantity to current reporting at the national or local level. The commenters ask that EPA provide information on the magnitude of releases that would be reported to allow commenters to evaluate EPA's proposed options. One commenter (C-1866) requests that EPA conduct a review of the facilities subject to TRI to determine if they will be reporting "significant" percentages of the PBT chemicals. The commenters question how it is possible for EPA to conclude that a significant amount of the releases and other waste management activities involving PBT chemicals are not being captured at current thresholds, or that significantly more release information would be captured under any option without predicting what will be reported. Commenters (C-1421, C-1850) suggest that EPA consider "existing information such as its Report to Congress on mercury, its draft inventory of dioxin emissions, information collected under other federal programs, and various information collected by the states."

Response: In the Federal Register notice for this rule, EPA stated that

"EPA has not estimated the total national releases to all media for the toxic chemicals in this proposed rule (and in previously proposed and final rules) because EPA believes that (1) there is insufficient information currently available for these chemicals and (2) there is insufficient information on the numerous processes employed by all the sectors involved to calculate a comprehensive release estimate for the sector. While there are data available for some chemicals for some sectors, comprehensive data for all sectors and chemicals are unavailable and consequently, decisions would need to be based on an incomplete data set. It was also suggested that EPA might consider "throughput" (i.e., manufacture, processing, and use) in setting reporting thresholds. While data are generally more available on throughput than on releases, EPA also did not attempt to estimate the proportion of throughput covered by alternative reporting thresholds because of its concern that these estimates may not be of sufficient quality and completeness to help inform the selection of appropriate reporting thresholds with sufficient scientific certainty. EPA invites comment on these approaches and requests comment as well on appropriate methodologies for estimating releases and/or throughput, and on estimating releases from throughput data. EPA welcomes suggestions as well on other approaches that may assist the Agency when it is developing options for lowering TRI reporting thresholds, adding new facilities or adding additional chemicals." (64 FR 718).

Existing data do not support estimates of releases and other waste management activities to multiple environmental media from the full range of facilities that may be affected by the rule because most of the data required for the analysis would only be available after the rule is in place. For most PBT chemicals and industry sectors, up-to-date multi-media release estimates for affected facilities do not exist. Even where release estimates are available for an industry sector, most are derived from national activity levels rather than from facility-level information. To the extent that release estimates are available, they tend to cover only a single medium such as air. EPA does not believe that there is sufficient information to make reasonable predictions of the multi-media releases and other waste management information that will be reported as a result of EPCRA section 313 rulemakings.

Some commenters note that EPA has estimated releases of certain PBT chemicals in recent reports such as the Mercury Study Report to Congress (U.S. EPA, 1997) and the Inventory of Source of Dioxin in the United States (U.S. EPA, 1998). In fact, EPA reported the results of these reports in its economic analysis for this proposal. These studies, which include

caveats acknowledging the uncertainties associated with the estimates they contain, do not indicate that the releases of PBT chemicals and other waste management activities are well characterized. These studies do not provide community- or facility-level release estimates.

The estimates in these studies are derived using a “top-down” methodology in which emission factors are applied to entire industries. While having an estimate of multi-media PBT releases for a specific industry sector is a first step, other information would also be required to estimate the releases that would be reported as a result of the proposal. Assuming that multi-media release estimates were available for an entire industry sector, these releases would still have to be divided among individual facilities according to some currently unknown distribution. An even, or average, distribution of releases among facilities would be unlikely to reflect reality due to varying activity levels, pollution prevention practices, and control technology at facilities. In addition, there is the complication that TRI reporting thresholds are based on chemical throughput (manufacture, process, or use) rather than chemical release. The relationship between 1) a chemical throughput that triggers the submission of a report, and 2) the releases reported will vary in some currently unknown manner between industries, as well as among facilities within an industry.

EPA does not believe that there is sufficient information to make reliable release estimates for this rule, when considering all the affected chemicals and industries. The uncertainties in the estimated values that go into such a calculation make predictions of facility-level reporting extremely imprecise. Historical attempts to estimate the releases expected to be reported to TRI would have been imprecise to the point of being misleading, particularly in respect to estimates of releases per report or per facility (which some commenters have suggested that EPA should make). This can be demonstrated by examining two different predictions of the number of reports expected as a result of the initial TRI rule and comparing it to the data that were actually reported by facilities as a result. One of the values for the estimated number of reports is from EPA's economic analysis of the original TRI rule, and the other is based on the Small Business Administration's comments on the rule.

In the economic analysis for the initial rule, EPA estimated that there could be up to 31,800 facilities submitting an average of 10 reports each, for a total of 318,000 reports submitted to TRI. (*Regulatory Impact Analysis in Support of Final Rulemaking Under Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986*, U.S. Environmental Protection Agency, Office of Toxic Substances, February 1988). The Small Business Administration claimed that EPA had underestimated the number of facilities. SBA claimed that there would be between 20,000 and 120,000 facilities with less than 100 employees reporting, compared to EPA's estimate of 31,800 facilities of all sizes. (Letter from Frank S. Swain, Chief Counsel for Advocacy, U.S. Small Business Administration, to Lee M. Thomas, Administrator, U.S. Environmental Protection Agency. August 3, 1987. OPTS Docket Number 400002, Comment number C-092. *Re: Section 313 of Title III, Superfund Amendments and Reauthorization Act (SARA) of 1986; Toxic Chemical Release Reporting; Docket No. OPTS-400002.*) Using the larger figure would imply approximately 150,000 facilities of all sizes would report, since there would also be facilities with over 100 employees reporting. Using EPA's estimate of an average of 10 reports per facility, this would yield an estimate of 1,500,000 reports.

For the 1987 reporting year there were 74,152 reports from 19,278 facilities of all sizes. This represents 22% of EPA's estimate of the number of reports, and 5% of the number of reports derived from SBA's estimate of small businesses reporting. These calculations are for the entire rule, where under- or over-estimates for an individual chemical or industry would offset each other to some degree. Predictions for a particular chemical, industry, or locality would have an even greater degree of uncertainty associated with them. The imprecision in these estimates alone demonstrates the uncertainties inherent in such predictions. Furthermore, estimates of releases would be even less reliable, since estimating releases adds a layer of inaccuracy on top of the uncertainty in the estimated number of facilities and reports.

Aside from the general issue of uncertainty in the estimates of aggregate releases, predictions of releases per facility or per report (or dollars of reporting cost per pound of releases) are likely to be misleading due to the biases built into the estimates. The predicted number of reports (and thus costs) is generally an overestimate, since EPA's economic analyses use conservative estimates to avoid underestimating true costs. On the other hand, predictions of releases will tend to underestimate emissions, because while there may be information available on releases of some chemicals from some sectors, such estimates will not include other sources where releases are not identified until more detailed data (such as TRI data) are collected. Combining the two sets of estimates compounds the problem. Since estimated pounds of releases are underestimated and reports are overestimated, pounds per report are biased significantly downward. Likewise, estimates of dollars of reporting cost per pound of releases (which varies as the inverse of pounds per report) will be biased significantly upward.

EPA notes that there were various reports and studies about air emissions of toxic chemicals prior to TRI, but the collection of facility-level data showed that actual releases were much different from what had been anticipated. EPA has not seen any evidence to indicate that the TRI emissions that will be reported as a result of the PBT rule can be predicted any more accurately now than the quantities reported as a result of the original TRI rule could have been predicted prior to 1987.

Aside from the issue of whether comprehensive release estimates for such a rulemaking can reliably be predicted, EPA notes that pounds of releases and other waste management activities (even if known) are not a reasonable proxy for the benefits of the information being provided. This is because the benefits of an informational regulation are not a linear function of the magnitude of the information being reported. This can be demonstrated by applying this “cost-effectiveness” rationale to other regulations requiring information provision. For example, automobile manufacturers are required to provide information about fuel economy on the stickers for new cars. Assuming that the quantity reported is a measure of the value of the information would lead to the mistaken conclusion that there is 100 percent difference in the benefit of requiring the information to be provided on a car that gets 15 miles per gallon compared to another car that gets 30 mpg. To use another example, nutritional labels are required on food packages. Assuming that the benefits of information provision are linearly related to the quantity that is reported would yield the conclusion that if one product has 6 grams of fat per serving and another has 2 grams, the benefit of the nutritional labeling requirement are three times higher for the former than the latter. EPA disagrees with this conclusion.

EPA disagrees with the implicit assumption by commenters that the benefits of information from different facilities is strictly and systematically related to the quantity reported as being released. A calculation such as the commenters have suggested presumes that the benefit to the public to know about a release of 20,000 pounds is twice as large as the benefit of knowing about a release of 10,000 pounds; and that the benefit of knowing about a 40,000 pound release is twice the benefit of knowing about a 20,000 pound release, and four times the benefit of knowing about a 10,000 pound release. One of the central purposes of TRI data is to inform the public about releases and other waste management of EPCRA section 313 listed toxic chemicals in their community and nationally so that the public can form its own conclusions about risks. The amount of releases and other waste management activities that a community may find relevant or useful will vary depending numerous factors specific to that community, such as the toxicity of the various chemicals, potential exposure to these toxic chemicals, and the number of other facilities in the area that release EPCRA section 313 listed toxic chemicals. Section 313(h) of EPCRA states that the data are “to inform persons about releases and other waste management activities of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development if appropriate regulations, guidelines, and standards; and for other similar purposes.” Pounds of releases and other waste management activities reported does not measure how the data perform these functions, and thus is not a measure of benefits.

Finally, EPA notes that commenters on this rule did not provide information on approaches or methodologies for estimating releases and other waste management activities and/or throughput, or on estimating releases and other waste management activities from throughput data, for the spectrum of industries, chemicals, and facilities covered by the rule. Instead, some commenters submitted data from EPA studies (that EPA had already reviewed in the context of this rule and used as references for the economic analysis of the proposed rule) for very narrow slices of the regulated universe (for example, estimated mercury releases and other waste management activities from electric utilities or estimated dioxin releases and other waste management activities from the vinyl industry). Other commenters simply stated that EPA should consider releases and other waste management activities without referencing any data. None of the commenters suggested new methodologies or approaches, or provided information from any sources that EPA had not already reviewed and considered. As a result, EPA continues to conclude that while there are data available to estimate releases and other waste management activities for some chemicals for some sectors, comprehensive, reliable data for all sectors and chemicals are unavailable, resulting in an incomplete data set. Furthermore, as stated previously, the quantity of releases and other waste management activities reported are not a measure of the benefits of the rule. EPA does not believe that inaccurate or incomplete estimates of releases and other waste management activities would aid the decision-making process for the rule. Therefore, EPA has not estimated the releases and other waste management activities that would be reported as a result of the rule.

Comment: Two commenters (C-1353, C-1866) assert that information on the quantity of releases and other waste management activities expected to be reported will better characterize the increased burden that will be placed on reporting facilities.

Response: EPA disagrees. In most cases, the cost of providing information is unrelated to the magnitude of the quantity of toxic chemicals reported as released. Therefore, a “cost-effectiveness” calculation using costs divided by releases and other waste management activities as suggested by the commenters would merely maintain the differential in quantities. In the nutritional labeling example above, if it costs the same to provide the labeling information for both products, a “cost-effectiveness” test for the labeling requirement would show a three-fold difference between the two products, despite the fact that

the informational value may be unrelated to the quantity being reported. Such a calculation does not shed any additional light on costs and benefits of the regulation requiring the information provision, and thus would not be useful in deciding whether to exclude certain products from the information provision requirements, what thresholds to set for reporting, or other regulatory determinations. In fact, in the case of the PBT chemicals, such a calculation is likely to be misleading because of uncertainties in the release estimates.

Comment: A commenter (C-1353) asserts that to follow Vice-Presidential direction to select an option that “minimizes cost and other burdens on business,” an estimate of the possible quantities released at each threshold level should be considered. The commenter claims that the number of additional reports is of “secondary importance” with respect to the intent of TRI for the public and the cost of TRI to the affected industries.

Response: EPA believes that it has followed the Vice President’s direction of April 21, 1998. The Vice President directed EPA to expand every community’s right to know about potentially harmful chemicals released into our air, land and water in a way that minimizes costs and other burdens to businesses. EPA has proposed changes to reporting under EPCRA section 313 that significantly expand the public’s right to know about persistent, bioaccumulative compounds while taking the burden of reporting into consideration. The number of additional reports is important in the selection of an appropriate threshold level because each report represents additional information about persistent bioaccumulative toxic chemicals. With respect to the cost of the proposal to affected industries, the total cost and burden is related to the activities associated with reporting and the number of additional reports, rather than the quantities of toxic chemicals reported as released.

Comment: Three commenters (C-1421, C-1858, C-1865) assert that many of the reports are likely to be zero-release reports, and the proposed reporting thresholds are unlikely to capture significant new amounts of releases and other waste management activities. The commenters cite an SBA memo that asserts that “thousands, if not ten thousand” of the new reports will report zero or near zero amounts of releases and other waste management activities.

One commenter (C-1865) contends that EPA must estimate the quantity of releases and other waste management activities to be captured by the proposed changes and then evaluate (1) whether the substantial majority test is met, (2) whether the information will contribute significantly to risk reduction efforts, and (3) whether the benefits of the additional information outweigh the costs of providing and processing it.

Response: EPA disagrees. The proposal is necessary because there is not an existing source of reliable data about multi-media releases and other waste management activities and other waste management of PBT chemicals at the facility, community, or national level. Due to this lack of information, it is impossible to accurately predict the quantities that will be reported as a result of the proposal. Past attempts to estimate the quantities of releases and other waste management activities prior to actual reporting have been grossly inaccurate.

Even if some reports reflect zero releases and other waste management activities, EPA notes that one commenter (C-1432) argues that there is a significant value to reports of zero releases and other waste management activities because they allow the identification of facilities that employ successful methods of pollution prevention and control that can be analyzed and applied to other facilities. Furthermore, based on the persistent and bioaccumulative properties of the toxic chemicals covered by the proposal, it is reasonable to expect that reports on releases and other waste management activities of any size would have benefits to the public. In addition to information on releases and other waste management activities from facilities, the TRI reporting form also contains important information on quantities of waste otherwise managed on-site and transferred for off-site management, as well as qualitative information on source reduction activities. Focusing exclusively on releases and other waste management activities ignores the value of this other information.

EPA disagrees with the assertion that it is required to estimate the quantity of releases and other waste management activities to be captured by the proposed changes to reporting under EPCRA section 313. As stated in the Federal Register text of the proposal, when EPA lowers reporting thresholds the substantial majority test is met as a matter of logical necessity because the lowered thresholds result in additional reporting.

EPA also disagrees with the assertion that it is required to determine whether the information would contribute significantly to risk reduction efforts. The data collected under EPCRA section 313 are intended to inform the public about the releases and other waste management activities of toxic chemicals, assist in the conduct of research and data gathering, and to aid in the development of appropriate government actions. While risk reduction may be an outcome of this information provision and distribution, EPA is not required to demonstrate that it will necessarily occur as a direct result.

Finally, EPA has evaluated the costs and benefits of the proposal. EPA has stated that it believes the benefits provided by the information to be reported under the proposal will outweigh the costs.

7.b. Rule is not cost-effective

Commenter list: C-1427, C-1815, C-1842, C-1853

Comment: A commenter (C-1815) notes that EPA estimates that the proposed rule will impose \$126 million in first year costs, and \$70 million in subsequent year reporting costs. The commenter asserts that these costs are excessive, particularly when added to the costs of TRI compliance under the existing program. The commenter strongly recommends that EPA adopt the least costly regulatory alternative that accomplishes the objective of obtaining meaningful data on PBT emissions.

Response: EPA believes that it has proposed the least costly regulatory alternative that accomplishes the objective of expanding the public benefits of the TRI program by exercising EPA's discretionary authority to add chemicals to the program and to lower reporting thresholds, thereby increasing the amount of information available to the public regarding the use, management, and disposal of listed toxic chemicals. EPA adopted a two-tier approach to setting lower thresholds to reflect the chemicals' varying potentials to persist and bioaccumulate. In selecting reporting thresholds, EPA also considered the potential burden that might be imposed on the regulated community. Given the potential for adverse effects on humans and the environment of PBT chemicals, EPA does not believe that the cost of providing information on releases and other waste management activities to the public as proposed is excessive.

Comment: A commenter (C-1842) contends that the proposed rule should not target sources that burn fuel for heat or power. The commenter contends that EPA can "more efficiently obtain information on the impact of fuel burning from sources other than reports by every individual user."

Response: EPA disagrees. EPA is not aware of any source of information that provides facility-specific data on the amount of PBT chemical releases and other waste management activities to each environmental media from fuel consumption. EPA notes that the commenter has not identified any alternative sources of information that EPA and the public could use in the place of TRI reporting to obtain information on the impact of fuel burning at the community and national level. EPA believes that facility managers are in the best position to report on the releases of PBT chemicals and other waste management activities associated with fuel use because of their knowledge of facility-level fuel consumption, pollution prevention practices, and pollution control technology.

Comment: A commenter (C-1427) provides the following estimates of the number of coal-fired electric utilities facilities that would be expected to report at each reporting threshold, as well as estimates of the total amount of mercury that would be reported:

Summary of Various Mercury Reporting Thresholds

| Reporting Threshold | Number of Plants Exceeding Threshold | Percent of Plants Exceeding Threshold | Percent of Mercury Accounted for |
|---------------------|--------------------------------------|---------------------------------------|----------------------------------|
| 1,000 lb/yr | 31 | 7.7% | 32.8% |
| 500 lb/yr | 108 | 26.8% | 67.9% |
| 100 lb/yr | 287 | 71.0% | 96.3% |
| 10 lb/yr | 396 | 98.3% | 100% |

The commenter indicates that these estimates are based on the amount of coal burned by each plant in a given year and the state-average mercury in coal concentration times the amount of coal received from each supplying state. Based on the total amount of coal received by the utility industry in 1997 and the state-average mercury in coal concentrations, the commenter estimates a total mercury release (to all environmental media) of about 146,000 pounds per year (73 tpy). Since a reporting threshold of 500 pounds per year is estimated to account for 67.9 percent of the mercury, it means that a total of $146,000 \times 0.679 = 99,000$ pounds per year would be reported on Form Rs. The commenter notes that a Section 313 mercury reporting threshold of 100 pounds per year would account for an “overwhelming majority” of mercury released by the utility industry while not requiring about 30 percent of the plants to incur the burden of preparing and submitting Form Rs.

Response: EPA does not dispute that a 10 pound reporting threshold for mercury and mercury compounds would result in reporting from most or all coal-fired electric utility facilities. However, EPA notes that the commenters’ data apply to a very limited subset of facilities. This ignores oil-fired electric utilities, electric utilities in other SIC codes such as 4931 and 4939, and facilities in every other covered industry sector. It is not clear how this information, in the absence of comparable information for all other industry groups, would help in the selection of a lower reporting threshold. Furthermore, focusing exclusively on total national releases of PBT chemicals ignores the strong *community* right-to-know characteristics of the program and potential uses of the data at the local level. According to the commenter’s data, over 5,400 pounds of mercury from 109 coal-fired electric utilities would remain unreported to communities each year at the 100 pound reporting threshold.

Comment: A commenter (C-1853) asserts that under the proposed reporting threshold for dioxin, 30 of 31 EDC/VCM, EDC/VCM/PVC and PVC manufacturing sites would be required to report on dioxin. The commenter also evaluated two scenarios: (1) dioxin emissions reported as TEQ's with a reporting threshold of 0.00022 lb/y TEQ, and (2) dioxin emissions reported as TEQ's with a reporting threshold of 0.0022 lb/y TEQ. According to the commenter, under the first scenario, only 11 of the 31 EDC/VCM and PVC sites would be required to report dioxin releases, yet 98 percent of the estimated dioxin releases from these sites would be captured. Under the second scenario, 6 of the 31 EDC/VCM and PVC sites would be required to report dioxin releases, yet 88 percent of the estimated dioxin releases from these sites would be reported.

Response: EPA has incorporated this information into its estimate of additional reporting in the economic analysis of the final rule. EPA notes that these results apply to a very limited subset of facilities. The results ignore facilities in every other industry sector. It is not clear how this information, in the absence of comparable information for all other industry groups, would help in the selection of a lower reporting threshold. Furthermore, focusing exclusively on total national releases of PBT chemicals ignores the strong *community* right-to-know characteristics of the program and potential uses of the data at the local level. EPA also notes that, based on the comment, it appears that these facilities have readily available information that would allow TRI reporting. EPA also notes that the trade association submitting the comment appears to have had little difficulty obtaining the data, performing calculations, estimating releases, and projecting which facilities would report at various alternative thresholds. At this point, the mere submission of this data (that is readily available to the facilities) to TRI would therefore represent a small incremental burden for these facilities.

7.c. EPA has misestimated the number of reports

Commenter list: C-1423, C-1424, C-1433, C-1436, C-1458, C-1825, C-1850, C-1863

Comment: Two commenters (C-1825, C-1850) assert that EPA has not explained the methodology used to estimate the number of reporting forms under each option.

Response: EPA disagrees. The economic analyses of the proposed and final rules, which are available in the public docket for this rulemaking, contain a detailed description of the methodology used to estimate the number of additional reports under each option considered.

Comment: A commenter (C-1458) asserts that EPA may have overestimated the number of reports that will result from new thresholds because facilities that do not have readily available data are not required to report under EPCRA section 313. The commenter asserts that most of the PBT chemicals are present at facilities in “minute quantities.” The commenter claims that because the proposed thresholds are “so low,” it will be impossible or impractical for facilities to determine if they meet the thresholds, and will lack information to make reasonable estimates.

Response: EPA acknowledges that it may have overestimated the number of reports and the estimated cost of the proposal for this and other reasons. While some facilities may not have readily available information to support TRI reporting, EPA believes that many facilities will have sufficient information to make reasonable estimates. EPA will assist in this effort by providing guidance documents to assist the reporting efforts of affected facilities.

Comment: A commenter (C-1423) states that EPA estimates that 9,500 facilities will submit 17,000 additional reports on PBTs. This estimate assumes that each facility will submit approximately two new reports. However, electric utilities may submit as many as ten new reports per facility. The commenter estimates a cost of \$156 million for compliance by the electric utility industry alone, using EPA’s estimate that 977 electric power plant facilities are subject to EPCRA section 313 and assuming that each facility files 10 reports.

Response: EPA disagrees that it has underestimated the number of reports from the electric utility industry. While it is true that EPA estimated that 9,500 facilities will submit 17,000 additional reports on PBTs (yielding an average of two reports per facility for all reporting facilities) in the economic analysis of the proposed rule, this does not mean that EPA estimated that electric utilities would submit two reports each. EPA did not estimate the number of reports by assuming that facilities would submit two reports each and then multiplying the number of facilities by two. Instead, EPA made separate predictions of the number of reports from different industry types for each PBT chemical. EPA estimated the number of reports from electric utilities using data on the type of fuel used at different utility facilities, the annual fuel consumption at each facility, the concentration of PBT chemicals in different fuels, and the PBT chemicals coincidentally manufactured through the combustion of these fuels.

EPA estimated that electric utility facilities will submit reports for up to seven chemicals as a result of this rule: dioxin, hexachlorobenzene, mercury, PACs, benzo(g,h,i)perylene, PCBs, and vanadium (with the fume or dust qualifier removed, but without the threshold being lowered). EPA estimated that electric utilities will submit between 1 and 7 reports per facility, depending on the facility, with an average of 4 reports per facility.

The commenter has provided no evidence to support its contention that electric utility facilities will submit up to ten reports per facility. The commenter has made a simplistic assumption that because one unnamed facility has made an unsubstantiated claim that it may submit as many as 10 reports, that electric utilities as a whole will submit an average of 10 reports each. The commenter has not even indicated which additional chemicals (beyond the seven chemicals identified by EPA) it believes electric utilities will report on. Therefore, EPA has no basis on which to increase its estimated number of reports for electric utilities, and has not done so. The Agency believes that it has made a reasonable estimate of the expected number of reports from electric utilities.

Comment: A commenter (C-1433) asserts that EPA’s economic analysis did not account for additional reports that would be filed at the 10 pound threshold by facilities that do not meet the 10 pound threshold, but which desire to avoid EPA enforcement actions or citizen actions.

Response: EPA’s economic analysis of the proposal accounts for costs that are attributable to actions that are required by the rule. EPA believes that it is inappropriate to consider the cost of activities, such as voluntary reporting, which are not required by the proposal. EPA notes that the commenter has not provided any estimate of the number of facilities that would file voluntary reports out of a desire to avoid EPA enforcement actions or citizen actions, nor has the commenter provided any evidence that the number of voluntary reports will be greater at the lower proposed threshold than at current thresholds. EPA notes that while these potential costs were not included in the economic analysis, neither were any benefits from voluntary reporting to the proposed rule.

Comment: A commenter (C-1424) asserts that EPA overlooked certain facilities who may report PCB releases under the proposal. One category of facilities operates electrical equipment using PCBs. The commenter asserts that the proposed changes to the *de minimis* exemption and release reporting rounding will disqualify electrical equipment as articles for which reporting is not required. Another category of facilities inadvertently generates PCBs during manufacture of other chemicals. A third category of facilities process chemicals containing trace level PCBs that, albeit at very low levels, are ubiquitous in the environment.

Response: EPA disagrees that it overlooked certain facilities who may report PCB releases under the proposal. With regard to facilities that solely operate electrical equipment using PCBs, EPA notes that according to EPCRA Section 313 Policy Directive #6, the threshold determination for PCBs in electrical equipment is based on PCB-containing fluid that is *added* to equipment, not the amount of fluid that is contained in the equipment, removed, or lost. EPA believes that most of these facilities remove and dispose of PCB-containing equipment in its entirety following the active life of the equipment, or retrofill the equipment with fluid that does not contain PCBs. In either case, these activities do not constitute manufacture, process, or otherwise use of PCBs regardless of the level at which reported releases may be rounded to zero. The commenter should also note that the changes to the *de minimis* exemption cannot disqualify electrical equipment as an article because the exemption is currently not considered for purposes of determining whether the equipment meets the definition of article.

With regard to facilities that inadvertently generate PCBs, EPA notes that unintentional manufacturers and importers are required to notify EPA of their activity annually under Section 6 of TSCA (although, unlike TRI, they do not report their releases or other waste management activities under TSCA). As noted in the economic analysis of the proposed rule, an average of 3 facilities per year reported between 1994 and 1998. These facilities represent a small portion of the over 2,000 facilities expected to report to TRI at the proposed threshold of 10 pounds.

With regard to facilities that “process chemicals containing trace level PCBs that, albeit at low levels, are ubiquitous in the environment,” EPA notes that the commenter did not identify any chemicals for which this is an issue, nor did the commenter provide any estimate of the number of facilities that would fall into this category. EPA was unable to identify any facilities in this situation. EPA notes that in reporting releases and other waste management activities, the statute requires the reporter to use readily available data or, if no data are available, reasonable estimates. If information on PCB levels in chemicals is not available, facilities are not required to report.

Comment: A commenter (C-1436) asserts that all facilities manufacturing pendimethalin already file TRI reports for pendimethalin and the lowering of the reporting threshold would not capture additional reports. The commenter indicates that there is one manufacturing plant and three formulating plants, all of which have been identified in the FIFRA pesticide reregistration eligibility decision (RED) document.

Response: EPA disagrees. The commenter asserts that there are only four facilities that report to TRI on pendimethalin at current reporting thresholds, and that this is consistent with the number of manufacturers identified in EPA’s RED for the pesticide. However, EPA notes that a RED does not identify all manufacturers of a pesticide. It would not, for example, necessarily identify manufacturers of the pesticide products derived from the pesticide active, nor would it identify the manufacturers of the pesticide if solely for export. In 1997, the latest reporting year for which TRI data are currently available, five facilities submitted reports. In 1996, six facilities submitted reports. Based on reporting under Section 7 of FIFRA, EPA estimates that additional reports would be submitted for pendimethalin at lower TRI reporting thresholds. Due to FIFRA Confidential Business Information, EPA cannot disclose the exact estimate for additional pendimethalin reporting to TRI. However, for all affected pesticides EPA estimates 264 additional reports. The majority of these reports are for pesticides—like pendimethalin— with active registrations and/or manufactured for export. EPA acknowledges the possibility that it may have overestimated the number of reports that would be submitted, but this possibility only indicates that EPA’s cost estimate is based upon conservative assumptions.

Comment: A commenter (C-1850) states that facilities in the nonferrous mining and primary smelting and refining industry do not manufacture, process, or otherwise use tetraethyl or tetramethyl lead, and therefore would not be expected to report releases of these chemicals if the rule is finalized. The commenter notes that Table B-2 of the document Economic Analysis of the Proposed Rule to Modify Reporting of Persistent Bioaccumulative Toxic Chemicals Under EPCRA Section 313, is entitled, “Summary of TRI Reporting for Alkyl Leads, 1996.” The commenter questions how EPA obtained this information, since companies are not currently required to report alkyl lead separately. In this table, EPA identifies one metal mining facility (SIC code 10) as reporting releases of alkyl leads and 213 primary nonferrous metals facilities (SIC Code 33), as filing reports for alkyl leads. The commenter notes that tetraethyl and tetramethyl lead are organometallic compounds that are manufactured

separately from the primary metals smelting and refining process. The commenter suggests that EPA correct this apparent error in the Economic Analysis. Another commenter (C-1863) asserts that mines and smelters (specifically the primary nonferrous mineral processing sector) are not intended to, and do not, manufacture, process or otherwise use dioxins or alkyl leads under normal conditions. The commenter asserts EPA and the public should understand that facilities in these sectors are not likely to file reports on these chemicals.

Response: Table B-2 of the economic analysis of the proposed rule reflects reporting in 1996 on lead compounds. EPA proposed that facilities filing TRI reports on lead compounds would file additional reports on alkyl leads if 1 or more pounds of tetraethyl lead or tetramethyl lead is part of the facility's threshold calculation. EPA did not intend to imply that all these facilities manufacture, process, or otherwise use alkyl lead in addition to other lead compounds, but the number of facilities reporting lead compounds help bound the estimate of reporting on alkyl leads. Based on available information, EPA did not predict reporting on alkyl leads from facilities engaged in mining or the smelting of nonferrous metals in the economic analysis of the proposed rule. Finally, EPA notes that it is not modifying the reporting of alkyl leads as part of the final rulemaking.

With regard to dioxin, EPA notes that facilities that combust large amounts of coal or oil—such as smelters—may be required to report if they exceed reporting thresholds and if they have information that allows reporting. In the economic analysis of the final rule, EPA did not estimate any additional reporting from manufacturing facilities due to combustion because of the lack of appropriate facility-level emission factors. However, there may be some manufacturing facilities that are able to report on dioxin because they have conducted previous testing, monitoring, or analysis.

7.d. EPA has underestimated burden

Commenter list: C-792, C-849/403, C-1168, C-1352, C-1353, C-1405, C-1406, C-1409, C-1420, C-1421, C-1422, C-1423, C-1427, C-1428, C-1428b, C-1431, C-1431b, C-1432, C-1435, C-1438, C-1440, C-1445, C-1448, C-1457, C-1458, C-1813, C-1815, C-1820, C-1826, C-1836, C-1841, C-1843, C-1844, C-1855, C-1857, C-1858, C-1861, C-1862, C-1863, C-1864, C-1865, C-1869

Comment: A commenter (C-849/403) states that EPA did not analyze the cost of requiring all facilities with certain “dioxin-producing processes” to report regardless of quantities actually manufactured.

Response: EPA acknowledges that it did not present a cost estimate for this scenario because EPA is not requiring all such facilities to report. EPA believes that a zero threshold would be impractical. Attempting to require facilities to determine if they manufacture, process, or otherwise use any amount whatsoever of dioxin and dioxin-like compounds would be extremely burdensome and perhaps technically impossible. Without an actual numerical threshold, many facilities might report some amount of dioxin in a misguided attempt to assure compliance. This could lead to misleading and inaccurate data on the actual sources of dioxin and dioxin-like compounds. EPA believes that rather than setting a zero reporting threshold, it would be better to set a very low threshold that provides facilities with a clear indicator of when they are required to report.

EPA notes that it did estimate that approximately 5,700 facilities would be expected to report on dioxin and dioxin-like compounds at a threshold approaching but greater than zero in the economic analysis of the proposed rule. EPA's estimate includes categories of facilities identified in the Inventory of Sources of Dioxin in the United States (USEPA, 1998). EPA's estimate does not include facilities for which there is no evidence to indicate dioxin manufacture, or facilities in SIC codes for which only order of magnitude estimates of dioxin releases are available.

The commenter advocates reporting by all facilities that employ certain manufacturing processes, regardless of whether dioxin is actually manufactured. The commenter does not provide any criteria by which a process would be classified as “dioxin-producing.” The commenter does not address the following issues: 1) what level of evidence would be necessary to label a process as “dioxin-producing”; 2) whether a process would be labeled “dioxin-producing” on the basis of a single test; 3) how to resolve conflicting test results (e.g., one detect vs. many non-detects); 4) how to treat processes that are theoretically capable of dioxin production but for which actual test results are below detection limits; and 5) the acceptability of data from outside the U.S. as applied to U.S. facilities without test data. These would become critical issues to be resolved if EPA were to adopt the commenter's proposal. EPA also notes that developing and maintaining a list of “dioxin-producing” processes for the purpose of TRI reporting may delay implementation of reporting because such an approach may require further notice-and-comment rulemaking.

Comment: A commenter (C-849/403) claims that EPA's cost analysis did not specifically address potential reporting costs related to separate reporting of individual dioxin-like chemicals or individual dioxin-like PCBs. The commenter claims that EPA cannot conclude that the proposal to require dioxins or dioxin-like PCBs to be reported separately would be more burdensome than requiring their reporting as part of categories. For dioxin, the commenter asserts that the cost to industry of reporting each congener separately "could be minimal" because it would be "limited to writing extra reports" because the commenter asserts that dioxin-like compounds are measured and analyzed individually. However, another commenter (C-792) claims that "requiring facilities to break out their releases into all subsets of the dioxin-like category members would be extremely burdensome, if not infeasible."

Response: While EPA did not present a total cost estimate for the specific option of listing each congener individually, EPA did consider a reasonable range of options. EPA is not required to consider every possible permutation of reporting requirements. EPA did not generate a total cost estimate assuming that individual dioxin-like chemicals would be reported separately, but it is reasonable to conclude that requiring facilities to generate 17 separate 5 page reports for dioxin congeners would be more burdensome for a facility than filing a single report for the category of dioxin and dioxin-like compounds. At a reporting threshold of 0.1 g for dioxin and dioxin-like compounds, EPA could potentially receive over 32,000 reports if, as indicated in the economic analysis of the proposed rule, approximately 1,900 facilities each filed 17 separate reports on dioxin congeners. This reasoning also applies to the dioxin-like PCBs. Apart from any feasibility issues, with 11 separate listing for dioxin-like PCBs, EPA could receive 11 times the number of reports as with a single category listing for all PCBs. Not only would this be burdensome (and needlessly tedious) for the filers, it would also increase EPA's data management costs. For comparative purposes, in 1997 EPA received approximately 72,000 forms from 21,500 facilities.

After consideration of all of the comments on this issue, EPA has decided that the best way to report on dioxin and dioxin-like compounds is to report them as a category. This is consistent with the way EPA has addressed groups of chemicals that share the same toxic effect and in this case are also generated as complex mixtures. As discussed elsewhere in this document, reporting as a category but based on TEQs would not provide users of the data with information on which compounds contribute the most to the TEQ total. In addition, requiring facilities to report each compound individually would impose an additional burden on the industries that will be required to report. However, EPA agrees that being able to determine the amounts of the individual dioxin and dioxin-like compounds would make the data more useful. Therefore EPA will add a section to the Form R that will require the reporting facility to provide the distribution of dioxin and each dioxin-like compound for the quantities that they are reporting. As with all other reporting under EPCRA section 313, this information will only be required if the facility has information that can be used to make a reasonable estimate of the distribution. With the distribution of congeners reported on each Form R, the user of the data can determine the grams of dioxin and each individual dioxin-like compound that makes up the quantities reported on the Form R.

Comment: A commenter (C-849/403) claims that EPA underestimated the cost of compliance determination for dioxin by \$50 to \$200 million per year. In part, this is based on the commenter's assertion that EPA may have underestimated the cost of compliance determination for dioxin at the proposed reporting threshold of 0.1 g. The commenter claims that estimating the quantities of dioxin will be more difficult than estimating quantities of chemicals that are present in larger quantities. Furthermore, the commenter claims that EPA underestimated the number of facilities that will incur threshold determination costs. The commenter claims that EPA assumes that facilities that do not report PBT chemicals will not make threshold determinations for PBT chemicals and are not assigned the full cost of compliance determination. The commenter notes that EPA has applied scaling factors based on a ratio of new reports to current reports to adjust compliance determination costs. The commenter asserts that the correct method for calculating dioxin-related compliance costs associated with EPA's proposed option would be to multiply the total number of facilities that are potentially subject to TRI reporting (190,497) by the full cost of compliance determination (\$1,119 first year; \$280 subsequent years).

Response: The commenter appears to misunderstand EPA's methodology for estimating the cost of compliance determination associated with the proposal. EPA's economic analysis of the proposed rule estimated that compliance determination would take an average of 2.4 hours in the first year and 0.6 hours in subsequent years *for the PBT chemicals as a group* across all subject facilities. The PBT chemicals are a much smaller group of chemicals than the current list of TRI chemicals. In many cases, PBT chemicals are byproducts and impurities associated with a limited number of manufacturing processes or raw materials present at a limited number of facilities. Therefore, it is reasonable to expect that average *incremental* compliance determination costs for the PBT chemicals would be less than current compliance determination costs.

The scaling factors mentioned by the commenter were applied by EPA to the average time currently required for compliance determination, not the number of facilities that must determine if they must report. The estimates for

compliance determination for the PBT chemicals are incremental to the time currently required for compliance determination for existing reporting requirements. When added to the hours per year EPA estimates for the current reporting requirements, this yields a total of 18.4 hours in the first year and 4.6 hours in subsequent years. All 190,497 facilities with 10 or more employees that are in SIC codes subject to reporting under EPCRA Section 313 must carry out compliance determination activities.

EPA disagrees with the commenter's assertion that estimating quantities of dioxin will be more difficult than estimating quantities of chemicals that are present in larger quantities. The statute directs reporters to use readily available information or reasonable estimates. They are not required by EPCRA to conduct additional testing, sampling, or analysis. The techniques of estimation (mass balance equations, engineering calculations) employed by reporters will function the same regardless of the size of the numbers that are plugged into the equations. The values used in the equations and the results may be smaller than for current TRI chemicals, but there is no reason for the burden of performing these mathematical operations to be substantially greater for dioxin than for other TRI chemicals.

The commenter's estimate of total compliance determination costs is derived by multiplying the cost of compliance determination for all other TRI chemicals (approximately 600 chemicals) by the number of facilities in SIC codes that are subject to TRI reporting. This implies that the incremental cost of compliance determination for the roughly 25 PBT chemicals will be the same as the current cost of compliance determination for roughly 600 chemicals. EPA does not believe this is a reasonable assumption.

Comment: A commenter (C-849/403) proposes to require all facilities within industry categories that have been associated with dioxin to report each of 28 dioxin-like chemicals regardless of the quantity manufactured. The commenter claims that requiring all facilities with certain "dioxin-producing processes" to report regardless of quantities actually manufactured will result in less burden to industry and less total burden by completely eliminating time spent on threshold determination. This conclusion is based on the assumption that the commenter's approach would have no compliance determination costs, and that industry reporting costs would equal \$48 million (5,692 reports at \$8,454 per report) in the first year and \$25 million in subsequent years (5,692 reports at \$4,443 per report). For EPA costs, the commenter estimates \$13.2 million in the first year (5,692 facilities x 28 reports x 103 data elements per report x \$0.78/data element, plus \$400,000 in first year costs) and \$12.8 million in subsequent years (5,692 reports x 28 reports x 103 data elements per report x \$0.78/data element).

The commenter recommends that EPA revise its cost analysis to conclude that this alternative approach would not create an undue reporting burden. The commenter (C-1432) submitted additional comments in which it asserts that it would be easier to identify if a facility has a process associated with dioxin production than if that same facility has greater than threshold quantities of dioxin (for thresholds greater than zero). The commenter also asserts that it would be easier to confirm non-zero dioxin production than dioxin production above or below a given threshold. The commenter claims that these factors will lead to lower enforcement verification costs. The commenter also claims that facility-level costs will also be lower because there will be no compliance cost related to estimation of the amount produced. The commenter notes that EPA's estimate of reporting at the "zero threshold" would be limited to 5,692 facilities out of a potential reporting universe of 190,497. The commenter provides a list of industrial processes that the commenter claims are associated with dioxin production.

Response: EPA acknowledges that it did not present a cost estimate for this scenario. While EPA did not analyze this specific option, EPA did consider a reasonable range of options. EPA is not required to consider every possible permutation of reporting requirements. EPA believes that a zero threshold would be impractical. Attempting to require facilities to determine if they manufacture, process, or otherwise use any amount whatsoever of dioxin and dioxin-like compounds would be extremely burdensome and perhaps technically impossible. Without an actual numerical threshold, many facilities might report some amount of dioxin in a misguided attempt to assure compliance. This could lead to misleading and inaccurate data on the actual sources of dioxin and dioxin-like compounds. EPA believes that rather than setting a zero reporting threshold, it would be better to set a very low threshold that provides facilities with a clear indicator of when they are required to report.

The commenter advocates reporting by all facilities that employ certain manufacturing processes, regardless of whether dioxin is actually manufactured. The commenter does not provide any criteria by which a process would be classified as "dioxin-producing." The commenter does not address the following issues: 1) what level of evidence would be necessary to label a process as "dioxin-producing"; 2) whether a process would be labeled "dioxin-producing" on the basis of a single test; 3) how to resolve conflicting test results (e.g., one detect vs. many non-detects); 4) how to treat processes that are theoretically capable of dioxin production but for which actual test results are below detection limits; and 5) the acceptability of

data from outside the U.S. as applied to U.S. facilities without test data. These would become critical issues to be resolved if EPA were to adopt the commenter's proposal. EPA also notes that developing and maintaining a list of "dioxin-producing" processes for the purpose of TRI reporting would delay implementation of reporting by requiring further notice-and-comment rulemaking.

EPA disagrees that the approach suggested by the commenter would result in lower enforcement verification costs. This assertion is based on the assumption that enforcement of the proposed dioxin threshold would be extremely costly. However, current enforcement techniques as applied to facilities that report (or should report) dioxin would involve verification that the facility had used the best readily available information or reasonable estimates to make threshold determinations and to estimate releases and other waste management activities. The commenter appears to believe that current enforcement of EPCRA Section 313 involves independent emissions monitoring by EPA. This is not the case.

EPA disagrees that the approach suggested by the commenter would eliminate compliance determination costs related to estimation of the amount of dioxin produced. The commenter's assertion is based on the assumption that if all facilities with certain processes are required to report, then facilities would not have any costs associated with threshold calculations. However, under any approach (including the commenter's), facilities would have to calculate the total amount of dioxin and dioxin-like compounds manufactured at the facility before moving on to other reporting activities. A facility has to estimate the amount of dioxin manufactured before reporting how the amount of dioxin manufactured is partitioned among product impurities, releases to various media, and other waste management activities. The only activity eliminated by the commenter's approach is a comparison of the facility's amount manufactured, processed or otherwise used to the threshold amount. Under EPA's option, facilities that do not exceed the reporting threshold do not need to conduct any further work to estimate amounts released or otherwise managed as waste. In addition, under the commenter's approach, the facility would have compliance determination costs associated with a comparison of processes at the facility with the list of "dioxin-producing" processes.

The commenter's approach also ignores the cost to EPA of maintaining a list of "dioxin-producing" processes and the cost to facilities of familiarization with this list of processes. Presumably, the list of "dioxin-producing" processes may have to be updated periodically through notice-and-comment rulemaking. The commenter ignores that cost to EPA of maintaining an updated list of "dioxin-producing" processes. Any new information (including new test results and petitions) would have to be evaluated with by EPA. Furthermore, each time the list of processes changed, facilities would have to become familiar with the new list and determine if any of the newly added processes occur at the facility. To enforce the commenter's approach, EPA notes that it would be necessary to maintain up-to-date information on the processes employed at all facilities subject to EPCRA reporting.

EPA disagrees that the impact of the commenter's approach would be limited to 5,692 facilities. In the economic analysis of the proposed rule, EPA did estimate that approximately 5,700 facilities would be expected to report on dioxin and dioxin-like compounds at a threshold approaching but greater than zero. However, EPA's estimate only included categories of facilities identified in the Inventory of Sources of Dioxin in the United States (USEPA, 1998). Unlike the commenter's proposal, EPA's estimate does not include facilities for which there is limited or conflicting evidence to indicate dioxin manufacture, or facilities in SIC codes for which only order of magnitude estimates of dioxin releases are available.

Finally, EPA notes that the commenter has estimated a cost to EPA for data processing of dioxin reports under the commenter's approach of \$13.2 million in the first year and \$12.8 million in subsequent years. EPA's entire budget for TRI activities in FY 1999 was only \$19.8 million; and the President's proposed budget for FY 2000 is only \$18.8 (see, pg. 73 at <http://www.epa.gov/ocfo/2000bib.pdf>). Therefore, the commenter's approach would consume approximately 70 percent of the total budget for TRI activities just for processing reports on dioxin. EPA does not believe this would be an effective use of resources.

Comment: Two commenters (C-1353, C-1815) suggest that there is a "tremendous" unknown burden associated with EPA's proposal because additional TRI chemicals may be considered persistent and bioaccumulative in the future.

Response: EPA acknowledges that the proposal only presents data for those chemicals for which assessments were completed during the initial review, and that the proposed rule does not eliminate any chemical from possible future designation as persistent and bioaccumulative or from future consideration for lower reporting thresholds under EPCRA section 313. However, EPA disagrees that this constitutes an unknown burden associated with this particular proposal. The burden of this proposal is estimated in EPA's economic analysis of the proposal. As stated in the proposal, any future lowering of the

reporting thresholds for other PBT chemicals will be done through rulemaking, and EPA will consider the burden at that point. At this point, it is impossible for EPA to assess the potential future burden of lower thresholds for other chemicals because those chemicals have not been identified through screening for persistence and bioaccumulation.

Comment: Commenters (C-1353, C-1427, C-1428, C-1836) assert that EPA did not consider the cost of responding to public inquiries and pressures that arise with respect to reported releases. The commenter suggests that there will be public pressure not to emit or release any TRI substance even if it poses little or no risk to the public. The commenters contend that they are forced to contend with a “bad actor” perception that may occur when a TRI report is filed.

Response: EPA has estimated the cost and burden of reporting activities that are required by the proposed rule. Costs of activities such as community relations campaigns, which are not required by the proposal, are considered to be optional and are not included in the economic analysis of the proposal. However, even though these activities are not part of the rule, there is evidence that EPA’s unit cost estimates are sufficiently conservative that the cost of reporting plus the cost of some of these activities would be less than EPA’s cost estimates. The SOCOMA study discussed elsewhere in this section included the cost of responding to public inquiries, and the resulting unit cost estimate was still lower than EPA’s estimate.

Additionally, it is difficult to predict the public response to future TRI reporting. EPA recognizes that facilities may decide to conduct “follow-on” activities that are not required by the proposed rule. Some of these possible activities are discussed in the economic analysis of the proposed rule. These activities would have both costs and benefits apart from the costs and benefits of the reporting activities required by the proposed rule. Due to the inherent uncertainty in the chain of events following TRI reporting, EPA has not quantified the net social benefits of follow-on activities.

Comment: A commenter (C-1405) claims that the requirement to track and report all PCBs at quantities at or above 10 pounds presents a greater burden than the documentation and tracking requirements under the Toxic Substances Control Act (TSCA). The commenter notes that TSCA does not require the tracking of items with PCB concentrations below 50 ppm. The commenter says that the elimination of the *de minimis* exemption would increase reporter burden by requiring facilities to identify and track any material with any PCB concentration.

Response: EPA agrees that facilities will perform additional work over and above what is required by TSCA, which is why the proposal is expected to produce new data on releases and other waste management of PCBs and other PBT chemicals. TSCA reporting does not provide the release, waste management, and pollution prevention data that TRI reporting provides. The fact that facilities will perform new work indicates that the proposal is not duplicative of existing reporting requirements; additional time will be expended to produce additional data. With regard to the proposed elimination of the *de minimis* exemption, EPA notes that facilities are not required to identify and track every material containing PCBs for threshold determination purposes. The threshold determination for PCBs in electrical equipment is based on PCB-containing fluid that is *added* to equipment, not the amount of fluid that is contained in the equipment.

Comment: A number of commenters (C-1352, C-1405, C-1406, C-1422, C-1438, C-1457, C-1820, C-1836) assert that the proposed rule requires sampling and analysis to determine if reportable amounts of PBT chemicals are present, to make a reasonable estimate of the concentrations, and to determine if releases have occurred. The commenters assert that without the *de minimis* exemption, analysis will more than likely be conducted for most, if not all, streams generated at the site and for most, if not all, of the PBT chemicals involved. The commenters assert that performing site specific analysis would be seen as the only method available to report accurate information. As an example, one commenter (C-1438) notes that for PACs in carbon black, the concentrations and identities of PACs contained on carbon black are highly variable from process to process, from raw material to raw material, and even from batch to batch, so it is extremely difficult to develop any meaningful generalizations for use in estimating PAC releases. Another commenter (C-1457) asserts that reporting of dioxin in 100 microgram increments will force the regulated community to step up and measure, rather than to risk enforcement over an estimate with very little supporting documentation. Another commenter (C-1820) asserts that facilities faced with the use of erroneous emissions factors will need to conduct stack testing to disprove the presumably acceptable value of the emissions factors or face reporting emissions of chemicals that are not present or fall below a reporting threshold. The commenters contend that these analyses are expensive and should be calculated into the cost of the proposed rule. However, one commenter (C-1457) acknowledges that facilities will have different levels of knowledge, and the available data is likely to vary significantly.

Response: EPA acknowledges that available data may vary from chemical to chemical and facility to facility. However, EPCRA section 313(g)(2) states that “[i]n order to provide the information required under this section, the owner or operator of a facility

may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation." EPA has interpreted this to cover threshold determinations as well as release estimates (see "EPCRA Section 313 Questions and Answers, Revised 1998 Version"). The requirements on the use of available data are described in 40 CFR 372.30(b). As with other voluntary activities not required by the proposal, costs of sampling, testing, or analysis are considered to be optional and are not included in the economic analysis of the proposal.

Comment: A commenter (C-1405) asserts that EPA failed to adequately analyze the burden of the proposed regulation on the Federal government associated with the elimination of current Section 313 exemptions (*de minimis*, research use, maintenance use). The commenter notes that, with the signing of Executive Order 12856, Federal agencies and Federal facilities are included within the scope of EPCRA Section 313 reporting requirements. Within the Federal government are a number of facilities, including research and medical operations, which would be significantly affected by elimination of current Section 313 exemptions.

Response: EPA notes that the only Section 313 exemption it has proposed to eliminate in this rulemaking is the *de minimis* exemption. EPA solicited comment on the possibility of eliminating the other exemptions, but the elimination of these exemptions is not part of this proposal. EPA is aware that federal facilities are included within the scope of EPCRA Section 313 reporting requirements as a result of EO 12856. EPA was not able to locate any data regarding the prevalence of PBT chemicals above the lower reporting thresholds at federal facilities. EPA notes that the commenter did not provide any estimate of the number of federal facilities that may be affected, the number of PBT chemicals these facilities manufacture, process, or otherwise use, or the amount of PBT chemicals at federal facilities.

Comment: Commenters (C-1815, C-1841) claim that the burden associated with the loss of the *de minimis* exemption cannot be determined from the economic analysis. The commenters assert that EPA could estimate the percentage of additional Form Rs per chemical that directly result from the loss of the *de minimis* exemption. The commenters express a belief that this represents a significant increase in burden.

Response: EPA acknowledges that the cost of eliminating the *de minimis* exemption was not estimated separately from the cost of each regulatory option in the economic analysis of the proposed rule. The expected effects of eliminating the *de minimis* exemption were incorporated into the total estimates of additional reporting as presented in the economic analysis.

It is difficult to estimate the percentage of Form Rs per chemical that would result directly from the elimination of the *de minimis* exemption at lower thresholds. One of the main difficulties in estimating the cost of an information collection rule with activity-based reporting thresholds is that extensive facility-level data are not available prior to collection of the information. In fact, EPA is proposing the rule precisely because data on PBT chemical releases and waste management activities at the facility level are currently so limited.

In developing cost estimates for the proposal, EPA had to rely on data indicating the *presence or absence* of PBT chemicals at various facilities. Estimating the cost impact associated with eliminating the *de minimis* exemption would require data on the exact *concentration* of PBT chemicals in mixtures and tradename products at facilities subject to EPCRA section 313 reporting. This information is either not available, or would require assuming that the concentration of PBT chemicals is the same at all facilities. With the proposed elimination of the *de minimis* exemption, EPA was able to assume that facilities would report on PBT chemicals if the lower reporting threshold were exceeded, regardless of the concentration of the PBT chemical. EPA does not believe that the available data support a reliable quantitative estimate of the cost directly attributable to eliminating the *de minimis* exemption (as opposed to the cost of lower reporting thresholds and no *de minimis* exemption).

While EPA did not provide a quantitative analysis of eliminating the *de minimis* exemption in the economic analysis of the proposed rule, EPA indicated that the incremental cost of eliminating the *de minimis* exemption is expected to be limited because many of the chemicals identified in the proposed action are manufactured as byproducts. The *de minimis* exemption does not apply to the manufacture of chemicals as byproducts. Thus, eliminating it will have no net effect on the reporting of those chemicals manufactured as byproducts. In addition, EPCRA does not require additional monitoring or sampling in order to comply with the reporting requirements under EPCRA section 313. Even with the elimination of the *de minimis* exemption for PBT chemicals, no further monitoring or analysis of production, process, or use is required.

Furthermore, EPA identified the following examples in which eliminating the *de minimis* exemption might lead to additional reporting at lower reporting thresholds:

- Processing or otherwise use of PBT chemicals found as trace contaminants in ores, coal, petroleum products, and other fuels; and
- Manufacture, processing, or otherwise use of PBT chemicals found as impurities in certain pesticides and chlorinated organic chemicals.

Therefore, EPA believes that sufficient information was provided to potentially affected facilities to allow comment on the proposal.

Comment: Commenters (C-1406, C-1409, C-1428b, C-1431, C-1431b, C-1435, C-1858, C-1863) assert that EPA failed to include costs of facilities to determine whether a report has to be filed, even if they are not ultimately required to file TRI reports. One commenter (C-1409) further contends that industry representatives on EPA's NACEPT committee have indicated that threshold determination, rather than report completion, is often the most significant cost to a facility. One commenter (C-1863) asserts that, based on affidavits, affected mining companies have spent at least twice EPA's estimate of \$16,000 per facility to comply with initial reporting requirements. The commenter further asserts that given the low proposed thresholds, it is not unreasonable to believe that facilities that may not have to report a PBT chemical in one year could trigger the reporting threshold in a subsequent year, thus increasing the number of reports filed and increasing the costs of the rule as even EPA estimates those costs.

Response: EPA's economic analysis of the proposed rule does include the costs to facilities to determine whether a report must be filed. The economic analysis estimates that compliance determination for the proposed changes in TRI reporting will take an average of 2.4 hours in the first year and 0.6 hours in subsequent years. These estimates are incremental to the time currently required for compliance determination. When added to the hours per year EPA estimates for the current reporting requirements, this yields a total of 18.4 hours in the first year and 4.6 hours in subsequent years. All 190,497 facilities with 10 or more employees that are in SIC codes subject to reporting under EPCRA Section 313 must carry out compliance determination activities.

The unit time estimates used by EPA are average values. As with any average, some facilities will be above the average and others will be below it. EPA recognizes that large multi-divisional, multi-departmental facilities may require more than the average time to comply. However, there are many other facilities that are not large multi-divisional or multi-departmental, which will often lead to a simpler compliance determination process that requires less time than the average. With regard to the estimates provided by the commenter, it is unclear from the affidavits that costs incurred by the affected mining companies result from activities required by the EPCRA Section 313. For example, the affidavits mention legal fees, but do not specify whether these fees were for compliance with the rule or to contest the legality of the rulemaking. There is no requirement that companies hire attorneys to contest the legality of agency rulemakings. The legal fees associated with these activities are considered to be optional and are not included in the economic analyses of the proposed rulemakings.

Facilities are only required to report on those chemicals that are above the threshold volumes. These thresholds were proposed to reduce the burden on industry. Without performing the compliance determination, facilities would not know what chemicals they were required to report for. The alternative would be for facilities to report on all chemicals, whether they were above the threshold or not. While EPA agrees that there is a burden to performing this compliance determination, the Agency does not believe that it is unjustified. EPA believes that its estimates of annual reporting attributable to the proposed rule are reasonable. While there may be some fluctuation in numbers of reports from year to year, EPA does not expect this would significantly change the total cost estimate.

Comment: A commenter (C-1863) contends that EPA first noted the number of additional reports that the options would initially require, but then focused on costs incurred for such reports in the "out" years, i.e., those years subsequent to the initial reporting year. The commenter contends that these costs are not and cannot be the sole measure of the cost of this rule.

Response: EPA disagrees with this characterization. EPA estimated industry reporting costs of \$126 million for the first year and subsequent year costs of \$70 million per year in the economic analysis of the proposed rule. While EPA believes that subsequent year costs are the best measure to judge the continuing costs of the proposal, many of the regulatory determinations for the proposal were made using first year costs. Under Executive Order 12866, EPA determined that this proposal is an economically "significant regulatory action" based on its estimated cost for the first reporting year. If EPA had relied solely on subsequent year costs, the rule would not have been classified as an economically "significant regulatory

action.” Likewise, under the Unfunded Mandates Reform Act, EPA determined that this proposal may result in expenditures of \$100 million or more for the private in any one year based on its estimated cost in the first reporting year. With regard to potential impact to small entities as defined by the Regulatory Flexibility Act, EPA estimated potential impacts for the first reporting year as well as for subsequent reporting years.

Comment: A commenter (C-1406) claims that EPA did not consider the amount of labor time not available to be spent on pollution prevention activities as a result of time spent on TRI reporting.

Response: Prior experience with TRI reporting indicates that it actually promotes pollution prevention activities at reporting facilities. Chapter 6 of the economic analysis of the proposed rule summarizes a number of cases reported in journals, magazines, and public conferences in which TRI information has helped companies identify waste reduction opportunities. Furthermore, a recent survey of 490 manufacturers in Wisconsin resulted in the following findings:

[I]nnovative firms noted that they often used the environmental data generated to support their environmental decision making. Moreover, firms indicated that having to take time for required reporting *acted as an important incentive* to change processes and thereby avoid the reporting burdens of the regulatory system. (See, Eggert, Thomas, “Moving Forward by Looking Back: the Role of Enforcement in Promoting P2,” in *Pollution Prevention Review*, Spring 1999, p. 1-5.)

EPA notes that the commenter was a participant in the US Automotive Pollution Prevention Project (described at <http://www.deq.state.mi.us/ead/p2sect/auto/98prgrpt.pdf>). Between 1991 and 1998, this project focused on the reduction of reportable releases of Great Lakes Persistent Toxic Substances from the automotive industry. Participating companies (including the commenter) achieved a 46 percent reduction in all TRI reportable releases on a vehicle produced basis since 1991. EPA notes the chemicals of concern were all TRI chemicals, and that companies measured progress using release data reported to TRI. TRI did not appear to impede pollution prevention activities for the commenter.

Comment: A commenter (C-1421) claims that EPA did not include the costs of eliminating range reporting and existing rules for rounding and whole numbers in its economic analysis.

Response: EPA did not change the unit cost of reporting because it does not expect the elimination of range reporting and changes to the existing rules for rounding and whole numbers to significantly affect the unit cost of reporting. EPA believes its unit cost estimates for reporting are reflective of point estimate reporting since many current reporters do not use range reporting. Even reporters who currently use range reporting in section 5 and 6 of the Form R are required to report whole numbers rather than ranges in section 8.

Furthermore, EPA believes that range reporting is related to how information is *presented* on the reporting form rather than how it is *calculated*. For example, a facility would calculate its estimate of chemical releases or other waste management activities based on readily available information. Under current reporting rules, the facility then has the option of presenting the result (if less than 1,000 pounds) as a point estimate or as a range in sections 5 and 6 of the Form R. There is no range reporting option for the presentation of data in section 8. As an issue of presentation, the elimination of range reporting is not expected to have any significant effect on unit reporting costs.

Comment: Two commenters (C-1445, C-1844) assert that in past TRI rulemakings, EPA has underestimated the economic impact by approximately 25 percent. The commenters assert that there are several costs that have not been considered, but only mention costs associated with the review and reprinting of Material Safety Data Sheets and additional analytical data. Another commenter (C-1862) also stated that the rule will require scrutiny of MSDSs, information review, and additional recordkeeping beyond what is currently required.

Response: The commenters have not provided any evidence to support the assertion that EPA has underestimated the economic impact of past rulemakings by 25 percent. There is abundant evidence (including comments on this rule, comments on previous rules, and other studies), some of which is described in this document, that EPA is not underestimating costs and that it may in fact be overestimating costs.

EPA has considered the costs associated with the review and reprinting of Material Safety Data Sheets as a result of this rule. The supplier notification provisions under EPCRA section 313 require certain suppliers of mixtures or trade name products containing listed chemicals above *de minimis* levels to notify their customers of the contents of their products on an annual basis. Such notifications can be provided on the Materials Safety Data Sheet for the product, or in a letter. EPA has not

proposed changing the supplier notification requirements. Thus, the only facilities expected to incur additional supplier notification costs as a result of the rule are those in SIC Codes 20-39 selling or otherwise distributing mixtures or trade name products containing PBT chemicals that 1) are not currently listed under EPCRA section 313, and 2) are present above *de minimis* levels in the mixture or trade name product. EPA's economic analysis for the proposed rule predicted that three PBT chemicals (tetrabromobisphenol A, vanadium compounds, and pentachlorobenzene) met these criteria, and included costs for supplier notification for these chemicals.

EPCRA section 313(g)(2) states that "In order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation." EPA has interpreted this to cover threshold determinations as well as release estimates. The requirements on the use of available data are described in 40 CFR 372.30(b). Facilities would not be required to perform additional sampling and analysis as a result of this rule to fulfill their obligations under EPCRA section 313. Any further analysis would be done at their discretion. Therefore, EPA does not believe that it is appropriate to include any testing or analytical costs as part of the economic analysis.

EPA notes that its cost estimate for reporting under EPCRA section 313 includes time for a variety of activities. These activities include, but are not limited to scrutiny of MSDSs, information review, and additional recordkeeping.

Comment: A commenter (C-1843), the Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA), stated that it has found that EPA typically underestimates the impacts of reporting requirements, particularly on small businesses and, more generally, the specialty chemical industry.

Response: EPA disagrees with this comment. The commenter has not substantiated the assertion that EPA has underestimated the impact of reporting. Furthermore, there is evidence, including from the commenter, that supports the opposite conclusion (i.e., that EPA has overestimated the costs of reporting). This commenter (SOCMA) commissioned a study entitled "Project Real Cost" that was released in December 1998. The purpose of the study was to determine whether EPA's estimates of regulatory costs exceeded or fell short of actual expenditures. This was determined by performing an in-depth study of actual reporting costs at several SOCMA member facilities (i.e., specialty chemical manufacturers), and comparing the result to the cost that would be estimated for these facilities using EPA's cost estimation methodology. Using EPA's methodology, the estimated cost of reporting ranged from \$16,273 to \$40,408 per facility (depending on the particular facility), with an average cost of \$30,300. However, based on an extensive review of the reporting process at these facilities, the SOCMA report concluded that the actual cost of reporting varied from \$14,959 to \$35,612 per facility, with an average cost of \$23,430. Thus, the SOCMA report found that the actual average cost of TRI reporting at these facilities was only three-quarters of EPA's estimated cost. EPA believes that SOCMA's estimates may overstate the actual costs of reporting for many facilities subject to TRI reporting. Based on the available evidence, including the commenter's own study, EPA disagrees that it has underestimated the typical cost of reporting for TRI facilities, including small businesses and the specialty chemical industry.

Comment: A number of commenters (C-1168, C-1423, C-1440, C-1458, C-1861) claim that EPA has underestimated the costs of compliance for electric utilities. The commenters assert that EPA has underestimated the cost and burden of compliance in past analyses. As an example, the commenters state that when EPA proposed adding electric utilities to TRI, it estimated the first year of reporting would cost \$27,310 for each reporting facility, and \$26.6 million for the industry as a whole. In response to comments, EPA nearly doubled the original estimates for electric utilities in the final rule, stating that the cost in the first year was expected to be \$45,957 for each reporting facility and \$44.9 million for the industry as a whole.

The commenters state that even with this significant increase in the estimate EPA still dramatically underestimated the actual reporting costs, and provide alternative estimates of their compliance expenditures. One commenter (C-1168) claims to have spent nearly \$125,000 in preparing TRI reports for the first reporting year. Another commenter (C-1440) asserts that compliance with the current TRI reporting requirements is closer to \$99,000 per facility for the first year and \$68,000 for subsequent years if the regulatory requirements do not change. Another commenter (C-1861) estimates that it will spend 2.3 professional man-years to prepare reports for three facilities. The commenter's cost per man-year with benefits is roughly \$75,000, which corresponds to \$57,500 per reporting facility. Another comment (C-1423) claims that one electric utility company has estimated compliance costs of \$1 million dollars based on an average cost of \$16,000 per Form R. The commenter extrapolates this cost to the entire electric utility industry to suggest a total industry cost in excess of \$120 million. For this proposal, the commenter asserts that electric utilities may submit as many as ten new reports per facility. For 977

electric power plant facilities, the commenter suggests that the cost of the proposal could be as much as \$156 million in the first year. The commenters conclude that EPA's original estimate of how much it would cost the electric utility industry to comply was off by nearly 100%, and assert this was due in large part to EPA's inability to appreciate the complex legal and technical issues specific to electric utilities that need to be addressed in order to understand compliance obligations.

Response: EPA disagrees that it has underestimated the cost of compliance for electric utilities. First, EPA does not believe that the change in estimated costs for electric utilities in a previous rulemaking is relevant here. However, to clarify the issue, EPA notes that its estimate of the time needed to report a chemical to TRI did not change between the proposed and final rulemaking adding electric utilities to TRI. Instead, in response to comments, EPA increased its estimate of the number of reports that would be submitted by electric utilities, which had the effect of increasing the estimated total cost to electric utilities. No evidence has been submitted by these commenters that EPA has underestimated the number of reports for this proposed rulemaking. Furthermore, the fact that EPA has previously increased its estimates in response to comments (even when the result has been to overestimate reporting) demonstrates that EPA takes the comments seriously and is willing to revise its estimates if there is a reasonable argument to do so. This lends credibility to EPA's position when it judges that there is not reasonable evidence to revise its estimates (as is the case here).

Part of the commenters' confusion seems to be based on a fundamental misunderstanding of what an average represents, how distributions can vary around an average, and what EPA's estimates represent. An arithmetic mean (commonly referred to as an average) is the number obtained by dividing the sum of a set of given quantities by the number of quantities in the set. The resulting number typifies the set of which it is a function. This does not mean that every quantity in the set must equal the arithmetic mean. This would only be the case if all members of the set had the same value, in which case there would be little need to calculate a mean. Furthermore, the fact that a member of a set differs from an estimated arithmetic mean does not denote that the estimated mean is incorrect.

EPA's cost estimates involve a variety of factors, some of which are calculated based on averages. EPA's time estimates for various activities related to TRI reporting (compliance determination, rule familiarization, calculations and report completion, etc.) represent the average amount of time expected to be required to fulfill the various tasks in complying with the rule. These time estimates were based on EPA's experience with the manufacturing sector, but EPA believes that they are reasonable estimates for non-manufacturing industries as well. There are facilities subject to EPCRA section 313 with "simple" situations that do not require extensive effort to compile and report in addition to the facilities with more complicated situations that require more time. The Agency's estimates represent average costs. As with any average, some facilities will be above the average and others will be below it. EPA believes that its estimates provide reasonable estimates of the overall cost of the regulation for both manufacturing and non-manufacturing facilities.

The commenters have derived what they state is EPA's cost per facility by dividing EPA's estimate of the cost for all electric utilities by the number of electric utilities that EPA estimated would report. For example, the commenters divided EPA's estimate of first year costs for electric utilities from the industry expansion final rule (\$44.9 million) by the number of electric utility facilities that EPA estimated would report (977 facilities), yielding an estimate of \$45,957 per facility. While the commenters have correctly calculated an arithmetic mean, they have not interpreted it correctly. This calculation does not result in the conclusion, as the commenters have claimed, that EPA estimated that each facility would incur costs of \$45,957. Instead, this is an estimate of the average cost per facility to report. The fact that the cost for a particular individual facility differs from this estimated average does not prove that the average has been estimated incorrectly. The cause may instead be the normal variation of observations around an average.

As explained in the economic analysis for the industry expansion rule, as well as the economic analysis for the PBT rule, the total estimated compliance burden for each electric utility parent company was calculated based on the number of subsidiary facilities affected under the final rule and the expected number of reports from these facilities. The company-specific compliance cost estimates were developed using the information in the Utility Data Institute (UDI) database on fuel type, annual fuel consumption, and annual electricity production for each generating facility in the database.

When the data supporting the TRI industry expansion economic analysis is compared to the claims made by the commenters, the results indicate that EPA has made reasonable estimates of reporting costs for electric utilities. When EPA's estimate of reporting costs for Duquesne Light (C-1168) from the industry expansion rule is updated to 1998 dollars, the result is an estimated cost of \$156,128 for the first year of reporting. Thus, EPA's estimate is higher than what Duquesne has reported as its real cost of reporting (closer to \$125,000 than to the average cost for all utilities of \$45,957). When EPA's estimate for Indianapolis Power & Light (C-1861) is updated to 1998 dollars and averaged over IPLs' three reporting facilities, the result is an

EPA estimate of \$79,110 per facility. Again, this is higher than the \$57,500 that IPL reported as its real cost of reporting. When a similar calculation is made for the Tennessee Valley Authority (C-1440), the result is an estimate of \$83,763 in the first year and \$58,884 in subsequent years. This is not as much as the amount that is claimed by TVA (\$99,000 in the first year, and \$68,000 in the subsequent years). TVA does not provide any supporting documentation to explain how it generated these estimates, or what is covered by them, so EPA is not able to evaluate the validity of TVA's claims. But even if TVA's claims are accurate, EPA does believe that this would invalidate its cost estimates for electric utilities. Two of the three electric utilities that provided cost estimates were lower than EPA's estimates, and TVA's estimate is not significantly higher than EPA's. As stated before, some facilities will be below EPA's average cost estimate and some will be above it, but this does not mean that EPA's estimate is invalid. EPA believes that its cost estimates, including those for the electric utility industry, are reasonable.

EPA notes that there is an incentive bias in comments about its burden estimates. Companies that have higher costs than EPA's average cost estimates (or which believe they have higher costs) will write in to complain, but companies that have costs lower than average will not have any incentive to comment on EPA's cost estimates. Given that it is generally the high cost facilities that comment on the costs estimates, it seems likely that there are other facilities where the costs are even further below EPA's estimates than Duquesne Light and Indianapolis Power and Light.

In response to the comment that EPA is unable to appreciate the complex legal and technical issues specific to electric utilities that need to be addressed in order to understand compliance obligations, EPA notes that the message the utility industry gives out on this issue appears to be tailored to the recipient. While the industry has emphasized the complexity of reporting to EPA, it has emphasized the simplicity of its TRI reporting obligations to its customers. For instance, in the Public Meeting held in Washington, DC on February 16, 1999, a representative of the Potomac Electric Power Company (PEPCO) stated that EPA has underestimated the cost of compliance for electric utilities because it does not understand the "complex legal and technical issues" facing electric utilities (see Public Meeting Record, D-001, OPPTS Public Docket #400132). However, in a flyer sent to its customers with their electric bill, PEPCO (an EEI member) states that "TRI simply mandates that utilities summarize release data into a new format that is more readily available to larger segments of the public." (Potomac Electric Power Company. *Lines*, Volume 28, Issue 4, April 1999.) EPA believes that for most electric utilities, the truth is somewhere in between these two extremes.

EPA disagrees with the comment from the Edison Electric Institute that reporting for PBT chemicals may cost electric utilities as much as \$156 million in the first year, calculated by multiplying 977 electric utility facilities by 10 reports for PBT chemicals per facility by \$16,000 per Form R. First, as described previously, this estimate is based on an unsubstantiated claim that an unnamed electric utility facility will report on up to 10 PBT chemicals. Even if this particular company were to report on 10 PBT chemicals, this would seem to be a worst case scenario not a typical situation. EEI has presented no evidence to suggest that a typical electric utility facility would submit 10 reports. Similarly, there is no evidence presented to support the claim that reporting will cost this unnamed electric utility company a total of \$1 million dollars. This is significantly higher than the estimates provided by EEI members Duquesne Light and Indianapolis Power and Light. Again, even if the estimate of \$16,000 per Form R were accurate for this particular facility (and the commenter has provided no information with which EPA can use to judge the accuracy of the estimate), EEI has not presented any information to show that this is a typical cost. Aside from questions of the accuracy of the estimates, EEI appears to have multiplied an estimate of the maximum number of reports per facility by an estimate of the maximum cost per report, and then assumed that the result applies to every facility in the industry. This will not result in an accurate estimate of total costs. EPA believes that its estimates are more reflective of the cost of the rule. After reviewing the evidence, EPA has concluded that it has not underestimated the cost and burden of the rule.

Comment: A commenter (C-1428) expresses concern that the proposed elimination of the *de minimis* exemption may result in increased burden on facilities to obtain data for threshold and release calculations because suppliers are not required to provide information on levels below 1% or 0.1% for carcinogens.

Response: EPA agrees that facilities will perform additional work to compile readily available information and to make reasonable release estimates when monitoring data are not available. EPA's unit cost estimate for reporting includes time for compiling readily available data, whether from MSDSs provided by supplier or other sources. EPA acknowledges that available data may vary from chemical to chemical and facility to facility. EPCRA section 313(g)(2) states that "[i]n order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of

law or regulation." EPA has interpreted this to cover threshold determinations as well as release estimates. The requirements on the use of available data are described in 40 CFR 372.30(b). As with other voluntary activities not required by the proposal, costs of sampling, testing, or analysis are considered to be optional and are not included in the economic analysis of the proposal.

Comment: Two commenters (C-1428b, C-1448) assert that EPA's economic analysis does not reflect the true social cost of the information collection mandate. The commenters say that EPA should consider 1) the state, local, and other federal regulations that are triggered by a TRI listing such as pollution prevention plans or storm water treatment requirements, and 2) state fees or taxes for TRI chemicals reported on Form Rs. One commenter (C-1448) cites a 1994 study of EPA's proposed rule to expand the TRI estimating that the overall cost of these requirements could be as much as six times EPA's estimate. (Price and Crandall, "Critique of USEPA's Regulatory Impact Analysis of the Proposed Rule to Add Certain Chemicals to the Toxics Release Inventory," prepared for the Ad Hoc Industry TRI Chemical Expansion Group. May 2, 1994.) The commenter notes that this study found that the most significant programs triggered by a TRI listing were: the federal storm water permit program, the federal procurement requirement that agencies reduce their purchases of products containing TRI chemicals, and various state requirements to develop and implement pollution prevention programs for TRI chemicals.

Response: The commenters cite cost estimates prepared by Price Associates, Inc., and submitted to EPA as comments in response to the proposed chemical expansion rulemaking (59 FR 1788, January 12, 1994; final rule 59 FR 61432, November 30, 1994). EPA's Response to Comments for the chemical expansion rule demonstrated that these estimates are biased and flawed. (See sections 7.1 and 7.5 of the "Response to Comments Received on the January 12, 1994 Proposed Rule to Expand the EPCRA Section 313 List". U.S. Environmental Protection Agency, Washington, DC, 1994, contained in docket number OPPTS-400082B.)

As explained in the Response to Comments for the chemical expansion rulemaking, the Price Associates estimates were based on what Price Associates termed a "limited survey". EPA believes that the questionnaire used by the commenters was flawed. The questionnaire included EPA's time and cost estimates in the instructions, which would tend to bias the results upward. At least one question was not clear about whether it related to the total time required for TRI reporting or just the incremental time required for the additional chemicals. Another question was answered by a small number of respondents and the responses may have been hypothetical, since respondents were instructed to answer the question whether or not they had any actual experience. Finally, there is a lack of supporting information, without which it is not possible to make appropriate use of the Price Associates results. EPA does not feel that the Price Associates estimates provide useful information because of its flawed methodology.

EPA believes that the Price Associates' estimates would apply to few, if any, facilities, because it is unlikely that any facilities meet all the conditions required of the Price Associates' estimates. The Price Associates' estimates require that all of the following conditions be true:

- a facility be located in one of the twelve states with state taxes or fees for TRI reporters; and
- that it be one of the states with extremely high fees and taxes; and
- that it be located in one of the few states that are not authorized to administer the NPDES program or in those states that are authorized to administer the NPDES program and have elected to adopt the EPA permits; and
- that the materials or activities come into contact with storm water; and
- that the facility has sought coverage under the federal "baseline" general permit instead of a multi-sector general permit; and
- be one of the facilities that have EPCRA section 313 reporting obligations for the first time because of the proposed TRI reporting changes; and
- have no existing containment systems that meet any of the NPDES requirements; and
- be located in one of the nine states with pollution prevention planning requirements.

The likelihood of a facility meeting all of these requirements can be demonstrated by the fact that not all of the nine states that require pollution prevention plans also have fees or taxes. While some states have relatively high fees and taxes, in other states the fees and taxes are much lower. For instance, in Texas the fee is \$25 per form, with a maximum of \$250. Therefore, EPA does not believe it is appropriate to apply the maximum state fees at the national level.

EPA recognizes that sixteen states currently have pollution prevention fees and/or planning requirements that are triggered by the filing of Federal Form R. However, from a social perspective, taxes and fees are not classified as costs

imposed on society but are instead considered to be transfer payments. Transfer payments are not social costs because they shift resources from one party to another, and do not compensate for socially costly goods or services provided by one party to another. Hence, the cost of the transfer to one party is exactly offset by the gain to the recipient and the net cost to society is zero. Other examples of transfer payments are monopoly profits and insurance payments for losses sustained. These payments should not be attributed as costs of the rule because they do not constitute costs.

“Manufacturing,” “processing” and “otherwise using” toxic chemicals often create external costs, such as health effects and environmental damage. In such cases, the private costs of producing toxic chemicals are less than social costs by an amount equal to the external costs. Policies which narrow the gap between private and social costs, such as environmental taxes and fees levied on toxic chemicals, can lead to a net gain to society by encouraging firms to reduce some or all of the costs that are imposed on others. Taxes and fees that firms pay to governments are, therefore, transfers which serve as a means of internalizing these external costs. The ideal situation is for these taxes to be equal to the level of external costs, which ensures that firms pay the full amount of the social costs. The economic analysis did not determine whether or not state and local taxes are in fact equal to the externalities that are imposed by firms from the release of EPCRA section 313 toxic chemicals, because states and localities are responsible for determining the level of taxes and fees that they impose.

Unlike taxes and fees, planning requirements do impose social costs. However, if the costs of state pollution prevention requirements were included in the economic analysis, the benefits associated with these programs would also have to be included. Such programs may have net benefits to participating facilities as well as to society. For example, preliminary evidence from the New Jersey Pollution Prevention Program showed that for every dollar spent on the Pollution Prevention Planning Process the facilities themselves expected a net savings of \$5 to \$8 (New Jersey Department of Environmental Protection, Early Findings of the Pollution Prevention Program, Part I: On-Site Reviews of Pollution Prevention Plans, June 1995). This estimate did not include indirect benefits from pollution prevention, such as reduced environmental and worker health impacts and benefits to facilities from increased market share. Similarly, a study in Massachusetts found that from 1990 through 1997 the monetized costs of the Toxics Use Reduction Act program were \$76.6 million, while the monetized benefits were \$90.5 million. (The Massachusetts Toxics Use Reduction Program, Evaluating Progress, A Report on the Findings of the Massachusetts Toxics Use Reduction Program, Executive Summary, March 1997). The monetized benefits did not include indirect benefits from pollution prevention, such as human health and ecological benefits, or increased revenue from improvements in processes and products.

Although data are not available for all cases of state-imposed requirements which may be associated with TRI, it seems safe to assume that the state-mandated programs are so mandated for good reasons. Certainly the limited data available supports this proposition. A consequence of an appropriately mandated program is that social benefits equal or exceed social costs. To account for the costs of these programs without being able to account for the corresponding benefits would be incorrect.

In addition to the fact that state taxes and fees do not constitute costs and that both taxes and fees and pollution prevention planning requirements can be expected to generate net benefits that would have to be taken into account along with any costs, EPA believes that for analytical purposes, it is appropriate to limit its assessment of costs and benefits of the rule to those directly resulting from the rule. Although the state fees, taxes and pollution prevention planning requirements are associated with EPCRA section 313 reporting, they are not required by this or any other rule issued by EPA under EPCRA section 313. States may enact, amend, and/or repeal their associated requirements at any time without any involvement of or action by EPA. Indeed, EPA has found that as the section 313 program came into being and subsequently evolved, numerous states (such as New Jersey) have modified their own toxics reporting and reduction programs. Therefore, EPA has not included either the costs or benefits of associated state requirements along with the costs and benefits of the rule.

For these reasons, EPA does not accept the commenters' contention that the costs of compliance with the proposed rule are up to six times the cost estimates in the economic analysis.

Comment: Commenters (C-1420, C-1423, C-1865) assert that EPA creates burden by changing TRI requirements. The commenters note that facilities must study the changes to comply. The commenters assert that imposing different thresholds for different chemicals would make the annual reporting process even more difficult and time consuming for industry, and it would produce inconsistent and conflicting data of dubious value for the public. A commenter (C-1423) also suggests that costs in subsequent years may not be “significantly less” because “EPA has established a pattern of changing its guidance and interpretation of TRI reporting requirements on an irregular but frequent basis.” The commenter calls EPA’s guidance “notoriously

vague, confusing, ambiguous and internally inconsistent”, and claims to have expended significant resources over a two-year period in trying to understand reporting obligations under EPCRA § 313.

Response: EPA recognizes that there are costs associated with changes to the TRI program. EPA has estimated costs of rule familiarization and compliance determination for this proposal at \$37.8 million in the first year and \$7.8 million in subsequent years at the preferred option. The commenter has not addressed these estimates, nor has the commenter provided any alternate estimates of the costs associated with facilities assessing the new requirements. The commenter does not provide any evidence that the proposal would produce “inconsistent and conflicting data of dubious value for the public.” In fact, EPA has received many comments asserting that data on PBT chemicals is highly valued by the public, and requesting a reporting threshold even lower than the thresholds proposed.

Comment: A commenter (C-1448) asserts that an estimate of the full social cost of the requirement must consider the opportunity cost of the collection, any social costs due to actions based on inaccurate, incomplete, or misleading information, and the social costs associated with misuse of the information (i.e., industrial espionage and sabotage).

Response: EPA notes that this comment actually points out the need for the proposed rule. Society is more likely to incur social costs as a result of “inaccurate, incomplete, or misleading information” when facilities are not required to report their releases and other waste management of PBT chemicals. This is the situation that currently exists. Absent TRI information from facilities, society is forced to act without any facility-level information or with information derived without the input of facility managers who are most knowledgeable about polluting processes.

With regard to misuse of the information, the commenter fails to provide any scenario (credible or otherwise) in which the reporting of PBT chemicals under EPCRA Section 313 could lead to industrial espionage or sabotage. EPA notes that many of the PBT chemicals are unwanted byproducts of production with no economic value. It seems unlikely that any company would want to steal the secret of how to produce more dioxin or octachlorostyrene. Furthermore, many commenters have noted that PBT chemicals are present in low concentrations. This automatically reduces the opportunity for sabotage aimed at suddenly releasing these chemicals on an unsuspecting community.

Comment: Commenter (C-1458) assert that requiring facilities to report at the level of “accuracy” described in the proposal will impose a great burden on TRI reporters and leave them few options for developing reasonable estimates for their reports.

Response: EPA disagrees. EPCRA only requires reporting to be based on the best readily available information or reasonable estimates. Covered facilities need only report more accurately if estimation techniques allow for greater accuracy.

Comment: A commenter (C-1409) asserts that it is unclear from EPA’s economic analysis how many facilities would be reporting for the first time under the 10 or 100 pound threshold options. The commenter contends that it is difficult to determine if the extra costs forecast by EPA are due to new facilities reporting or extra reporting costs at facilities that already report.

Response: EPA provided this information in Table 3-2 of the economic analysis of the proposed rule, which is available in the public docket for this rulemaking. Under Option 2—the preferred option—2,600 of the 9,515 affected facilities are expected to be filing TRI reports for the first time as a result of the proposed rule. Under Option 3, 1,384 of the 6,187 affected facilities are expected to be filing TRI reports for the first time as a result of the proposed rule.

Comment: A commenter (C-1813) notes that vanadium is widely used in irons and steels, specialty steels, cutting tool alloys, and superalloys in amounts which range from a few tenths of a percent to several percent. The commenter asserts that the increased reporting required by the proposed rule could be substantial for many companies, particularly small businesses, and the benefit realized by such increased reporting would be marginal at best. The commenter concludes that the effects of the increased vanadium reporting requirements could be far greater than anticipated by EPA, and far greater than justified by any risk from the presence of these elements.

Response: The commenter has not provided any quantification of the extent to which the commenter believes that the EPA may have underestimated the effects of the proposal on businesses. EPA therefore is unable to make any adjustments in its estimate of the cost and burden of the proposal as a result of this comment. EPA also notes that it has proposed an alloys exemption that would exempt many facilities working with alloys containing vanadium from reporting at lower thresholds. Therefore, EPA disagrees that the effect of increased vanadium reporting would be greater than predicted.

Comment: A commenter (C-1826) asserts that reducing the reporting thresholds by 3 orders of magnitude “significantly, and unreasonably” increases the reporting burden, particularly for small miner operations that are members of the NWMA. The commenter contends that all rocks contain regulated trace metals at low concentrations. The commenter asserts that the proposed changes in threshold concentrations will “greatly increase the number of mine sites required to report under TRI.” The commenter contends that at the proposed threshold of 10 lbs. per year, mines moving rock with an average crustal abundance concentration for sediments (0.5 ppm) would be required to report above 10,000 tons of annual production. The commenter notes that, under EPCRA, mines are not required to collect additional data for reporting purposes. The commenter contends that available data characterizing mercury content of mined materials are typically assay data, which range in detection limit from 0.05% (or 500 ppm) for data collected more than 10 years ago to 0.001% (or 10 ppm) for data collected using the most current (1999) methods. The commenter contends that at a 10 pound threshold and using half the current assay detection limit of 5 ppm, mines producing more than 1,000 tons of ore per year will be required to report under TRI for values measured at detection limit. The commenter provides the example of one small mining operation in the Northwest where mercury occurs in the highly insoluble telluride mineral coloradoite (HgTe) in veins at concentrations ranging between 0.5 to 23 ppm. The commenter contends that TRI reporting above the 10 lb. threshold would be required above 10,000 tons despite the fact that no ore is processed at the site, as it is all shipped to smelter, and despite the fact that no mercury has ever been detected in surface water monitoring conducted at the site due the insoluble nature of the mineral complex.

Response: EPA does not agree that the proposal significantly or unreasonably increases the reporting burden of small mining operations. As shown in EPA’s small entity impact analysis for the proposed rule, the annual reporting burden on small mining companies is less than 1 percent of revenues in all years. EPA notes that the commenter has made threshold determinations rather easily for member companies. This indicates that mining companies have readily available information that would allow them to file reports without a significant degree of difficulty. EPA notes that the activities described by the commenter do qualify as “processing” under EPCRA Section 313. However, EPA notes that the small mining operation in the Northwest may be able to take advantage of the overburden exemption for mining operations based on the description of the operation.

Comment: Commenters (C-1815, C-1841) state that if the PBT rule is finalized, the reporting costs will have increased from \$75 million in 1988 to \$372 million in 2000 in constant dollars, and from \$65 million to \$444 million in real dollar terms. The commenters support their estimates with a complex table of calculations (which they claim uses EPA’s own estimates of the costs of the TRI reporting program.) The commenters state that EPA should not only consider the costs of the proposed rule in terms of the total direct costs it imposes, but in terms of the additional cost burden relative to overall TRI reporting.

Response: The estimate that the cost of TRI reporting increased from \$75 million in 1988 to \$372 million in 2000 is the commenters’, not EPA’s. The commenters have prepared this estimate based on information in a number of Federal Register notices proposing or finalizing changes to the regulations under EPCRA section 313. The commenters calculations are based on a number of inaccurate or misleading assumptions. A footnote to the table showing the commenters’ calculations states that there were inconsistencies in EPA’s estimates within multiple Federal Register notices for the same year, and that they had to apply judgement and professional knowledge in assigning costs to each year. EPA disagrees that its estimates were inconsistent. The problem appears to be that the commenter did not read the economic analyses for any of the rulemakings, but relied solely upon the summary data in the Federal Register notices. The result was that the commenter does not appear to have understood the methodology EPA used to estimate costs. The apparent inconsistencies are due to the flaws in the commenters’ assumptions, not problems in EPA’s methodology.

There are a number of flaws in the commenters’s estimates; a few of the major problems are described below. For example, the commenters only include the cost of form completion (based on the number of reports affected and an inaccurate estimate of cost per report). The commenters leave out several other components of EPA’s cost estimates (rule familiarization, compliance determination, and supplier notification). Leaving out these costs makes the relative increase in reporting costs seem greater than it really is. The commenters have not differentiated correctly between EPA’s estimates of first year and subsequent year costs. Part of the reason they appeared to see inconsistencies in EPA cost estimates was that they did not differentiate between rules adding new reports (which had a first year cost component) and rules deleting chemicals (which only had subsequent year costs estimated).

Because the omissions described above, the commenters’ assumed estimates of EPA’s costs are incorrect. This can be demonstrated by examining the what the commenter has labeled “Constant Cost per Form R”. This value is calculated by applying an implicit price deflator to the commenters’ estimate of “EPA’s Cost per Form R”. The result is anything but constant, since it differs in each of the 11 years in the commenters’ table, with a total change of over 200 percent from 1988 to 2000.

However, there has only been one rule (the 1991 rule implementing the Pollution Prevention Act) that changed the cost of preparing a single Form R, and EPA estimates that the PPA rule increased TRI reporting costs by approximately 30%.

EPA notes that the commenters choice of 1988 as their base year serves to exaggerate the increase in TRI reporting costs over time. While the 1988 reporting year is commonly used as a base year for comparing changes in reporting, its use as a base year here overstates the increase in TRI reporting costs over time. This is because 1987 was the first year of TRI reporting, and facilities incurred higher costs in the first year. The commenters' table notes this, since it mentions that EPA estimated the cost per Form R to be \$1,290 for the first year compared to \$833 for later years. However, the commenters do not make use of the first year costs, and instead use only the \$833 value. (The commenters' estimates do not include first year costs, or any other costs, for compliance determination or rule familiarization.) A complete comparison that began with the 1987 reporting year would show a decrease in reporting cost after the first year, and a less dramatic increase in costs over the life of the program.

The inaccuracy of the commenters' estimates can be seen by comparing their estimates for the first decade of TRI reporting (the period for which data are available) to the changes in the TRI program that took place over that time period. The commenters estimate that constant dollar costs increased from \$75 million in 1988 to \$202 million in 1996, an increase of 2.7 times over eight years. (The commenters have presented their estimates in both constant dollars and nominal dollars, which they refer to as "real" dollars. In a calculation such as this, constant dollars present an appropriate measure, as nominal dollars will have increased based solely on inflation, even if nothing else changed.) The TRI rulemakings affecting the 1987 to 1997 reporting years can be grouped into three categories. First, there were a number of rules that added or deleted chemicals. The net effect of these rules was a slight decrease in the number of reports (from 74,152 reports in 1987 to 71,670 reports in 1997), so the overall result was to decrease reporting costs. Second, in response to the Congressional mandate in the Pollution Prevention Act, EPA added data elements to the Form R. As stated above, EPA estimates that the PPA data elements increased the cost of Form R reporting by about 30%. Third, EPA promulgated the alternate threshold rule and created the Form A, which served to decrease industry reporting costs. In addition, the Agency developed various guidance documents and automated TRI reporting software to make reporting easier for the regulated community. These facts do not support the commenters contention that there has been a substantial increase in TRI reporting burden over the first ten years of the program.

Reporting burden is expected to increase beginning with the 1998 reporting year as a result of the industry expansion rule and the PBT rule. EPA has estimated that the industry expansion rule could generate up to 46,000 reports, and that the PBT rule as proposed could result in 17,000 additional reports. EPA notes that its estimates of the number of reports due to these rules were based on a number of conservative assumptions that will tend to overestimate actual reporting. EPA also used conservative assumptions when it estimated that the original TRI rule would result in 318,000 reports and that the chemical expansion rule would result in 14,000 reports. The actual results were 74,000 and 4,400 reports, respectively, so that the overestimates for the earlier rules were between 200 and 300 percent. It is entirely possible that the conservative assumptions in the industry expansion and PBT rules will result in overestimates of a similar magnitude. Therefore, the actual increase in the cost of the TRI program may be much less than what is predicted in EPA's economic analyses.

EPA believes that considering the incremental costs and benefits of rulemakings provides the appropriate information to make decisions regarding these rulemakings. Nonetheless, the Agency does address the overall burden of the TRI program whenever an Information Collection Request (ICR) update is needed. EPA notes that Table 12 of the proposed addendum to the Form R ICR (for the PBT rule) showed the change in TRI burden relative to other changes in Form R burden going back to 1992.

Comment: A commenter (C-1855) asserts that EPA may have overestimated some of the first-year costs of the proposal because many facilities reporting under this proposal will already be familiar with TRI reporting requirements because of previous reporting.

Response: EPA has estimated rule familiarization costs for facilities that have not previously reported to TRI for any chemical. As reported in EPA's economic analysis of the proposed rule, EPA's estimate of the number of facilities reporting to TRI for the first time as a result of the rule is 2,600. EPA believes that facilities that already report to TRI for at least one other chemical at current threshold are familiar with the process of reporting, albeit at higher reporting thresholds.

Comment: A commenter (C-1857) asserts that EPA failed to properly estimate burdens, including those on small businesses, because EPA did not identify or estimate the number of lime manufacturing and geothermal power facilities that would have to

submit reports on mercury as a result of the proposed rule. According to the commenter, the primary reason that lime plants are potentially subject to this rule is because of the trace contaminants present in or created by fossil fuels.

Response: In the economic analysis of the proposed rule, EPA considered facilities that are expected to report due to the trace contaminants present in or created by fossil fuels. The number of reports expected from lime manufacturing facilities was estimated by applying industry-wide fuel throughput information to the number of facilities in SIC 3274 (lime manufacturing) using each type of fuel. This allowed EPA to estimate the number of fuel-burning facilities expected to report for mercury at each threshold level. The results for SIC 3274 are shown in the table below. While the results were not presented at the four-digit SIC code level in the economic analysis of the proposed rule, these facilities were included in EPA's estimates of the total number of affected facilities for the cost and small entity impact analyses of the proposed rule. A detailed description of this methodology was provided in Appendix A of the economic analysis of the proposed rule.

EPA notes that lime manufacturing facilities may exceed lower reporting thresholds for reasons other than fuel combustion. Based on the comment, EPA revisited its analysis to determine if lime manufacturing facilities may exceed the reporting thresholds for mercury for manufacturing, processing or otherwise use activities besides fuel combustion. EPA determined that lime manufacturing facilities may trigger reporting requirements due to trace mercury found in the limestone used to manufacture lime. The approach used to estimate the number of facilities expected to submit additional reports for mercury because of mercury in limestone is described below:

- Divide the facilities in SIC 3274 into employee size categories and obtain the number of facilities in each categories from the 1995 County Business Patterns;
- Estimate the percentage of industry activity for each employee size category using a ratio of the total number of employees in the size category to the total number of employees in SIC 3274;
- Obtain an estimate of the total amount of lime produced annually in the U.S. from USGS data (18.5 million metric tons);
- Estimate total lime production for each size category by applying the percent of industry activity to the total tons of lime produced;
- Estimate the average amount of limestone used at each facility in the size group assuming 2 pounds of limestone are used for each pound of lime produced;
- Estimate the average mercury activity per facility by applying the estimated concentration of mercury in limestone (0.5 ppm);
- Determine the total number of facilities that may submit TRI reports for mercury based on otherwise using mercury in the production of lime at each threshold.

For the one-, ten- and 100- pound thresholds, EPA estimates that all lime manufacturing facilities with ten or more employees may report due to mercury in limestone. For the economic analysis of the final rule, EPA has revised the estimated number of additional reports from lime manufacturing facilities for mercury as shown in the following table.

| Estimated number of affected facilities in SIC 3274 | Number of Facilities Exceeding the Lower Reporting Thresholds | | | |
|--|---|-------|--------|----------|
| | 1 lb | 10 lb | 100 lb | 1,000 lb |
| Facilities in SIC 3274 with 10 or more employees | 65 | 65 | 65 | 65 |
| Facilities expected to report based on limestone used | 65 | 65 | 65 | 14 |
| Facilities expected to report based on fossil fuel used (originally included in the Economic Analysis of proposed rule) | 38 | 19 | 2 | 0 |
| Facilities added to Economic Analysis of final rule | 27 | 46 | 63 | 14 |

With regard to geothermal power facilities, EPA did not estimate additional reporting because non-fossil-fuel-fired power facilities are not subject to reporting under EPCRA Section 313 unless they are co-located with (part of the same facilities as) coal/oil units. The electric generation facilities in SIC 49 subject to reporting under EPCRA Section 313 are those in SIC codes

4911, 4931, and 4939 (limited to facilities that combust coal and/or oil for the purpose of generating electricity for distribution in commerce).

Comment: A commenter (C-1857) asserts that EPA has provided no information to allow the reader to judge the scope and accuracy of the ICCR database.

Response: EPA disagrees with the assertion that EPA provided no information to allow the reader to judge the scope and adequacy of the ICCR database. EPA provided the following description of the ICCR database on page A-4 of the economic analysis of the proposed rule:

To determine the percentage of manufacturing facilities burning sufficient fuel to exceed the 1-, 10-, 100-, 1,000-, 10,000-, and 25,000-lb/yr reporting thresholds, the Industrial Combustion Coordinated Rulemaking (ICCR) database created by EPA in 1998 was used. The ICCR database is a combustion unit inventory database that contains information on industrial and commercial combustion sources. The ICCR database includes information from EPA and state electronic databases, most importantly the EPA Aerometric Information Retrieval System (AIRS) and the Ozone Transport Assessment Group (OTAG) databases. In addition, 17 state databases were merged into the ICCR database. In merging these various databases, care was given not to enter duplicate records for any facility or combustion unit.

The ICCR database does not include information to determine the precise amount of fuel throughput for every facility. While approximately 60 percent of the boiler-specific records contain a fuel flow rate or operating rate that can be used as a fuel throughput, the other 40 percent do not have this information. For records without flow rate or operating rate information, fuel throughput was estimated using the design capacity and operating hours. Since approximately 20 percent of boilers in the ICCR database burn multiple fuels, individual fuel throughput is overestimated for these records. The fuel throughputs for each boiler at a given facility burning a given fuel type were summed to determine the facility level fuel usage in a given fuel type.

EPA then provided a summary of the ICCR information for manufacturing facilities, including maximum fuel throughput and the number of facilities by decile. In addition, EPA placed a copy of the data from the ICCR for each fuel type in the public docket for this rulemaking. Finally, EPA notes that the complete ICCR database, along with documentation describing its compilation, is available for downloading on EPA's website at: <http://www.epa.gov/ttnuatw1/combust/iccrarch/iccrarch.html>.

Comment: A commenter (C-1863) states that EPA has underestimated the cost of TRI reporting for the mining industry. The commenter states that EPA estimated an average cost of approximately \$17,000 per facility in the TRI industry expansion rule, and that companies (some of which operate multiple facilities) have spent significantly more than that. According to the commenter, Independence Mining Company Inc. will spend \$170,000 for compliance in the first year, Trapper Mining Inc. will spend \$48,000, Hecla Mining Company will spend \$85,000 to \$116,000, and MAPCO Coal, Inc. will spend \$250,000.

Response: The commenter derives an estimate of \$16,665 for EPA's average first year cost per facility by dividing EPA's \$3.9 million cost estimate for the mining industry by the 234 metal mining facilities that EPA estimated would report. However, the commenter fails to mention that the \$3.9 million cost estimate was predicated on the assumption that the 234 metal mining facilities would file 677 reports, for an average of less than 3 reports per facility. (EPA estimated that 321 coal mining facilities would file 642 reports, for an average of 2 reports per facility.) While the commenter states that \$17,000 per facility underestimates the actual cost of reporting for the Independence Mining Company, Trapper Mining Inc., Hecla Mining Company, and MAPCO Coal, Inc., the commenter does not indicate how many reports these companies will submit.

The number of reports filed is a key determinant in EPA's cost estimation methodology. Since the first year's reports from the mining industry were not due to EPA until July 1, 1999, EPA has not finished processing the 1998 data yet and does not know how many reports Independence Mining Company, Trapper Mining Inc., Hecla Mining Company, or MAPCO Coal, Inc. submitted. However, there are results available for mining companies that have voluntarily posted summaries of their TRI data on their Internet sites. The Internet sites for Phelps Dodge Corporation and Cyprus Amax Minerals Company have summaries of their reporting data by facility and chemical. According to Phelps Dodge, it submitted 85 reports for 7 facilities (an average of 12 reports per facility), while Cyprus Amax indicates that it submitted 45 reports from 4 facilities, for an average of 11 reports per facility. Thus, these facilities are submitting 4 times as many reports, on average, as EPA predicted. Using this number of

reports and facilities, EPA would estimate that Phelps Dodge would spend \$456,971 to report for the first year, and that Cyprus Amax would spend \$242,987. These figures are as large as or larger than the estimates provided by the commenter.

Given that the number of reports is a key factor in EPA's cost estimation methodology, it is not surprising that facilities may incur higher costs than EPA predicted for the industry expansion rule if the facilities are submitting significantly more reports than predicted. However, if EPA underestimated the number of reports per facility for the industry expansion rule (and thus the cost per facility), this was due to comments by the mining industry. The mining industry's comments on the proposed industry expansion rule were not that EPA had underestimated the number of reports per facility, but that it had overestimated them. (See Section 10.1.1 in *Response to Comments: Final Rule to Add Certain Industries to EPCRA Section 313*, U.S. Environmental Protection Agency, April 1997.) In other industries, EPA increased the estimated number of reports in response to comments on the proposed rule. (For example, in response to industry comments, EPA revised its analysis of coal-fired steam electric to include metal compounds coincidentally manufactured during flue gas desulfurization, and changed the data it used on the constituents of petroleum products. Both of these actions increased the estimated number of reports.) However, in response to comments from the mining industry, EPA decreased its estimate of the number of reports between the proposed and final industry expansion rules. If the result was to underestimate actual reporting costs for the mining industry, it was due to the misleading comments from the mining industry.

EPA does not believe that it has underestimated the number of reports for PBT chemicals, nor has the commenter presented any evidence that EPA has underestimated the number of reports for PBT chemicals. EPA's cost estimates are averages, and there will always be facilities with costs that are above average. Furthermore, the commenter's estimates of reporting costs at certain facilities may include activities that should not be assigned to the rule because they are not required by the rule or because they are shared with other activities and thus not solely due to EPCRA section 313 reporting. The commenter has not presented any evidence that EPA's unit cost estimates are not reasonable. Therefore, EPA continues to believe that its cost estimates are reasonable, and does not believe that the cost of compliance for reporting on PBT chemicals is substantially in excess of the amount that it has predicted.

Comment: A commenter (C-1864) states that lower reporting thresholds will increase the reporting burden on industry. The commenter notes that the economic burden as estimated by EPA is not insignificant.

Response: EPA has estimated first year industry reporting costs of \$126 million and subsequent year industry reporting costs of \$70 million in the economic analysis of the proposed rule. EPA acknowledges that this is an economically significant action under Executive Order 12866.

Comment: A commenter (C-1869) indicates that \$300,000 is spent per year at their largest facility, and that Option 2 would add about 20% to that figure.

Response: The commenter has not provided enough information about the number of additional reports at the commenter's largest facility to evaluate this comment completely. A 20 percent increase over current reporting costs at the commenter's facility would indicate that the facility would spend an additional \$60,000. In the impact analysis of the proposed rule, EPA estimated a maximum facility-level impact of approximately \$77,000 based on a facility submitting 15 additional reports. This comment indicates that EPA has correctly characterized the upper end of facility-level impact.

Comment: A commenter (C-1865) asserts that EPA has underestimated the burden for facilities in SIC code 5171 (petroleum terminals and bulk storage facilities). The commenter contends that EPA did not consider the concentration data for several petroleum products and PBT chemicals (i.e., vanadium in jet fuel and distillate fuel oil, and PACs in distillate fuel oil). The commenter also contends that the concentration for mercury in crude oil in the economic analysis (10 ppm) is different from the concentration provided in a January 1999 guidance document for facilities in SIC 5171 (6 ppm). The commenter contends that this discrepancy will "grossly affect" the reporting from facilities that use these concentrations for determining the reporting threshold. The commenter speculates that "in the rush to meet Vice President Gore's PBT agenda, EPA hastily prepared an economic analysis for the proposed rule which clearly contains errors that materially change the associated burden and cost estimates."

Response: EPA disagrees with the commenter's characterization. EPA thoroughly reviewed the available literature for concentration data on PBT chemicals in petroleum products handled by facilities in SIC code 5171. The concentration data used to estimate the number of reports associated with each product were derived from a variety of sources, including the main source suggested by the commenter: American Petroleum Institute, *Transport and Fate of non-BTEX Petroleum Chemicals in*

EPA disagrees with the assertion that concentration data for *several* petroleum products and PBT chemicals were not considered. The commenter identifies only one petroleum product, jet fuel, for which EPA did not identify *any* concentration data for any PBT chemical. The commenter cites an Environment Canada report which indicates that jet fuel contains trace concentrations of a single PBT chemical, vanadium. In Table 2 of the comment, the commenter estimates that EPA's omission of the vanadium concentration data for jet fuel results in an underestimate of the reporting burden to facilities in SIC code 5171 by a maximum of 5 reports. EPA notes that this represents less than 0.1 percent of the total reporting predicted from SIC 5171 by the commenter, a vanishingly small omission.

Furthermore, EPA disagrees with the commenter's estimate of additional reporting attributable to vanadium in jet fuel. EPA's review of the commenter's methodology for estimating the number of vanadium reports associated with jet fuel and review of the supporting tables presented in Appendix A of the comment revealed the following inconsistencies:

- The maximum and minimum number of reports associated with jet fuel presented in Table 2 of the comment are not consistent with the estimates displayed in the supporting tables in Appendix A of the comment. The supporting tables estimate a maximum of 13 reports for vanadium while Table 2 estimates a maximum of 5 reports (in either case, a tiny portion of the total predicted reporting from SIC 5171).
- The commenter's estimate of the throughput of jet fuel associated with the two size categories from which facilities are expected to submit reports for vanadium is not supported by the Census data cited by the commenter (1992 Census of Wholesale Trade, Subject Series, Miscellaneous Subjects, Bureau of the Census, U.S. Department of Commerce, WC-92-S-4, Tables 14 and 15). The commenter estimates fuel throughput for each size category by multiplying the total facility storage capacity for each size category by the ratio of total 1992 sales to total 1992 storage capacity. The commenter estimates a throughput of 21.7 billion gallons of jet fuel for the largest size category. However, using the commenter's methodology and the Census data cited by the commenter, EPA calculates a throughput of only 3.9 billion gallons of jet fuel for the largest size category:

$$457,179,000 \text{ gal} \times (6,402,192,000 \text{ gal} / 753,013,000 \text{ gal}) = 3,886,981,600 \text{ gal}$$

The commenter estimates a throughput of 3.9 billion gallons for the next largest size category. However, the Census data cited by the commenter indicates a throughput of 1.8 billion gallons:

$$207,193,000 \text{ gal} \times (6,402,192,000 \text{ gal} / 753,013,000 \text{ gal}) = 1,761,575,600 \text{ gal}$$

By overstating fuel throughput, this error results in an overestimate in the number of reports by the commenter.

- The commenter miscalculated the annual throughput of jet fuel required to trigger reporting for vanadium at the proposed threshold. The commenter estimates that it would require a jet fuel throughput of 1.9 billion gallons to trigger reporting under the proposed option. However, based on the concentration value provided by the commenter, it appears that the commenter calculated the annual throughput required to trigger reporting based on a threshold of 10,000 lbs. Under the proposed rule, facilities in SIC 5171 would be expected to report for processing PBT chemicals present in petroleum products. The threshold for vanadium that is processed is 25,000 lbs. Using the commenter's concentration data for vanadium in jet fuel (0.72 ppm) and assuming a density of 6.7 lbs/gal (0.804 kg/L) for jet fuel, the annual throughput required to exceed the 25,000 lb threshold can be estimated as follows:

$$25,000 \text{ lbs} / (0.72 \text{ mg/kg} \times 0.804 \text{ kg/L} \times 3.785 \text{ L/gal}) \times (1 \text{ kg} / 1,000,000 \text{ mg}) \times 2.2 \text{ lbs/kg} = 5.2 \text{ billion gallons}$$

Thus, the commenter's error results in an overestimate of the number of reports.

In response to the comment, EPA has incorporated information on vanadium concentrations in jet fuel into the economic analysis of the final rule. However, EPA estimates that no additional reporting on vanadium would be triggered solely by processing of jet fuel at facilities in SIC 5171.

With respect to vanadium in distillate fuel oils, EPA acknowledges that it did not use the data suggested by the commenter in the economic analysis of the proposed rule. However, EPA disagrees with commenter's estimate of 17 vanadium reports (less than 1 percent of total estimated reporting) associated with distillate fuel oil. In Table 1 of the comment, the commenter cites an Environment Canada report to support the conclusion that the percent weight concentration of vanadium in distillate fuel oil is 0.0000068. However, the commenter's analysis uses a value of 0.000068 in Appendix A of the comment, which is an error of an order of magnitude. In addition, the commenter's analysis calculates the annual throughput required to trigger reporting based on a threshold of 10,000 lbs. Under the proposed rule, facilities in SIC 5171 would be expected to report for processing PBT chemicals present in petroleum products. The threshold for vanadium that is processed is 25,000 lbs. These errors result in an underestimate of the throughput of distillate fuel oil required to exceed reporting thresholds and an overestimate of the number of reports. In response to this comment, EPA has incorporated the commenter's value for vanadium in distillate fuel oil into the economic analysis of the final rule. Using the value of 0.0000068 provided in Table 1 of the comment to estimate the throughput required to exceed the 25,000 lb reporting threshold, EPA finds that no facilities would be expected to submit reports for vanadium in distillate fuel oil under the proposed option.

With respect to PACs in distillate fuel oil, EPA did include data on PACs in distillate fuel oil in the economic analysis of the proposed rule, albeit at a lower concentration than the commenter suggests. EPA has revised the economic analysis for the final rule to incorporate the commenter's data on PAC concentrations in distillate fuel oil. However, this modification does not result in an additional 3,893 reports from SIC 5171 as the commenter claims. The commenter's analysis estimates that 3,893 facilities in SIC 5171 will submit reports on PACs in residual fuel oil, and that these same facilities will also submit reports for PACs in distillate fuel oil. However, the proposed PBT rule only requires facilities to submit a single report for each PBT chemical manufactured, processed, or otherwise used in excess of thresholds. Therefore, by counting PAC reports associated with both products, the commenter's analysis double-counts the number of reports expected to be submitted for PACs as a result of the proposed rule and overestimates the reporting burden by 3,893 reports. The commenter's assertion that EPA's analysis of PACs in distillate fuel oil results in an underestimation of approximately 3,900 reports is then incorrect. Based on the commenter concentration data, EPA estimates that the actual TRI reporting burden would be associated with PACs in distillate fuel oil at facilities in SIC 5171 at the 10 lb reporting threshold is 2,323 reports. This estimate has been incorporated into EPA's economic analysis of the final rule.

Finally, the commenter's assertion that EPA's use of concentration data is inconsistent with its own guidance document for SIC 5171 is incorrect. The commenter contends that EPA uses 10 ppm as the concentration for mercury in crude oil in the economic analysis of the proposed PBT rule while the industry guidance document for SIC code 5171 states that the concentration is 6 ppm. However, EPA's economic analysis did use a concentration of 6 ppm for mercury in crude oil. This concentration value is presented no less than three times in the appendix addressing additional mercury reports in the economic analysis of the proposed rule (see pp. F-27, F-28, F-29).

Comment: A commenter (C-1865) asserts that based on the 1992 Census of Manufactures, there are 3,863 facilities with more than 10 employees in SIC code 5171 rather than the 3,842 used in EPA's analysis. The commenter also asserts that because these facilities have "substantial capital equipment and relatively few employees," they "may contract many services from outside firms. The commenter notes that there are 1,565 facilities in SIC code 5171 that employ between 7 and 9 employees and may exceed the employee threshold in any given year based on contracting.

Response: The estimated number of potentially affected facilities in SIC 5171 used in the economic analysis of the proposed rule was derived from data presented in the 1990 County Business Patterns published by the Bureau of the Census. The commenter's estimate is based on the 1992 Census of Manufactures. It should not be surprising that different data sources representing different years would present different estimates of the total number of facilities in SIC 5171. EPA notes that in this case the difference of 21 facilities is minuscule (approximately 0.5 percent of the total). However, in response to this comment, EPA obtained the most recent estimate of the number of facilities in SIC 5171 with 10 or more employees from the 1996 County Business Patterns published by the Bureau of the Census: 3,381 facilities. EPA notes that this figure is 12.5 percent lower than that suggested by the commenter. EPA chose to continue using an estimate of 3,842 facilities in SIC 5171 subject to EPCRA section 313 for the economic analysis of the final rule, although the actual number of facilities may actually be 12.5 percent lower.

The commenter is correct that the hours of contract workers would count toward the employee threshold for reporting. EPA acknowledges that these hours are not included in the Census estimates from which EPA's estimates are based. However, EPA believes that this is offset by the fact that Census employee counts include all full- and part-time employees without adjusting for part-time hours as does the TRI FTE threshold. Therefore, EPA's use of Census data for establishments with 10 or more employees actually overestimates the number of facilities with 10 or more FTEs including contract workers. Furthermore, the commenter provided no information to quantify the extent of such contract work. Therefore, EPA made no adjustment to the economic analysis of the final rule to reflect facilities with 7 to 9 employees.

Comment: A commenter (C-1865) suggests an alternative method of calculating the expected number of reports from SIC 5171. The commenter asserts that the actual burden on these facilities would be 3 times EPA's estimate in the first year and 5 times EPA's estimate for subsequent years. The commenter further asserts that its cost estimates are still underestimates since they do not include capital costs, such as for computers and tracking and monitoring systems.

Response: EPA disagrees. The commenter's analysis, which estimates significantly higher product throughput and additional reporting than EPA's economic analysis, contains so many errors and inconsistencies that EPA cannot accept the commenter's results.

First, the commenter's analysis grossly overestimates the number of reports by failing to account for the fact that facilities handling more than one petroleum product containing the same PBT chemical would submit (at most) one report on that PBT chemical. For example, using the commenter's methodology for estimating product throughput, the 179 facilities in the largest size category are assumed to exceed the annual throughput required to trigger reporting for PACs for three petroleum products: No. 6 fuel oil, No. 2 fuel oil, and crude oil. The commenter concludes that each of these facilities will submit three separate reports for PACs, one for each product. The commenter asserts that there are 3,893 facilities in SIC code 5171 potentially affected by the proposed rule. Therefore, the maximum number of reports submitted for any one PBT chemical from this SIC code is 3,893. However, the commenter estimates that a maximum of 10,646 reports will be submitted for PACs, an overestimate of 6,753 reports assuming every facility reports for PACs. Correcting for this error across all chemicals drastically reduces the commenter's maximum and minimum estimates of the reporting burden associated with this rule.

In addition, the commenter's analysis assumes that all facilities in each size category handle all petroleum products. EPA believes that this assumption is unrealistic and results in an overestimation of the number of reporting facilities. EPA's economic analysis uses data presented in the Independent Liquid Terminal Association (ILTA) Directory to estimate the percentage of facilities handling each petroleum product containing at least one PBT chemical. EPA believes that this approach provides a more realistic estimate of reporting associated with the rule.

The commenter's analysis used the wrong number of affected facilities for the size category corresponding to facilities with storage capacities between 1,050,000 and 6,299,999 gallons. The Census data cited by the commenter indicates that there are 764 facilities in this category while the commenter estimates that 794 facilities are expected to submit reports for PBT chemicals in three petroleum products (1992 Census of Wholesale Trade, Table 14).

Furthermore, the commenter appears to have overestimated the throughput of jet fuel associated with each of the five facility size categories. EPA was unable to reproduce the commenter's estimates using the methodology presented in the comment and the same 1992 Census data cited by the commenter. By overestimating the throughput of jet fuel associated with facilities in the largest two size categories, the commenter's analysis overestimates the number of facilities expected to report.

The commenter's analysis also incorrectly calculates the annual throughput of jet fuel required to trigger reporting for vanadium based on a threshold of 10,000 lbs. Under the proposed rule, facilities in SIC 5171 could report for processing PBT chemicals present in petroleum products. However, the threshold for vanadium that is processed is 25,000 lbs. By underestimating the throughput of jet fuel required to trigger reporting, the commenter's analysis overestimates the number of facilities expected to report.

With regard to capital costs, the commenter provides no quantification of the possible extent of capital expenditures by facilities in SIC 5171. EPA notes that facilities are not required to undertake any capital expenditures for the purposes of reporting under EPCRA Section 313. If a facility does undertake capital expenditures, EPA expects there would be an offsetting reduction in cost and burden hours spent completing TRI forms.

Because EPA believes that the commenter's estimates are the result of a flawed methodology and error-filled analysis, EPA has not adopted them. However, based on the review of the commenter's methodology, EPA re-examined the issue of facility double-counting. The commenter's analysis overestimates the number of reports by assuming that all facilities process all petroleum products and failing to account for facilities handling more than one petroleum product containing trace amounts of the same PBT chemical. EPA's analysis of SIC code 5171 for the proposed rule used data from the Independent Liquid Terminal Association (ILTA) Directory to estimate the percentage of facilities in SIC 5171 that handle each petroleum product. EPA has revised its methodology for the economic analysis of the final rule to utilize the ILTA data in the estimation of the number of facilities with sufficient throughput of multiple products to trigger reporting for at least one PBT chemical. This modification allows EPA to control for double-counting when estimating the reporting burden associated with SIC code 5171. In addition, EPA has included the commenter's concentration data for PACs and benzo(g,h,i)perylene in distillate fuel oil and for vanadium in jet fuel and distillate fuel oil. EPA continues using data from ILTA to estimate the percentage of facilities in SIC 5171 that handle each petroleum product. These changes have increased the estimated number of additional reports on PBT chemicals for SIC code 5171, although not as much as the commenter suggests. (A complete description of EPA's methodology and results is provided in the economic analysis of the final rule.)

7.e. EPA has not shown that benefits exceed cost

Commenter list: C-446, C-1168, C-1352, C-1356, C-1405, C-1406, C-1417, C-1421, C-1423, C-1424, C-1425, C-1428, C-1431, C-1431b, C-1433, C-1434a, C-1435, C-1436, C-1439, C-1445, C-1447, C-1448, C-1450, C-1457, C-1458, C-1815, C-1817, C-1819, C-1820, C-1832, C-1833, C-1836, C-1837, C-1838, C-1841, C-1844, C-1845, C-1847, C-1852, C-1857, C-1858, C-1861, C-1865, C-1869, C-1870

Comment: A number of commenters (C-1406, C-1421, C-1428, C-1431, C-1431b, C-1435, C-1457, C-1836, C-1448, C-1847, C-1815, C-1845, C-1857, C-1858, C-1869) question the adequacy of EPA's economic analysis of the potential benefits of the proposal. The commenters criticize EPA's analysis of benefits as being "an incredibly general regurgitation of the basic information-gathering purpose of the TRI program," "nebulous," and "generic." The commenters note that EPA did not quantify or monetize the potential benefits of the preferred option, or each of the specific threshold alternatives. The commenters question how they are to compare costs and benefits when they are not expressed in the same metric, and argue that EPA has not adequately substantiated why the proposal is necessary, how it would benefit the public, that the net benefits of the preferred reporting thresholds exceed those of alternative thresholds, or that the optimal amount of information will be obtained. One commenter (C-1448) notes that EPA's discussion of market failure is generally sound, but the commenter asserts that it neglects the fact that information is a costly good that, absent some market failure, is likely to divert scarce resources from other more valued uses. One commenter (C-1406) directs EPA to a 1961 article on the economics of information by George Stigler that discusses the cost-effectiveness of obtaining information and calculating the point of diminishing returns.

Response: EPA disagrees that its economic analysis of the potential benefits of the proposal is inadequate. In its economic analysis, EPA explained the theoretical basis for assessing the informational benefits of additional reporting on PBT chemicals. Releases of PBT chemicals lead to market failure through negative externalities and asymmetric information. Negative externalities for PBT chemicals exist when a production process imposes uncompensated (or "external") costs on another party. The problem of asymmetric information arises for PBT chemicals when consumers lack sufficient information regarding the health and environmental consequences of purchasing decisions. The information provided by TRI reporting addresses these market failures by increasing knowledge of the amount of toxic chemicals released to the environment and the potential pathways of exposure. Benefits of activities required by the rule include improved knowledge about the release and waste management of chemicals, which leads to improvements in understanding, awareness, and decision making.

Because the state of knowledge about the economics of information is not highly developed, EPA did not attempt to quantify the benefits of adding chemicals to TRI or changing reporting thresholds. Furthermore, because of the inherent uncertainty in the subsequent chain of events, EPA has not attempted to predict the changes in behavior that result from the information, or the resultant net benefits. EPA does not believe that there are adequate methodologies to make reasonable monetary estimates of either the benefits of the activities required by the proposed rule, or the follow-on activities. The economic analysis of the proposed rule, however, does provide a qualitative discussion along with illustrative examples of how the proposed rule will improve the availability of information on PBT chemicals. EPA described how consumers, industry, the financial and business community, academics, environmental groups, communities, and the media are expected to use the

results of TRI reporting on PBT chemicals. EPA also presented a case study of the benefits of TRI reporting for the Great Lakes region.

With regard to quantification of benefits, EPA notes that Executive Order 12866 does not require that benefits be quantified. The Executive Order states that “Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider.” EPA believes that its assessment of the benefits meets the requirements of Executive Order 12866. This issue is addressed further in Section 7.f.1. of this document.

The commenters offer no evidence that EPA has failed to adequately substantiate why the proposal is necessary, how it would benefit the public, that the net benefits of the preferred reporting thresholds exceed those of alternative thresholds, or that the optimal amount of information will be obtained. EPA notes that despite the commenters’ criticisms of EPA’s approach to evaluating benefits, the commenters do not suggest any alternate methodology for quantifying or monetizing the benefits of EPA’s proposal. Likewise, the commenters offer no quantitative estimates of the benefits of EPA’s proposal. The commenters offer only nebulous and generic criticisms of EPA’s evaluation of the benefits of the proposed rule.

The Stigler article mentioned by one commenter (Stigler, George, “The Economics of Information,” in *The Journal of Political Economy*, Vol LXIX, No 3, June 1961) is not relevant to the proposed rule. The article explores the optimal level of costly “searching” that will be undertaken to ascertain the market prices for goods that are bought and sold in a non-centralized marketplace. As EPA explained in its benefits analysis of the proposed rule, part of the need for government action is that information on PBT chemical releases and other waste management activities is not a commodity that is available in the marketplace. TRI information has the characteristics of a “public good”; once the information is gathered, one person’s use of the information does not preclude another’s use of the same information, and it is difficult to prevent uncontrolled distribution (in economic terms, it is non-rival and non-excludable). Economic theory demonstrates that, absent some form of collective action, the private market will fail to supply an economically efficient quantity of a public good. TRI overcomes firms’ lack of incentive to provide information on the release and other waste management of toxic chemicals. The Stigler article is not relevant to the proposed rule, except to point out that information is a valuable resource.

Comment: A number of commenters (C-1168, C-1356, C-1423, C-1433, C-1434a, C-1458, C-1815, C-1817, C-1819, C-1832, C-1833, C-1837, C-1838, C-1841) assert that the cost of the proposal may outweigh the benefits. This assertion is based on the belief that resulting reports may not provide the public with useful information, that the reports will be on small amounts, that the reports may be unreliable, that the reports may not provide the public with information on “real” health concerns, and that the “vast majority” of chemical releases are not included in TRI. One commenter (C-1841) claims that the increased reporting burden from Options 1 or 2 are “unacceptable” because the reporting only pertains to 16 chemicals and 3 chemical categories. Another (C-1815) states that belief that the costs of the proposal are “excessive,” particularly when added to the existing regulatory burden of the TRI program. This commenter suggests that EPA should not only consider the costs of the proposed rule in terms of the total direct costs it imposes, but in terms of the additional cost burden relative to overall TRI reporting. One commenter (C-1844) contends that the cost of the information seems excessive given the historical lack of interest by the general public in the TRI and given that these costs are in large part passed to the consumer.

Response: Given the persistence and bioaccumulative properties of the toxic chemicals addressed by the proposal, EPA believes that the benefits of the proposal outweigh the costs. EPA does not agree with the comment that the increased reporting burden is unacceptable because reporting only pertains to a limited number of chemicals. The chemicals covered by the proposal have been identified as some of the most persistent and bioaccumulative toxic chemicals. The commenters offer a number of assertions about factors that could affect the net social benefits of the proposal, but no evidence to support these assertions.

As EPA has explained, the toxic chemicals persist and bioaccumulate in the environment leading to human health and environmental impacts of concern. Because of persistence and bioaccumulation, these effects may occur even if the releases from any one facility in any one year are small relative to total national releases. As EPA has indicated, part of the rationale for the rule is that information on PBT chemical releases and waste management from individual facilities in communities across the nation is extremely limited.

EPA disagrees with the commenter’s assertion that the reports may not provide the public with information on “real” health concerns. The commenter provides no information to indicate what a “real” health concern is, or what levels of PBT chemicals would be associated with “real” health concerns. As discussed elsewhere, TRI data do not, in themselves, provide

information on risk, which is what EPA assumes the commenter is trying to convey through his use of the term “health concern.” The toxic chemicals addressed by the proposal are persistent and bioaccumulative. PBT chemicals have been well documented to persist in the environment and bioaccumulate in organisms. For example, in 1997 there were 2,299 fish consumption advisories in 47 states, the District of Columbia and the American Territory of Samoa for persistent bioaccumulative pollutants such as mercury, dioxin, PCBs, and chlordane. Eighteen states currently have statewide fish consumption advisories in effect. Currently, 100 percent of the Great Lakes and their connecting waters are also under advisory (see, <http://www.epa.gov/OST/fishadvice/fishadv.pdf>). EPA’s proposal would help identify the facilities contributing to pollutant loadings that ultimately result in fish that are contaminated to a level at which human consumption would create a “real” health concern.

With regard to the additional cost of the rule relative to the entire TRI program, EPA believes that calculating the incremental costs and benefits of rulemakings provides the appropriate information to make decisions regarding these rulemakings. EPA addressed the cumulative burden of TRI reporting in the Information Collection Request (ICR) supporting statement for the information collection under the rule.

Finally, EPA disagrees with the assertion that there is a historical lack of interest by the general public in TRI. As discussed in EPA’s economic analysis, a bibliography prepared by the Working Group on Community-Right-to-Know in 1994 listed well over 100 state and local reports and more than 30 national reports compiled by public interest groups using TRI data (see p. 6-21). Recently, the Environmental Defense Fund unveiled an interactive website from which TRI data can be obtained. After the site was announced, the access rate was close to 40 requests *per second*, making the site one of the Internet’s most heavily accessed purely database-backed sites (see p. 6-22). Public interest extends to EPA’s plans for expanded reporting of PBT chemicals. During the comment period for this proposed rulemaking, EPA received over 35,000 comments from the general public demanding lower reporting thresholds for PBT chemicals. EPA also notes that there are other users of TRI data aside from the general public which include educational institutions, the financial and business community, industry, EPA, and other federal, state and local governments.

Comment: A commenter (C-1450) asserts that the proposed reporting threshold for mercury “poses an unnecessary burden on utilities.” The commenter cites a November 1994 EPRI study of electric utility stack emissions. The commenter asserts that these results indicate that reporting on a majority of mercury stack emissions could be obtained at higher thresholds.

Response: EPA disagrees that the proposed reporting threshold for mercury poses an unnecessary reporting burden for electric utilities. Focusing exclusively on facilities that account for a majority of total national releases ignores the strong *community* right-to-know characteristics of the program. Each TRI report represents information about a facility in a specific community, as well as that facility’s contributions to local, regional, national, and international pollutant loadings. An electric utility may represent the largest local contributor to environmental loadings of mercury in a community.

With regard to the issue of burden, at least one electric utility company has stated that “TRI simply mandates that utilities summarize release data into a new format that is more readily available to larger segments of the public.” (Potomac Electric Power Company. *Lines*, Volume 28, Issue 4, April 1999.) A group of electric utility companies known as the Clean Energy Group stated that “As a matter of principle, we fully endorse the public disclosure of environmental release data, and support the lowering of reporting thresholds for PBT chemicals” (C-1809). EPA notes that the Clean Energy Group includes member companies that combust all fossil fuel types, including coal. These statements indicate that TRI reporting does not represent an unreasonable or unnecessary burden on utilities.

Furthermore, the study cited by the commenter provides emissions test results for a limited number of facilities at some point in the past. The results may not be representative of facilities in all communities, and the results are already at least five years old. By contrast, the TRI data are reported every year from every facility subject to reporting under EPCRA Section 313 that exceeds the applicable reporting threshold. This allows a variety of audiences to assess patterns in releases and other waste management activities over time from facilities across the nation.

Comment: A commenter (C-1405) asserts that the proposal will present an unreasonable regulatory burden on Federal facilities specifically, and requests EPA to reconsider its proposed rule and modify the rule to lessen the regulatory burden while still retaining environmental protections.

Response: EPA disagrees. Whether the release of a PBT chemical originates from a federal or private facility, the concerns for human health and the environment are the same. EPA notes that the commenter has not provided any information to allow EPA

to further evaluate the burden this proposal would create for federal facilities (i.e., the number of federal facilities handling PBT chemicals, the number of PBT chemicals handled at an average federal facility, the amounts of PBT chemicals handled). It is also important to note that this rule was developed in response to a Vice-Presidential directive issued on February 21, 1998, that instructed EPA to review “persistent bioaccumulative toxics” and determine whether they should be subject to TRI reporting and lower thresholds. Furthermore, the requirement that Federal Facilities comply with TRI reporting, as set forth in Executive Order 12856, demonstrates that the federal government is committed to the right-to-know objectives of EPCRA and providing local communities with important release and other waste management information.

Comment: A commenter (C-1439) asserts that the benefits of reporting submitted under a reporting threshold of “zero” would “far outweigh the costs.” The commenter asserts that this conclusion is implied by EPA’s discussion of costs and benefits in the preamble. The commenter states that EPA’s analysis is “one-sided” because it quantifies the cost of reporting under several options, but not the benefits. The commenter claims that EPA “expressly declines” to add the benefits resulting from reductions in PBT releases that would result from lower reporting thresholds. The commenter indicates that PBT reductions would lead to improvements in health and the environment that would “justify reporting costs far greater than the \$127 million estimated for the 10 pound/1 pound thresholds.”

Response: EPA acknowledges that it did not present a cost estimate for this scenario because EPA is not requiring all such facilities to report. EPA believes that a zero threshold would be impractical. Attempting to require facilities to determine if they manufacture, process, or otherwise use any amount whatsoever of dioxin and dioxin-like compounds would be extremely burdensome and perhaps technically impossible. Without an actual numerical threshold, many facilities might report some amount of dioxin in a misguided attempt to assure compliance. This could lead to misleading and inaccurate data on the actual sources of dioxin and dioxin-like compounds. EPA believes that rather than setting a zero reporting threshold, it would be better to set a very low threshold that provides facilities with a clear indicator of when they are required to report.

EPA disagrees that its analysis was “one-sided” because the benefits of the rule were not quantified. EPA did not attempt to quantify the benefits of changing reporting thresholds because the state of knowledge about the economics of information is not highly developed. EPA notes that the commenter did not provide any quantitative analysis of the benefits of the rule in support of the comment. EPA does not believe that there are adequate methodologies to make reasonable monetary estimates of the benefits of the rule. Despite this limitation, the economic analysis of the proposed rule provides a qualitative discussion along with illustrative examples of how the proposed rule will improve the availability of information on PBT chemicals. EPA also presented a case study of the benefits of TRI reporting for the Great Lakes region. EPA believes that its assessment of the benefits meets the requirements of Executive Order 12866.

EPA has not “expressly decline[d]” to add the benefits resulting from reductions in PBT releases that result from lower reporting thresholds. The benefits of the proposed rule are related to the provision and distribution of PBT chemical information, and include improvements in understanding, awareness, and decision-making. The rule does not require any reduction in PBT chemical releases. However, as EPA recognized in the economic analysis of the proposed rule, providing information can lead to follow-on activities, such as reductions in releases of PBT chemicals, that yield health and environmental benefits. These follow-on activities will have an associated cost, and the net benefits of the follow-on activities are the difference between the benefits of decreased PBT releases and the costs of the actions needed to achieve the decreases. Because of the inherent uncertainty in the subsequent chain of events, EPA has not attempted to predict the changes in behavior that result from the information, or the resultant net benefits, (i.e., the difference between benefits and costs).

Comment: Commenters (C-1433, C-1448, C-1841) assert that because the “vast majority” of chemical releases are not included in TRI, TRI cannot be used to measure progress in reducing emissions. One commenter (C-1841) asserts that it is inappropriate to impose a costly national program on U.S. industry, in the hopes that its global competitors might also be compelled to participate in like programs. Another commenter (C-1815) questions how the costs of the rule are justified if the reporting facilities are not responsible for a high percentage of total loadings.

Response: EPA disagrees with the commenters’ assertion that that TRI cannot be used to measure progress in reducing emissions. TRI provides annual data on releases and other waste management activities from individual facilities in the following U.S. industry sectors: manufacturing, mining, electric utilities, waste treatment and disposal facilities, chemical wholesalers, petroleum bulk terminals, and solvent recovery services. These data allow the public to measure progress in reducing emissions and preventing pollution at facility, local, regional, state, and national levels. In addition, many companies have indicated that TRI information is useful for the purposes of pollution prevention activities.

Databases are rarely completely comprehensive, but that fact does not diminish the utility of the data that are reported. The fact that not all industry sectors or sources of releases are currently covered does not mean that data from U.S. industry sectors subject to reporting are not meaningful. Even though not all releases in the U.S. or other countries are covered under the lower thresholds, the utility of TRI information has been documented extensively in EPA's economic analysis.

EPA notes that the inherent persistence, bioaccumulation, and toxicity of PBT chemicals create concern about human health and environmental effects in even the smallest amounts or concentrations. Even if a single facility or industry is not responsible for a "high" percentage of total national loadings, the releases from that facility or industry may still be of concern to the public. The percentage of total national releases that an individual facility or industry represents does not reflect the potential human health and environmental effects of even small amounts of PBT chemicals, especially when multiple facilities release PBT chemicals that persist and bioaccumulate.

Comment: A commenter (C-1841) claims that the economic analysis of the proposal overstates the benefits of TRI without discussing its shortcomings. The commenter asserts that many of the studies done by "Education and Research Institutions" attempt to bring appropriate context to TRI in terms of science and risk.

Response: EPA disagrees that it has overstated the benefits of TRI without discussing its shortcomings. EPA is aware of the limitations of TRI data, and communicates these limitations to users of TRI data in the annual public data release. With respect to risk, EPA recognizes that TRI reports reflect releases and other waste management activities. The determination of potential risk depends on many additional factors, including the toxicity of the chemical, the fate of the chemical after it is released, and the human or other populations that are exposed to the chemical after it is released. Nevertheless, as discussed in the economic analysis, a number of education and research institutes have found TRI data to be a useful input. Although additional information may be necessary to assess exposure and risk, TRI data can be used to identify areas of potential concern. Furthermore, TRI data, in conjunction with other information, can be used as a starting point in evaluating exposures that may result from releases and other waste management activities of toxic chemicals. Not only has EPA not overstated the benefits of TRI, but the comment indicates that TRI data are used in the context of research, fulfilling one of the goals of EPCRA Section 313(h).

Comment: Two commenters (C-1841, C-1815) claim that EPA's use of a case study on PBT chemicals in the Great Lakes indicates that the need for PBT chemical information may be limited to the Great Lakes. The commenters question whether the experience of the Great Lakes Basin is relevant to other areas. The commenters suggest that regional needs should not drive national policy, and that it is inappropriate to collect PBT chemical information nationally when the need is region-specific, and when states in that region have or are developing their own data collection programs.

Response: EPA developed this case study to provide an illustrative example of how additional TRI information on PBT chemicals would be useful at the regional level. EPA believes that other regions of the country will also benefit from the information provided by the rule. EPA notes that the commenters provide no evidence to indicate that TRI information on PBT chemicals would not be useful for the Great Lakes or other regions.

Although the commenter asserts that states in the Great Lakes region "have or are developing their own data collection programs," no further details are provided. EPA is aware of data collections programs in Minnesota and Wisconsin that specifically address mercury. However, EPA notes that mercury is only one of the PBT chemicals. Furthermore, electric utilities, one of the most prominent sources of mercury, have been exempted from state-level reporting in Minnesota through a fossil fuel exemption. In Wisconsin, the reporting threshold varies between 3.7 and 37 pounds of mercury based on the speciation of mercury releases. In addition, only releases to air are reported under these state programs.

Given the persistence of the chemicals addressed by this rulemaking, releases in one region may affect another region. This supports the need for information that is collected consistently across the nation. The following comment addresses the utility of the proposed action for an area outside the Great Lakes.

Comment: A commenter (C-1447) states that the additional information collected because of this new rule will improve the scope of multi-media data on the release and disposition of PBT chemicals in Oregon. This, in turn, will provide information to Oregon citizens and empower them to play a meaningful role in environmental decision-making concerning PBTs. The commenter states that DEQ reporting programs do not provide the release information that is available from TRI data, therefore, this data will also assist environmental decision-making in the HW Program. In addition, this action will serve to generate

information that reporting facilities themselves may find useful in such areas as highlighting opportunities to reduce chemical use or release and thereby lower costs of production and/or waste management.

Response: The commenter provides additional support to EPA's contention that the rule will provide useful information to citizens and state governments. EPA notes that Oregon is not located in the Great Lakes region, but that additional information on PBT chemicals is expected to provide net social benefits.

Comment: A commenter (C-1448) asserts that because the chemicals reported under TRI are "all" subject to numerous environmental and occupational regulations, it is unlikely that there are any external costs associated with the release of TRI chemicals. The commenter asserts that "absent a compelling public need," private entities should not be required to release private information to the public, which may include competitors or saboteurs. Another commenter (C-1865) notes that many reported releases are permitted.

Response: EPA disagrees. The commenter has drawn a conclusion about the external costs associated with environmental releases of TRI chemicals based on broad assertions about the scope of regulation with no factual basis or supporting evidence. EPA disagrees that all external costs are internalized by existing regulations.

The commenter provides no evidence to support the assertion that releases for "all" TRI chemicals are covered by regulations that are specific to each pollutant, media of release, and facility. In fact, EPCRA section 313 covers many releases that are not addressed by other statutes, regulations, or permitting. As an example for just one environmental medium, consider releases to water. A 1994 study by the General Accounting Office found that the vast majority of toxic pollutants discharged from 200 of 236 pesticide, pharmaceutical, and paper plants examined were "uncontrolled" pollutants that are exempt from regulation under the pollution permitting process of the Clean Water Act. The study noted that "uncontrolled" pollutants can pose human health and aquatic life risks (US GAO, Poor quality assurance and limited pollutant coverage undermine EPA's Control of Toxic Substances. GAO/PEMD-94-9. 1994). EPA notes that GAO was only able to conduct this study because of the availability of TRI release data on a broad range of pollutants from individual facilities.

Even when facility releases are covered by permits, this does not guarantee that facilities will always comply with those permits. A recent analysis of EPA enforcement records revealed that more than 39 percent (227 out of 575) of all major facilities in auto assembly, iron and steel, petroleum refining, pulp manufacturing, and the metal smelting industries violated the Clean Air Act standards between January 1997 and December 1998. Fifty-three of the facilities were out of compliance with the CAA every quarter during the two-year period analyzed (Environmental Working Group, Above the Law: How the Government Lets Major Air Polluters Off the Hook, May 1999). Even if permit levels were set to internalize all externalities, as the commenter suggests, non-compliance with existing permits indicates a compelling social need for information on PBT chemicals to help address market failure.

Additionally, the commenter ignores the other mechanism of market failure identified by EPA: asymmetric information. This market failure occurs when interested parties such as consumers, employees and other members of the public and government make decisions without the benefit of full knowledge of the consequences of their choices. This rule will provide useful information to these decision makers, thereby enabling them to make efficient choices. Asymmetric information is identified as one of the major types of market failures to be addressed under Executive Order 12866.

With respect to TRI coverage of releases covered by permits and other regulations, the commenter appears to have overlooked congressional intent for EPCRA Section 313. Congress did not intend that the chemicals listed under EPCRA section 313 be limited to those that are not regulated under other environmental statutes and for which no information is collected pursuant to other requirements. The initial list of chemicals that Congress included in section 313 consisted of substances regulated under RCRA, CWA, SDWA, CERCLA and CAA. The legislative history for section 313 establishes that Congress intended all releases of toxic chemicals, whether permitted or not, or regulated or not, to be reported. The Conference Report states at the very outset of its discussion of section 313, that reporting thereunder "covers releases that occur as a result of normal business operations," H. Conf. Rep. 99-962 at 292, which would include permitted releases. Representative Edgar, the principal House author of EPCRA and a member of the House-Senate Conference Committee that negotiated the version of EPCRA that became law, emphasized that under the Conference Committee version, the toxic chemical release form should include

[A]ny releases into the air, water, land as well as releases from waste treatment and storage facilities. This should include all releases of toxic chemicals into surface waters whether or not such releases are pursuant to Clean Water Act permits. Similarly, all toxic chemicals dumped into land disposal facilities must be reported

whether or not such facilities are regulated under the Resource Conservation and Recovery Act and whether or not such facilities are onsite or offsite.

132 Cong. Rec. H9595 (Oct. 8, 1986). Likewise, Senator Stafford, a Senate conferee on section 313, emphasized that this law

goes beyond concern about accidental releases of ... toxic and hazardous chemicals. It also recognizes that the public has a right to be informed about routine releases of these chemicals to the air and the water and the land. Just as the public has a right to know about releases that might happen as a result of an accident, the public also has a right to know about releases that do happen every hour and every day as some manufacturing facilities operate.

Thus, Congress clearly intended all activities constituting a release of toxic chemicals under EPCRA to be reported, even where such activities are regulated and permitted under other statutes.

EPCRA was enacted to collect and disseminate information to the public. TRI consolidates data addressing toxic chemical releases to all environmental media and other waste management activities into an inventory that is: a single, multi-media data resource; consistently defined and formatted; annually aggregated; and, readily available to the public. The benefit of TRI is that it empowers the public, through access to release, transfer, and other waste management data on toxic chemicals, to make determinations about risks in their communities based on TRI data, site-specific information, and the properties of the chemical(s). Indeed, one important use of TRI data may be to cross-check reported TRI emissions against permit limits and emissions standards to ensure that such limits and standards are adequately protecting public health and the environment, a use which would be significantly curtailed if reporting were only required when emissions exceeded the already-established permit limits or standards.

Permitting processes under other environmental statutes, while providing opportunities for public participation, do not afford the public the kind of information made available through TRI. In fact, information reported to the TRI are often used both by members of the public to enhance their participation in these permit processes, and by federal, state, and local government decision makers in administering permit processes.

EPA's justification of the need for publicly available, facility-level release and other waste management data for PBT chemicals is extensively documented in the Federal Register announcement of the preamble and in the supporting record. With regard to the potential misuse of the information, EPA notes that the commenter fails to provide any scenario (credible or otherwise) in which the reporting of PBT chemicals under EPCRA Section 313 could lead to industrial espionage or sabotage.

Comment: A commenter (C-1352) states that EPA's discussion of the need for the rule does not address industry's contribution to public well being and the balance between industry's contribution and detracting from this end. The commenter asserts that the PBT chemicals are found in such low concentrations as not to be of regulatory concern. The commenter adds that technology is not available to remove low concentrations of PBT chemicals.

Response: EPA's analysis of the need for the rule focused on market failures associated with PBT chemicals. In general, industry contributes to societal well being by supplying products that are demanded by the public at a price determined through a competitive market. Industry's contribution to public well being is already reflected through the marketplace for products which are bought and sold in commerce. In a competitive market where there are no external costs (i.e., costs which are not reflected in the market price) and both buyers and sellers have perfect information, there may be limited need for government intervention for the sake of economically efficient outcomes. However, as EPA's economic analysis indicates, production that is associated with PBT chemicals creates external costs that are not reflected in the market price of goods. Furthermore, consumers are unable to completely evaluate the attributes of goods because they lack information on the PBT chemicals associated with those goods. In other words, the market does not adequately balance "industry's contribution and detracting" from public well being where PBT chemicals are concerned.

The commenter has not supported the assertion that PBT chemicals are found in such low concentrations as not to be of regulatory concern. Because of their persistence and bioaccumulative properties, EPA believes that PBT chemicals present concerns even in small amounts (or low concentrations). Furthermore, although PBT chemicals may be found in "low" concentrations, the throughput of the material containing the PBT chemical may be great enough that the total quantity of PBT chemical adds up to a substantial amount. One example of this is mercury in coal that is consumed at electric utilities. A typical concentration value for mercury in coal is 0.21 parts per million. Even at this level, emissions from coal-fired electric

utilities account for over 30 percent of anthropogenic mercury releases, contributing to mercury contamination at levels that have lead to the issuance of almost 1,800 fish consumption advisories in 1997 (<http://www.epa.gov/OST/fishadvice/fishadv.pdf>).

EPA believes that the availability of technology to remove PBT chemicals is irrelevant to this rulemaking. This rule requires information provision to ensure the public's right-to-know about toxic chemicals; it does not require that PBT chemicals be removed from materials containing PBT chemicals. The rule only requires that facilities that are subject to EPCRA Section 313 report their releases and other waste management activities to TRI if reporting thresholds are exceeded. Furthermore, EPA notes that the commenter has not provided any evidence to support the assertion that technologies are not available to remove PBT chemicals. For example, research has shown a number of techniques such as coal cleaning and flue gas treatment are available that could reduce emissions of mercury (see, Mercury Study Report to Congress, Vol 8 at <http://www.epa.gov/ttn/uatw/112nmerc/volume8.pdf>). EPA notes that facilities that desire to reduce releases of PBT chemicals have other options such as fuel switching that may have the same result as physically removing PBT chemicals from source materials or installing additional control technology.

Comment: A commenter (C-1448) asserts that the benefits attributed to the proposed rule accrue only from subsequent activities that are facilitated by information reported to TRI. The commenter notes that these activities also involve costs that the commenter claims "may well exceed the benefits of the activities." The commenter disputes whether PBT pollution reduction would lead to net social benefits. The commenter argues, using examples of Alar concerns and a Peruvian cholera epidemic, that the public can overreact to information by taking actions that lead to net social costs. The commenter contends that recent empirical evidence indicates that individuals do not respond rationally to diverse information on risks, weighting high-risk assessments much greater than low-risk assessments, regardless of source. ("Alarmist Decisions with Divergent Risk Information," *The Economic Journal*, 107 (November 1997) 1657-1670.) The commenter asserts that EPA does not recognize that any new action would, itself, involve costs as well as benefits, and that all of the subsequent actions to which the rule attributes qualitative benefits could, in reality, impose net social costs.

Response: EPA disagrees that the benefits of expanded TRI reporting on PBT chemicals are only attributable to subsequent activities that are facilitated by information reported to TRI. The benefits of the proposed rule are related to the provision and distribution of PBT chemical information, and include improvements in understanding, awareness, and decision-making. The information reported to TRI increases knowledge of the levels of pollutants released to the environment and the potential pathways of exposure, thereby improving scientific understanding of the health and environmental risks of toxic chemicals; allowing the public to make better-informed decisions on matters such as where to work and live; enhancing the ability of corporate leaders and purchasers to gauge a facility's potential environmental liabilities; and assisting federal, state, and local authorities in making better decisions on acceptable levels of toxic chemicals.

As discussed in the economic analysis of the proposed rule, EPA recognizes that providing information can lead to follow-on activities that create additional costs, as well as benefits. These follow-on activities, including reductions in releases of and changes in the waste management practices for toxic chemicals, may yield health and environmental benefits. These changes in behavior come at some cost, and the net benefits of the follow-on activities are the difference between the benefits of decreased chemical releases and transfers and the costs of the actions needed to achieve the decreases. EPA has not quantified the costs or benefits of follow-on activities, but believes there are net benefits to the follow-on activities.

The commenter has not provided any evidence to support the assertion that the costs of the proposal may outweigh the benefits. The commenter cites examples of Alar concerns and a Peruvian cholera epidemic to suggest that the public can overreact to information by taking actions that lead to net social costs. The commenter's examples do not constitute an actual analysis of possible responses to TRI information on PBT chemicals. The commenter fails to explain how these examples have any more relevance to this rulemaking than public concerns and reactions to DDT or the Bhopal, India disaster. EPA questions whether the commenter would argue that the public overreacted to these issues. EPA notes that the public did not "overreact" to two previous expansions of right-to-know information. In 1987, the first year of TRI reporting was received. In 1994, EPA expanded the list of reportable chemicals. In both cases, EPA believes that the public reacted responsibly to the expansion of public right-to-know. The commenter has provided no evidence that the reaction to the current rulemaking would lead to irresponsible, irrational behavior by the public.

With regard to the article by Viscusi cited by the commenter, EPA notes that it relates to *divergent* information from *multiple* sources. The author finds that when survey respondents are presented with a high and low risk estimates from different sources (in this case government and industry), the respondents tend to overweight the value of the high risk judgement. Respondents "veer toward the worst case judgement when there are two differing sources that disagree."

The article's findings actually support the reporting of additional information on PBT chemicals to TRI. Currently, there is no comprehensive multi-media, facility-level reporting of PBT chemicals. EPA has estimated the nationwide releases of certain chemicals (e.g., mercury) to a single media (e.g., air) from various industries (e.g., coal-fired electric utilities). These estimates are not based on facility-level reporting, but on "top-down" assumptions about emission factors and industry activity. Industry often disputes the resulting estimates. For example, in the case of air emissions of mercury, EPA has estimated nationwide releases of 51.6 tons per year from coal-fired utilities. By contrast, the Electric Power Research Institute estimate is 44 tons per year (Mercury Study Report to Congress, Vol 2, p. 4-2). TRI provides a "convergent" source of information on releases and other waste management of toxic chemicals in that industry develops facility-level data and reports it to the government. The results are then provided to the public, eliminating the potential confusion of divergent estimates. In this fashion, TRI serves as a "neutral yardstick" by which all affected stakeholders can measure progress. Therefore, the cited article actually supports the intent of this rule, and indicates that the benefits would exceed the costs.

Comment: A commenter (C-1448) disputes that changes in stock price levels in response to TRI information can be claimed as a benefit because this conclusion assumes that TRI information leads to a more accurate picture of companies' true values. The commenter notes that shareholders might not consider a decline in value of stock as a benefit.

Response: The commenter confuses private benefits with social benefits. If stock is overvalued because buyers and sellers lack information related to chemical releases and other waste management, then societal resources are not allocated efficiently. EPA notes that the collection and dissemination of other government data (inflation, unemployment, consumer confidence, SEC disclosures, etc.) may cause declines in stock prices, but that does not mean the information should not be released. Information, reflecting both good news and bad news, assists in the efficient functioning of markets by helping participants better understand the factors that contribute to the value of an asset.

Several studies have pointed to fluctuations in stock valuation as evidence that investors pay attention to information like TRI that indicates potential future liabilities associated with regulatory compliance, torts, or consumer reactions. EPA believes that the data reported to TRI help investors to incorporate the risks of major environmental liabilities, to assess the overall quality of management, or to verify that business practices are in accordance with investor preferences. This leads to more efficient pricing of assets.

EPA notes that the use of TRI data by the financial community is voluntary. Investors use TRI data to the extent it has proven useful in the past and to the extent they expect it to be useful in the future. EPA notes that if TRI information did not lead to a "more accurate picture of companies' true values," savvy investors would capitalize on this opportunity through purchases of the discounted stock. This would eventually drive the price back up, leaving shareholders unaffected.

Comment: A commenter (C-1448) questions whether examples of unions negotiating with companies during contract discussions to reduce a facility's use and release of TRI chemicals can be assumed to be a benefit to the company, the union employees, the surrounding community, or consumers of the goods and services provided by the facility without information on the risk those chemicals posed, and what the opportunity cost of those agreements were. The commenter questions whether the union could have negotiated a more comprehensive health and benefits package, or higher wages, which would have improved health and welfare more than the reduction in chemicals at the facility. The commenter asserts that information that focuses on certain factors (such as toxic chemical releases) can lead people to infer that other workplace issues (such as health benefits or salary) are less important to their health and safety. The commenter asserts that this may distort the market. The commenter claims that the positive correlation between income and health has long been recognized. One recent empirical study estimated that every \$15 million in regulatory costs results in one additional statistical death. (Lutter, Morrall and Viscusi, "The Cost per Life Saved Cutoff for Safety-Enhancing Regulations," Journal of Economic Literature, forthcoming.) The commenter concludes that it is not sufficient to conclude that the reduction in TRI chemicals triggered by the release of the data had a net positive impact on health or welfare.

Response: This comment is purely speculative, with no supporting evidence to indicate that voluntary agreements reached between unions and employers are detrimental to health and safety. There is no reason to believe that the commenter would be in a better position to judge on the benefits of union/employer agreements than the unions and businesses that developed those agreements. Furthermore, the commenter provides no evidence that unions are so blinded by TRI information that other health, safety, wage, and benefits information is ignored. The commenter appears to believe that unions are too unsophisticated to evaluate information from multiple sources relating to the health, safety, and welfare of their members.

EPA believes that unions are sufficiently experienced and sophisticated to evaluate any potential health, safety, and welfare tradeoffs involving their members. Unions have years of experience interpreting information from a wide variety of

sources including EPA, OSHA, and NIOSH and negotiating on behalf of their members. EPA does not believe that the availability of TRI information will cause unions to ignore other information of relevance to their members. EPA notes that the AFL-CIO submitted comments (C-1810) that support lowering TRI reporting thresholds:

We believe the proposal represents an important step towards strengthening this important source of information to workers and the communities in which they live. The Toxic Release Inventory can be a valuable source of information on employer practices, potential worker exposure to these chemicals and serve as a means of verifying information provided under other worker health and safety regulations...Workers must have complete information about these dangerous toxins in their workplaces and communities in order to protect themselves and their families as well as to create safer work environments.

The study the commenter references is part of a literature known as Health-Health Analysis (HHA). HHA is based on the observation that wealth and health status are positively correlated. According to HHA, if the costs of a regulation are large enough the reduction in wealth for those bearing the regulation's costs may lower their health status sufficiently that the resultant increased risks may be greater than the direct risk-reduction benefits of the regulation. To quantify the health risks associated with regulatory spending, HHA estimates a threshold value representing the dollar amount of regulatory compliance spending that induces one statistical fatality. If a regulation's average cost per life saved exceeds the threshold, HHA holds that the regulation probably will lower social welfare, because more lives would be lost than gained.

There are a number of shortcomings to HHA that make it inappropriate for making decisions about this rule. First, the HHA literature only addresses human mortality, and does not account for reductions in morbidity or environmental effects. Second, a key determinant in the calculation of the threshold value (the dollar amount of regulatory compliance spending that induces one statistical fatality) is the estimated value for the Marginal Propensity to Spend (MPS) on Health. There is great deal of uncertainty regarding the appropriate value to use for MPS on Health, which can have a significant impact on the estimation of the threshold value. In addition, most investigators seem to estimate this value using gross estimates of healthcare spending. Since the health-health models are considering only risks from mortality, the assumption appears to be that resources are devoted to healthcare to avoid mortality. However, gross estimates of healthcare costs may include amounts that individuals spend to avoid morbidity effects or to improve their quality of life (such as expenditures on birth control, cosmetic surgery, prosthetic devices, eye care, dental care, etc.). Thus, the value for MPS that is estimated may not be appropriate for calculating the impact on mortality.

Third, the value that is estimated for the threshold level is sensitive to assumptions about who bears the cost of the regulation. HHA models typically assume that costs are spread evenly throughout society. But if households with higher incomes bear more of the regulatory costs, the threshold value that is calculated would be significantly higher. For instance, if the costs are borne by a small number of wealthy corporate shareholders, there may be little or no impact on health outcomes.

Fourth, the estimates of induced fatalities are based on the existence of opportunity costs (the value of goods and services forgone as a result of spending for regulatory compliance). Health-health analyses assume that engineering-type compliance costs estimates equal opportunity costs. But engineering cost estimates may not reflect opportunity costs because the engineering estimates may be inaccurate or because they may not equal opportunity costs. There is ample evidence, as described elsewhere in this response to comments document, that EPA has overestimated compliance costs for many facilities reporting under EPCRA section 313. Furthermore, there can be significant differences between engineering and opportunity costs as economic adjustments take place over time. If opportunity costs are a fraction of estimated compliance costs, the HHA threshold values could rise to several times current estimates.

Fifth, HHA does not account for the fact that regulatory spending can lead to higher incomes for some people and, based on the HHA paradigm, improved health for them. If a regulation imposed a small cost on a large number of consumers but increased the employment and income of a small number of poorer workers, the indirect health impacts of the rule could be positive, not negative.

Sixth, there is an array of considerations that influence whether people find a risk to be acceptable, such as whether it is assumed voluntarily or borne involuntarily, whether the effect is immediate or is delayed, whether the risk is known with certainty or is not known, and whether it is a common hazard or a "dread" hazard. (For example, see "Of Acceptable Risk" by William Lowrance, William Kaufmann, Inc., 1976). Since people view some types of deaths (such as cancer) as being worse than others, society is willing to pay more to avoid these hazards. HHA assumes a uniform valuation of fatalities, and thus is not suited to decision-making about risks such as cancer from environmental exposure.

HHA assumes that all regulatory costs imposed on all firms affect individuals health spending in exactly the same way. However, market structure and other factors may alter this relationship. Estimates of thresholds may not accurately reflect the tradeoffs made by those bearing the costs of a regulation. Use of existing, mean threshold estimates may then provide biased indicators of whether the regulation passes a health-health test. As a review of HHA stated, "This approach [HHA] must also grapple with a fairly stringent standard of proof regarding the health impacts of regulation-induced changes in income or wealth. As outlined earlier, it is one thing to quote statistical evidence from a variety of sources on the income-health relationship, but it is quite another to make definitive and defensible quantitative statements about the impact of a specific regulation on particular subsets of the population. What would be needed is believable estimates of cost incidence and other transitory and permanent changes in income and wealth attributable to a particular regulation, and causal health-income relationships that are sensitive to the variety of factors that influence health status. The level of effort necessary to obtain robust results is likely to be substantial and probably beyond the value of the information to policy makers." ("On the Relevance of Risk-Risk Analysis to Policy Evaluation", Frank. S. Arnold, Environmental Law Institute, August 16, 1995.) The resource requirements of performing such studies would be significant. Applying HHA to these expenditures the same way that HHA advocates would apply it to regulatory expenditures would lead to the conclusion that the opportunity cost of this analytical expenditure could also lead to statistical fatalities. But HHA proponents have done nothing to demonstrate that the value of the ensuing information would justify the statistical fatalities that their own methodology would predict from this additional analysis.

The indirect effects hypothesized by the commenter are secondary effects. However, EPA has not included the secondary benefits of the rule in the analysis, and it would lead to a biased result to include secondary costs without the equivalent benefits. While the commenter states that reductions in chemical releases cannot be assumed to be beneficial without information such as the risks those chemicals posed, such information cannot be determined without the type of release data reported to TRI. As described in section 1.4.1 of the economic analysis for the rule, information-based strategies such as TRI can be more efficient than other approaches (such as command-and-control regulations) in the absence of sufficient information. Providing information may result in the adoption of voluntary (least-cost) release reductions instead of the need to require mandatory release reductions, or may result in the design of more efficient incentive or command-and-control programs. By improving efficiency, information provision results in more social resources being available for a variety of purposes, including health care. In sum, EPA disagrees with the commenters contentions, and believes that the available evidence demonstrates that TRI has had a net positive impact on health and welfare.

Comment: A commenter (C-1448) asserts that there is no evidence that compliance with regional and international goals for reducing levels of PBT chemicals would represent net social benefits.

Response: The commenter is vague about which regional or international goals are at issue. The commenter has not identified any binding agreements, as opposed to voluntary or non-binding goals, which might lead to net social costs.

The goal of the rule is information collection and provision. TRI allows interested parties to evaluate chemical releases of toxic chemicals and other waste management activities. As such, TRI information provides one component of the information that would be required to evaluate whether compliance with regional and international goals for reducing levels of PBT chemicals would result in net social benefits. It would be difficult or impossible to attempt to make a quantitative determination of the net social benefits of reducing PBT pollution (complying with regional or international goals) without detailed information on what facilities release PBT chemicals and in what amounts. Perhaps this is why the commenter's analysis of the issue is limited to a single sentence.

Comment: A number of commenters (C-1457) assert that EPA has not shown significant benefit associated with the burden imposed by eliminating the *de minimis* exemption for PBT chemicals. One commenter (C-1820) asserts that requiring sources to undertake threshold calculations for *de minimis* substances in the fuel they burn poses an unnecessary burden with no benefit.

Response: EPA believes that allowing facilities to continue to take the *de minimis* exemption for PBT chemicals would deprive the public of important information. Facilities with large throughputs of materials containing a PBT chemical at concentrations less than 0.1 percent or 1 percent may exceed the lower reporting threshold for the PBT chemical, but not report the PBT chemical releases and other waste management activities unless the *de minimis* exemption is eliminated. If the *de minimis* exemption is eliminated, facilities with identical amounts of PBT chemicals would report to TRI regardless of the concentration at which the PBT chemical is found. This is important because chemicals that exist in mixtures persist and bioconcentrate in the environment and in organisms, even if they are present at below the current *de minimis* concentrations.

EPA disagrees that requiring sources to undertake threshold calculations for substances in the fuel they burn poses an unnecessary burden with no benefit. Performing the threshold calculation allows certain facilities that do not exceed reporting thresholds to avoid the further work associated with estimating and reporting on releases and other waste management activities. These thresholds were proposed to reduce the burden on industry. Without performing the threshold calculations, facilities would not know what chemicals they were required to report for. Although one can imagine an alternative that would require facilities to report on all chemicals, whether they are above the threshold or not, EPA has not taken such an approach. While EPA agrees that there is a burden to performing this compliance determination, the Agency does not believe that it is unjustified.

With regard to the importance of release reporting from facilities that combust fuels, EPA notes that combustion of fuel containing less than one percent of PBT chemicals can result in substantial releases. For example, a typical concentration value for mercury in coal is 0.21 ppm, which is well below current *de minimis* concentrations. Nevertheless, combustion of coal by electric utilities and industrial/commercial boilers is estimated to result in over 140,000 pounds of mercury releases to air per year. This is estimated to be over 45 percent of all mercury released to the atmosphere by anthropogenic sources in the United States (see Economic Analysis of the Proposed Rule to Modify Reporting of PBT Chemicals under EPCRA Section 313, p. F-3).

With regard to the burden imposed by the elimination of the *de minimis* exemption, EPA notes that EPCRA does not require additional monitoring or sampling. Information used for reporting may include production records, monitoring, or analytical data, guidance documents provided by EPA and trade associations and reasonable judgement on the part of the facility's management. Even with the elimination of the *de minimis* exemption for PBT chemicals, no further monitoring or analysis of production, process, or use is required of covered facilities.

Comment: A commenter (C-446) asserts that removing the *de minimis* exemption would lead to over-reporting by facilities just to ensure compliance and would produce potentially significantly misleading and inaccurate data. The commenter asserts that the likelihood of this scenario occurring is compounded in light of EPA's proposal to disallow reporting in ranges for PBT chemicals. The commenter asserts that given the virtually impossible task to detect, accurately calculate/estimate, and ultimately account for very small amounts of PBT chemicals used, EPA's proposal would call for a disproportionate amount of dedication of resources by reporting facilities, while yielding no additional environmental benefit.

Response: EPA's economic analysis of the proposed rule accounted for costs that are attributable to reporting required by the rule. EPA's estimates assume that threshold calculations will be conducted for PBT chemicals without regard to *de minimis* levels, and that reporters cannot use ranges. EPA believes that it is inappropriate to consider the cost of activities, such as voluntary reporting, which are not required by the terms of EPCRA section 313 or this rule. EPA notes that the commenter has not provided any estimate of the number of facilities that would file voluntary reports out of fear of theoretical EPA enforcement actions. EPA further notes that EPCRA does not require additional monitoring or sampling. Information used for reporting may include production records, monitoring, or analytical data, guidance documents provided by EPA and trade associations, and reasonable judgement on the part of the facility's management. EPA agrees that there is a cost associated with reporting on PBT chemicals, and has estimated these costs in its economic analysis. However, EPA does not agree that reporting is impossible, or that it would produce significantly misleading and inaccurate data. The commenter has not provided any evidence that this would be the case. Given the concerns presented by PBT chemicals and the demand for additional information on the releases of PBT chemicals and other waste management activities, EPA believes that the benefits of its proposal would exceed the costs.

Comment: A commenter (C-1424) asserts that the proposed rule will greatly expand the number of reports for PCBs without any appreciable increase in information about PCB releases. The commenter notes that EPA has estimated that the "chief contributors" to PCB emissions are municipal, medical, and hazardous waste incinerators that are already subject to TRI reporting under current thresholds. The commenter notes that the new reporting facilities are those that combust the assumed 10% of all residual fuel oil that contains PCBs. The commenter asserts that these sources in total contribute at most 0.1% to all PCB releases to air. The commenter suggests that if further information is needed it should be achieved through SIC code revisions to capture all emitters rather than through threshold revisions.

Response: EPA does not agree that the proposed rule will greatly expand the number of reports for PCBs without any appreciable increase in information about PCB releases. EPA notes that PBT chemicals present concerns for human health and the environment in small amounts; each TRI report represents information from a facility that is manufacturing, processing, or otherwise using a PBT chemical above the applicable threshold. For PBT chemicals, the contribution of a single facility or

class of facilities to total national emissions does not necessarily indicate whether reporting is warranted, because PBT chemicals can present concerns in very small amounts. A facility or industry may be of significant concern to a local community even if releases from that facility do not constitute a major proportion of national releases. EPA also notes that the commenter ignores any information that TRI reporting would provide about PCB releases to land or water from these same sources.

EPA notes that, contrary to the commenter's assertion, municipal and medical waste incinerators are not subject to reporting under EPCRA Section 313. EPA may consider further additions to the list of industries subject to reporting, but is not adding any industries at this time.

Comment: Two commenters (C-1417, C-1445) assert that the removal of the dust and fume modifier from the vanadium listing and the addition of the vanadium compounds category will cause "significant adverse economic effect without commensurate benefit." The commenters note that vanadium is not listed in the National Recommended Water Quality Criteria and many vanadium compounds are insoluble in water. One commenter notes that his facility derives no economic benefit from vanadium, but that reporting to TRI would represent a cost to the facility.

Response: EPA does not believe that the removal of the dust and fume modifier from the vanadium listing and the addition of the vanadium compounds category will cause "significant adverse economic effect without commensurate benefit." As discussed in elsewhere in this document, vanadium and vanadium compounds meet the applicable EPCRA section 313 (d)(2) listing criteria. Without this rule, communities will not have access to information on the releases of vanadium and vanadium compounds and other waste management activities from the facilities that will report on vanadium in forms other than fume or dust and on vanadium compounds.

The status of the National Recommended Water Quality Criteria has no relevance to the status of vanadium or vanadium compounds as TRI chemicals. EPA notes that vanadium is listed in Table V (Toxic Pollutants and Hazardous Substances Required to be Identified by Existing Dischargers if Expected to be Present) of 40 CFR Part 122 Appendix D (NPDES Permit Application Testing Requirements). EPA notes that vanadium is also listed on the Drinking Water Contaminant Candidate List: a list of chemicals that are not subject to any proposed or promulgated national primary drinking water regulations, which are known or anticipated to occur in public water systems, and which may require regulation. EPA also notes that, in addition to water, vanadium and vanadium compounds can be released to air or land.

Finally, EPA acknowledges that the reporting of vanadium and vanadium compounds will be associated with additional costs as described in EPA's economic analysis of the proposed rule. However, the commenter has not disputed the EPA's specific estimates as presented in the economic analysis for the proposed rule. EPA believes that the 655 additional reports on vanadium and vanadium compounds does not represent a "significant adverse economic effect without commensurate benefit." In addition, the commenter appears to confuse social and private benefits. The benefits of the proposal accrue to society through the provision of additional information on the releases of toxic chemicals and other waste management activities. The public is interested in toxic chemicals like vanadium because of concerns for human health and the environment. This is unrelated to whether the commenter derives private economic benefit from the use of vanadium at the commenter's facility.

Comment: Several commenters (C-1352, C-1436, C-1448, C-1870) dispute whether TRI offers benefits to regulated industries themselves by revealing information that encourages changes in processes that reduce costs. One commenter claims that "economic theory" does not support the notion that mandating the public release of private information would offer the provider of the information any opportunities to increase efficiency and lower costs that it did not already have. Another commenter contends that EPA need not develop strategies to address metals as part of its waste minimization and pollution prevention efforts, because the overwhelming majority of metals reported under the TRI program already are recycled, and there is only limited opportunity to realize additional waste minimization. A third commenter asserts that there is no benefit to the public in lowering the reporting threshold for pendimethalin to encourage waste minimization because adequate incentives and requirements already exist. The commenter notes that pendimethalin is a commercial product so manufacturers have incentives to minimize losses to waste. The commenter also notes that a recent rule regulating wastewater discharges requires facilities to meet a "zero pollutant discharge" requirement or implement certain pollution prevention practices.

Response: In general, if a chemical can be recycled or sold as a product, firms have an incentive to spend up to the price of the product to prevent releases. However, the health and environmental damages caused by these releases may mean that it would be socially optimal to spend more to prevent releases. For instance, if the price of a chemical is \$10 per pound, a firm may be willing to spend up to \$10 to prevent a pound of this chemical from being released. However, the firm would not be willing to

spend \$15 to recapture a pound of chemical that is only worth \$10. But if each pound of the chemical released causes \$25 per pound of damages to human health and the environment, the purchase price of the chemical provides an insufficient incentive to control releases to the socially optimal level. EPA does not believe that the fact that a chemical is a commercial product or is recycled necessarily provides sufficient financial incentives to limit releases to the socially optimal level.

Furthermore, reporting under TRI impacts a facility's toxics management practices in ways that are unique compared to other data collections. Evidence suggests that the exercise of TRI reporting creates an important incentive for the implementation of pollution prevention measures and provides reporters with the information necessary to monitor progress toward emissions reductions. For example, the General Accounting Office (GAO) surveyed over 800 randomly selected TRI reporting facilities and showed a substantial response in seeking out environmental management opportunities as a result of TRI reporting. The administrative changes most frequently occurring, as reported by survey respondents, were improved inventory controls (39 percent); improved chemical use controls (30 percent); and use of alternative chemicals (30 percent). (General Accounting Office; *Toxic Chemicals: EPA's Toxics Release Inventory is Useful But Can be Improved*, 1991.) In addition, current TRI reporters have made statements indicating that TRI reporting has impacted their toxics management practices in ways that are clearly unique to TRI:

It's not necessarily that we didn't want to [reduce emissions] before. We never had the information we needed to know if progress was being made. (Statement by Steven Schoger, BP Chemicals (Cleveland, Ohio) in Occupational Hazards, July 1991 as cited by Working Group on Community Right-To-Know newsletter, July 6, 1995.)

As we considered the data -- data representing a potentially powerful new form of disclosure -- we recognized that the numbers, and what the numbers represented, were unacceptable...Thus we announced our goal to reduce toxic air emissions worldwide 90 percent by the end of 1992, and then to work toward the ultimate goal of zero. (Statement by Richard Mahoney, Monsanto (September, 1993) as cited by Working Group on Community Right-To-Know newsletter, July 6, 1995.)

From our company's point of view, [TRI] helped us to discover a problem that we weren't even aware of. We discovered we had leaking sewers and potential contamination of our water supplies. (Statement by Richard Harding, Eastman Gelatine in the North Shore Sunday (Danvers, Mass., August 12, 1990) as cited by the Working Group on Community Right-To-Know newsletter, July 6, 1995.)

The exercise of reporting this information has really increased awareness a lot. There are a lot of organizations and facilities paying attention now. (Statement by Heidi Grether, Michigan Manufacturers Association in The Ann Arbor News, January 27, 1992 as cited by Working Group on Community Right-To-Know newsletter, July 6, 1995.)

For the first time, engineers have had to scrutinize their processes as a whole and quantify the wastes released to all media...in some cases [this] has revealed valuable information for process improvements. (Statement by Elizabeth Fisher, Rohm and Haas at the Proceedings, International Conference on Reporting Releases of Toxic Chemicals, November, 1991 as cited by the Working Group on Community Right-To-Know newsletter, July 6, 1995.)

Revealing these numbers in terms of pounds per year rather than the pounds per hour or the parts per million we had tended to think about raised a lot of eyebrows within industry as well as within the community. And a lot of -- a lot of our leadership looked at numbers that were in the hundreds of thousands of pounds per year and said that's too much -- (A) it's too much to expect the community to accept; and (B) it's too much product for us to be wasting by releasing it into the environment. (Statement by Mort Mullins, Vice President, Regulatory Affairs, Chemical Manufacturers Association Morning Edition/National Public Radio, December 5, 1996.)

These comments provide strong evidence that TRI reporting has motivated reductions in toxic emissions; however, they also suggest that reporters did not have the information necessary to monitor their pollution prevention efforts and in some cases were not aware that releases were occurring despite existing reporting requirements (*i.e.* AIRS and PCS). TRI has been shown to motivate voluntary pollution prevention measures and inform facilities of releases for which they were not previously aware or had not quantified in a meaningful way to measure progress toward pollution prevention objectives.

Comment: A commenter (C-1857) states that because of concerns about the characterization of metals as PBT chemicals, the commenter questions whether the increased record keeping and reporting burdens are justified, and whether the public is being provided meaningful information on metals and their associated risks.

Response: As discussed in elsewhere in this document, EPA believes that the characterization of metal and metal compounds compounds as PBT chemicals is scientifically justified. The persistence, bioaccumulative properties, and toxicity of certain metals and metal compounds, such as mercury and mercury compounds, create human health and environmental concerns which justify the burden associated with informing the public about releases and other waste management of these chemicals. Therefore, EPA believes that the increased record keeping and reporting burdens are justified, and the public will be provided meaningful information on metals by increasing the number of reports received by EPA.

Comment: A commenter (C-1861) notes that even if some facilities believe they cannot determine thresholds or releases for some of the PBT's at such low thresholds, they cannot disregard the obligation to determine whether this in fact is the case. The commenter asserts that the cost to facilities to conduct these initial applicability determinations could be outweighed by the fact that many of the facilities ultimately may not submit reports on the PBT's because they have concluded that they either do not exceed the thresholds or simply do not have the data or methodology to report the PBT's. The commenter further asserts that the cost of compliance may be further outweighed by the fact that any resulting reports may not provide the public with useful information.

Response: EPA acknowledges that facilities will incur costs associated with compliance determination for reporting on PBT chemicals. EPA's economic analysis of the proposed rule estimated that compliance determination would take an average of 2.4 hours per facility in the first year and 0.6 hours per facility in subsequent years for the PBT chemicals as a group. The estimates for compliance determination for the PBT chemicals are incremental to the time currently required for compliance determination for existing reporting requirements. All 190,497 facilities with 10 or more employees that are in SIC codes subject to reporting under EPCRA Section 313 must carry out compliance determination activities. EPA estimated that, for the preferred option as presented in the proposal, the cost of compliance determination would be \$31 million in the first year and \$7.8 million in subsequent years

EPA does not believe that the costs of compliance determination are unreasonable. Based on EPA's economic analysis of the proposed rule, compliance determination costs for PBT chemicals would be responsible for approximately 25 percent of total costs in the first year and 11 percent of total costs in subsequent years. Compliance determination allows certain facilities that do not exceed reporting thresholds to avoid the further work associated with estimating and reporting on releases and other waste management. EPA proposed activity thresholds to reduce the burden on industry. While EPA agrees that there is a burden to performing this compliance determination, the Agency does not believe that it is unjustified.

Finally, EPA believes that the resulting reports will provide the public with useful information. As EPA has stated elsewhere in this document, the additional information provided by TRI reporting on PBT chemicals will allow the public to better evaluate the risks posed by PBT chemicals and inform decision making at a variety of levels.

Comment: A commenter (C-1448) asserts that based on the titles of publications by community and public interest groups, these reports may serve more to frighten than to educate. The commenter notes that Beales, Craswell, and Salop observe that scale economies in information generation and dissemination can lead to natural monopoly problems which convey high levels of market power on information intermediaries. The commenter contends that whether such efforts provide net social benefits depends, in large part, on whether the alarm they generate is worthy of the risks they seek to mitigate, or whether it causes unnecessary fear and non-productive actions. The commenter quotes Viscusi (1997) who noted, "media and advocacy groups often highlight the worst case scenarios, which tend to intensify the kinds of biases [in weighting high risk information more heavily than is rational] observed here [in his interactive computer survey]."

Response: Although the commenter contends that these reports by community and public interest groups "may" serve more to frighten than to educate, the commenter bases the assertion entirely on the titles of the publications. The commenter provides no evidence that the reports based on TRI information are inaccurate, that they in fact frighten the public, or that they do not educate the public about releases of toxic chemicals. What is certain is that the commenter provides no substantive evaluation of the content of these studies. Any critique based solely on the title of a report would have to be classified as superficial.

The commenter asserts, based on an article by Beales *et al.*, that scale economies in information generation and dissemination can lead to natural monopoly problems which convey high levels of market power on information intermediaries.

However, the commenter fails to mention that the natural monopoly problems discussed in the article relate to information that is provided *through the private market*. Furthermore, the authors of the article conclude that even for information provided through the private market, “scale economies are often small enough to make the natural monopoly problem insignificant.” (p. 505). Unlike information provided through the private market, the entire TRI data set is distributed without charge through public channels. The commenter fails to note that TRI information is equally available to trade associations, private industry, academia, and think-tanks, all of whom are free to contest the findings of community and public interest groups. These competing information intermediaries include the Chemical Manufacturers Association, the American Petroleum Institute, and the Mercatus Center at George Mason University (the commenter). Therefore, it seems highly unlikely that there would be any problems associated with monopolistic control of the information in the publically available TRI database.

With regard to Viscusi’s observation that media and advocacy groups often highlight worst case scenarios, EPA notes that TRI provides a neutral yardstick by which all affected stakeholders can measure progress by industrial facilities in reducing releases of toxic chemicals. The information supplied to TRI comes directly from industrial facilities. If anything, this would tend to narrow the range of scenarios by providing facility-level release and waste transfer information. In the absence of TRI reporting, members of the public who are concerned about toxic chemical releases may be forced to guess about facility-level releases without the benefit of any facility-specific information to inform their assumptions. By providing information directly from facility personnel who are most knowledgeable about their operations, TRI provides reliable information to narrow the range between best and worst case scenarios. Therefore, EPA believes that the rule provides net social benefits by providing the public with more reliable information that can be used to evaluate the release and other waste management of PBT chemicals.

7.f. Regulatory assessment issues

Commenter list: C-849/403, C-1353, C-1407, C-1421, C-1431, C-1431b, C-1435, C-1438, C-1448, C-1815, C-1841, C-1843, C-1846, C-1850, C-1857, C-1858, C-1863, C-1865

7.f.1 Executive Order 12866

Comment: A commenter (C-1421) claims that although EPA appears to be attempting to present a cost/benefit type of rationale for the proposed thresholds, EPA has conducted no cost/benefit analysis of the rule.

Response: EPA’s cost-benefit analysis was contained in the economic analysis for the proposed rule (*Economic Analysis of the Proposed Rule to Modify Reporting of Persistent Bioaccumulative Toxic Chemicals Under EPCRA Section 313*), which was reference 79 in the Federal Register notice. The economic analysis contains a quantitative estimate of the costs and a qualitative discussion of the benefits of the rule. This document, and its supporting documentation, were included in the public docket for review and comment. The economic analysis for the final rule has also been placed in the public docket.

Comment: Commenters (C-1421, C-1850) claim that the proposal is inconsistent with the requirements of Executive Order 12866 because the proposed regulation is not required by law, is not necessary to interpret the law, and has not been made necessary by a compelling public need.

Response: The proposal is not inconsistent with Executive Order 12866. Section 1(a) of Executive Order 12866 states that “Federal agencies should promulgate only such regulations as are required by law, necessary to interpret the law, or are made necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people.”

EPA addressed the market failures that create the need for the rule in section 1.4 (*Statement of Need*) of the economic analysis, as well as in Unit X.A of the preamble (64 FR 719). Given the potential for PBT chemicals to create adverse effects on humans and the environment, EPA believes that it has demonstrated a compelling need to lower the reporting threshold for these chemicals. Gathering more information on PBT chemicals by lowering reporting thresholds is an important step in protecting and improving the health and safety of the public, the environment, and the well-being of the American people.

Thus, this rule is consistent with the principles of Executive Order 12866 because it is “made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, environment, or the well-being of the American people.”

Comment: Commenters (C-1421, C-1843) claim that the proposal is inconsistent with Executive Order 12866 because EPA has not considered the option of no additional regulation, and did not present the baseline in its economic analysis or preamble.

Response: The proposal is not inconsistent with Executive Order 12866. EPA did consider the option of not regulating, and addressed what would happen in the absence of this rule (which is the baseline). As EPA noted in the preamble, "If EPA were not to take this proposed action adding certain PBT chemicals and lowering reporting thresholds, the market failure (and the associated social costs) resulting from the limited information on the release and disposition of PBT chemicals would continue" (64 FR 719). The discussion of costs and benefits in the economic analysis and preamble are all relative to the baseline of not regulating beyond the current list of toxic chemicals and the current reporting thresholds.

Comment: Commenters (C-1438, C-1843) assert that EPA has ignored Executive Order 12866 because the proposal does not evince any concern for cost-effectiveness.

Response: EPA has not ignored EO 12866. EPA notes that section 1(b)(3) of Executive Order 12866 states that "Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, *or providing information upon which choices can be made by the public*" (emphasis added). TRI provides the public with information that improves decision making. EPA examined various possible types of regulation in section 1.4.1 of the economic analysis for the rule and found that when there is a lack of sufficient information (as is the case with PBT chemicals), information-based strategies such as TRI can be more cost-effective in addressing externalities than other approaches (such as command-and-control regulations). Lowering reporting thresholds for PBT chemicals under EPCRA section 313 is a cost-effective alternative to direct command and control regulation of releases and other waste management practices for these chemicals, and is consistent with the intent of Executive Order 12866.

Comment: A commenter (C-1438) asserts the proposal is inconsistent with Executive Order 12866 because that EPA has not tailored its regulatory requirements to impose the least burden on businesses.

Response: The proposal is not inconsistent with Executive Order 12866. Section 1(b)(11) of EO 12866 states that "Each agency shall tailor its regulations to impose the least burden on society, individuals, businesses of different sizes, and other entities (including small communities and governmental entities), *consistent with obtaining the regulatory objectives ...*" (emphasis added). As EPA noted in the proposal, "In choosing the proposed EPCRA section 313 thresholds for these PBT chemicals EPA took into consideration a number of factors including small business impacts, overall reporting burden, and report generation in addition to utility of the information. It has been EPA's goal, under the EPCRA section 313 program, to maintain a balance between community right-to-know and overall reporting burden for the affected industry" (64 FR 712). Furthermore, existing burden-reducing measures (e.g., the laboratory exemption, and the otherwise use exemptions, which include the routine janitorial or facility grounds maintenance exemption, motor vehicle maintenance exemption, structural component exemption, intake air and water exemption and the personal use exemption) will continue to apply to the facilities that file new reports as a result of this proposed rule. EPA also will be assisting small entities subject to the proposed rule, by such means as providing meetings, training, and compliance guides in the future, which also will ease the burdens of compliance. EPA believes that it has tailored its regulation to impose the least burden, consistent with obtaining the regulatory objectives of EPCRA section 313.

The primary objective for this rulemaking is to address one of the most significant gaps in the information currently reported under EPCRA section 313 -- information on releases and other waste management practices relating to PBT chemicals. Addressing this gap will improve the usefulness of the range of data on these chemicals and will provide the public, government agencies, and researchers with access to critical information on PBT chemicals that can be used for many purposes, including, for example, to track the progress of national and international efforts addressing concerns about PBT chemicals. Throughout the course of this rulemaking, EPA was sensitive to the burdens the rule might impose. Any further steps taken to minimize the burden of this rule would necessarily lower the degree to which the rule obtains the intended regulatory objective.

Comment: Commenters (C-1438, C-1843, C-1850) state that EPA should have considered and issued for public comment a wider range of alternatives. Executive Order 12866 requires agencies to "identify and assess the available alternatives to direct regulation" [section 1(b)(3)] and to "identify and assess alternative forms of regulation" [section 1(b)(8)]. However, EPA has limited the scope of alternatives to a variety of different threshold levels. Consistent with Executive Order 12866 EPA should have considered and presented for public comment other regulatory options, such as expanding the SIC codes subject to the program, expanding the manufacturing-only qualifier from dioxin to all PBTs, and using a multi-year Form R, as well as non-regulatory options such as voluntary reporting programs.

Response: Section 1(b)(3) of EO 12866 states in full that “Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or *providing information upon which choices can be made by the public*” [emphasis added] One of the key purposes of the regulations under EPCRA 313 is to provide information upon which choices can be made by the public. Therefore, not only is the regulation not inconsistent with section 1(b)(3) of Executive Order 12866, but it is exactly the type of regulation that is envisioned by the Executive Order as an alternative to command and control regulations that directly limit or reduce the emissions of chemicals.

Similarly, section 1(b)(8) states that “Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.” EPA has, to the extent feasible, avoided specifying the manner of compliance that facilities must adopt to achieve the objective of providing information on the quantities of toxic chemicals that they have released, transferred, or managed as waste. EPA believes that facilities themselves are in the best position to determine how to make these estimates. Thus, the section 313 regulations allow facilities to determine what calculation methodology best suits their facility (such as monitoring data, mass balance calculations, emission factors, engineering calculations, or engineering judgement), instead of requiring all facilities to use a particular emission factor or an identical methodology in all circumstances. Therefore, EPA believes that the regulations comply to the extent feasible with section 1(b)(8) of Executive Order 12866.

The commenters state that EPA should have considered and presented additional options for comment. EPA considered a reasonable number and range of alternatives, and specifically asked for comment on several of these. For instance, EPA specifically requested comment on whether it should consider an alternate threshold and reportable quantity for PBT chemicals, whether it should establish a lower *de minimis* threshold instead of eliminating the *de minimis* threshold for PBT chemicals, and whether to modulate the reporting frequency for the lower thresholds (64 FR 718). Moreover, the commenters were free to express their opinions on additional options beyond those that EPA specifically requested comment on, and a number of commenters did so. However, EO 12866 does not require, nor was it feasible, for the economic analysis to address all the options suggested by the commenters.

Comment: Commenters (C-1421, C-1843) assert that the proposal is inconsistent with Executive Order 12866, which states that agencies should propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Commenters also claim that EPA has not followed Executive Order 12866 because EPA has not quantified benefits to the fullest extent possible, because EPA did not make predictions of the volumes of releases that would be reported under various options.

Response: The proposal is consistent with Executive Order 12866, as EPA did propose the regulation upon a reasoned determination that the benefits justify the costs. The commenters seem to imply that EPA must monetize benefits and compare them to costs in order to be consistent with Executive Order 12866. However, Executive Order 12866 does not require agencies to make a determination that quantified benefits exceed quantified costs. Section (1)(a) of Executive Order 12866 states that “Costs and benefits shall be understood to include both quantifiable measures (*to the fullest extent that these can be usefully estimated*) and *qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider*” [emphasis added]. The Executive Order goes on to state in Section (1)(b)(6) that “Each agency shall assess both the costs and the benefits of the intended regulation and, *recognizing that some costs and benefits are difficult to quantify* [emphasis added], propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.” EPA’s economic analysis has addressed the costs of the proposal in a quantified manner and the benefits in a qualitative manner. Upon review of this evidence, EPA has made a reasoned determination that the benefits of the regulation justify its costs. Therefore, EPA believes that this rulemaking follows the principles of Executive Order 12866.

EPA disagrees with the contention that because it has not estimated the volume of releases that would be reported under various options, it has not quantified benefits to the fullest extent possible. As explained in Section 7.A of this response to comments document, EPA does not believe that it can reliably (and thus usefully) estimate the quantity of releases that will be reported as a result of this rule. As explained in detail in section 7.C of this response to comments document, releases are not a measure of benefits. EPA disagrees with the implicit assumption that the benefits of information from different facilities is a monotonic function of the quantity released. Such an assumption incorrectly presumes that the benefit to the public to know about a release of 20,000 pounds is twice as large as the benefit of knowing about a release of 10,000 pounds; and that the benefit of knowing about a 40,000 pound release is twice the benefit of knowing about a 20,000 pound release, and four times the benefit of knowing about a 10,000 pound release. Since the benefit of information from different facilities is not based on the amount released, even if releases could be reliably predicted they would not be a useful quantification of benefits.

Executive Order 12866 recognizes that it may not be feasible to derive quantitative estimates of benefits in all cases. The value of information falls into this category. Because the state of knowledge about the economics of information is not highly developed, EPA has not attempted to quantify the benefits of the rule. Comparing the cost of the reporting to the quantity that would be reported does not compare costs and benefits. Section 313(g) of EPCRA states that the data are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities, to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes. The quantity of releases reported does not measure how well the data performs these functions, and thus releases are not a measure of benefits. The benefits of the rule include improvements in understanding, awareness, and decision making related to the provision of information. Even if reliable estimates of releases were possible, pounds of releases would not measure of the value of the information provided. Improvements in understanding are not measured in pounds, nor are improvements in awareness or decision making.

While it is not possible to quantify the benefits of the rule, EPA has qualitatively examined the benefits of the rule. Based on this review, EPA believes that the benefits provided by the information to be reported under this rule will significantly outweigh the costs. EPA further believes that it has met all of its obligations under Executive Order 12866.

7.f.2 Paperwork Reduction Act

Comment: Commenters (C-1421, C-1815, C-1850) claim that EPA has not met the requirements of the Paperwork Reduction Act because EPA has not prepared a separate ICR that addresses the burden for this rulemaking, but rather only an addendum to the existing ICR for TRI reporting. These commenters state that EPA is incorrect in asserting that the proposed rule does not contain any new information collection requirements or expand the universe of potential respondents because threshold under the proposal are lower, chemicals are added, and an estimated 2,600 facilities report for the first time under the proposal. The commenters asserts that this is a significant departure from the statutorily mandated information collection requirements, thus a new ICR is required. In addition, the commenters claim that new individual reporting requirements for vanadium, and alkyl lead are also proposed, requiring authorization by the Office of Management and Budget. The commenters claim that EPA submitted a separate ICR when it expanded the list of industrial groups subject to TRI.

Response: EPA did not fail to meet the requirements of the Paperwork Reduction Act (PRA). Typically, EPA only prepares a separate ICR when there are substantial changes to an information collection. EPA did not need to submit a separate ICR to the Office of Management and budget (OMB) with the proposed rule because the basic information collection activities currently approved under the existing ICR remain unchanged. The proposed rule would not change the underlying information collection activity itself (*i.e.*, the potential respondent universe, respondent activities, use of Form R, and recordkeeping). Similarly, the final rule does not change the potential respondent universe or the recordkeeping requirements, and makes only minor changes to the Form R. As such, EPA must only request that the burden hours related to the amendments be added to the existing OMB approval before EPA can impose the reporting at the lower reporting threshold. In such cases, an increase in the total burden hours approved by OMB can be accomplished with an Information Correction Worksheet submitted to OMB with the Final Rule. Although information on burden and costs were included in the Economic Analysis for the proposal, EPA also included this information in an addendum to the existing ICR that was submitted to OMB.

As indicated in Unit VII.C of the preamble to the proposed rule, the information collection activities contained in 40 CFR 372 are approved by OMB under the PRA. OMB has assigned OMB Control number 2070-0093 to this activity, which includes the use of EPA Form R. The existing approval is not affected by the January 5, 1999 proposed amendments to 40 CFR 372 until the final rule is issued and OMB has approved the related burden under the PRA.

The January 5, 1999 proposed amendment would lower the reporting threshold that would trigger reporting under 40 CFR 372, thereby increasing the number of Form Rs that would be submitted to EPA, and the total burden related to the information collection activities contained in 40 CFR 372, as amended. As proposed, the existing information collection activity would remain the same, (*i.e.*, EPA would continue to use the Form R and any respondent required to report under the lower threshold would answer the same questions as those reporting on Form R at the existing threshold). The universe of potential respondents remains limited to the facilities covered by the existing approval (*i.e.*, those with the equivalent of 10 or more full-time employees that are in a Standard Industrial Classification (SIC) code listed under 40 CFR 372.22 -- major group codes 10 (except 1011, 1081, and 1094), 12 (except 1241), or 20 through 39; industry codes 4911, 4931, or 4939 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); 4953 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. section 6921 et seq.), 5169, 5171, or 7389 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis)). The per activity burden associated with completing a Form R is estimated to remain the same. All of this is clearly presented in the Economic Analysis for the proposed rule, the preamble to the proposed rule, and the ICR document that EPA submitted to OMB. All of these documents were also made available as part of the public version of the official rulemaking record for the proposed rule.

Although the Agency has estimated that there may be some additional facilities that would submit a Form R for the first time under the proposed lower reporting thresholds, these facilities are not being added to the potential respondent universe. The existing ICR approved by OMB already covers any facility within the specified SIC codes listed in 40 CFR 372.22 with the equivalent of 10 or more full-time employees, including any facility that may manufacture, process, or otherwise use any of the listed toxic chemicals, or any of the chemicals proposed for addition. The proposed amendments do not in any way add any new facilities to those that are already covered by 40 CFR 372.22. As such, the potential respondent universe remains the same.

In response to comments received on the proposal, EPA is making minor changes to the Form R in conjunction with the final rule. Namely, when a facility has information on the distribution of dioxin and dioxin-like compounds the facility must report either the distribution that best represents the distribution of the total quantity of dioxin released to all media from

the facility or its one best media-specific distribution. Because this is not a substantial change to the Form R, a separate ICR is not needed.

Because the rule does not change the potential respondent universe or the basic information collection activities associated with Form R, the Agency believes it is appropriate to submit an addendum to the existing ICR instead of a separate ICR. Furthermore, EPA notes that the information in the complete addendum package (including appendices) is essentially the same information that would be included in a separate ICR. EPA attached a copy of the existing, approved ICR (EPA ICR #1363.06) as an appendix to the ICR addendum. EPA referenced that ICR where the information for this rulemaking was the same as in the existing ICR; EPA provided specific responses in the addendum where the information was unique to this rulemaking. Therefore, EPA provided OMB and the public with the information needed to comply with the PRA in either the body of the ICR addendum or the appendix containing the existing ICR. The ICR addendum package basically differs only in title and organization from a separate ICR. EPA believes that its actions in this rulemaking have complied with the requirements and procedures of the PRA, its implementing regulations and OMB guidance, as well as EPA guidance.

Comment: A commenter (C-1865) asserts that EPA's ICR for the proposal was not submitted as required. The commenter asserts that OMB must be provided with a copy of the ICR not later than the date on which the notice of proposed rulemaking is published in the Federal Register. The commenter asserts that OMB did not receive the ICR from EPA until February 24, 1999, which is 49 days after the proposed rule was published. Since OMB did not receive the ICR until February 24, 1999, the OMB 60 day period would not end until April 26, 1999. However, the public comment period ended on April 7, 1999. The commenter believes that it is appropriate for OMB to disapprove the ICR and suspend the action until the identified deficiencies are corrected. The commenter further contends that OMB is obligated to respond to the ICR within 60 days of the proposed rulemaking. The commenter contends that OMB's review period for the ICR did not coincide with the public comment period for the rule.

Response: While the Agency acknowledges that the ICR addendum was not submitted to OMB on the day that the proposed rule published in the Federal Register, both OMB and the public were nevertheless afforded the requisite timeframe to review and comment on the ICR addendum. The PRA regulations provide that OMB may choose to disapprove an ICR because it was not submitted to OMB on the day that the proposed rule published in the Federal Register (5 CFR 1320.11(d)). In this case, however, OMB did not choose to exercise this authority.

The PRA regulations specify that OMB may file comments within 60 days of publication of the proposed rule (5 CFR 1320.11(c)), however, OMB must allow at least 30 days after receipt of the proposed ICR for public comment before OMB may take an action on the proposed ICR (5 CFR 1320.11(e)). Since the OMB Action Notice for the proposed ICR is dated June 30, 1999, OMB complied with the regulatory procedures for information collections contained in proposed rules in 5 CFR 1320.11.

Comment: A commenter (C-1865) asserts the proposed rule requires significant changes in the information reported by industry. The commenter asserts that because EPA did not provide a revised Form R or the reporting instructions in the proposed rule, OMB should disapprove EPA's collection of information. According to the commenter, OMB's Information Collection Review Handbook states that materials to be submitted for review must be accompanied by the documents to be used in the collection of information (i.e., forms, schedules, questionnaires, handbook, manual, interview plan or guide, rule, regulation, or other document) and any other explanatory material to be given or sent to prospective respondents. The commenter asserts that EPA's stated intention to provide guidance documents after the rule is finalized circumvents adequate notice and comment.

Response: As previously indicated, the proposed rule did not contain significant changes in the information reported by industry. EPA proposed using the existing Form R for reports that would be required under the lower reporting threshold. Since EPA did not propose to amend the Form R, and the existing Form R was already approved by OMB, EPA was not required to submit the Form R separately with the ICR amendment at the proposed rule stage. Nevertheless, the addendum ICR that EPA submitted to OMB included a copy of the existing ICR approved by OMB, along with a copy of the Form R. The existing ICR also specifically describes all of the existing reporting elements on Form R.

EPA strongly disagrees with the suggestion that it has circumvented the notice and comment process. The preamble to the proposed rule, the economic analysis, and the ICR all specifically describe EPA's proposal to add chemicals, lower reporting thresholds, change the reporting requirements so as not to allow use of the *de minimis* exemption, range reporting or Form A for reports submitted under the lowered thresholds, and to require reporting down to the tenth of a pound for quantities under 10 pounds, and 100 micrograms for dioxin. The Federal Register provided public notice and specifically

solicited public comments on the changes to reporting that were being considered, as well as on the Agency's associated burden estimates. The Agency provided a functional description of the changes in reporting that would result from his rule. Therefore, EPA was in compliance with the PRA and with OMB requirements.

Comment: Various commenters (C-1421, C-1850, C-1865) have questioned whether the data collected as a part of this rulemaking will have practical utility.

Response: The commenters do not define what they mean by their use of "practical utility," but the term is defined in the Paperwork Reduction Act of 1995 (PRA). According to 44 United States Code section 3502(11), "the term 'practical utility' means the ability of an agency to use information, particularly the capability to process such information in a timely and useful fashion." OMB's regulatory definition of "practical utility" at 5 CFR Part 1320.3(l) includes not only the theoretical or potential usefulness of information to an Agency, but its actual usefulness, taking into account its accuracy, validity, adequacy, and reliability, and the Agency's ability to process the information in a useful and timely fashion, and taking into account whether the Agency demonstrates actual timely use of the data either by the Agency to carry out the Agency's own functions or by third parties. This issue will be addressed in two parts: first, the accuracy, adequacy, timeliness, and reliability of the data; and second, the use of the data by EPA and third parties.

By statute, owners or operators of facilities subject to EPCRA section 313 requirements must report on or before July 1 data showing releases and other waste management during the previous calendar year. EPA has undertaken a variety of activities to enhance the accuracy and reliability of the data including: preparing guidance documents for both general estimation of releases and industry-specific estimation procedures; providing outreach through EPA regional offices and directly to industry through train-the-trainers classes, meetings with affected parties, and a toll-free hotline; supplying annually up-dated reporting packages which include electronic reporting forms; verifying submitted data, including automated data quality checks and retrospective reviews to assess data entry accuracy rates. EPA has also conducted audits of facilities to determine how well facilities used available data to estimate releases and other waste management of section 313 chemicals. These issues are discussed in more detail in the Information Collection Request for the TRI program, EPA #1363.07, dated November 12, 1996, in section four, "Methodology and Information Management."

As far as the adequacy of the data are concerned, many EPA programs use TRI data for various program purposes even when other sources of data are available. This argues strongly for the proposition that the data are adequate; certainly they are preferred to alternative data sources. EPA's Office of Pollution Prevention and Toxics uses the TRI data for risk screening, determining testing needs and priorities, and for development of pollution prevention actions. The Office of Air and Radiation has used TRI data to develop standards for hazardous air pollutants. The Office of Enforcement and Compliance Assurance uses TRI data to target inspection and enforcement activities. The Office of Solid Waste and Emergency Response uses the data to assist in priority setting for waste minimization activities. The Office of Water uses TRI data in the development of management plans to identify the sources of toxic discharges into selected estuaries and coastal waters. More detail on the use of TRI data is provided in the Information Collection Request cited above (EPA #1363.07) in section two, "Need for and Use of the Collection".

TRI data are available in a timely manner. These data are released by EPA as a national database approximately nine months after the initial submission deadline. When the data are released by EPA, they are available on-line and in hard-copy. Guidance and assistance for using the information are provided as well.

Some indication of the many uses of TRI data by EPA offices was provided above. In addition states use TRI data for numerous purposes, including: identifying and prioritizing facilities for implementing pollution prevention measures; emergency prevention planning; making facility siting and permitting decisions; developing or revising permit limits; targeting for permit compliance inspections; and risk screening or risk analysis. Community and public interest groups also use TRI data for various purposes, including environmental justice analyses. A fuller discussion of the uses made of the TRI data is provided in section two of the Form R Information Collection Request document cited above (EPA #1363.07), and in chapter 6 of the Economic Analysis for this rule.

EPA strongly believes that the data requested by this rulemaking has practical utility as demonstrated by the timely provision of useful, reliable information which is used by a wide variety of parties, both inside and outside of EPA.

Comment: Commenters (C-1863, C-1850, C-1865) assert that EPA fails to meet Paperwork Reduction Act requirements because it has not demonstrated that a significant amount of the releases and other waste management activities involving PBT

chemicals are not being captured, or estimated the amount of PBT chemicals that will be captured by each of the reporting options. The commenters contend that many reports will report releases of zero or near zero. The commenters assert that if EPA cannot show how much more will be reported (or is likely to be reported) based on the lowered thresholds, then there is no realistic showing of the need for and utility of this rule.

Response: Practical utility, as defined by OMB, is not predicated on the reporting of a particular quantity of releases. Practical utility as defined by OMB, 60 FR at 44987 (August 29, 1995) includes “actual ... usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability, and the agency’s ability to process the information it collects ... in a useful and timely fashion. In determining whether information will have ‘practical utility’, OMB will take into account whether the agency demonstrates actual timely use for the information either to carry out its functions or to make it available to third parties or the public ...” Past experience with the TRI program demonstrates that the information is useful, and that EPA has processed the information it receives in a timely and useful fashion, and made it available to third parties.

Comment: Commenters (C-1421, C-1850) dispute that EPA has demonstrated that its information collection reduces, to the extent practicable and appropriate, the burden on persons providing the information to EPA.

Response: EPA considered the burden that would be imposed by four sets of reporting thresholds. EPA attempted to balance burden on industry with the purposes of EPCRA listed in 313(h). EPA believes it is appropriate to lower the reporting thresholds to a level that would capture significantly more information about PBT chemicals than current thresholds but that would not be unduly burdensome on industry. Therefore, EPA is proposing to lower the manufacture, process, and otherwise use thresholds to 100 pounds for toxic chemicals meeting the 2- to 6-month and 1,000 to 5,000 criteria and to 10 pounds for toxic chemicals meeting the 6-month or greater and 5,000 or greater criteria. While it may be true that additional alternatives could potentially further reduce burden, they would also reduce the amount of information available, such alternatives would so diminish EPA’s ability to achieve the objectives of EPCRA that they would not be appropriate.

The primary objective for this rulemaking is to address one of the most significant gaps in the information currently reported under EPCRA section 313 -- information on releases and other waste management practices relating to PBT chemicals. Addressing this gap will improve the usefulness of the range of data on these chemicals and will provide the public, government agencies, and researchers with access to critical information on PBT chemicals that can be used for many purposes, including, for example, to track the progress of national and international efforts addressing concerns about PBT chemicals.

As EPA noted in the preamble, “In choosing the proposed EPCRA section 313 thresholds for these PBT chemicals EPA took into consideration a number of factors including small business impacts, overall reporting burden, and report generation in addition to utility of the information. It has been EPA’s goal, under the EPCRA section 313 program, to maintain a balance between community right-to-know and overall reporting burden for the affected industry” (64 FR 712). In addition, existing burden-reducing measures (e.g., the laboratory exemption, and the otherwise use exemptions, which include the routine janitorial or facility grounds maintenance exemption, motor vehicle maintenance exemption, structural component exemption, intake air and water exemption and the personal use exemption) will continue to apply to the facilities that file new reports as a result of this proposed rule. EPA also will be assisting small entities subject to the proposed rule, by such means as providing meetings, training, and compliance guides in the future, which also will ease the burdens of compliance. As a result, EPA believes that it has tailored its regulation to reduce burden to the extent practical and appropriate.

Comment: Several commenters (C-1407, C-1421, C-1431, C-1431b, C-1435, C-1448, C-1850, C-1858, C-1865) state that EPA has not demonstrated that this information collection is not unnecessarily duplicative of information EPA can otherwise reasonably access. The commenters assert that the added burden of reporting under lower reporting thresholds is unnecessary because EPA has compiled inventories that account for the vast majority of releases from many of the identified PBTs. The commenters claim that extensive release data have already been compiled for several of the key chemicals subject to this proposal, and mention the Inventory of Sources of Dioxin, the Mercury Study Report to Congress, reports under section 112(c)(6) of the Clean Air Act, operating permits, the Emergency Response Notification System (ERNS), the Permit Compliance System (PCS), the Aerometric Information Retrieval System (AIRS), and the Resource Conservation and Recovery Information System (RCRIS). One commenter stated that EPA requires extensive tracking of PCB management activities under TSCA, which is more thorough than that which would be provided under TRI and provides better information. The commenter also stated that there is a data collection underway to collect detailed information from utilities that combust coal that would allow emissions estimates that may be more precise than those that would otherwise be provided under the proposed rule.

Commenters argue that EPA has not justified the need for additional, arguably less accurate, release information from TRI, and that EPA should conduct a data gap analysis before promulgating this proposal.

Response: EPA disagrees that existing data make this information collection unnecessary, or that the information collection is unnecessarily duplicative of information EPA can otherwise reasonably access. The sources mentioned by the commenters do not substitute for the data that would be collected under this rule.

For most PBT chemicals and industry sectors, release estimates for affected facilities do not exist. Even where release estimates are available for an industry sector, most are derived from national activity levels rather than facility-level reporting. Multi-media data for PBT chemicals are extremely limited. To the extent that release estimates are available, they tend to cover only a single medium such as air. Where there are air release estimates available for a sector, the estimates have often been based in part on data from facilities that already report to TRI under current reporting thresholds. Furthermore, the estimates described by the commenter include one-time studies that utilize a "top-down" methodology in which emission factors are applied to entire industries. This is not the same as having annual facility-level information on multi-media releases. Releases will differ among facilities due to various factors, including activity levels, pollution prevention practices, and control technologies.

The Mercury Study Report to Congress (U.S. EPA, 1997) was a one-time study that focused only on air emissions and includes a number of top-down estimates. The Inventory of Source of Dioxin in the United States (U.S. EPA, 1998) is also based on top-down estimates, extrapolated from test data at a few facilities. The 1990 Emissions Inventory of Section 112(c)(6) Pollutants (U.S. EPA 1998) is a one-time study and covers only six chemicals derived from a combination of existing inventories (including TRI) and top-down estimates.

There are a number of reasons why permit data cannot be readily substituted for TRI data. Permits may not require much release information (just enough to determine if the facility should be classified as a major source, meets emission requirements, etc.), and in some cases no emissions estimates are required. Permits are typically renewed every five years, so they do not provide annual information like TRI. Permits are theoretical ceilings but do not indicate what actual release levels are. In addition, states and other permitting authorities use TRI to determine appropriate permit levels, so permit data cannot be substituted for information reported to TRI. Finally, TRI includes releases and other waste management activities that are not addressed by permitting

ERNS contains notifications of accidental releases of oil and hazardous substances reported to the National Response Center, the ten EPA Regions, or the U.S. Coast Guard. ERNS is a database of initial notifications, made as or immediately after a release occurs. Because the data are reported to ERNS at such an early stage, the details of the incident (including the magnitude of the release) are often uncertain or missing.

The Resource Conservation and Recovery Information System (RCRIS) contains information that is submitted to EPA on Form 8700-12 (Notification Of Regulated Waste Activity) and Form 8700-23 (Hazardous Waste Permit Application Part A). Small quantity generators (SQGs) and large quantity generators (LQGs) and facilities that treat, store, dispose of, transport, or offer for transport hazardous waste must notify EPA of these activities using Form 8700-12. This form is typically submitted one time per site or location. (Subsequent notifications are submitted if activities at the facility are changes.) In addition to facility identification information, the Form 8700-12 includes the type of hazardous waste activity the facility is engaged in (e.g., generator, transporter, treater, storer, disposer, etc.), and the type of hazardous waste (e.g., the RCRA waste code, or whether the waste is ignitable, corrosive, reactive, or toxic). The information differs from the information reported on Form R in many ways. First, the Form 8700-12 is essentially a one-time notification, unlike the annual reporting under section 313. Second, conditionally exempt small quantity generators (CESQGs), which generate less than 220 pounds per month, are not required to file Form 8700-12. A CESQG can generate as much as 26,400 pounds over the course of a year, which is significantly higher than the reporting thresholds that are being proposed for PBT chemicals under section 313. Third, some RCRA waste codes represent a mixture of various materials (instead of a single, unique chemical). Finally, the Form 8700-12 does not contain any information on quantities released, transferred, or managed as waste, as does Form R. Therefore, the Form 8700-12 does not substitute or duplicate the information that is provided on the Form R about releases, transfers, and waste management of toxic chemicals.

Owners or operators of a hazardous waste treatment, storage, or disposal facility must complete a Form 8700-23, RCRA Part A Permit Application. This form is also typically submitted one time per site or location. In addition to facility identification information, the Form 8700-23 includes a description of the processes to be used for treating, storing, and

disposing of hazardous waste, and the design capacity of these items; an estimate of the quantity of hazardous wastes to be treated, stored, or disposed annually, and a general description of the processes to be used for such wastes; as well as a scale drawing and photographs of the facility and topographic maps.

This data differs from the information reported on Form R in a number of important respects. First, the Form 8700-23 is essentially a one-time notification, unlike the annual reporting under section 313. Second, it only applies to hazardous waste treatment, storage and disposal facilities, which are a small fraction of all the facilities covered by EPCRA section 313. Third, some RCRA waste codes represent a mixture of various materials (instead of a single, unique chemical), and RCRA waste streams can be a mixture of one or more hazardous materials in a non-hazardous matrix (such as soil or water). Therefore, it may not be possible to determine the quantity of a particular individual chemical in a waste stream. Finally, while the Form 8700-12 contains an estimate of the annual quantity of waste handled, it does not contain any information on quantities released to each environmental medium or the types, quantities, and locations of transfers off-site or other waste management activities. Therefore, the information provided on the Form 8700-12 does not substitute or duplicate the information that is provided on the Form R.

The Aerometric Information Retrieval System (AIRS) is a computer-based repository of information on airborne pollution in the United States and various World Health Organization (WHO) member countries. AIRS is comprised of four major databases - Air Quality (AQS), AIRS Facility Subsystem (AFS), Area/Mobile Source (AMS), Geo-Common (GCS) subsystems, and a mapping utility for all AIRS data called AIRS Graphics (AG). Each subsystem addresses different, but connected, aspects of the Clean Air Act regulatory requirements. AIRS is administered by EPA's Office of Air and Radiation (OAR).

The AIRS Facility Subsystem (AFS) is the database component of AIRS which tracks air emissions from industrial plants. AFS contains emissions, compliance, and enforcement data on air pollution point sources regulated by EPA, state and local environmental regulatory agencies. OAR uses AFS to track emissions of pollutants that have been proven to be detrimental to public health, known as *criteria pollutants*, as defined in the national ambient air quality standards. The six criteria pollutants which states must report to AFS include: particulate matter less than 10 microns in size (PM₁₀), carbon monoxide (CO), sulfur dioxide (SO₂), nitrogen dioxide (NO₂), lead (Pb), and ozone (reported as volatile organic compounds, an ozone precursor). States are required to report ambient air quality data on a quarterly basis, and point source data on a yearly basis, for the criteria pollutants listed. In addition, states may choose to use the AIRS system to store data on a wide variety of other pollutants and related variables. At the plant or facility level, sources with air emissions greater than 1,000 tons per year (tpy) for CO, 100 tpy for VOC, PM-10, SO_x or NO_x or 5 tpy for lead must report actual or estimated annual emissions data. At the point level, such as a stack or any single piece of equipment or process where emissions occur, sources with air emissions greater than 25 tpy for VOC, PM-10, SO_x or NO_x, 250 tpy for CO, or 5 tpy for lead must report actual or estimated annual emissions data.

AIRS data do not duplicate or substitute for data that will be reported to TRI as a result of the this rulemaking. The PBT chemicals covered by this rulemaking are not among the criteria pollutants that are required to be reported to AIRS. Also, EPA does not require facilities to report to AIRS unless they emit multiple tons of criteria pollutants annually. These thresholds are orders of magnitude higher than the thresholds that EPA is setting for PBT chemicals in this rulemaking. And AIRS only covers air releases, while TRI provides data on multi-media releases, transfers, and waste management. More information comparing data available through AIRS to TRI data is available in Chapter 8 of the *Economic Analysis of the Final Rule to Add Certain Industry Groups to EPCRA Section 313* (EPA, April 1997).

The Permit Compliance System (PCS) tracks permit compliance and enforcement status of facilities regulated by the National Pollutant Discharge Elimination System (NPDES) under the Clean Water Act (CWA). PCS tracks all point source discharges to surface waters, but does not include indirect discharges such as discharges to Publicly Owned Treatment Works (POTWs). Permits are classified as major or minor based on facility discharge characteristics such as toxic pollutant potential and flow volume. Major dischargers report compliance with their NPDES permit limits through Discharge Monitoring Reports (DMRs). About ten percent of permits are classified as major. Data collected via DMRs are entered into PCS, including concentration and quantity values for regulated pollutants. EPA requires monitoring data only for those permits classified as major. For minor facilities the database contains only general facility-level information.

A facility's permit record may not include all pollutants actually being discharged by the facility. The monitoring data available through PCS for major dischargers include only those chemicals for which a monitoring requirement has been set in the permit. Federal effluent guidelines exist for many major industries and determine chemicals for which monitoring is

required. However, the guidelines may not consider the same chemicals across industries. Therefore, two facilities in different industries with similar chemical discharges may not necessarily both report the same set of chemicals to PCS. Also, for facilities not covered by a Federal effluent guideline, it is left to the discretion of the permit writers to decide which pollutants will be included in the permit, how often monitoring must occur, and which parameters and units of measure are to be used. In addition, not all the PBT chemicals covered by the proposed rule are matched to PCS.

NPDES permit discharge limits are written in terms of PCS pollutant parameters, and a PCS parameter may represent multiple CAS numbers, or there may be multiple PCS parameters that match to a single CAS number. Discharge statistics are often reported in PCS in terms of concentrations (sometimes in terms of a minimum, maximum, and average concentration). Concentrations can be converted to units of mass where flow rates are available, although in some cases flow rates are not provided, or are not available for all twelve months.

Because PCS is a permit tracking system, and not a pollutant loadings system, it cannot provide a suitable substitute for TRI release data. Within PCS, discharge data are only available for major facilities, and are reported in terms of PCS parameters, not specific chemicals. These chemical parameters cannot always be directly converted into unique CAS numbers. In addition, only those chemical parameters actually specified in the facility permit have monitoring requirements. In some cases, data may be reported in units of concentration rather than units of mass. If flow rates are also reported, concentration data can be used to estimate total discharges, although flow rates are not always available. There are several complicating factors in producing an annual loadings estimate from PCS data.. (For example, facilities with episodic discharges may be required to report discharges at their peak level and not an average annual quantity.) More information comparing data available through PCS to TRI data is available in Chapter 8 of the *Economic Analysis of the Final Rule to Add Certain Industry Groups to EPCRA Section 313* (EPA, April 1997).

One commenter (C-1407) stated that EPA requires extensive tracking of PCB management activities under TSCA which is more thorough than the reporting to be provided under TRI and which provides better information. The commenter states that the information reported to TRI would be redundant and of lower quality than that submitted under TSCA. Although the commenter does not specify what provisions of TSCA the commenter believes provide superior information, EPA believes that the commenter is referring to the provisions of TSCA codified at 40 CFR 761. The main provisions of these regulations are summarized below:

- EPA requires a one-time registration of PCB transformers with EPA Headquarters. In general, a PCB Transformer is any transformer that contains 500 ppm or greater of PCB dielectric. EPA requires the following information: (1) company name and address, (2) contact name and telephone number, (3) location of transformer(s), (4) number of PCB transformers and the total weight of the transformers in kilograms, and (5) whether any transformers at this location contain flammable dielectric fluid (optional). Note that the quantity of PCBs, as opposed to the total weight of the reported item, is not reported.
- EPA also requires a notification of PCB activity from certain facilities. EPA requires the following information: (1) name of facility and owner, (2) EPA identification number, (3) facility mailing address and location, (4) contact information, and (5) type of PCB activity (e.g. generator with on-site storage facility, commercial storer, transporter, approved disposer, etc). Note that no PCB quantity information is required.
- Finally, EPA has annual reporting requirements associated with in-service records and disposal and storage-for-disposal records. Generators and disposers are required to report information annually on a variety of PCB contaminated items (such as transformers, capacitors, etc.) and PCB bulk waste. Although the requirements vary by type of regulated item and whether the item is in-service or disposed, in general the required information includes (1) the number of items, (2) the total weight in kilograms of all items, and (3) tracking information for the item. Note that the quantity of PCBs, as opposed to the total weight of the reported item, is not reported.

From this description, it is clear that reporting requirements for PCBs under TSCA are not comparable to the reporting requirements of EPCRA section 313. The two sets of reporting requirements collect different information and are not substitutes for each other. For example, reports on PCBs submitted under EPCRA section 313 collect information on the release and other waste management of PCBs at reporting facilities. By contrast, the TSCA reporting provisions focus on the identity of facilities that manage PCBs, the location PCB-contaminated items and the total weight of those items. TSCA reporting does not provide information on the quantity of PCBs released or otherwise managed as waste. Thus while TSCA reporting meets a need for tracking and registration information on PCB-contaminated equipment and facilities that generate,

store or dispose of PCBs, this reporting does not duplicate or substitute for reporting under EPCRA section 313. Therefore, EPA disagrees with the commenter.

A commenter stated that there is a data collection underway to collect detailed information from utilities that combust coal that would allow emissions estimates that may be more precise than those that would otherwise be provided under the proposed rule. The commenter is presumably referring to the Electric Utility Steam Generating Unit Mercury Emissions Information Collection Effort (EPA ICR No. 1858.01). This ICR has two components. The first component will gather data on the amount of coal consumed and the mercury concentration in the coal at 421 electric utility facilities with steam generating units of 25 megawatts or greater capacity. The second component will gather data on stack emissions of mercury from 30 coal-fired electric utility steam generating units. The ICR covers a single year.

Lowering section 313 reporting thresholds for PBT chemicals (including mercury) collects much data that is not covered by the utility ICR. The utility ICR does not collect any information on the PBT chemicals other than mercury that are included in this regulation, including the releases and other waste management activities at utility facilities. In addition, section 313 covers numerous industries that are not affected by the utility ICR. This is demonstrated by EPA's estimate that lowering the reporting threshold for mercury to 10 pounds will result in over 5,000 additional reports under section 313. In addition, section 313 reporting also covers more of the electric utility industry (including coal-fired facilities under 25 megawatts and oil-fired facilities) than the utility ICR, and is estimated to result in reporting from approximately 600 electric utility facilities. Finally, even for the electric utility facilities that are included in the utility ICR, section 313 reporting provides additional unique information. Section 313 reporting covers multi-media releases, transfers, and waste management, while the utility ICR includes only air releases (and only from 30 facilities). And section 313 reporting provides annual reporting data, which the utility ICR does not.

At least one segment of the electric utility industry concurs with EPA that section 313 does not create duplicate reporting with the utility ICR. The Clean Energy Group, which is composed of major electric generating companies, submitted comments (C-1809) stating that "We have heard the view from some critics of EPA's proposal to lower the PBT threshold that the mercury ICR obviates the need to lower the reporting threshold for mercury, by creating redundant reporting mechanisms. We disagree and support the Agency's decision to lower the reporting threshold for PBT chemicals, notwithstanding the mercury ICR. The mercury ICR, while useful, is of limited duration and applies only to one source category out of the many covered by TRI."

The comment that the utility ICR would allow emissions estimates that may be more precise than those that would otherwise be provided under the proposed rule is true insofar that the utility ICR complements section 313 reporting. The utility ICR will increase knowledge about air emissions of mercury from electric utilities, and this increased knowledge can then be applied to section 313 reporting. However, this does not mean that the information from the utility ICR will be more precise than that provided under section 313, since section 313 reporting is not limited to a single estimation technique or methodology, but is instead based on the best readily available information (which may include concentration data or emission factors developed using the utility ICR data).

The commenters have not done any analysis or made any effort to provide support for statements that other data sources could substitute for the information to be collected under this rule. The commenters simply list EPA data collections and claim that this data collection duplicates them, or state that EPA hasn't shown that it doesn't duplicate them. In the past, EPA has performed extensive analysis comparing EPCRA section 313 data to alternate data sources (see Chapter 8 and Appendix O of the *Economic Analysis of the Final Rule to Add Certain Industry Groups to EPCRA Section 313*, U.S. EPA, April 1997), yet commenters ignore this body of evidence. The previous analysis demonstrated that these alternate data sources do not duplicate TRI data when the EPCRA section 313 reporting threshold is 25,000 pounds. An EPCRA section 313 threshold of 10 pounds or 100 pounds includes much additional reporting that is not captured by these other systems. Therefore, there is even less overlap between EPCRA section 313 and these alternate data sources than EPA's previous analysis demonstrated. The commenters have not acknowledged this previous analysis, or submitted any new factual matter that addresses it. Other than making unsubstantiated assertions, the commenters have not shown that these other reports and databases, singly or in combination, can substitute for TRI data.

In summary, EPA does not believe that there is sufficient information to substitute for the information that will be reported as a result of TRI rulemakings. EPA also disagrees with the commenters that TRI data will be less accurate than the alternate data sources that the commenter mentions. TRI estimates are based on the reporting facility's judgement about what data and methodology to use. This will not result in less accurate data than existing sources. If the data and methodologies

used in preparing the reports mentioned by the commenters were the most accurate available, the reporting facilities would use them in reporting to TRI. However, submitters typically have information that allows them to tailor their estimates to the situation at their individual facility, and thus will use whatever estimation methodology provides the best estimate. The result will only be an improvement over existing data sources. This is demonstrated by the fact that many of the existing top-down estimates that the commenters point to as alternatives to TRI actually use TRI data where it is available to make their estimates. Past experience with TRI has shown that reported data provided a better picture of releases and other waste management activities than the existing data sources prior to reporting, and EPA believes that the same situation will occur with the PBT chemicals.

Comment: The commenter (C-1843) contends that the proposed rule conflicts with the Administration's program on Reinventing Environmental Regulation (March 16, 1995), which calls for environmental protection in a common sense, cost-effective manner and a reduction in existing reporting and recordkeeping burden hours by 25%. In the May 1, 1997 rule expanding the industries subject to TRI reporting, EPA further committed to "improving the TRI program by reducing the cost of reporting while increasing the utility of toxic release information." 62 Fed. Reg. at 23887. The commenter contends that a proposal to add 1.9 million paperwork burden hours is not consistent with these commitments.

Response: The 25% burden reduction target contained in the 1995 Reinventing Environmental Information Report was to be measured across the Agency, not for every individual regulation, program, or Office within EPA. Moreover, the commitment was to reduce the burden of existing regulations; it was not intended to bar further Agency action to protect human health and the environment. In terms of the TRI program, EPA has reduced burden through chemical delistings, industry-specific guidance documents, enhanced electronic reporting, and the promulgation of an alternate reporting threshold. However, EPA continues to be very concerned about burden reduction, and has initiated a number of additional burden reducing activities in the TRI program. For example, EPA is reviewing the original list of EPCRA section 313 chemicals to determine if other chemicals should be delisted. EPA is developing additional reporting guidance which will simplify and ease reporting burdens, and is improving the reporting software to include built-in calculation methodologies and error checking routines. EPA is also developing a single facility identification program for facilities that report to EPA, and developing guidance to facilitate more consistent use of chemical nomenclature, reporting units, and time frames across different programs.

EPA believes that the additional information provided by lowering the TRI reporting thresholds for PBT chemicals will be valuable to communities and will significantly enhance their knowledge about toxic chemical releases and other waste management activities that may be of concern to them. EPA believes that this action does represent a common sense, cost-effective approach to environmental protection, and is consistent with reinventing environmental regulation.

Comment: A commenter (C-1815) asserts that EPA has not considered the additional reporting costs of the proposed rule in the context of overall TRI reporting costs. The commenter asserts that EPA should consider the additional cost burden relative to overall TRI reporting.

Response: Table 12 of the ICR addendum, dated January 26, 1999, put the reporting burden of this proposed rule into context, as it included the number of Form Rs (and the resulting burden) due to this rule and for the entire program.

7.f.3 Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act

Comment: A commenter (C-849/403) recommends that EPA's analysis of potential small entity impacts should exclude businesses with large revenues. The commenter states that use of SBA size standards (which classify companies with 500 to 1,500 employees as small) inflates the perceived burden on small businesses because there are many very wealthy firms with less than 500 employees.

Response: EPA agrees that the SBA size standards may be too expansive. Section 601(3) of the Regulatory Flexibility Act allows an agency to adopt a small business definition that is more appropriate to its activities after consulting with the SBA Office of Advocacy, providing an opportunity for public comment, and publishing the definition in the Federal Register. At some point in the future, EPA may consider revising the small business definition that it uses to analyze potential small entity impacts of EPCRA section 313 rulemakings. However, for the time being, the Agency is using the SBA size standards to analyze section 313 rulemakings.

Comment: A commenter (C-849/403) suggests that EPA should have considered the positive economic effect that an effective proposal could have on small businesses that are adversely affected by current dioxin pollution. The commenter suggests that the TRI information would be used to identify sources of dioxin releases and to stop and prevent pollution that affects fishery

resources. The commenter concludes that reporting of dioxin to TRI would decrease pollution costs including lost resource value and health care insurance costs borne by many thousands of small businesses. The proposal would provide information to better identify causes of pollution and examples of successful pollution prevention. This will result in better public and private actions to stop and prevent pollution. That pollution is known to reduce the availability of uncontaminated fishery resources, reduce public confidence in these food resources, and increase health problems and health care costs for diagnosis and treatment (health care costs for a person to die from cancer are an estimated \$1 million in the U.S. today). Thus, the proposal would decrease pollution costs including lost resource value and health care insurance costs borne by many thousands of small businesses. CBE and the Pacific Coast Federation of Fisheries Associations provided this evidence in public hearing comments on EPA's dioxin reporting proposal in 1997. Many small businesses that do not produce dioxin will derive significant economic benefits from dioxin release reporting.

Response: EPA agrees that the rule may have positive follow-on effects for some businesses, including small businesses, but EPA has not incorporated these positive effects into the small entity analysis. First, it is not clear to what extent the positive effects will accrue to the same facilities that will report. It may be appropriate to consider the net impact on facilities where there is both a positive and negative impact on the same facilities. However, it is generally not appropriate to net out the effects where a rule has a positive impact on one type of small entity and negative impacts on another type of small entity. Second, the positive effects that the commenter describes are due to the indirect effects resulting from the rule (i.e., behavior changes that reduce the level of pollution), and not as a direct result of reporting. EPA has not included indirect effects (whether positive or negative) in its analysis of the rule.

Comment: A commenter (C-1438) asserts that EPA's analysis of small entity impacts is flawed because EPA has not provided sufficient detail to permit the commenting party to discern whether there has been a rigorous analysis of impacts on small entities in the proposed rule. For example, at 64 Fed. Reg. 721 (column 3), EPA estimates that approximately 16 small businesses may bear compliance costs between 1% and 3% of revenues. But, the agency gives us no explanation of the methodology used to reach that conclusion.

Response: The commenter obviously read only the Federal Register notice, and did not examine the economic analysis for the rule. As the Agency stated in the preamble at 64 FR 719, "EPA has prepared an economic analysis of the impact of this proposed action, which is contained in a document entitled 'Economic Analysis of the Proposed Rule to Modify Reporting of Persistent Bioaccumulative Toxic Chemicals under EPCRA Section 313' (Ref. 79). This document is available in the public docket for this rulemaking. The analysis assesses the costs, benefits, and associated impacts of the proposed rule, including potential effects on small entities. The major findings of the analysis are briefly summarized here."

Chapter 5 of the economic analysis ("Estimated Impacts of the Rule") provides a 25 page explanation of the methodology EPA used to reach the conclusion that there would be 16 small businesses bearing compliance costs between 1% and 3% of revenues in the first year of reporting. The economic analysis did provide sufficient detail to permit commenters who read it determine that the Agency had conducted a rigorous analysis of small entity impacts.

Comment: A commenter (C-1438) asserts that before suspending the *de minimis* exception for the PACs found on carbon black, EPA must consider less burdensome alternatives to the proposed regulation. The commenter claims that the burden of estimating and reporting PAC releases on carbon black is disproportionately high. Therefore, the commenter asserts that EPA violated the Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement Fairness Act (SBREFA) by failing to consider less burdensome alternatives for this industry.

Response: The Regulatory Flexibility Act, which was amended by SBREFA, requires agencies to consider less burdensome alternatives when an Initial Regulatory Flexibility Analysis (IRFA) is prepared for a rule. An IRFA must be prepared for certain types of rules unless the Agency certifies that the rule will not have a significant impact on a substantial number of small entities. EPA analyzed the impact of the rule and determined that there will not be a significant impact on a substantial number of small entities. Therefore, the RFA does not require EPA to analyze less burdensome alternatives for this rulemaking. Nonetheless, EPA has considered less burdensome alternatives, as it considered alternatives with higher reporting thresholds (i.e., 100 pounds for the 6-month and 5,000 group and 1,000 pounds for the 2-month and 1,000 group, as well as 1,000 pounds for both groups). However, EPA is not required, nor would it be practical, to consider burden reducing options for every individual facet of the regulation or every subset of the regulated universe. Therefore, EPA is not required to analyze alternatives specific to the removal of the *de minimis* exemption for PACs found in carbon black.

Comment: A commenter (C-1438) asserts that the RFA requires EPA to publish an initial regulatory flexibility analysis that identifies any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. U.S.C. 603(c). The commenter asserts that SBREFA amended Section 604 of the RFA to require a final regulatory flexibility analysis that includes a “description of an estimate of the number of small entities to which the rule will apply or an estimate of why no such estimate is available.” 5 U.S.C. § 604(a)(3). The commenter asserts that SBREFA also requires EPA to provide “a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes’ including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities were rejected.” 5 U.S.C. § 604(a)(5).

Response: Section 605(b) of the Regulatory Flexibility Act states that “Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.” EPA has certified that the rule will not have a significant economic impact on a substantial number of small entities (see 64 FR 725). This certification was based on EPA’s screening analysis for the rule, which was contained in the economic analysis for the rule. The Federal Register notice also contained a succinct statement explaining the reasons for the certification.

Because EPA has certified that the rule will not have a significant economic impact on a substantial number of small entities, EPA is not subject to the section 603 and 604 RFA requirements that the commenter has cited. Nonetheless, EPA has addressed the issues which the commenter raises. Table 5-4 in Chapter 5 (*Estimated Impacts of the Rule*) in the economic analysis of the proposed rule estimates the number small entities estimated to be affected by the rule. Furthermore, as the Agency stated in the proposed rule, “Notwithstanding the Agency’s certification of this rule under section 605(b) of the RFA, EPA remains committed to minimizing real impacts on small entities where this does not unacceptably compromise the informational benefits of the rule. Although not required, EPA intends to prepare guidance for reporting on dioxin that will assist facilities in determining their compliance needs and in properly completing the form, which will help ensure that small entities receive assistance to ease their burden of compliance” (64 FR 725).

Comment: A commenter (C-1448) claims that EPA does not justify its percent-of-revenue metric, or why it would be a good measure of impact across different industry segments. The commenter notes that high volume, low margin industries might have profits that are only a few percent of total revenue, in which case, costs that are close to one percent of revenue would be a very large percent of profit, while lower volume, higher margin industries may have profits that are a much higher percent of revenue. The commenter cites SBA’s Federal Agency Review Draft Practitioner’s Guidance as saying “agencies considering using revenue or profit criteria such as annualized capital compliance costs greater than ‘1 percent of revenues’ or ‘10% of pre-tax profits’ should explain in their analytical report the relationship of these levels to solvency and why 1 percent, compared with other levels, constitutes a significant impact.” The commenter says that EPA should use several different metrics to determine economic impacts, and to determine how those impacts would be distributed across companies of different sizes and industry segments.

Response: Contrary to the commenter’s claim, EPA did justify its choice of one percent as a metric for assessing small entity impacts. As EPA stated at 64 FR 721, “EPA used annual compliance costs as a percentage of annual company sales to assess the potential impacts on small businesses of this rule. EPA believes that this is a good measure of a firm’s ability to afford the costs attributable to a regulatory requirement, because comparing compliance costs to revenues provides a reasonable indication of the magnitude of the regulatory burden relative to a commonly available measure of a company’s business volume. Where regulatory costs represent a small fraction of a typical firm’s revenue (for example, less than 1%, but not greater than 3%), EPA believes that the financial impacts of the regulation may be considered not significant.”

The commenter suggests that EPA should use profits as a measure of impact. As EPA explained in the industry expansion response to comments [*Response to Comments: Final Rule to Add Certain Industries to EPCRA Section 313*, U.S. EPA, April 1997], EPA has a long history of using the relationship between cost of compliance with a regulation and total revenue of the firm (price times quantity of goods sold) to determine whether a regulation has a significant economic impact on substantial number of small entities. Although at first blush the notion of using profits is attractive, tracking with an economist’s and a layman’s notion of one way to assess the burdens of regulation, a closer evaluation reveals that there may be both practical and theoretical problems with using profits as a measure of impacts. The practical problem centers on the often substantial difference between economists’ conception of “profits” and what is measured through accounting techniques as “profits.” The notion of profits which some economists might use as a measure of ability to meet regulatory costs is a short-run measure equal to revenues minus only variable costs, which are the minimum costs required to continue production. It does not

include, for example, revenue which must be set aside for eventual replacement of machinery and other investments necessary for production. Unfortunately, this ideal economic measure of profit is not what accountants calculate and report. Accounting profits correspond to definitions developed for accounting and tax purposes, and thus do not meet data needs for assessing economic impacts.

Indeed, reported accounting profits may be a very poor proxy for a firm's ability to shoulder compliance costs. Over the long run a firm must set aside enough revenue to replace capital (machinery, etc.), when such capital reaches the end of its useful life (through wearing out or becoming obsolete through technological innovation). But, in any particular time period these funds are available to meet the day to day expenses of a firm, including costs of complying with regulations. The accounting recognition of the need to replace capital is 'depreciation'. In accounting terms, depreciation is subtracted from revenues (along with other subtractions) to arrive at 'profit'. But in economic terms, 'depreciation' is revenue available in the short run to meet other cost obligations. Thus, accounting profits generally are lower than the actual sums firms have available for such expenses as complying with environmental regulations.

Further, the definition and schedule for depreciation expenses come from the tax code, and are often used as instruments to accomplish other policy goals. For example, if a decision is made to encourage investments in certain geographical or industry areas, one instrument which can be used to achieve this policy end is to permit accelerated depreciation of investments in those areas. Qualifying firms can depreciate capital equipment more rapidly. The result of this accounting and tax convention is lower accounting profits and taxes - because of the higher depreciation - when in fact the firm has a higher cash-flow and, hence, greater purchasing power (including ability to pay for regulatory costs).

There are other reasons why 'profits' as measured in practice, as opposed to economic 'profits' in theory, may be poor proxies for a firm's ability to pay for regulatory costs. Short-run profits are what remains after variable costs (expenses) have been deducted. But what is a business expense? Although there are some items that clearly fit the economic description of a business expense, other costs allowed by the tax code do not track well with economic theory. For example, consider the salary of the owner of a small business. Is this a fixed amount or is it actually a "residual" and hence, more akin to a profit notion? Clearly, payments to labor are required to keep workers producing. But when the owners of a firm are paid the residual profits as salaries, the firm will never show a profit even when the owner is compensated far above what would be required to maintain his/her resources in that use.

Yet other issues associated with defining expenses arise because there are many items firms are able to deduct from revenues that do not correspond to economic notions of variable production costs. All of these issues are exacerbated when dealing with small businesses, which are the entities generally covered by the Regulatory Flexibility Act. Entities which are not publicly traded are not required to subject themselves to an annual audit and reporting according to strict accounting standards. Under these circumstances owners of the firm have wide discretion in determining what constitutes a "business expense".

Apart from these definitional issues, which affect both the reliability and the consistency of impact tests using profit data, there are other practical considerations which argue against using profits to estimate the impacts of compliance costs. Unlike revenue data, profit data are not widely collected. There are some proprietary data bases which assemble profit data, but these data are based on very small sample sizes. Small sample sizes mean that data on profits are not very robust, *i.e.*, the ranges of uncertainty which result from use of these data are large. This is all the more true because the definition of 'profit' is not consistent among data bases (for example, some collect pre-tax profit while others tabulate post-tax), and so the samples cannot be combined to yield a larger sample and consequently more robust estimates. In addition, these data are not available for all of the four-digit SIC codes, so the usefulness of the data are even further circumscribed.

It is abundantly clear that even if economic notions of short-run profitability are appropriate measures of business' ability to pay for environmental compliance costs, reported accounting profits may be such poor measures of profits that they should not be used in regulatory impact assessments. But it is also less than obvious that short-run economic profits are even theoretically the best indicator of ability to shoulder regulatory costs. In fact, the attractiveness of comparing compliance costs to 'profits' as opposed to revenues, particularly for predicting such significant impacts as firm closures, is based more on the mere appearance of greater analytical rigor than any reality.

It is a basic tenet of microeconomic theory that firms make economic decisions about whether to continue operation of a business based on expected long-run profitability, which in turn incorporates forecasts of possibly significant market adjustments. One particularly important long-run market consideration is whether the price of a regulated firm's output

will increase to cover some or all of the newly imposed compliance costs. Unless demand for the product is perfectly elastic (*i.e.*, there are numerous, perfect substitutes for the product) firms in the industry will have the ability to pass at least some of these costs along to their consumers. To the degree that compliance costs are borne not by the regulated firms, but by their customers, the predictive power of a comparison of past short-run profits with incremental regulatory costs is essentially nil.

Another consequence of the method by which profit information is calculated, which is by calculating of a 'profit margin' and applying this proportion to revenue data, is that uncertainties in the profit data, outlined above, are overlaid on revenue data. In other words, profits data are not an independently calculated measure which could provide another window on the question of impacts; rather, they are an unreliable and inconsistent measure, which when multiplied by revenue data serve to produce a derived measure based on the revenue data already being used to produce the measure of impacts.

The primary advantage of using revenue to measure impacts is that it is a stable, easily accessible, and easily understood measure which provides a basis for comparing this rule to other rules. Unlike profits information, the definition is consistent and not subject to the widely varying definitions and interpretations of terms that affect 'profit' measures. Another advantage is that revenue data, unlike profits information, are widely available. The proprietary databases which assemble profits data not only also have revenue data, but the proportion of firms for which revenue data are available generally greatly exceeds the proportion of firms for which profit data are available. In addition, there are a number of databases, including the Census, which collect and publish revenue data but not profit data.

The third important advantage of using revenue as opposed to profit data for impact analyses is that revenue data are easily understood. For example, if the impact of compliance costs on a firm is 1% of revenue, in order to cover the costs of the regulation a firm would need to raise its prices 1%. This is a clear, easy to understand measure, that can help decision-makers determine whether additional measures to reduce the impact of a regulation are warranted.

The commenter implies that EPA has not followed the suggestions in a draft SBA report. EPA notes that the draft SBA document referenced by the commenter represents the SBA Office of Advocacy's opinion, and the suggestions in the document often go beyond the statutory requirements of the RFA. EPA is not obligated to accede to SBA's opinion about these matters.

In summary, EPA believes that the revenue test used in the analysis of this rule is preferable because it is simple to apply and based on readily available data, which allows consistent application of the methodology from rule to rule. Therefore, EPA does not agree that it needs to use several different metrics to determine economic impacts.

Comment: A commenter (C-1857) asserts that because sources such as lime plants and geothermal power are not included in EPA's analysis, the economic and small business impact estimates are incomplete. According to the commenter, the primary reason that lime plants are potentially subject to this rule is because of the trace contaminants present in or created by fossil fuels. The commenter asserts that this shortcoming is particularly important for the analysis of the more stringent Option 1, which is likely to require reporting by most lime plants, including small businesses. The commenter asserts that if EPA chooses to pursue thresholds that will require lime plant reporting, it must first correct its economic and small business analyses and evaluate options to mitigate small business impacts as required by the Small Business Regulatory Enforcement Fairness Act.

Response: As explained in a response in section 7d ("EPA has underestimated burden") of this document, EPA did include reporting due to fossil fuel combustion in the analysis of the proposed rule, including combustion at lime manufacturers. However, further analysis has shown that the commenter's claim that fuel combustion is the primary reason that lime manufacturers will report is incorrect. Instead, most lime manufacturers will report due to mercury in limestone. In response, EPA has modified the economic analysis for the final rule to include the additional reports from mercury in limestone. After including the additional reports, EPA has determined that the rule still does not have a significant impact on a substantial number of small entities. Therefore, the requirements in the Regulatory Flexibility Act (which require agencies to analyze and evaluate options to mitigate small entity impacts where there is a significant impact on a substantial number of small entities) do not apply. The commenter is mistaken that SBREFA requires agencies to analyze and evaluate options to mitigate small entity impacts. SBREFA amended certain sections of the Regulatory Flexibility Act, but these particular requirements were not modified by SBREFA.

7.f.4 Executive Order 12898 and 13045

Comment: A commenter (C-849/403) asserts that EPA has failed to consider adequately the impacts of this action on low income and minority populations as required by EO 12898. The commenter argues that EPA ignored the disproportionate health risks and impacts on subsistence anglers caused by water discharges from facilities that would not report at the preferred reporting threshold option of 0.1 g for dioxin. The commenter notes that three-quarters of those who fish in San Francisco are people of color who are exposed to dioxin levels greater than the general population. The commenter further argues that facilities in the San Francisco area could exceed their NPDES permit levels for dioxin concentrations in effluents, but still not report to TRI.

The commenter also asserts that EPA has failed to identify and assess environmental health risks that disproportionately affect children as required by EO 13045. The commenter argues that EPA ignored the disproportionate health risks and impacts on children of subsistence anglers caused by water discharges from facilities that would not report at the preferred reporting threshold option of 0.1 g for dioxin. The commenter notes that children may be exposed to dioxin in the womb or through mother's milk.

Response: EPA disagrees that it has not considered the impacts of the rule on low income and minority populations. As EPA stated in the proposed rule, "By lowering the section 313 reporting thresholds for PBT chemicals, EPA is providing communities across the United States (including low-income populations and minority populations) with access to data that may assist them in lowering exposures and consequently reducing chemical risks for themselves and their children. This information can also be used by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Therefore, the informational benefits of the proposed rule will have a positive impact on the human health and environmental impacts of minority populations, low-income populations, and children" (64 FR 727). The commenter's statements support EPA's belief that low income and minority populations and children will benefit from this rule.

Comment: A commenter (C-1448) claims that the distributional impacts of the proposal are superficially evaluated. The commenter states that the economic analysis of the proposal does not attempt to examine the costs or benefits that accrue specifically to low income and minority populations or children. The commenter asserts that low income populations in particular may experience negative health and welfare impacts to the extent the information encourages actions that increase the costs of consumer goods and services, reduce wages, alter firms' location decisions, and divert resources from other health-improving activities.

Response: The commenter does not attempt to justify the claim that low income populations *in particular* may experience negative health and welfare impacts. The commenter has made a blanket assertion without providing any evidence to support it. Also, the commenter postulates that these effects *may* occur, but only *to the extent* that the information encourages actions that increase the costs of consumer goods and services, reduce wages, alter firms' location decisions, and divert resources from other health-improving activities. However, the commenter provides no data to indicate that any of these results (increased costs, reduced wages, etc.) *will* occur. Therefore, the comment is nothing but unsubstantiated speculation, without any examination of the evidence on whether or not these theoretical negative impacts have ever occurred in ten years of EPCRA section 313 reporting, and without providing any basis to conclude that they will occur as a result of this rule. The commenter makes only passing reference to the fact that the rule will have benefits for these populations, and does not address what these positive impacts will be. However, EPA received a number of comments on the proposed rule from groups concerned with the health and welfare of low income and minority populations and children, such as the Charlotte Organizing Project (C-17/432, representing low-income and minority neighborhoods in Charlotte), Physicians for Social Responsibility (C-1932, concerned with patients, particularly children and economically disadvantaged members of society), the Grandmothers and Mothers Alliance for the Future (C-22), the Coalition for Family Safety (C-589), the Illinois Maternal and Child Health Coalition (C-1590), Mothers Organized to Stop Environmental Sins (C-1889), the Coalition to Protect America's Elders (C-1897), and Protect All Children's Environment (C-2106). These commenters were all in support of lowering TRI reporting thresholds for TRI chemicals. EPA believes that people know what is best for their own communities and given the facts, they themselves will determine what is best to protect public health and the environment. EPA believes that the fact that organizations representing low income and minority populations and children believe that the information resulting from lowered reporting thresholds will be beneficial to members of the populations they represent is a better indication of the impact of the rule on these populations than this individual commenter's unsubstantiated speculation.

7.g. TRI reporting creates perverse incentives

Commenter list: C-1406, C-1431, C-1445, C-1448, C-1456, C-1815, C-1817, C-1836, C-1841, C-1844, C-1858

Comment: A commenter (C-1406) claims that the proposal will reduce the amount of time that plant environmental engineers will spend pursuing pollution prevention opportunities because they will have to spend extra time completing additional Form Rs. The commenter asserts that generators of PBT chemicals already have all the information they need to identify pollution prevention opportunities from non-EPCRA programs.

Response: EPA disagrees that reporting to TRI on PBT chemicals will reduce the amount of time that facility personnel spend pursuing pollution prevention opportunities. TRI reporting assists facilities with two very important aspects of pollution prevention: 1) identification of pollution prevention opportunities, and 2) measurement of pollution prevention effectiveness. To pursue pollution prevention opportunities, a facility must first identify aspects of the production process that contribute to pollution. Once these opportunities have been identified and steps taken to prevent pollution, the facility needs a way to measure the effectiveness of pollution prevention measures. As indicated by the statements of several current TRI reporters, TRI provides unique insight into opportunities from reducing pollution:

It's not necessarily that we didn't want to [reduce emissions] before. We never had the information we needed to know if progress was being made. (Statement by Steven Schoger, BP Chemicals (Cleveland, Ohio) in Occupational Hazards, July 1991 as cited by Working Group on Community Right-To-Know newsletter, July 6, 1995.)

From our company's point of view, [TRI] helped us to discover a problem that we weren't even aware of. We discovered we had leaking sewers and potential contamination of our water supplies. (Statement by Richard Harding, Eastman Gelatine in the North Shore Sunday (Danvers, Mass., August 12, 1990) as cited by the Working Group on Community Right-To-Know newsletter, July 6, 1995.)

For the first time, engineers have had to scrutinize their processes as a whole and quantify the wastes released to all media...in some cases [this] has revealed valuable information for process improvements. (Statement by Elizabeth Fisher, Rohm and Haas at the Proceedings, International Conference on Reporting Releases of Toxic Chemicals, November, 1991 as cited by the Working Group on Community Right-To-Know newsletter, July 6, 1995.)

Revealing these numbers in terms of pounds per year rather than the pounds per hour or the parts per million we had tended to think about raised a lot of eyebrows within industry as well as within the community. And a lot of -- a lot of our leadership looked at numbers that were in the hundreds of thousands of pounds per year and said that's too much -- (A) it's too much to expect the community to accept; and (B) it's too much product for us to be wasting by releasing it into the environment. (Statement by Mort Mullins, Vice President, Regulatory Affairs, Chemical Manufacturers Association Morning Edition/National Public Radio, December 5, 1996.)

These statements indicate that reporters were not aware that releases were occurring despite existing, non-EPCRA reporting requirements (e.g., AIRS and PCS). The last statement indicates that TRI provides facilities with a useful and informative format for information on releases, even when this information is already "available" as a result of monitoring or regulatory compliance.

The commenter (General Motors) has used TRI data to measure the effectiveness of its own pollution prevention efforts. As EPA has noted elsewhere in this document, the commenter was a participant in the US Automotive Pollution Prevention Project, which measured progress using release data reported to TRI (see <http://www.deq.state.mi.us/ead/p2sect/auto/98prgrpt.pdf>).

For all these reasons, EPA believes that TRI reporting plays an integral role in pollution prevention activities at the facility level by identifying opportunities for pollution prevention and measuring progress in attaining pollution reductions. TRI has been shown to motivate voluntary pollution prevention measures, inform facilities of releases for which they were not previously aware or had not quantified in a meaningful way, and to measure progress toward pollution prevention objectives.

Comment: A commenter (C-1406) claims that the proposed rule will "very likely serve to complicate and lengthen the transitions involved in external cost internalization." The commenter notes that "social values become integrated into markets through

environmental, tax, and financial accounting regulations and guidelines” and that “when environmental ‘social inefficiencies’ occur, it is due more to inherent failures in the regulatory process, not the markets themselves” because “markets by themselves do not possess values in an ontological sense apart from societal values.” The commenter notes that release information serves to “provide data to effected [sic] communities on the amount of release” and to “provide a means of accounting for the societal cost and risks of that release.” The commenter claims that “publication of TRI data does not automatically result in lower generator releases, and when they do occur, are likely to be quite low in proportion to overall releases.” The commenter asserts that the proposal is “premature and inadequate” to internalize external costs.

Response: The commenter does not explain why TRI reporting would “complicate and lengthen” the effort to incorporate external costs into market transactions. As the commenter admits, release information serves to “provide data to effected [sic] communities on the amount of release” and to “provide a means of accounting for the societal cost and risks of that release.” Therefore, TRI provides essential information for any effort to account for the full social costs of industry activity by identifying the facilities that are responsible for releases that impose social costs, and by quantifying those releases.

The commenter asserts that “environmental ‘social inefficiencies’ occur” as a result of “inherent failures in the regulatory process” because markets “do not possess values in the ontological sense apart from social values.” The commenter does not dispute that releases of PBT chemicals are associated with social costs and inefficient outcomes, but the commenter prefers to assign blame for this situation to the regulatory framework within which markets operate. What EPA, in accordance with widely-used economic terminology, calls a “market failure” is redefined by the commenter as “regulatory failure.” In effect, the commenter implies that when markets do not produce efficient results, it is an inherent failure in the regulatory process for government not to intervene.

Both the commenter and EPA appear to agree that there is currently a “failure” to attain societal goals. While EPA believes the commenter’s terminology is convoluted and confusing, EPA agrees that the current situation would be improved through government intervention by means of regulation. The commenter does not dispute EPA’s identification of externalities and asymmetric information as factors which lead to inefficient outcomes. The effect of these factors will be addressed through EPA’s proposed intervention of additional reporting on PBT chemicals through TRI. As EPA stated in the Federal Register notice for the proposed rule:

Through the collection and distribution of facility-specific data on toxic chemicals, TRI overcomes firms’ lack of incentive to provide certain information, and thereby serves to inform the public of releases and other waste management of PBT chemicals. This information enables individuals to make choices that enhance their overall well-being. Choices made by a more informed public, including consumers, corporate lenders, and communities, may lead firms to internalize into their business decisions at least some of the costs to society relating to their releases and other waste management activities involving PBT chemicals. In addition, by helping to identify areas of concern, set priorities and monitor trends, TRI data can also be used to make more informed decisions regarding the design of more efficient regulations and voluntary programs, which also moves society towards an optimal allocation of resources.

With regard to the comment that TRI reporting does not result in significantly lower releases, EPA notes that the actual experience of the commenter (General Motors) belies this assertion. The commenter was a participant in the US Automotive Pollution Prevention Project. Participating companies achieved a 46 percent reduction in all TRI reportable releases on a vehicle produced basis since 1991. This would appear to qualify as a reduction in generator releases that is high in proportion to overall releases (for further details on this project, see <http://www.deq.state.mi.us/ead/p2sect/auto/98prgrpt.pdf>). Furthermore, as indicated in the previous response, TRI reporters have stated on many occasions that TRI reporting assists facilities in reducing emissions. In conclusion, EPA has identified both a need for the proposed rule and an intervention that remedies this need.

Comment: A commenter (C-1431, C-1858) expresses concern that the identification of metals as PBT substances could result in reduced demand for environmentally beneficial stainless and specialty steel products, such as cookware, surgical instruments and implants. Another commenter (C-1445) asserts reporting on vanadium will force people away from a substance of use without having a suitable substitute available.

Response: The commenters provide no evidence to support the contention that identification of metals as PBT chemicals would result in reduced demand for these metals. EPA notes that these metals are already reportable to TRI as toxic chemicals (i.e., with a 10,000/25,000 lb threshold), and there is no evidence of reduced demand for steel products such as cookware, surgical

instruments, or implants. Economic indicators of production and consumption of TRI chemicals demonstrate that TRI is associated with reductions in releases, but not reductions in economic activity. Between 1989 and 1996, manufacturing production *increased* 17.6 percent while TRI on- and off-site releases and transfers for treatment decreased 39 percent (1996 Toxics Release Inventory, Public Data Release, Industry Sector Analyses, December 1998).

EPA has also examined production changes in specific TRI chemicals. In response to suggestions that listing a chemical on TRI would cause a reduction in sales, EPA looked at the change in sales for the 50 highest production volume chemicals between 1987 (prior to the start of TRI reporting) and 1992 (which was the latest year for which TRI data were available at the time this analysis was completed). EPA used production volume information from the Chemical & Engineering News (C&EN) series on the top 50 chemicals in the U.S. to examine the change in production between 1987 and 1992. Thirty-one of the top 50 chemicals are listed under EPCRA section 313. The data showed that production decreased a total of five percent for only three of the 31 chemicals. However, sales for the other 28 chemicals increased a total of 17 percent.

The results are not very different from the change in production volume for the C&EN top 50 chemicals that were not listed under EPCRA section 313. There are eighteen of these chemicals for which data were available for both 1987 and 1992. For the 18 chemicals, 13 had sales increase totaling 19 percent during the period of interest (which is only slightly higher than the 17 percent for the chemicals listed under EPCRA section 313). The sales of the other five chemicals decreased by a total of 21 percent, which is greater than the 5 percent decrease for chemicals listed under EPCRA Section 313 (Summary of and Response to Public Comments Submitted in Response to the Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right-to-Know Proposed Rule, 59 FR 1788, January 12, 1994, Docket # OPPTS-400082A, pg 305-307). These data do not support the contention that a change in the TRI status of a chemical significantly impacts sales or use of that chemical, as opposed to releases.

Comment: A commenter (C-1448) claims that information on chemical releases and other waste management activities may confuse rather than inform. The commenter cites the following example:

How does information on the pounds of certain chemicals emitted from certain facilities, even if it were perfectly accurate, advance an individual's knowledge of the potential risks he faces by living near those facilities? Consider the alarm that might be engendered by the revelation that a plant near one's home emitted quantities of the following toxic, and potentially carcinogenic, chemicals: acetaldehyde, benzaldehyde, caffeic acid, d-limonene, estragole, and quercetin glycosides. Informed citizens might demand that the facility minimize or prevent the use and release of these chemicals. In fact, these chemicals occur naturally and are likely to be found on a fresh fruit platter of apples, pears, grapes, and mangos.

The commenter also cites a recent article by Viscusi in support of this argument, arguing that individuals do not always act "rationally" in response to risk information. The commenter claims that because TRI itself does not provide toxicity or exposure information, data from TRI may "misinform and mislead communities about potential health risks."

Response: EPA disagrees with the commenter's underlying assumption that the public needs to be "protected" from *information* on toxic chemicals, as opposed to the toxic chemicals themselves. The commenter offers no evidence or examples to support the assumption that "informed citizens" are unable to evaluate data on toxic chemicals that are released by facilities to the air, water, or land of a surrounding community. Part of the commenter's scenario of alarm and confusion appears to be based on the fact that certain chemicals have unfamiliar, multi-syllabic names. EPA does not share the commenter's low opinion about the intelligence of the public or the ability of the public to process information on chemicals. For example, the public is able to process information on prescription drugs, which typically are synthetic chemicals. EPA does not believe that the use of a chemical name, in itself, will scare the public. Further, as discussed elsewhere in this document, the commenter does not appear to be familiar with the intent of EPCRA section 313 or with the intended audience for TRI data. The intended audience includes Federal, state and local governments, researchers and the public in communities surrounding facilities subject to EPCRA section 313 (see section 313(h)). There are varying levels of technical sophistication within and among these groups. However, even if the targeted audience is unsophisticated, this does not mean that this audience does not have a right to information on releases of toxic chemicals in their environment or other waste management activities.

EPA believes that the commenter's comments reflect the level of sophistication that the commenter attributes to the public. The commenter notes that acetaldehyde, benzaldehyde, caffeic acid, d-limonene, estragole, and quercetin glycosides are components of fruit and implies that, thus, they are all innocuous. The first chemical in the commenter's list is acetaldehyde. While acetaldehyde is present in fruit, which humans eat rather than inhale, acetaldehyde has been shown to

cause adverse effects via the inhalation route. Specifically, acetaldehyde is classified as a probable human carcinogen (B2) because it caused an increased incidence of nasal tumors in male and female rats and laryngeal tumors in male and female hamsters after inhalation exposure. In addition, acetaldehyde causes some non-cancer adverse effects via inhalation exposure (see Integrated Risk Information System: Acetaldehyde, CASRN 75-07-0 at <http://www.epa.gov/iris/subst/0290.htm> for a description of the adverse effects associated with this chemical). Clearly, acetaldehyde is not as innocuous as the commenter suggests. EPA believes that it would not be unreasonable of the public to want to further investigate the releases and other waste management of acetaldehyde, particularly the 12.7 million pounds that were released to air in 1997 (12.6 million were released in 1996; 13.2 million were released in 1995) from facilities submitting TRI reports.

In addition, in reference to the ingestion of fruit containing acetaldehyde, the commenter ignores the vast difference in scale between the acetaldehyde that occurs naturally in fruit and that released by facilities reporting to TRI. Acetaldehyde has been identified as a natural constituent of fruits in amounts ranging from 0.0005 to 230 ppm (Feron, V.J., et al., "Aldehydes: occurrence, carcinogenic potential, mechanism of action, and risk assessment" in *Mutation Research*, 259 (1991), 363-385). Therefore, a fresh fruit platter weighing 1 kilogram (2.21 pounds) might contain 115 mg (0.00025 lb) of acetaldehyde, assuming an average concentration of 115 ppm. By contrast, in 1996 the average annual amount of acetaldehyde released per TRI-reporting facility was 52,000 pounds (13 million lbs / 250 facilities). To reach this amount of acetaldehyde, the fresh fruit platter mentioned by the commenter would have to weigh 460 million pounds. Finally, EPA notes that the TRI data base includes releases on chemicals that meet the toxicity criteria of EPCRA section 313(d)(2). While the chemicals included in today's action and acetaldehyde meet these criteria, the other chemicals mentioned by the commenter that are components of fruit are not listed on TRI. Therefore, the public will not receive data on these chemicals.

With regard to the article by Viscusi cited by the commenter, EPA has clarified elsewhere in this document that it relates to *divergent* information from *multiple* sources. The author finds that when survey respondents are presented with a high and low risk estimates from different sources, the respondents tend to "veer toward the worst case judgement." The article's findings actually support the reporting of additional information on PBT chemicals to TRI because TRI provides a "convergent" source of information on releases and other waste management of toxic chemicals. Under TRI, industry develops facility-level data and reports it to the government. The results are then provided to the public, eliminating the potential confusion of divergent estimates by government and industry. In this fashion, TRI serves as a "neutral yardstick" by which all affected stakeholders can measure progress.

Finally, EPA does not believe that TRI may "misinform and mislead communities about potential health risks." EPA is very clear in communicating the limitations of TRI data in the annual public data release and other venues. With respect to risk, EPA recognizes that TRI reports reflect releases and other waste management activities. The determination of potential risk depends on many additional factors, including the toxicity of the chemical, the fate of the chemical after it is released, and the human or other populations that are exposed to the chemical after it is released. As discussed at length elsewhere in this document, the commenter misunderstands the purpose of TRI data. The TRI data do not, in themselves, convey risk information. Nevertheless, as discussed in the economic analysis, many users have found TRI data to be a useful input. Although additional information is necessary to assess exposure and risk, TRI data can be used to identify areas of potential concern. Furthermore, TRI data, in conjunction with other information, can be used as a starting point in evaluating exposures that may result from releases and other waste management activities of toxic chemicals.

Comment: A commenter (C-1448) states that the time and money required to compile and report on releases of certain chemicals diverts resources from other activities, some of which may be more effective at protecting health and the environment. The commenter claims that requiring the disclosure of information on certain product attributes can shift competition among sellers into those attributes, and away from undisclosed attributes, potentially causing distortions in the product market. The commenter indicates that an article by Beales, Craswell, and Salop supports this position. The commenter claims that for TRI disclosures this distortion can result when the release of information encourages facilities to take actions to reduce their use or release of certain chemicals at the expense of other actions that may be more effective at protecting health and the environment, or at achieving other social goals. To the extent the information reported is inaccurate or used to mislead people about threats to their health or well-being, the commenter asserts that it is very likely to result in actions that are not warranted by objective risk analysis and which divert scarce resources from actions that actually could reduce health risks and environmental harm.

Response: The commenter's scenario is completely hypothetical, with no concrete examples or supporting evidence. The commenter claims that TRI reporting is unrelated to efforts to protect health and the environment. However, the commenter has not identified specific activities which would be more effective at protecting health and the environment than TRI reporting. In

fact, as described elsewhere in this document, TRI reporting actually assists facilities in identifying pollution prevention opportunities and measuring pollution prevention effectiveness.

With regard to the assertion that TRI disclosures will distort the market, the commenter has again misinterpreted the economic literature. In fact, it is the market as it currently exists that is distorted. Consider the following quotation from the same article cited by the commenter:

Taking a more general equilibrium view, the marketplace responds by channeling competition toward more easily observable product attributes and signals of unobservable product characteristics. By generalizing the concept of the “lemons” equilibrium, we can show that, if price is more easily observed than quality, competition may be skewed toward less expensive, lower-quality products. If consumers cannot easily obtain information about a product’s safety (but can easily observe its price), price competition may reward those who cut their price by offering a less safe product (Beales, H., R. Craswell, and S. Salop, “The Efficient Regulation of Consumer Information” in *The Journal of Law and Economics*, Vol. XXIV (3), December 1981, p. 510-511).

This quotation describes the situation that currently exists for products and processes associated with PBT chemicals. Absent TRI reporting, it is difficult for consumers to become informed of the PBT chemical releases and other waste management activities. Environmental performance and associated impact is a product “quality” attribute that often cannot be evaluated without regulatory intervention (such as TRI reporting).

Without TRI reporting, consumers lack information to evaluate the full range of product characteristics. Therefore, the market rewards lower-quality, less safe products associated with PBT chemical releases. The commenter may be correct that TRI will affect product markets. However, rather than creating distortions, these effects will bring markets closer to an efficient outcome by providing information to help consumers more fully evaluate products.

Comment: A commenter (C-1456) asserts that TRI reporting requirements may discourage companies from efforts to reduce PCBs from their electrical system because a voluntary phase down will add to the total reported release of PCBs. The commenter asserts that other utilities will find themselves in a position similar to the commenter, who reported on quantities of PCBs removed from a generating station as an off-site transfer. The commenter indicates that if PCB removal is counted as a “release,” companies will have a disincentive to phase out PCBs.

Response: EPA believes that the commenter has not correctly interpreted the existing and proposed requirements for reporting PCBs to TRI. According to EPCRA Section 313 Policy Directive #6, the threshold determination for PCBs in electrical equipment is based on PCB-containing fluid that is *added* to equipment, not the amount of fluid that is contained in the equipment, removed, or lost. It appears that most facilities remove and dispose of PCB-containing equipment in its entirety following the active life of the equipment, or refill the equipment with fluid that does not contain PCBs. In either case, these activities do not constitute manufacture, process, or otherwise use of PCBs for the purpose of threshold determination and reporting as long as the facility is not sending the PCBs off-site for recycling. Because facilities that only remove PCBs for off-site transfer and disposal would not count these quantities for the purpose of threshold determination, EPA does not expect that the final rule will create a disincentive to phase out PCBs from this application.

Comment: A number of commenters (C-1815, C-1817, C-1836, C-1844) assert that the cost to comply with the PBT TRI as proposed, will be very high, driving up the costs of goods to consumers. One commenter (C-1836) asserts that the major effect of the proposed rule will be to significantly increase the number of reports of zero releases and over-estimated releases (which may cause undue alarm) at a significant cost (reporting and otherwise) to businesses, with little or no benefit to society. The commenter asserts that the public will ultimately pay for this burden in the form of higher prices and/or loss of jobs. Another commenter (C-1841) asserts that competing firms in foreign countries will be advantaged by EPA’s proposal because the proposal does not correspond to regulations abroad and U.S. firms cannot pass the costs along to the customer. A commenter (C-1448) asserts that TRI has other important distributional impacts that are implicit in EPA’s analysis, but not directly addressed. The commenter asks EPA to consider benefits that will also accrue to competitors, national and international, seeking a competitive advantage.

Response: EPA disagrees that the cost to comply with the proposed rule will be very high. As shown in EPA’s analysis of the estimated impact of the proposed rule, only 4 of approximately 3,600 small businesses are expected to experience annual cost impacts between 1 and 3 percent of annual revenues in subsequent years of reporting. All other small businesses are expected to experience annual cost impacts that are less than 1 percent of annual revenues. As shown in Table 5-2 of the economic

analysis of the proposed rule, the expected cost impact of the proposal is insignificant for almost all possible combinations of reports per facility and annual revenue levels. The commenters have provided no data or analysis to refute this conclusion. At these low impact levels, it is unlikely that job losses would result. EPA notes that the commenters have provided no evidence that costs would be passed along in their entirety to consumers, or that these costs would be significant. In fact, one commenter argues that none of the costs could be passed along to consumers. Furthermore, the commenters have not provided any evidence that the insignificant impacts of the proposed rule at the firm level would provide a noticeable advantage to foreign competitors. Again, the commenters provide only unsubstantiated assertions.

As stated elsewhere in this document, EPA's economic analysis of the proposal accounts for costs that are attributable to actions that are required by the rule. EPA requires that facilities complete their EPCRA section 313 reports using their best readily available information, or reasonable estimates. The commenter has provided no examples of situations in which using this information would lead to over-estimated releases. In fact, EPA has proposed eliminating range reporting for PBT chemicals to avoid the misinterpretation through overestimation of data reported in ranges.

EPA disagrees with the contention that the proposed rule will significantly increase the number of "zero release" reports. Due to a lack of existing sources of reliable data about multi-media releases and other waste management of PBT chemicals at the facility, community, or national level, it is impossible to accurately predict the quantities that will be reported as a result of the proposal. Past attempts to estimate the quantities of releases prior to actual reporting have been grossly inaccurate. Furthermore, the commenter provides no evidence to support this contention.

Even if some reports reflect zero releases, EPA notes that one commenter (C-1432) has argued that there is a significant value to reports of zero releases because they allow the identification of facilities that employ successful methods of pollution prevention and control that can be analyzed and applied to other facilities. Furthermore, the TRI reporting form also contains important information on quantities of waste otherwise managed on-site and transferred for off-site management, as well as qualitative information on source reduction activities. Focusing exclusively on releases ignores the value of this information.

Commenter List: C-1405; C-1419; C-1427; C-1440; C-1857

Comment: Commenters are concerned about the burden imposed by lower reporting thresholds for mercury. Commenter states that the proposed lower mercury reporting threshold, particularly combined with the elimination of existing EPCRA section 313 exemptions, would require covered facilities to locate and inventory every device containing mercury, including thermometers, and record every "release" of mercury from such instances as thermometer breakage. These requirements are excessive, and commenter questions whether the information collected will provide any real value to the reduction in the use of PBT chemicals or their presence in the environment. Commenter states that many facilities are in the process of replacing mercury filled apparatuses with non-hazardous alternatives – such initiatives should be encouraged rather than subjected to increased reporting burdens. Commenter states that managing the new reporting requirements for mercury, and working on a facility-by-facility basis, will take resources away from developing solutions.

Response: There are still a number of exemptions in place, such as the article exemption, the otherwise use exemptions, and the laboratory activities exemption, which have the effect of limiting reporting burden. To use the commenter's example, certain thermometers are still exempted under the otherwise use exemptions (although process related thermometers would not be exempted). And mercury-filled apparatuses such as thermometers that remain sealed should qualify for the article exemption.

While the rule removes the *de minimis* exemption for PBT chemicals, the rule does not affect the fact that all quantities that are not exempted must be considered in threshold and release calculations, regardless of the quantity of the chemical involved. Facilities were not previously allowed to disregard particular sources simply because of their size. Instead, the lowering of reporting thresholds for PBT chemicals affects whether a particular facility exceeds the threshold and has to file a report.

EPA disagrees that these requirements are excessive. Given that even small quantities of mercury and other PBT chemicals can be of concern, EPA believes that the information collected will be of real value to citizens, researchers, and government officials in providing a more comprehensive picture of the releases and other waste management activities for PBT chemicals.

EPA does not believe that the reporting requirements discourage facilities from replacing mercury with non-toxic, non-hazardous alternatives. Based on the experience of facilities that have reported to TRI in the past, EPA believes that the revised regulations will focus facilities' attention on their activities involving mercury. This will complement, and not detract from, activities to develop solutions.

7.h. Other comments on economic aspects of the rule

Commenter list: C-1353, C-1356, C-1421, C-1431, C-1425, C-1435, C-1438, C-1439, C-1447, C-1448, C-1841, C-1850, C-1852, C-1858, C-1865

Comment: A commenter (C-1448) disputes whether TRI provides reliable information on inter-temporal and inter-facility trends as indicated in the economic analysis of the proposal. The commenter quotes the 1991 PDR, which stated that "Estimation technique changes" and "other factors" accounted for 82 percent of the increases reported between 1989 and 1990, and 67 percent of the 1989 to 1990 decreases (EPA, "1991 Toxics Release Inventory – Public Data Release." 1991, p. 163).

Response: The commenter cites several results from a statistical study conducted to assess the comparative impact of various real and "paper" changes on the TRI data between 1989 and 1990. The commenter provides no reason for citing changes in reporting that occurred 10 years ago near the beginning of the TRI program, but it is apparent that the commenter selectively chose statistics to support the position that TRI does not provide reliable information on inter-temporal and inter-facility trends.

The commenter fails to note that "estimation technique changes" accounted for only 3 percent of the net change in TRI releases and transfers between 1989 and 1990: a relatively small percentage. "Other factors" accounted for 48 percent of the net change in TRI releases and transfers between 1989 and 1990, but almost half of this change is attributable to the modification of the single chemical listing for ammonium sulfate. Other real (as opposed to "paper") reasons for changes in the "other factors" category include accidental releases, one-time releases, and increased recycling (EPA, "1991 Toxics Release Inventory – Public Data Release." 1991, p. 163).

The commenter also fails to note that production change was the most frequently cited reason for reported emissions changes. Nearly 70 percent of facilities contacted cited "production change" as responsible for at least part of their reported release/transfer change, and it accounted for a larger share of total net changes than "estimation technique changes." Furthermore, "source reduction" was cited as a reason for change by 40 percent of facilities. Source reduction accounted for 45 percent of the net change TRI releases and transfers between 1989 and 1990 (EPA, "1991 Toxics Release Inventory – Public Data Release." 1991, p. 163).

A less selective examination of the results of the study indicate that changes in reported emissions and transfer are far more likely to be the result of real changes in facility operations such as the changes in production, source reduction activities, recycling, and accidental or one-time releases. "Estimation technique changes" are a relatively small contributor to inter-temporal or inter-facility trends, and when the change in the listing for ammonium sulfate is disregarded, "other factors" are more likely to be associated with real facility-level events that change actual releases and transfers of toxic chemicals.

In comments on the TRI industry expansion rule (D2-356), the Chemical Manufacturers Association (CMA) noted that companies use TRI reports to target pollution prevention efforts, including source reduction and recycling activities, track any movement up the pollution prevention hierarchy, establish goals for environmental performance, and measure progress in meeting these goals over time. CMA also stated that it uses TRI data to measure progress under CMA's Responsible Care® Pollution Prevention Code. In an article on the Toxics Release Inventory, the Chemical Manufacturers Association is quoted as saying that "Reporting of releases to the environment is a good scorecard for tracking how our industry and other industries are doing in reducing and preventing pollution" (David Hanson, "Manufacturing facilities emitting fewer chemicals", Chemical and Engineering News, May 26, 1997, p. 10.)

A recent review of corporate environmental reports stated that "Since their introduction in the late 1980's, corporate environmental reports have catered to public demand by providing more technical information and fewer florid assertions about commitment to environmental protection. As a result, the reports have evolved from glossy brochures into slim texts composed primarily of bar graphs, an attempt to allow stakeholders to quickly chart a company's environmental performance." ("Sustainability Concerns Drive Demand for Data", Chemical Week, August 13, 1997, pp. 48 - 50.) The article includes a table

summarizing what metrics are included in the corporate environmental reports for 37 chemical companies. TRI data was the only metric that was included by all 37 companies. For examples, see the environmental health and safety reports by:

- Monsanto
http://www.monsanto.com/monsanto/about/sustainability/es&h_performance.html#
- Exxon
http://www.exxon.com/exxoncorp/main_frame_3.html
- Chemical Manufacturers Association
<http://www.cmahq.com/cmawebpage.nsf/pages/responsiblecare>
- American Petroleum Institute
<http://www.api.org/step/piep.htm>

TRI data is used by investors and financial institutions to evaluate a company's performance over time and compare it to competitors. "Repeated provision of information allows investors to benchmark a firm's environmental performance and make comparisons of performance over time as well as across firms. It is this feature of the TRI that enables stockholders to react to the changes in a firm's environmental performance over time." (Khanna et. al., "Toxics Release Information: A Policy Tool for Environmental Protection", Journal of Environmental Economics and Management, vol. 36 (1998), Article No. EE981048, p. 265). The fact that companies and investors choose to use TRI data in this way demonstrates that they have judged that it provides reliable information.

Comment: A commenter (C-1448) claims that the mandate that business information be made public creates a public good, with its own associated issues.

Response: The commenter does not indicate what the "associated issues" are, therefore EPA is not able to specifically address these issues. Furthermore, the commenter misapplies the meaning of "public good" as an economic term, and its applicability to this rulemaking activity. Information on chemical releases and waste management can be characterized as a "public good" because once the information is gathered, one person's use of the information does not preclude another's use of the same information, and it is difficult to prevent uncontrolled distribution of the information. In economic terms, the information is non-rival and non-excludable. Economic theory demonstrates that, absent some form of collective action or government intervention, private markets will fail to supply an economically efficient quantity of a public good. Indeed, the information reported to TRI is not available in the private market. EPA's rule reflects a government intervention in the private market to require the collection of this information by industry and the distribution of this information to the public. EPA's proposal supplies more of a public good that is currently undersupplied in economically inefficient quantities.

Comment: A commenter (C-1852) asserts that there is no justification for imposing a reporting burden on companies that process and use materials contaminated with hexachlorobenzene (HCB) or octachlorostyrene (OCS), and who have no information on the releases of these compounds. The commenter suggests applying the manufacture only activity qualifier.

Response: The justification for imposing a reporting requirement is that the chemicals meet the toxicity criteria, and the information provided will satisfy EPCRA Section 313(h). They also meet the persistence and bioaccumulation criteria as explained in the proposal and in section 3 of this document. It would be inconsistent for facilities handling materials contaminated with OCS or HCB not to report when facilities handling materials contaminated with other PBT chemicals have to report. The commenter has provided no justification why OCS and HCB should be treated differently than other PBT chemicals.

The commenter has provided no evidence that facilities that process and otherwise use materials contaminated with HCB or OCS have no information on the releases of these compounds. Facility release estimates should be based on the best readily available data including production records, monitoring, analytical data, guidance documents provided by EPA and trade associations, and reasonable judgement on the part of the facility's management. EPA believes that these sources of information will allow facilities to make reasonable release estimates for these chemical contaminants.

Comment: A commenter (C-1447) states that the positive externalities associated with personal incomes created by the industrial activities, whether to the shareholders, employees, or local support industries, should not be factored into the decision to collect and report chemical release information.

Response: Positive externalities, if any, associated with personal incomes created by the industrial activities were not estimated in the economic analysis of the proposed rule.

Comment: A commenter (C-1425) asserts that EPA must demonstrate that the releases of PBT chemicals at facilities that would report under the lower thresholds would pose risks to human health or the environment. The commenter asserts that without such a demonstration, reporting of PBT chemicals will impose extensive costs on the regulated community without commensurate benefits to communities. A commenter (C-1820) asserts that TRI reporting is a fruitless waste of resources if there is no health risk posed by the release of these chemicals.

Response: As noted elsewhere in this document, EPA does not agree that a risk assessment component should be part of EPCRA section 313 determinations. EPCRA section 313 is an information collection and dissemination provision that is fundamentally different from other environmental statutes that control or restrict chemical activities. The intent of EPCRA is not that EPA pre-determine what level of risk precludes gathering information that would otherwise be shared with a community. Rather, the statute charges EPA with collecting and disseminating information on releases and other waste management so that communities, researchers, and governments can estimate exposure and risks. EPA believes that placing the decision making on whether a community's potential risk is "acceptable" in the hands of EPA is not consistent with EPCRA.

Community empowerment is a cornerstone of the right-to-know program. By listing chemicals that present a hazard and providing TRI data on these chemicals to the public, EPA allows the public to make the determination of whether there may be unacceptable exposures and resultant risks. EPA believes that there is a strong demand for the information that would be gathered by the proposed rule as demonstrated by the large number of comments from members of the public supporting the rule. Therefore, EPA does not agree that reporting of PBT chemicals imposes extensive costs on the regulated community without commensurate benefits to communities.

Comment: A commenter (C-1850) asserts that EPA has not considered whether it would be more effective to add industries instead of lowering thresholds to capture additional reporting. Another commenter (C-1439) claims that the costs of adding medical and municipal waste incinerators to TRI reporting of dioxin would be minimal because these facilities already report their dioxin releases under other statutes (RCRA and CAA) implemented by EPA and the states.

Response: EPA acknowledges that the potential costs, benefits, or impacts of TRI reporting from these industries was not estimated as part of this rulemaking. At this time, EPA is not proposing to add medical and municipal waste incinerators. EPA may propose reporting from these industries in the future. With regard to dioxin, EPA notes that final standards and guidelines have been issued under the authority of the Clean Air Act to reduce air pollution from both medical and municipal waste incinerators. These standards are expected to reduce air emissions of dioxin by about 99 percent for municipal waste incinerators and 95 percent for medical waste incinerators from 1995 levels (for details, see the following URLs:

1) <http://www.epa.gov/ttn/uatw/129/hmiwi/hmiwifs.html>

2) <http://www.epa.gov/ttn/uatw/129/mwc/fsmwcs.html>.

Comment: A commenter (C-1356) suggests that EPA could obtain reporting on a substantial majority of total releases by combining a 100/1000 pound threshold with "emergency release reporting" and "continuous release reporting" information as reportable quantities (RQs) under EPCRA.

Response: The commenter suggests using accidental release data reported to the Emergency Response Notification System (ERNS) as a substitute for TRI data. The commenter has not provided any analysis to support the contention that EPA could obtain reporting on a substantial majority of total releases by combining a 100/1000 pound threshold with "emergency release reporting" and "continuous release reporting" information as reportable quantities (RQs) under EPCRA. TRI reporting thresholds apply to the manufacture, processing, or otherwise use of a listed toxic chemical over the course of a calendar year. By contrast, reportable quantities (RQs) are quantities released in a 24 hour period. Over the course of an entire year, 1 or 10 pounds released per day could result in a much larger amount than the proposed 10/100 pound TRI reporting thresholds.

The repository for data reporting as a result of RQs is ERNS. This is an EPA database that contains release notifications of oil and hazardous substances reported to the National Response Center (NRC), the ten EPA Regions, or the U.S. Coast Guard. ERNS contains data reported under the release notification requirements of several federal statutes: Section 103 of CERCLA; Section 304 of EPCRA; Section 1808(b) of the Hazardous Material Transportation Act (HMTA); and Section

311 of the Clean Water Act (CWA). ERNS is a database of initial notifications, made during or immediately after a release occurs. For this reason, data within ERNS may be incomplete or inaccurate and will not substitute for TRI release data. ERNS notifications are typically used by On-Scene Coordinators (OSCs) to determine the appropriate federal response action. Because data is reported to ERNS at such an early stage, the exact details of the release are often unknown and are therefore not reported. Approximately two-thirds of the 193 data fields in ERNS are not completed for most release notifications. Data in ERNS are generally reported over the telephone. Therefore, data inconsistencies may result from data entry mistakes. In addition, duplicate reports may appear in the database because of follow up calls that are not identified as such or observers reporting a release that has already been reported (http://www.epa.gov/ERNS/docs/erns_doc.htm). Furthermore, some aspects of the data captured by EPCRA section 313 and section 6607 of the PPA have no equivalent in the ERNS dataset, e.g., information on other waste management and off-site transfers. Therefore, ERNS records do not provide a suitable replacement for TRI data.

Comment: A commenter (C-1421) claims that EPA arbitrarily picked 10 and 100 pounds, and then moved in orders of magnitude to construct alternatives, and provided a rationale that it chose the thresholds to lower the reporting thresholds to a level that would capture significantly more information about PBT chemicals than current thresholds but that would not be unduly burdensome on industry. The commenter claims that this rationale does not hold up under scrutiny for several reasons. First, the analysis EPA presents in the preamble and supporting economic analysis document does not include the current thresholds. Thus, there is no information for comparing the proposed options with the current thresholds in order to determine whether the options capture significantly more information. Second, EPA does not estimate quantities of releases to be captured by lower thresholds, only the number of reports. Thus, there is no indication of what quantities of releases will be captured, or whether it will be significantly more than under current thresholds. Finally, EPA provides no definition or explanation of "significantly more information" or "unduly burdensome."

Response: EPA strongly objects to the claim that it arbitrarily picked 10 and 100 pounds, and then moved in orders of magnitude to construct alternatives, as the commenter states. The sequence of events was the opposite of what the commenter implies (that EPA made a decision and then created alternatives simply so that it could dismiss them). EPA chose four options (1 and 10 pounds, 10 and 100 pounds, 100 and 1,000 pounds, and 1,000 and 1,000 pounds), which it believed provided a reasonable range of alternatives. The Agency then reviewed the evidence and selected 10 and 100 pounds as the preferred option. This in no way represents an arbitrary and capricious action by EPA.

The Agency notes that if the baseless and erroneous accusation implied by this comment were true, then it would not matter how many alternatives were presented, as a dozen or even a hundred alternatives would not prove that the Agency had not put up alternatives just to knock them down without giving them due consideration. The actual situation was the reverse of this; EPA limited the analysis to a manageable set of alternatives so that it could give them serious consideration before making a decision.

EPA estimated the number of reports that would be submitted by each industry sector for four groups of thresholds, 1 and 10 pounds, 10 and 100 pounds, 100 and 1,000 pounds, and 1,000 pounds for both classes of chemicals (highly persistent and highly bioaccumulative chemicals, and persistent and bioaccumulative chemicals). These options were selected for the following reasons. EPA needed a reasonable but finite number of options to evaluate, and the options described above represent a reasonable picture of the entire range of potential revised thresholds. Data limitations on the manufacturing, processing, and otherwise use of PBT chemicals in the numerous industries, processes, and uses covered by EPCRA section 313 constrained EPA's ability to make meaningful and reliable distinctions between threshold options that are less than an order of magnitude apart. For example, while EPA believes it can reliably estimate the difference in the number of reports from a 10 pound reporting threshold and a 100 pound reporting threshold, EPA believes that the data are insufficient to allow it to make a meaningful and reliable distinction in estimates of options that are closer than an order of magnitude such as 35 pounds and 50 pounds. EPA explained its data limitations in the proposal, and commenters provided no information that would allow the Agency to increase the resolution of its analysis. The commenter provides no evidence that these order of magnitude alternatives are not reasonable.

The economic analysis was based on estimates of average amounts of different chemicals used in different industries. If the commenter so desired, it could have used this information to estimate reporting and costs for the current thresholds. Therefore, EPA disagrees that the analysis did not present information to allow comparison of the proposed options with the current thresholds. The economic analysis estimated the number of reports and facilities by chemical. The proposed rule proposed lowering reporting thresholds for hexachlorobenzene, mercury and mercury compounds, polychlorinated biphenyls, polycyclic aromatic compounds, and several pesticides (aldrin, chlordane, dicofol, heptachlor, isodrin, methoxychlor,

pendimethalin, toxaphene, and triflurlin), all of which are currently listed under EPCRA section 313. The appendices in the economic analysis did list the number of reports at current thresholds for these chemicals. (In addition, this information is readily available in the TRI database.) Thus, the commenter could have easily chosen to compare the proposed options with the current thresholds, although there is no evidence that it did so.

EPA did not lower the reporting threshold for vanadium, but proposed to expand the coverage of the listing from vanadium fume or dust to all vanadium and vanadium compounds. The economic analysis listed the industries and number of reports currently reporting vanadium fume or dust. The commenter could have found more details on these reports in the TRI database, if it desired.

Benzo(g,h,i)perlene, dioxin, octachlorostyrene, and pentachlorobenzene, are not currently listed under EPCRA section 313, but EPA made its estimates by calculating the average amount of each chemical in different industries, comparing this amount to the different thresholds (1, 10, 100, and 1,000 pounds), and tallying up the number of additional facilities in each industry where the average was estimated to exceed the threshold under consideration. The commenter could have used the data in the appendices of the economic analysis and applied this same methodology to a threshold of 10,000 or 25,000 pounds. Furthermore, EPA's economic analysis for the December 6, 1996 proposal to list dioxins and dioxin-like compounds indicated that there would be no reports submitted under current thresholds.

EPA is also adding tetrabromobisphenol A (TBBA) to EPCRA section 313. However, the analysis for TBBA specifically stated that there would be 146 reports submitted at current thresholds.

Finally, EPA proposed to add fluoranthene and 3-methylcholanthrene to the PACs category and lower the reporting threshold for these chemicals, but was not able to provide estimates for these new chemicals separate from the PACs that are currently listed. As EPA explained in the economic analysis, the emission factor data on which it based the estimates for the PAC category were based on groups of chemicals (such as 7 PACs and 16 PACs), instead of for each individual chemical in the PAC category. Therefore, EPA was not able to make separate estimates for these two chemicals. In any event, the commenters appear to have made no use of the available data to compare reporting under the proposed option to current thresholds for all the other chemicals discussed above. Therefore, there is no evidence that they would have made use of separate estimates for these two PAC chemicals even if such estimates were available.

In summary, while the economic analysis did not summarize the reporting expected at current thresholds in a single paragraph or table, it did contain all the information needed to readily assemble such a figure for each chemical or chemical category. Thus, the commenter's statement that there is no information for comparing the proposed options with the current thresholds is incorrect.

In response to the commenter's second objection (that EPA did not estimate quantities of releases to be captured by lower thresholds, so there is no indication of what quantities of releases will be captured, or whether it will be significantly more than under current thresholds), EPA has explained elsewhere in this response to comments document that it does not believe that it can make reliable estimates of the quantities of releases that would be reported at the lower thresholds, and that even if reliable estimates were available they would not measure the benefits of the information provided. Therefore, EPA has not estimated the quantity that would be reported. The Agency does not believe that the Administrative Procedures Act requires it to make such estimates in this situation.

Comment: A commenter (C-1846) notes that metal mining was not listed in the potentially affected entities box in the preamble. The commenter asks whether this omission was because EPA does not believe this newly added industry will be affected by the proposal or because it was not intended to be covered by the proposal. The commenter requests that EPA clarify if metal mining was not listed as a potentially impacted industry because it was not intended to be covered by the proposal or, alternatively, if EPA intended metal mining to be covered by the proposal, that EPA describe why metal mining was not specifically listed as a potentially impacted industry. The commenter asserts that if the metal mining industry is to be covered, the notice does not provide appropriate notice to that regulated community to satisfy the mandates of the Administrative Procedures Act ("APA"), see 5 U.S.C. § 553, and EPA should re-publish this proposed regulation with specific notice to the metal mining industry.

Response: The proposed rule did provide adequate notice to potentially impacted industries. The potentially affected entities box is intended only as an aid to readers, and not a comprehensive list of all entities that may be affected by the regulation. As such, the box is labeled as containing "examples" of potentially affected entities. Section I.A of the preamble ("Does This Action

Apply to Me?") states that "Potentially affected categories and entities may include, *but are not limited to*" those listed in the box. Furthermore, section I.A states that "This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in part 372 subpart B of Title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding "FOR FURTHER INFORMATION CONTACT" section." (64 FR 688). Furthermore, the economic analysis for the proposed rule (*Economic Analysis of the Proposed Rule to Modify Reporting of Persistent Bioaccumulative Toxic Chemicals Under EPCRA Section 313*), which was reference 79 in the Federal Register notice, clearly included the mining industry as being covered by the proposed rule.

If commenters had any questions about the coverage of the proposal they could have contacted EPA, as the preamble directed. However the numerous comments on the substance of the rule submitted by this and other commenters in the metal mining industry indicates that there was no confusion, and that they understood that they were covered by the proposal.

Comment: A commenter (C-1438) asserts that EPA has violated the principles underlying the Administration's "reinventing government" initiatives because the commenter does not believe that EPA has designed a regulation that achieves environmental goals while minimizing costs to individuals, businesses, and other levels of government.

Response: EPA disagrees that it has violated the principles of the "reinventing government" initiatives, and believes that the regulation does achieve its environmental goals while minimizing costs. As EPA noted in the proposal, "In choosing the proposed EPCRA section 313 thresholds for these PBT chemicals EPA took into consideration a number of factors including small business impacts, overall reporting burden, and report generation in addition to utility of the information. It has been EPA's goal, under the EPCRA section 313 program, to maintain a balance between community right-to-know and overall reporting burden for the affected industry" (64 FR 712).

EPA attempted to minimize the cost of the regulation to the extent that such consideration would not deny the public significant information from a range of covered industry sectors. However, the Agency's choices were governed by EPCRA section 313's overriding purpose, which is to provide government agencies, researchers, and local communities with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems.

The primary objective for this rulemaking is to address one of the most significant gaps in the information currently reported under EPCRA section 313 -- information on releases and other waste management practices relating to PBT chemicals. Addressing this gap will improve the usefulness of the range of data on these chemicals and will provide the public, government agencies, and researchers with access to critical information on PBT chemicals that can be used for many purposes, including, for example, to track the progress of national and international efforts addressing concerns about PBT chemicals. EPA believes that it has tailored its regulation to impose the least burden, consistent with achieving this objective.

Comment: In response to EPA's request for comment on the "propriety of the degree to which burden should be taken into consideration in this rulemaking," a commenter (C-1841) states that the Agency has a definite responsibility to consider the burden on industry. The commenter cites calculations that purport to show a five-fold increase in constant dollar TRI costs from 1988 to 2000. According to the commenter, competing firms in foreign countries will be advantaged by this proposal, making it more difficult for U.S. firms competing globally to pass the costs through to the customer. The commenter contends that U.S. industry cannot indefinitely absorb the costs of compliance for rule after rule promulgated by EPA that do not correspond to regulations abroad, and the potential for closures, for job losses through either closures or cost cutting measures, must be taken into consideration. Further, the commenter contends that EPA should account for the accumulative effect of rules under multiple statutes, because the effects of multiple rules may create undue hardship. The commenter contends that EPA has an obligation to consider alternatives that would reduce burden to the regulated community.

Response: EPA has taken burden into consideration in this rulemaking, which is why it chose the preferred option. As EPA explained in the proposed rule, "EPA believes that based solely on the degree of persistence and bioaccumulation it would be appropriate to set section 313 manufacture, process, and otherwise use thresholds to 10 pounds for chemicals meeting the 2- to 6-month and 1,000 to 5,000 criteria and to 1 pound for chemicals meeting both the 6-month or greater and 5,000 or greater criteria". (64 FR 711) It was because EPA considered the burden on industry that it proposed thresholds of 100 pounds and 10 pounds.

As explained elsewhere in this response to comments, the estimate that there has been a five-fold increase in constant dollar costs for the TRI program is fundamentally flawed, and is therefore not relevant. In response to the comment about the impact on U.S. firms compared to foreign competitors, other countries are considering banning PBTs, which is more burdensome than reporting on them. In addition, the U.S. has been a leader in the development of Pollutant Release and Transfer Registers (PRTs). Other nations are operating or are establishing databases similar to TRI. These nations may also lower the reporting thresholds for PBTs in their PRTs in the future, in which case foreign firms would be facing similar requirements. Finally, EPA notes that under section 313, imports are reportable as being manufactured, so goods produced abroad are not entirely exempt from reporting.

The commenter is correct that companies may pass part of the compliance costs through to their customers. To the extent that this occurs, EPA has overestimated the impact of the rule on small entities, since the analysis assumes that firms bear the full cost of compliance, without accounting for such pass through.

While the commenter states that the potential for job losses must be taken into consideration, the Office of Management and Budget has indicated that macroeconomic effects (such as job creation and the international competitiveness of U.S. goods and services) only tend to be measurable if the economic impact of a regulation reaches 0.25 percent to 0.5 percent of Gross Domestic Product (in the range of \$1.5 billion to \$3 billion). A regulation with a smaller aggregate effect is highly unlikely to have any measurable impact in macro-economic terms unless it is highly focused on a particular geographic region or economic sector. (Sally Katzen, Administrator, Office of Information and Regulatory Affairs, OMB. *Memorandum for the Heads of Executive Departments and Agencies*. March 31, 1995.) Neither this regulation or TRI in general is highly focused on a particular geographic region or economic sector. Therefore, EPA does not believe the regulation will have a measurable impact on the types of macroeconomic effects mentioned by the commenter. In addition, EPA notes that labor organizations such as the AFL-CIO, the Communications Workers of America, the Brotherhood of Railway Carmen, and the Coalition of Labor Union Women, submitted comments in support of the proposed rule.

In response to the comment that EPA should account for the accumulative effect of rules under multiple statutes, EPA believes that calculating the incremental costs, benefits, and impacts of a rulemaking provides the appropriate information to make decisions regarding that rulemaking. EPA notes that the ICR does estimate the cumulative burden of EPCRA section 313 rulemakings. EPA does not, however, believe that it is practical to estimate the cumulative impact of regulations under different statutes. In response to the comment that EPA should consider alternatives that would reduce burden to the regulated community, EPA notes that it did so, as it considered options with higher thresholds (and thus lower burden) than the preferred option.

In summary, EPA requested comment on the propriety of the degree to which burden should be taken into consideration in this rulemaking. The commenter stated that EPA should consider burden and then made a number of erroneous or unsubstantiated comments about burden, without addressing the issue of how EPA should consider burden. Therefore, EPA continues to believe that it has appropriately considered the degree to which burden should be taken into account in this rulemaking.

Comment: Commenters (C-1353, C-1865) assert that EPA has failed to satisfy the objectives of the Government Performance and Results Act (GPRA). The commenters assert that EPA's performance measure in the proposed rule is whether reporting on a substantial majority of total releases from regulated industry sectors has been captured. The commenters assert that an increase in reporting is not equivalent to an increase in the amount of useful information, and suggest that the appropriate performance measure would be an estimate of the quantity of new release data.

Response: EPA disagrees that it has failed to satisfy the objectives of the GPRA. The GPRA requires departments and agencies to clearly describe the goals and objectives of their programs, identify resources and actions needed to accomplish these goals and objectives, develop a means of measuring their progress, and regularly report on their achievements.

This regulation serves to further EPA's goals and objectives. For example, one of the goals in EPA's Strategic Plan is "Preventing Pollution and Reducing Risk in Communities, Homes, Workplaces and Ecosystems". As the Strategic Plan notes, "PBTs are of great concern regardless of how they are managed. Reducing the presence of these chemicals will lead to safer chemical substitutions and manufacturing processes, eliminate some occupational exposures to certain chemicals of concern and, in general, result in safer communities ... EPA will reduce the toxicity of waste by focusing on reductions in persistent, bioaccumulative and toxic chemicals (PBTs)." This rule satisfies the objectives of the GPRA because the

information that is collected under it is a means of measuring progress in achieving EPA's goals and objectives with regard to PBT chemicals.

The GPRA requires agencies to develop a means of measuring the success of their programs. The commenters seem to be suggesting that before an agency can adopt a particular measure, it must predict what the measurement will show, and that EPA must develop a measure to gauge the effectiveness of the measurements it plans to use to gauge the effectiveness of its programs. EPA does not believe that the GPRA imposes any such requirement.

Comment: Several commenters (C-1421, C-1431, C-1435, C-1850, C-1858, C-1865) state that many of the releases reported will be zero, near zero, or of questionable accuracy, and cite SBA's December 21, 1998 estimate that "thousands, if not ten thousand" of the additional reports will report zero or near zero amounts. Another commenter (C-1836) contends that the burden of the proposed rule is excessive, particularly for small facilities, and cites estimates by the U.S. Small Business Administration which indicate the cost of reporting vanadium, cobalt, mercury and PACs (polycyclic aromatic compounds) for petroleum bulk plants will exceed \$100 million/ton released. The commenter asserts this information will contribute "essentially nothing to right-to-know." Another commenter (C-1448) suggests that EPA use SBA's analysis on the fraction of total releases captured by different reporting thresholds to make more reasoned determinations on appropriate threshold levels.

Response: EPA does not believe that SBA's analysis is accurate, or that it would assist EPA in making a "more reasoned determination on appropriate threshold levels." SBA assumed that any report that was not filed as a result of fuel combustion would have a maximum releases of 0.01 pounds (so-called "zero or near-zero" releases). EPA does not believe that there is any factual basis for making this assumption. SBA has not indicated that it has any data not already considered by EPA. Therefore, EPA places no credence in SBA's release estimates. In addition, the estimate cited by the commenters is not relevant because the final rule did not include cobalt or lower the reporting threshold for vanadium and vanadium compounds, and PACs were moved from the classification of highly persistent bioaccumulative toxic chemicals under EPCRA section 313 to the classification of persistent bioaccumulative toxic chemicals under EPCRA section 313.

With regard to calculations of dollars of reporting cost per pound of release, EPA believes that tons are not a measure of the value of information. Therefore, cost per ton is not an appropriate metric to measure the value of reporting. EPA believes that even small amount of PBT chemicals are of concern because of the extent of their persistence and bioaccumulation. Furthermore, EPA disagrees that information collected by this rule will contribute "essentially nothing to right-to-know." EPA believes that the information will have significant benefits, and notes that the large number of public comments in support of the rule indicates that many members of the public share this belief.

Not only are SBA's assumptions unsupported by any new data, but as discussed elsewhere in this response to comments document, quantities of releases are not measures of benefits and estimates of release prior to TRI reporting will be extremely inaccurate. Any calculations based on these estimates are likely to be subject to such large error bounds as to be unreliable. Therefore, EPA believes that the use of SBA's release estimates and subsequent calculations would only misinform the decision-making process.

Comment: A commenter (C-1815) states that EPA cites a broad range of benefits from the TRI program, including the fact that the TRI system provides a neutral yardstick by which progress can be measured by all interested parties. The commenter claims that TRI is not a "neutral yardstick" for measuring progress. First, the TRI contains a limited set of data, reported from a limited set of sources. The majority of U.S. toxic releases, and potential sources, are not included in the TRI. Second, TRI data are made available to the general public without context being provided. A "complete" profile of emissions is simply not available through the TRI, particularly for those emissions (such as PBTs) where the majority of releases come from non-TRI sources. Third, EPA is proposing changes in this rule that will affect the Agency's guidance for reporting under the TRI, and which further impact the TRI as a "neutral yardstick." For example, EPA's past guidance on reporting "non-detects" at half the limit of detection is not appropriate at the lower thresholds proposed for PBTs. In addition, it is impossible to compare one covered TRI facility to another due to the different processes and technologies likely to be employed.

Response: The commenter's claim that TRI is not a neutral yardstick is belied by the fact that, as described elsewhere in this response to comments document, industry (including the commenter itself) uses TRI data itself. Companies such as Monsanto, Exxon, and General Motors, and associations such as the Chemical Manufacturers Association and the American Petroleum Institute all use TRI data to chart their progress. The fact that industry chooses to use TRI data to measure their environmental performance demonstrates its validity as a common metric that can be applied consistently, and used by all interested parties.

For example, the Chemical Manufacturers Association (CMA) noted in comments on the TRI industry expansion rule (59 FR 61432) that companies use TRI reports to target pollution prevention efforts, including source reduction and recycling activities, track any movement up the pollution prevention hierarchy, establish goals for environmental performance, and measure progress in meeting these goals over time. (See docket number OPPTS-400082, comment D2-356.) CMA also stated that it uses TRI data to measure progress under CMA's Responsible Care® Pollution Prevention Code. In an article on the Toxics Release Inventory, the Chemical Manufacturers Association is also quoted as saying that "Reporting of releases to the environment is a good scorecard for tracking how our industry and other industries are doing in reducing and preventing pollution" (David Hanson, "Manufacturing facilities emitting fewer chemicals", Chemical and Engineering News, May 26, 1997, p. 10.)

As another example, a recent review of corporate environmental reports stated that "Since their introduction in the late 1980's, corporate environmental reports have catered to public demand by providing more technical information and fewer florid assertions about commitment to environmental protection. As a result, the reports have evolved from glossy brochures into slim texts composed primarily of bar graphs, an attempt to allow stakeholders to quickly chart a company's environmental performance." ("Sustainability Concerns Drive Demand for Data", Chemical Week, August 13, 1997, pp. 48 - 50.) The article includes a table summarizing what metrics are included in the corporate environmental reports for 37 chemical companies. TRI data was the only metric that was included by all 37 companies.

As yet another example, TRI data is used by financial institutions to evaluate a company's performance over time and compare it to competitors. As a recent journal article noted, "Repeated provision of information allows investors to benchmark a firm's environmental performance and make comparisons of performance over time as well as across firms. It is this feature of the TRI that enables stockholders to react to the changes in a firm's environmental performance over time." (Khanna et. al., "Toxics Release Information: A Policy Tool for Environmental Protection", Journal of Environmental Economics and Management, vol. 36 (1998), Article No. EE981048, p. 265)

The commenter's statements are not internally consistent. The commenter states that TRI is not a neutral yardstick because certain sources do not report to TRI, but also argues in favor of modifying the proposed rule in ways that would reduce its coverage. If the commenter believes that the benefits of TRI are constrained because of the limited scope of reporting, restricting/constraining reporting as the commenter has suggested would only exacerbate the problem.

While TRI is a neutral yardstick, the Agency believes that there are still significant gaps in the picture the TRI data provides local communities, government agencies, and researchers. One of the most significant of these gaps is a comprehensive picture of the releases and potential exposure of PBT chemicals to humans and the environment. Currently, only a very limited picture of releases and other waste management of PBT chemicals is available from the TRI data, in part, as a result of the current thresholds. EPA strongly believes that increased reporting on PBT chemicals will improve the usefulness of the data on these chemicals. EPA believes the information that will be submitted is important to the public, government agencies, and researchers; for example, the information reported by facilities under the lower thresholds will help these groups assess the loadings of PBT chemicals in both local and regional ecosystems.

8.a. Alternative options suggested by commenters

Commenter List: C-403a and C-1432 (both from the same commenter)

Comment: The commenter suggests that EPA establish an alternative threshold/reporting scheme for dioxin and dioxin-like compounds rather than the 0.1 gram reporting threshold that EPA proposed. Specifically, the commenter asserts that EPA should establish a category of facilities that would be required to file a report for the dioxin and dioxin-like compounds category with no other threshold for reporting (or a threshold equivalent to zero). The commenter suggests that the facilities required to report be defined as facilities which use one or more of a list of processes known to produce and emit dioxin as identified by EPA's most recent "Inventory or Sources of Dioxin in the United States." The commenter claims that under this reporting scheme it can be readily verified whether a facility required to report has reported any releases since the only facilities that would not report amounts of dioxin and dioxin-like compounds would be those that have achieved zero dioxin. The commenter claims that even these facilities' success would be readily verifiable by the same combination of process engineering data and process verification testing which has confirmed zero dioxin production at other facilities. The commenter asserts that confirmation of zero dioxin production at facilities that claim zero can be verified by pollution prevention data collected by either: (1) requiring facilities that claim zero to report releases as zero and maintain the engineering, chemical feedstock, and other pollution prevention data on which they rely for their report for review upon request, or (2) require facilities claiming zero to report

engineering, chemical feedstock, and other data. In addition, they argue that this alternative threshold will be not be fraught with the compliance cost and enforcement concerns of EPA's proposed 0.1 gram threshold for the dioxin and dioxin-like compounds category.

Response: EPA disagrees with the commenters suggestions and conclusions concerning their alternative reporting scheme. First it must be noted that under EPCRA section 313 a facility does not have to file a report unless it is in a covered SIC code, has ten or more full-time employees, and exceeds the established reporting threshold. As EPCRA section 313(b)(1)(A) states:

“The requirements of this section shall apply to owners and operators of facilities that have 10 or more full-time employees and that are in Standard Industrial Classification Codes 20 through 39 (as in effect on July 1, 1985) and that manufactured, processed, or otherwise used a toxic chemical listed under subsection (c) in excess of the quantity of that toxic chemical established under subsection (f) during the calendar year for which a release form is required under this section”

Therefore, while under EPCRA section 313(f) EPA may establish a revised threshold based on categories of facilities, those facilities still have to exceed the revised reporting threshold before they are required to file a report. Further, the commenter's suggestion would have all of the problems that EPA has identified for a zero reporting threshold. EPA believes that a zero threshold would be impractical. Attempting to require facilities to determine if they manufacture, process, or otherwise use any amount whatsoever of these chemicals would be extremely burdensome and perhaps technically impossible. Without an actual numerical threshold, many facilities might report some amount of these chemicals just to make sure that they are in compliance. This could lead to misleading and inaccurate data on the actual sources of these chemicals as well as imposing increased burden on reporting facilities. EPA believes that rather than setting a zero reporting threshold it would be better to set a very low threshold that provides facilities with a clear indicator of when they are required to report. EPA explained these considerations in the proposed rule (at 64 FR 712) and has received no information from commenters that convinces the Agency to pursue a different approach.

In addition, although EPA's most recent inventory of sources of dioxin and dioxin-like compounds does identify sources, many of these sources are more appropriately characterized as “potential” sources rather than “known” sources. This is due to the fact that some source categories are made up of facilities that vary widely in terms of design and operating conditions and that for most source categories the specific combination of features that contributes most to releases of dioxin and dioxin-like compounds is not well understood. Thus, all facilities that may use one or more of the processes that the commenter identified are not necessarily going to coincidentally manufacture dioxin and dioxin-like compounds and in fact may never have produced these chemicals.

The fact that some facilities operating the processes that the commenter identified may never have produced dioxin and dioxin-like compounds is most important given the commenter's desire to have facilities maintain records to verify that they have “achieved zero dioxin.” If a facility determines that it has no production of dioxin and dioxin-like compounds and never did, how can the facility possibly document what it did to “achieve zero dioxin.” Most importantly, the recordkeeping requirements under EPCRA section 313 only apply to facilities subject to the reporting requirements under EPCRA section 313 (40 CFR 372.10(a)). To be subject to the reporting requirements, the facility must be in a covered SIC code, have 10 or more full-time employees, and exceed a reporting threshold. If a facility in a covered SIC code does not have ten or more full-time employees or does not exceed a reporting threshold, the facility is not subject to the recordkeeping requirements. Therefore, if a facility covered by the commenter's alternate reporting scheme because it operates one of the processes identified from EPA's dioxin inventory, determines that it does not produce dioxin, they are not subject to the recordkeeping requirements. This means that the facility would not be required to maintain the type of records the commenter suggests are necessary to confirm that dioxin and dioxin-like compounds have not been produced. Thus, EPA would not be able to review such records to determine if the facility did, in fact, produce dioxin and dioxin-like compounds or if why they may not have produced them.

EPA disagrees with the commenter's assertions that there will be no compliance costs or enforcement concerns associated with no threshold or a zero threshold for a certain class of facilities. As stated above, some facilities may actually produce zero dioxin and dioxin-like compounds and facilities are only required to report if they exceed a reporting threshold, including a zero threshold. Thus, at whatever thresholds are set, including a zero threshold, facilities will still need to perform compliance activities to determine whether or not they exceed the threshold and therefore need to file an EPCRA section 313 Form R. The commenter's concerns for enforcement of the proposed 0.1 gram reporting threshold would not be solved by requiring all facilities to report or by a zero threshold. Enforcement is dependent on EPA being able to determine that a facility did not report when it exceeded reporting thresholds or in the case of a requirement for all facilities to report, that EPA be able to

determine that the amounts reported are accurate. These issues do not change no matter what the reporting requirement may be. EPA will use its best information, including the guidance document that will be available for the dioxin and dioxin-like compounds category, to enforce the requirements of EPCRA section 313 at any threshold.

Commenter: C-800; C614; C580

Comment: The commenters assert that EPA should rely on bans and phase-outs to eliminate PBT chemicals with stringent enforcement and implementation of existing programs. They further contend that EPA should take steps to eliminate the use and release of toxins like mercury and dioxin by setting strict emissions standards for mercury from power plants, allowing for no new development of major polluting practices such as waste incineration, and phasing out any industrial chlorine process that results in the formation of dioxin. One commenter asserts that although zero discharge of all toxicants may not be feasible in the near future, it is a valid immediate goal for those substances with the highest documented risk, for example dioxins, and should be a long term goal for all persistent toxicants that bioaccumulate. Another commenter asserts that the PBT proposal should include all major sources of pollution, as well as information on toxic chemicals used in the work place, transported through communities, and placed in consumer products.

Response: EPA disagrees that EPCRA section 313 is the proper mechanism for the commenters' suggestions. EPCRA was not enacted to serve the same purpose as other regulatory programs but to collect and disseminate information to the public. Nor is EPCRA section 313 intended to regulate how a chemical may be used, the amount of chemical a facility manufactures, processes, otherwise uses, and releases, what media the chemical is released to, or how the chemical is otherwise managed as waste. Therefore, TRI, as an information collection and dissemination program, is not designed to directly impose controls for the protection of human health or the environment in the same manner as other regulatory programs. The benefit of the TRI program is that it empowers the public, through access to release, transfer, and waste management data on toxic chemicals, to make determinations about risks in their communities based on TRI data, site-specific information, and the properties of the chemicals.

Further, the commenters assert that additional information such as quantities of chemicals used in the work place, transported through communities and placed in consumer products should be collected under EPCRA section 313. EPA has considered collecting this type of information under EPCRA section 313 and the PPA (See 61 *FR* 51322; Oct. 1, 1996) but is not actively pursuing this option at the present time.

Commenters: C1573, C1631 and C0629 (both from the same organization); C1802, C0977, C1870, C2015, C0852, C1872, C1910, C1989, C0426, C 0624, C0619, C0428, C0429, C0575, C1132, C-433, C-447, C-577, C-579, C-581, C-582, C-583, C-586, C-591, C-593, C-601, C-603, C-608, C-610, C-617 ,632, C-791, C-844 ,847, C-850, C-855, C-858, C-859, C-862, C-981, C-983, C-988, C-992, C-993, C-1099, C-1831, C-1873, C-1874, C-1875, C-1876 , C-1878, C-1880, C-1881, C-1882, C-1883, C-1884, C-1885, C-1887, C-1888, C-1891, C-1893 , C-1895, C-1901,1903, C-1904, C-1906, C-1907, C-1908, C-1909, C-1915, C-1916, C-1917, C-1918, C-1920, C-1922, C-1923, C-1924, C-1925, C-1928, C-1931, C-1938, C-2027, C-2113 , C-2114, C-2115, C-2116 ,2117, C-2118, C-2119, C-2120, C-2121, C-2122, C-2123, C-2124, C-2125, C-2128, C-2129, C-2130, C-2132, C-2133, C-2134, C-2140

Comment: Several commenters assert that if EPA is concerned with the burden of the PBT rulemaking on small businesses, the Agency should explicitly provide for exemptions for small facilities.

Response: EPA disagrees that there should be a regulatory exemption for small businesses from PBT chemical reporting under EPCRA section 313. There is no provision in EPCRA section 313 that permits EPA to specifically exempt small businesses. EPCRA section 313(b)(1)(A) specifically states that:

[t]he requirements of this section shall apply to owners and operators of facilities that have 10 or more full-time employees and that are in Standard Industrial Classification Codes 20 through 39 (as in effect on July 1, 1985) and that manufactured, processed, or otherwise used a toxic chemical listed under subsection (c) in excess of the quantity of that toxic chemical established under subsection (f) during the calendar year for which a release form is required under this section.

Therefore, each owner and/or operator of a covered facility must file a report under EPCRA section 313 for each toxic chemical manufactured, processed, or otherwise used in excess of the activity threshold. There is no limitation or restriction on this requirement for a specific group of facilities such as small businesses. However, in a sense, Congress already provided an exemption for small businesses when enacting EPCRA section 313 by limiting reporting to facilities that employ ten or more workers. Facilities that have less than 10 full-time employees have always been excluded from complying with EPCRA section 313.

Further, the Small Business Administration definition of a small business includes any facility with less than 100 employees. This would include more than 96% of the facilities currently reporting under EPCRA section 313. EPA does not believe that exempting this many facilities would be consistent with the intent of informing the public about releases and other waste management of toxic chemicals in the community.

Commenters: C1815, C1822

Comment: The commenters suggest that EPA adopt a phased-in or step-wise approach to implementation of the PBT rulemaking. Under this approach, they assert, EPA would promulgate a rule with more limited application. EPA would then periodically review the data received, and adjust the program as needed to reflect the Agency's (and the public's) data needs. They argue that a step-wise approach would allow EPA and covered facilities to gain valuable reporting experience, identify potential roadblocks, and develop necessary solutions. They further contend that the effort would improve the quality of the data received, assist EPA in prioritizing sources of PBT chemical emissions, and reduce the burden on covered facilities.

Response: EPA disagrees that the Agency should use a phased-in approach for the PBT rulemaking. For some PBT chemicals currently on the list, such as mercury, mercury compounds and PCBs, EPA receives only a very few reports at the current thresholds. The currently available data provide a distorted picture of potential exposures to humans and the environment, because at the current thresholds only a fraction of the releases of these PBT chemicals from EPCRA section 313 covered facilities are reported. This limited reporting results in a significant underestimation of the actual releases from the industry sectors covered by EPCRA section 313. As such, the current data are of limited use for evaluating the potential exposures to humans and the environment of toxic chemicals that persist and bioaccumulate. Expanding the picture of potential exposures will increase the utility of all the TRI data on these chemicals. Not lowering thresholds substantially for these toxic chemicals would continue to severely limit the public's right-to-know.

In addition, EPA has already significantly limited the application of the final rule by considering burden in establishing thresholds. Although the Agency is not required to consider burden, EPA raised the thresholds it may have proposed by a factor of ten, if the Agency had only considered thresholds based on the chemicals' persistence and bioaccumulation potential.

Further, the commenters do not explain how this alternative would improve the quality of the data received or help EPA prioritize sources of PBT chemical emissions. Rather, implementing the PBT rulemaking in phases would restrict EPA's ability to determine the sources of PBT chemical emissions because the Agency would have a more limited inventory of such emissions from which to review.

Commenters: C1409

Comment: To help preserve year-to-year comparability of the TRI data, this commenter suggests that EPA add a yes/no check box to the Form R to indicate whether or not each PBT chemical specific form would have been required under the traditional thresholds of 25,000 and 10,000 pounds. Then, they assert, forms for PBT chemicals that would have met the old threshold could still be included in the year-to-year comparisons, where appropriate.

Response: EPA recognizes that changes in the EPCRA section 313 list and in the reporting requirements have an effect on the characterization of the TRI data. In fact, some change has occurred for every reporting year. In an attempt to provide useful year-to-year comparisons, EPA has presented the TRI data annually on a normalized list of chemicals, *i.e.*, the list of chemicals used for year-to-year comparisons is the same for every year in the comparison. EPA further recognizes the effect that the PBT rulemaking will have on the TRI data and will continue to work to find ways to make the data useable for cross-year comparisons. For example, EPA has used the 1995 reporting year as the base year for comparisons that include the chemicals added in 1995 under the chemical expansion rule.

EPA agrees that a yes/no check box indicating whether or not a given form would have been required under the 25,000 and 10,000 pound thresholds could be beneficial in making such comparisons. However, because EPA did not propose such an option for PBT chemicals, EPA could not, at this time, legally finalize such an option.

Commenter: 1428

Comment: The commenter encourages the Agency to expand its streamlining and burden reducing efforts to the list of toxic chemicals under EPCRA section 313. The commenter urges EPA to undertake a comprehensive review of the chemicals that are currently on the list with the goal of removing those chemicals that pose minimal risks to human health and the environment.

Response: EPA is in the process of reviewing the original list of EPCRA section 313 toxic chemicals to determine if these chemicals meet the toxic chemical criteria as outlined in EPCRA section 313 (d)(2). When, and if, EPA determines that any of the original chemicals on the list do not meet these criteria, EPA will propose to remove these chemicals from the list.

Commenter: C1408

Comment: The commenter contends that while the preamble language suggests a broad exemption for any facility that does not manufacture dioxin and dioxin-like compounds, the language in Section 372.28(a) refers to "processing, and otherwise using" these chemicals. They assert that the regulations should include only the term "manufacturing" and should delete the references to "processing" and "otherwise using." They argue that both of these terms could be construed to include facilities that process raw materials containing background levels of these chemicals.

Response: EPA disagrees that the regulatory text is unclear or inconsistent with the preamble language of the proposal. EPA is finalizing the listing for dioxin and dioxin-like compounds with the qualifier: "manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical." The regulatory text in 40 CFR 372.28(a) refers to all of the chemicals for which EPA has thus far lowered thresholds because of the chemicals' potential to persist and bioaccumulate in the environment. The chemical category dioxin and dioxin-like compounds is listed with its qualifier indicating that facilities need only consider these chemicals under certain circumstances. Traditionally, when listing the EPCRA section 313 toxic chemicals, EPA has always included each toxic chemical and, if appropriate, its qualifier. If a toxic chemical has a qualifier, covered facilities only consider the toxic chemical towards threshold determinations and release and other waste management calculations when the chemical is in the designated form or use. To EPA's knowledge, this practice has not thus far caused undue confusion for the regulated community or for the users of the TRI data. Therefore, EPA disagrees that including the chemical activities of processing and otherwise use in the regulatory text pertaining generally to PBT chemicals is likely to be misconstrued to include facilities that process raw materials that contain background levels of dioxins and dioxin-like compounds.

Commenter: C1448, C446

Comment: The commenters contend that EPA should limit the scope of the PBT rulemaking to a subset of facilities covered under EPCRA section 313. One commenter suggests exempting non-combustion sources while another commenter suggests focusing on sources such as coal-fire combustion units that contribute a significant amount of PBT chemicals to the environment.

Response: EPA disagrees with these commenters. Although EPA is aware that some processes may produce or use certain PBT chemicals, it is impossible to know exactly which facilities will manufacture, process or otherwise use these chemicals and in what quantities until the facilities closely review their processes. Historically, new, previously unknown information about releases and other waste management of toxic chemicals has come to light when facilities began complying with EPCRA section 313. With the PBT rulemaking, EPA has considered what information would provide communities with a comprehensive view of toxic chemical exposure given the attributes of PBT chemicals and with broad-based national information given the type of facilities covered by the rulemaking. Prematurely limiting reporting to a select group of covered facilities would unnecessarily restrict the information available to the public in the TRI database. Further, although limiting reporting to a subset of facilities covered under EPCRA section 313 might capture the very largest releases and other waste management of PBT chemicals from the EPCRA section 313 universe, many smaller sources would go unreported. In some

communities, these smaller quantities may constitute the entire amount of PBT chemicals release or otherwise managed as waste.

Commenter: C1438

Comment: The commenter contends that EPA should consider a variance mechanism for specific substances or matrices in which PBT chemicals may be found. A similar suggested vehicle could be a limited delisting mechanism for PBT chemicals that do not meet the listing criteria when presented in certain manners. They argue that such a mechanism, if properly structured, would prevent unnecessarily imposing regulatory burdens where there is no harm to the public, but at the same time a variance option would retain the underlying purposes of the PBT rule.

Response: Chemicals that meet the PBT criteria are PBT chemicals independent of whether they are contained in any other material. The commenter is really contending that PBT chemicals contained certain materials (*i.e.*, substances or matrices) are not bioavailable and thus there should be a mechanism for exempting the reporting of PBT chemicals when contained in such materials. However, such a mechanism already exists under EPCRA section 313. If the commenter believes that a PBT chemical is contained in a material from which it cannot become available then the commenter can submit a petition pursuant to EPCRA section 313(e)(1) to delete that PBT chemical from reporting when contained in such materials. EPA would address such a petition in a manner similar to the Agency's stated policy and guidance concerning petitions to delist individual members of the metal compounds categories (May 23, 1991, 56 FR 23703). Under the metals policy EPA considers whether the metal from a metal compound can become bioavailable under abiotic or biotic conditions. An assessment of the bioavailability of a PBT chemical contained in certain materials would include processes such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformation (both abiotic and biotic); bioavailability when the material is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs); and bioavailability when the material is inhaled (solubilization in and/or absorption from lungs, especially taking into account the likelihood that the material will lodge in the lungs and be converted to soluble forms by the lung's defense mechanism).

Commenter: C1448

Comment: The commenter suggests that EPA consider a wider range of alternatives, including raising the thresholds for non-PBT chemicals. They also argue that the Agency should estimate, at a minimum, the volume and fraction of releases that would be captured under different thresholds.

Response: EPA has already considered, and in fact has raised thresholds for a certain subset of EPCRA section 313 forms. Specifically, in 1994 EPA established the Form A certification statement for facilities meeting the requirements of an alternate threshold. Facilities that do not exceed 500 pounds for the total annual reportable amount for a chemical and that do not manufacture or process or otherwise use amounts in excess of one million pounds may avail themselves of this option. The annual reportable amount is equal to the combined total quantities released at the facility, disposed within the facility, treated at the facility, recovered at the facility as a result of recycle operations, combusted for the purpose of energy recovery at the facility, and amounts transferred from the facility to off-site locations for the purpose of recycle, energy recovery, treatment, and/or disposal. EPA believes it is inappropriate to further raise the reporting thresholds for the entire list of EPCRA section 313 chemicals and therefore is only lowering the reporting thresholds for PBT chemicals in this rulemaking.

Commenter: C1849

Comment: The commenter concludes from their comments on release and other waste management reporting under EPCRA section 313 and section 6607 of the PPA, that they would support the development of a different threshold for reporting PBT chemicals based on "releases" to the ambient environment.

Response: EPA disagrees that EPCRA section 313 would allow for such an option. The statute clearly states that the reporting thresholds under EPCRA section 313 are based on manufacturing, processing and otherwise use activities. (EPCRA section 313 (f)(1)). Basing thresholds solely on release estimates would be inconsistent with the statute. Further, EPA does not have release information on which to base such an alternate threshold for PBT chemicals. EPA is adding these

chemicals and lowering thresholds for the subset of PBT chemicals identified to determine the quantities being released from covered facilities. Therefore, EPA believes it is inappropriate to base thresholds on release estimates from covered facilities.

Commenter: C1849

Comment: The commenter asserts that EPA should consider opportunities under §6608 of the PPA (and perhaps as a revised report under §313(k) of EPCRA) to report to Congress the types of improvements in the management of environmental information that could result from changing various federal laws in order to eliminate duplicative reporting and provide for more efficient reporting under EPCRA section 313.

Response: EPA will consider the merits of this comment, and if the Agency determines that a report to Congress is appropriate, will do so.

Commenter: C1845

Comment: The commenter urges EPA to consider the use of a multi-year Form R -- a single filing that would stay on record until amended by the reporting source. They further contend that the Agency should consider broadening the reporting community for the special category of PBT chemicals. They argue that including all the major known or suspected sources of a PBT chemicals would provide both local communities and the nation as whole with a more complete understanding of PBT chemical releases. Further, they assert that it would create important opportunities to develop comprehensive national risk management strategies. The increased societal burden borne by broadening the reporting community could be off-set by reducing the reporting frequency for this special category. After more than a decade of experience with the TRI system, they contend that it is clear that year-to-year variations are less significant than the longer-term trends indicating overall progress; data collection every second or third year, *if* coupled with appropriate risk management action plans, could provide important information to track our national performance over the longer term.

Response: EPA disagrees that a multi-year Form R is appropriate for PBT chemicals specifically or for all toxic chemicals as a group. EPA believes that modulating the reporting thresholds would introduce confusion for both the regulated community and data users. For data users, EPA believes that modulating the reporting thresholds would limit the usefulness of the TRI data because there would be poor data consistency and poorer data quality. For the regulated community, EPA believes that the burden reduction would not be significant and would possibly be offset by the confusion that would be introduced by different thresholds in alternate years.

Further, as discussed elsewhere in these responses to comments, EPA disagrees that risk management action plans should be considered in determining strategies under EPCRA section 313. However, EPA does agree that it should consider broadening the universe of industries subject to EPCRA section 313 because of their potential to release or otherwise manage PBT chemicals as waste. EPA is therefore considering broadening the list of covered industries under EPCRA section 313 to include medical waste incinerators which are thought to generate considerable quantities of PBT chemicals.

Commenter: C1456

Comment: The commenter suggests that EPA change the Form R reporting instructions to focus on chemicals which currently are being produced and exclude toxic chemical which are being removed from service but were produced long ago. They assert that this could be worded to exclude chemicals produced before a certain date, such as the effective date of the EPCRA section 313 reporting regulations. Another option they suggest includes excluding chemicals for which production ceased more than a given number of years ago. They argue that either option would exclude "old" PCBs and focus reporting attention on "new" PCB production.

Response: There is no limitation under EPCRA section 313 or section 6607 of the PPA to not collect quantities of toxic chemicals in remediation wastes. Rather there is an explicit requirement under section 6607(b)(7) of the PPA to collect quantities of the toxic chemical that are released as a result of catastrophic events, one-time events and remedial activities not related to production. EPA is not planning to discontinue collecting these quantities of toxic chemicals from the reporting requirements of the TRI program. Further, EPA believes that requiring facilities to determine when a toxic chemical ceased

being produced or to determine if a toxic chemical was produced prior to some arbitrary date could be very burdensome for covered facilities. Therefore, EPA currently is not excluding PCBs or any other group of toxic chemicals from the EPCRA section 313 reporting requirements based on when the chemical was produced.

8.b. Need to put reported data in context

Comment List: C-1354, C-1453, C-1809, C-1815, C-1824, C-1844

Comment: Several commenters make the same general comment that EPCRA section 313 does not capture all sources of PBT chemical releases and therefore will not provide a complete or accurate picture of the releases of these chemicals. Commenters criticize the proposal for not putting the PBT releases from EPCRA section 313 covered facilities into context, in terms of either risk or the amount of PBT releases expected from non-covered facilities or sources. Some commenters stated that since EPCRA section 313 does not include exposure or risk considerations the data on PBT chemical releases will be misleading to the public by indicating risks where none exist. Another commenter adds that TRI contains a limited set of data, reported from a limited set of sources. Commenter states that the majority of U.S. toxic releases, and potential sources, are not included in the TRI. Thus, commenter believes that TRI data overstates the role of reporting facilities in emissions of covered chemicals.

Another commenter states that while they support the lowering of the reporting thresholds for PBT chemicals, they are concerned that the lowered thresholds could mislead the public in two very different ways:

- * The lowered thresholds imply that these PBT chemicals pose health risks even at very low levels of exposure. The inferences that the public could draw as a result may be misleading. Therefore, the public should be provided with more information about the health risks of each chemical at various levels of exposure.
- * The quantities of PBT chemicals reported in the TRI will be far smaller than the quantities of other chemicals which pose far lesser health risks. The small quantities could lead members of the public to overlook the data on PBT chemicals. Therefore, EPA should present PBT data in a way that draws the public's attention to it.

The commenter states that they see a danger that without sufficient education and guidance, the public may either overestimate or underestimate the health risks from PBT chemicals. Commenter believes that EPA should make a commitment to ensuring that the public is given the necessary education and guidance.

Another commenter expresses concern that release numbers for PBTs will not be comparable to those for other chemicals with higher reporting thresholds or to releases of the PBTs in previous years. Commenter adds that the lower thresholds may mislead the public into thinking that releases are rising or that a new chemical has been introduced at a facility.

Several commenters make suggestions about ways EPA could put data on PBT chemicals in context. These suggestions are summarized below.

- 1) When TRI data for dioxin and dioxin-like compounds are published, EPA should place a statement in the report that clearly indicates the percentage of total dioxin and dioxin-like compound emissions that these numbers represent. This percentage could change on a year-to-year basis depending upon the number of industries reporting and updates to the total dioxin and dioxin-like compounds emission estimates. This would help bring the emissions data from individual facilities into perspective.
- 2) EPA should consider ways to provide some context about releases and other waste management of PBT chemicals beyond what is provided by the "Public Data Release." By this the commenter means: a) information on the quantities of toxic chemicals emitted by non-TRI sources (to the extent that these data are available); and b) information on the human health and ecological risks of the various TRI chemicals (again, to the extent that these data are available). Commenter cites discussion in the "1996 Public Data Release," in the section entitled "Diffuse Sources," as a useful discussion and encourages EPA to do something similar that would include information on hazardous air pollutants.

- 3) EPA should provide support to state, county and local health departments, and schools of public health, which can evaluate the TRI data community by community and give the public impartial and credible guidance about what the data means.

Response: EPA disagrees with the implication by several commenters that simply because EPCRA section 313 may not capture all the sources of releases of PBT chemicals EPA should not attempt to capture more information from the facilities that do report under EPCRA section 313. This comment has been voiced in every major rulemaking under EPCRA section 313 but, as EPA has stated in the past, this is not an argument that EPA believes should restrict any efforts to collect additional data under EPCRA section 313. The mere fact that for some chemicals significant release sources are not captured does not in any way diminish the importance of the information that can be provided by those facilities that are required to report under EPCRA section 313. There is currently no one single reporting requirement that captures all of the releases of PBT chemicals and makes that information available to the public. For those chemicals that do have large release sources not captured under EPCRA section 313, EPA will use whatever additional data it has to assist the Agency in actions that might be taken under the Agency's PBT strategy or other PBT related programs and will not rely solely on the data collected under EPCRA section 313. In addition, if there are significant sources of PBT chemicals that are not reported under EPCRA section 313, EPA will attempt to let the public know that some sources are not captured. In fact, in the most recent TRI data release documents, EPA has been providing information to the public on other sources of releases for certain EPCRA section 313 chemicals. In addition, EPA will continue to improve and augment public information materials so that users of the data will have information available to put in context the releases and other waste management of PBT chemicals by industries reporting under EPCRA section 313 versus those industries that do not report under EPCRA section 313. In fact, rather than an argument against lowering the reporting thresholds for PBT chemicals, EPA believes that the argument the commenters are making is one that supports expanding the types of facilities that should be required to report under EPCRA section 313 and not an argument that supports denying the public the right to know about PBT chemical releases from EPCRA section 313 covered facilities.

Some commenters stated that since EPCRA section 313 does not include exposure or risk considerations the data on PBT chemical releases will be misleading to the public by indicating risks where none exist. EPCRA section 313 is not a risk-based reporting system; therefore, EPA disagrees with the commenter's suggestion that EPCRA section 313 should include exposure or risk considerations. EPA believes that a risk-based approach to EPCRA section 313 reporting is at odds with the basic premise of EPCRA section 313, which is to get information about the use, disposition, and management of toxic chemicals into the public domain, enabling the users of this information to evaluate the information and draw their own conclusions about risk. The intent of EPCRA section 313 is to move the determination of which risks are acceptable from EPA to the communities in which the releases occur. This basic, local empowerment is a cornerstone of the right-to-know program. EPCRA section 313 establishes an information collection and dissemination program. It provides the public with information that can be used with other site-specific factors to determine if releases into their communities result in risks that the community determines warrant further action given other factors, such as economic and environmental conditions, or particularly vulnerable human or ecological populations. In addition, EPA will continue to improve its annual public data release as well as its outreach and education efforts to assist users in understanding the data. Consequently, EPA disagrees with the commenters that EPCRA section 313 should be risk-based or that the information reported on releases and other waste management of PBT chemicals will be misleading to the public.

Another commenter states that the quantities of PBT chemicals reported in the TRI will be far smaller than the quantities of other chemicals which pose far less significant health risks. The commenter is concerned that the small quantities could lead members of the public to overlook the data on PBT chemicals. Therefore, the commenter argues that EPA should present PBT data in a way that draws the public's attention to it. The commenter states that they see a danger that without sufficient education and guidance, the public may either overestimate or underestimate the health risks from PBT chemicals. Commenter believes that EPA should make a commitment to ensuring that the public is given the necessary education and guidance. EPA understands that the quantities of PBT chemicals may be reported in smaller quantities than other chemicals under EPCRA section 313 and that these quantities have the potential to be overlooked. EPA is also sensitive to the issue that data on PBT chemicals must be presented clearly to assist data users in understanding how the information on PBT chemicals is different from that reported on other chemicals under EPCRA section 313. EPA will continue to improve its annual public data release as well as its outreach and education efforts to assist users in understanding the data. Despite the concerns voiced by the commenters, EPA still believes that it is important to collect and disseminate this information so that communities can use the information with other site-specific factors to determine if releases into their communities result in risks that the community determines warrant further action given other factors, such as economic and environmental conditions, or particularly vulnerable human or ecological populations.

Another commenter expresses concern that release numbers for PBTs will not be comparable to those for other chemicals with higher reporting thresholds or to releases of the PBTs in previous years. Commenter adds that the lower thresholds may mislead the public into thinking that releases are rising or that a new chemical has been introduced at a facility. EPA understands the commenters concern but does not believe this is a justification for not collecting additional information about PBT chemicals. EPA believes that it will be able to adequately explain to the public the different reporting requirements for PBT chemicals so that they are put in context of other TRI data. EPA will make clear which PBT chemicals were reportable prior to the finalization of this rule and what the reporting threshold was for these chemicals. Finally, EPA will continue to improve its annual public data release as well as its outreach and education efforts to assist users in understanding the data.

Several commenters make suggestions about ways EPA could put data on PBT chemicals in context. EPA will consider the suggestions offered by commenters for improving its outreach and education efforts.

8.c. Many significant sources of PBT's are not covered by the rule

Commenter List: C-001, C-004, C-008, C-021, C-024, C-044, C-353, C-514, C-521, C-526, C-529, C-531, C-532, C-555, C-559, C-561, C-564, C-566, C-573, C-794, C-801, C-837 C-1348, C-1349, C-1350, C-1410, C-1414, C-1439, C-1465, C-1462, C-1463, C-1824, C-1930, and C-1935

Comment: The commenters stated that the proposed rule fails to require municipal and medical waste incinerators report releases of PBT chemicals under EPCRA section 313. The commenters stated that these incinerators are a significant source of PBT chemicals such as mercury and dioxin and dioxin-like compounds, and requested that EPA require reporting under EPCRA section 313 for those facilities that operated such incinerators.

Response: EPA is going to review the information on municipal and medical waste incinerators to determine if they should be added to the facilities that must report under EPCRA section 313.

Commenter List: C-022, C-041, C-117, C-219, C-228, C-232, C-252, C-426, C-428, C-429, C-431, C-433, C-447, C-575, C-577, C-579, C-581, C-582, C-583, C-586, C-591, C-593, C-601, C-603, C-608, C-610, C-617, C-619, C-624, C-629, C-632, C-791, C-792, C-844, C-847, C-850, C-852, C-855, C-858, C-859, C-862, C-864, C-981, C-983, C-988, C-992, C-993, C-1099, C-1439, C-1810, C-1828, C-1831, C-1873, C-1874, C-1875, C-1876, C-1877, C-1878, C-1880, C-1881, C-1882, C-1883, C-1884, C-1885, C-1887, C-1888, C-1891, C-1893, C-1895, C-1901, C-1903, C-1904, C-1906, C-1907, C-1908, C-1909, C-1910, C-1914, C-1915, C-1916, C-1917, C-1918, C-1920, C-1921, C-1922, C-1923, C-1924, C-1925, C-1928, C-1929, C-1931, C-1938, C-2015, C-2027, C-2112, C-2113, C-2114, C-2115, C-2116, C-2117, C-2118, C-2119, C-2120, C-2121, C-2122, C-2123, C-2124, C-2125, C-2128, C-2129, C-2130, C-2132, C-2133, C-2134, C-2140, C-1573, C-1631, and C-1810.

Comment: The commenters stated that under the proposed reporting scheme for PBT chemicals many facilities would not have to report releases. The commenters stated that many power plants (which are the nation's largest source of mercury) would be exempt from reporting and that hundreds of oil refineries, paper mills, chemical plants, incinerators, and other industrial facilities would be able to hide their dioxin emissions and other pollution from the public. Many of these commenters requested that a reporting threshold of zero should be selected for dioxin and other PBT chemicals. Some commenters suggested that all dioxin sources should be required to report under EPCRA section 313. One commenter suggested that other major sources of PBT chemical releases be required to report under EPCRA section 313.

Response: EPA disagrees. EPA believes that most if not all of the power plants covered under EPCRA section 313 will have to report their releases of mercury. The situation for reporting on dioxin and dioxin-like compounds from power plants and the other types of facilities that the commenters mentioned is more complex. Whether a particular facility will be required to report for these compounds is not only based on the reporting threshold but also whether the facility has the ability to make at least a reasonable estimation of the quantities that are being manufacture, processed or otherwise used at the facility. EPCRA section 313(a) states in part that:

“The owner or operator of a facility subject to the requirements of this section shall complete a toxic chemical release form as published under subsection (g) for each toxic chemical listed under subsection (c) that was manufactured, processed, or otherwise used in quantities exceeding the toxic chemical threshold quantity established by subsection (f) during the preceding calendar year as such facility.”

And the provisions of EPCRA section 313(g)(2) state that:

“In order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation. In order to assure consistency, the Administrator shall require that data be expressed in common units.”

EPA will provide a guidance document to assist certain facilities in making thresholds and release determinations for dioxin and dioxin-like compounds but, given the language of section 313(a) and 313(g)(2), even if EPA were to attempt to require that all releases from all facilities be reported that would not necessarily mean that every facility would be required to report. Facilities that are not able to make at least a reasonable estimation of toxic chemical quantities do not have to report even if the reporting threshold is zero. In addition, EPA's selection of the lower reporting thresholds for PBT chemicals was based not only on the concerns for this class of chemicals but also reflected the fact that reporting burden is a consideration in the selection of reporting thresholds even if some facilities may not have to report. The issue of threshold selection is discussed in more detail elsewhere in these comment responses.

It would not be possible to have “all” dioxin sources report under EPCRA section 313 since some sources such as cigarette smoke, BBQ ranges, residential fireplaces, diesel exhaust, etc., would clearly not be facilities that could be required to report. With regard to facilities that could be covered under EPCRA section 313 but currently are not, EPA will evaluate the appropriateness of such additions in the future. The commenters may also be referring to “all” as all facilities currently subject to EPCRA section 313 which is a reporting threshold issue that is responded to elsewhere in these comment responses.

Commenter List: C-1354, C-1436, C-1440, C-1442, C-1443, C-1847, C-1448, C-1815, C-1844, C-1845, C-1847, C-1853, C-1866

Comment: These commenters all made the same general comment that EPCRA section 313 does not capture all sources of PBT chemical releases and therefore will not provide a complete or accurate picture of the releases of these chemicals. The commenters therefore suggest that this reporting under EPCRA section 313 is not appropriate and that EPA should use other mechanisms to provide this information to the public. Commenters stated that some industries covered by EPCRA section 313 will be required to report very small releases while other industries with much larger releases that are not covered under EPCRA section 313 will not be required to report and therefore reporting should not be required under EPCRA section 313. Some commenters stated that since EPCRA section 313 does not include exposure or risk considerations the data on PBT chemical releases will be misleading to the public by indicating risks where none exist. Many of these commenters specifically stated that dioxin and dioxin-like compounds should not be included because the major sources of these compounds are not captured under EPCRA section 313 and therefore the public will be provided with misleading data on emissions of dioxin and dioxin-like compounds. Some commenters stated that rather than requiring reporting for dioxin and dioxin-like compounds under EPCRA section 313 EPA should focus on those facilities and activities that have larger releases and exposures but are not captured under EPCRA section 313 reporting. One commenter stated that there are still dioxin sources that have not been identified and until this problem is addressed EPA should not require reporting under EPCRA section 313. One commenter stated that EPA should withdraw the proposal until facilities with large PBT chemical releases, such as municipal and medical waste incinerators which have large dioxin releases, are added to EPCRA section 313 so that the public would be given a more accurate view of the relative PBT sources. This commenter also stated that EPA should concentrate on ways to distribute the data which it already has and which it plans to collect in the near future from industries which are not subject to EPCRA section 313. One commenter stated that TRI reports are not put in context with releases from facilities that are not required to report and that relying on the TRI to target reduction efforts will result in misdirected efforts.

Response: EPA disagrees with the commenters statements that simply because EPCRA section 313 may not capture all the sources of releases of PBT chemicals EPA should not attempt to capture more information from the facilities that do report under EPCRA section 313. This comment has been voiced in every major rulemaking under EPCRA section 313 but, as EPA has stated in the past, this is not an argument that EPA believes should restrict any efforts to collect additional data under EPCRA section 313. The mere fact that for some chemicals significant release sources are not captured does not in any way diminish the importance of the information that can be provided by those facilities that are required to report under

EPCRA section 313. There is currently no one single reporting requirement that will be able to capture all of the releases of PBT chemicals and make that information available to the public. For those chemicals that do have large release sources not captured under EPCRA section 313, EPA will use whatever additional data it has to assist the Agency and other organizations in actions that might be taken under the Agency's PBT strategy or other PBT related programs and will not rely solely on the data collected under EPCRA section 313. In addition, if there are significant sources of PBT chemicals that are not reported under EPCRA section 313, EPA will attempt to let the public know that some sources are not captured. In fact, in the most recent TRI data release documents, EPA has been providing information to the public on other sources of releases for certain TRI chemicals. Rather than an argument against lowering the reporting thresholds for PBT chemical, EPA believes that the argument the commenters are making is one that supports expanding the types of facilities that should be required to report under EPCRA section 313 and not an argument that supports denying the public the right to know about PBT chemical releases from EPCRA section 313 covered facilities. As mentioned in another comment response on the specific issue of additional sources of dioxin releases, EPA is going to review the information on municipal and medical waste incinerators to determine if they should be added to the facilities that must report under EPCRA section 313.

Commenter List: C-1442

Comment: The commenter cited a statement in the preamble to the proposed rule that said "[a]ny revised threshold shall obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements." The commenter stated that for intentionally manufactured chemicals, "facilities subject to the requirements" often are few in number and easily identifiable. The commenter stated that for such chemicals, it is relatively easy to "[o]btain reporting on a substantial majority of total releases of a chemical at all facilities subject to the requirements." The commenter stated that dioxin is unlike other compounds on the TRI list in that it is not an intentionally manufactured chemical, it is formed in minute quantities as an unintentional by-product. The commenter stated that dioxin is formed in virtually all combustion processes, such as from cigarette smoke, BBQ ranges, residential fireplaces, diesel exhaust, accidental fires, etc. The commenter stated that these sources of dioxin release, while great in number, individually fall below the proposed 0.1 gram per year proposed EPCRA section 313 reporting threshold and that these dioxin sources, for the most part, are not covered under EPCRA.

The commenter stated that the utility of adding a chemical to the TRI is so that it conveys useful information to citizens living near these releases, allowing them to make informed choices. The commenter stated that the preamble states that, "[o]ne of Congress's articulated purposes for EPCRA section 313 was to provide local communities with relevant information on the release and other waste management activities of chemicals in their community, that may present a hazard (emphasis added)." The commenter stated that to understand the likelihood of any hazard requires that the TRI captures the majority or all releases and the majority of sources are not even covered under EPCRA and the proposed reporting threshold is still too high to capture those facilities that do fall under EPCRA jurisdiction. The commenter stated that for dioxin, where the sources of release are numerous, the quantities released small, and often not covered by EPCRA section 313, the intent of the above statement to provide "relevant" information for "hazard" characterization is unmet. The commenter stated that coupled with EPA's recognition that there are "reservoir" sources that continually and substantially redistribute dioxin in the environment previously deposited from historical practices and the likelihood that there are dioxin sources yet to be discovered the commenter concluded that the listing criteria and reporting threshold proposed for dioxin do not capture most dioxin sources and may not capture the majority of dioxin releases. The commenter stated that consequently, one cannot possibly understand potential health risks from reported releases when these reported releases represent a small percentage of all sources and may represent a minority of all releases.

Response: EPA disagrees with the commenter's statements. As discussed in the preceding comment response EPA does not believe that the fact that all releases or even a majority of releases of a chemical might not be captured under EPCRA section 313 is a reason not to require reporting from EPCRA section 313 facilities. The commenter's references to statements in the preamble are incomplete. Regarding the issue of thresholds selection and the substantial majority of releases requirement EPA stated:

"This provision provides EPA with broad authority to establish thresholds for particular chemicals, classes of chemicals, or categories of facilities, and commits to EPA's discretion the determination that a different threshold is warranted. Congress has also committed the determination of the levels at which to establish an alternate threshold to EPA's discretion, requiring only that any "revised threshold shall obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements" of section 313. 42 U.S.C. 11023(f)(2). For purposes of determining what constitutes a "substantial majority of total releases", EPA interprets "facilities subject to

the requirements” of section 313 as the facilities currently reporting, in part because section 313(b)(1)(A) provides that “the requirements of [section 313] shall apply” to facilities that meet all the reporting criteria and hence are required to file reports. Thus, in revising the reporting thresholds, EPA must ensure that under the new thresholds a substantial majority of releases currently being reported will continue to be reported. No further guidance for exercising this authority appears in the statute.” (64 FR 689, column 3).

It is clear from the above discussion, the rest of the preamble language, and the statutory language that the “substantial majority of releases” standard is tied to the releases from facilities currently subject to the requirements of EPCRA section 313; it is not tied to the aggregate national amount of releases from all sources. Additional discussion on this issue can be found elsewhere in these comment responses.

The commenter’s statements that dioxin is unlike other EPCRA section 313 chemicals because it is not an intentionally manufactured chemical rather it is formed in minute quantities as an unintentional by-product are not correct. There are other chemicals that are mainly unintentional by-products, some of these include the members of the polycyclic aromatic compounds category, many metal compounds, polychlorinated biphenyls, etc., and just like dioxin, these chemicals are also products of combustion processes.

The commenter’s reference to a statement in the preamble concerning one of Congress’s articulated purposes for EPCRA section 313 is also incomplete. EPA’s full statement was:

“As discussed in further detail in Unit V.A-B. of this preamble, EPA found that generally the various criteria for both persistence and bioaccumulation clustered around two criteria. For persistence in water, soil, and sediment, the criteria were grouped around half-lives of 1 to 2 months and 6 months, and for persistence in air, either 2 or 5 days. Bioaccumulation criteria were grouped around bioaccumulation factor and/or bioconcentration factor values of 1,000 and 5,000. Bearing in mind that one of Congress’s articulated purposes for EPCRA section 313 was to provide local communities with relevant information on the release and other waste management activities of chemicals in their community, that may present a hazard, EPA determined that the criteria that were most consistent with these purposes were, for persistence, half-lives of 2 months for water, sediment, and soil, and 2 days in air, and for bioaccumulation, bioaccumulation/bioconcentration factor values of 1,000 or greater.” (64 FR 692, column 2)

The statement the commenter cited was made in the context of the selection of persistence and bioaccumulation criteria and is only a reference to “one” of Congress’s proposes for EPCRA section 313. However, even if this was the only purpose of EPCRA section 313, EPA believes that the information that will be collected for PBT chemicals, including dioxin and dioxin-like compounds, is relevant information about toxic chemicals even if not all sources of these chemicals are reported under EPCRA section 313. If there are other sources of these chemicals that communities need to consider then, rather than denying communities the data collected under EPCRA section 313, these other sources should be considered along with the information from EPCRA section 313 sources.

Commenter List: C-426, C-428, C-429, C-1921, C-1989, and C-2015

Comment: The commenters stated that EPA should set a zero or lowest possible threshold for reporting on PBT chemicals and if EPA is concerned about the burden it would cause on small businesses then EPA should explicitly provide exemptions for small businesses.

Response: EPA believes that the commenters did not understand how burden factor into EPA’s proposed reporting thresholds for PBT chemicals. EPA’s consideration of burden in selecting the EPCRA section 313 reporting thresholds for PBT chemicals was not specifically focused on small businesses. The burden considerations were for the impact on all facilities both large and small. The commenters suggestion that EPA set zero or very low reporting thresholds and, if needed, EPA should provide exemptions for small businesses could result in even less facilities being required to report. This is because the impact of any exemption for small businesses is dependent on the classification of a small business. As EPA pointed out in the proposed rule:

“This proposed rule may affect both small businesses and small governments. For the purpose of its analysis for the proposed rule, EPA defined a small business using the small business size standards established by the Small Business Administration (SBA). (For example, the SBA size standard is 500 employees for approximately 75% of the manufacturing industries, and either 750, 1,000 or 1,500 for the remaining manufacturing industries, which would

mean that more than 98.5 percent of the manufacturing firms are classified as small businesses (Ref. 80))." (64 FR 721, column 1)

If EPA were to select a lower threshold more small businesses might indeed be brought into reporting but lowering the thresholds and then exempting small businesses could result in less reporting rather than more reporting as the commenters suggest. In addition, the fact that a facility is small does not automatically mean that the release and waste management quantities from that facility will not be important, especially for PBT chemicals. Any changes in the final rule reflect considerations of all the industries that must report including small businesses.

Commenter List: C-1847 and C-1866

Comment: The commenters stated that since EPCRA section 313 does not require facilities to monitor chemical releases only those facilities covered by EPCRA section 313 that have source-specific dioxin limits will be required to report their releases. One commenter stated that in many cases dioxin emissions may be non-detectable or non-quantifiable because of analytical constraints.

Response: EPA disagrees with the conclusion that only facilities that have source-specific dioxin limits will have to report. EPCRA section 313 only requires that a facility make a reasonable estimation of releases and does not require that they have monitoring data. EPA will provide a guidance document that will recommend how certain types facilities can estimate their release and threshold quantities. EPA is aware that even with guidance some facilities may not be able to report because of analytical constraints or other data limitations that do not allow at least a reasonable estimation to be made. However, EPA does not believe that this is a reason not to require the reporting of these highly persistence and highly bioaccumulative toxic chemicals from those facilities that will be able to make at least reasonable estimations.

Commenter List: C-403

Comment: The commenter stated that any accurate estimate of the number of facilities that will not report dioxin releases under the proposed 0.1 gram reporting threshold must address those facilities which will not report because they produce less than 0.1 gram annually, and those facilities which will not report because they fail to comply and escape enforcement to compel compliance. The commenter stated that approximately 5,692 facilities subject to EPCRA reporting requirements produce and release dioxin compounds and that EPA estimates that 1,863 facilities will file reports of dioxin releases under the less than 0.1 g exemption. The commenter states that by EPA's estimates 3,829 dioxin-producing facilities that are subject to EPCRA requirements, or 67% of all dioxin-producing facilities required to report releases under EPCRA, would not report dioxin releases in compliance with EPA's proposed revised threshold.

The commenter stated that a far greater percentage of dioxin-producing facilities, which may approach 100%, will not report releases if EPA establishes its proposed threshold, because EPA has no credible scheme to verify that 0.1 gram is produced and support a credible threat of enforcement. As an example the commenter stated that, all dioxin-producing facilities known to contribute to priority pollution of San Francisco Bay might avoid reporting under the less than 0.1 g exemption, if industries rely upon discredited local Air District release estimates. The commenter stated that according to Bay Area Air Quality Management District estimates, none of these individual facility's releases exceeded, or even approached, the 0.1 gram/year level. The commenter stated that the Air District estimates have been widely criticized, were retracted by the agency which produced them, and estimate toxicity of releases rather than grams of production. The commenter stated that nevertheless, these estimates remain the only facility-specific quantitative dioxin production or release estimates made by any government agency for these facilities. The commenter stated that they are concerned that facilities might rely upon such estimates to claim exemption under the proposed 0.1 gram threshold.

The commenter stated that if facilities which may produce more than 0.1 grams of dioxin per year claim unwarranted exemptions, EPA may not be able to enforce reporting of their releases. The commenter stated that dioxin compounds are inadvertent by-products which are not bought or measured as a production parameter and while production rate data are readily available from billing, production, and sales records for other chemicals, such data are not available for dioxin compounds. The commenter stated that EPA and other government agencies have not independently measured dioxin production rates at the vast majority of dioxin-producing facilities and that EPA has proposed no plan for this independent verification. The commenter stated that enforcement of the 0.1 gram/year dioxin production threshold requires independent verification that the threshold is exceeded. The commenter stated that since EPA appears unable to make this verification at

numerous facilities in a comprehensive and effective manner, its less than 0.1 g exemption would not be enforceable in an effective way, even in the event of widespread reporting fraud.

The commenter stated that because of these concerns the proposed 0.1 g exemption would not meet the requirement to obtain reporting on a substantial majority of total releases of dioxin-like chemicals at all facilities subject to these requirements.

Response: EPA disagrees that it must consider the number of facilities that will not report for the dioxin and dioxin-like compounds category because they fail to comply and escape enforcement to compel compliance. EPA estimates the number of facilities that may report based on the requirements of the rule and does believe it would be appropriate to exclude a certain percentage that may fail to comply with the rule. EPA also disagrees with the statement that 3,829 dioxin-producing facilities that are subject to EPCRA requirements or 67% of all dioxin-producing facilities required to report releases under EPCRA would be excluded from reporting. EPA's assessments were based on the worst case assumption that all EPCRA section 313 facilities that fall into the classes of facilities that EPA has determined may have dioxin releases would be required to report if the threshold were essentially zero. However, as discussed below not all facilities will have data that will allow them to make a reasonable estimate of threshold quantities and thus not all of these facilities would report. While lower thresholds may capture more facilities the exact number that would have enough information to report is not known.

Based on other comments from this commenter the commenter appears to believe that the issues they raise would be resolved if EPA required all facilities to report for the dioxin and dioxin-like compounds category, however, even if all facilities are required to submit a report this would not mean that enforcement would be easier or better. As EPA stated in another comment response:

"Whether a particular facility will be required to report for these compounds is not only based on the reporting threshold but also whether the facility has the ability to make at least a reasonable estimation of the quantities that are being manufactured, processed or otherwise used at the facility. EPCRA section 313(a) states in part that:

"The owner or operator of a facility subject to the requirements of this section shall complete a toxic chemical release form as published under subsection (g) for each toxic chemical listed under subsection (c) that was manufactured, processed, or otherwise used in quantities exceeding the toxic chemical threshold quantity established by subsection (f) during the preceding calendar year as such facility."

And the provisions of EPCRA section 313(g)(2) state that:

"In order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation. In order to assure consistency, the Administrator shall require that data be expressed in common units."

EPA will provide a guidance document to assist certain facilities in making thresholds and release determinations for dioxin and dioxin-like compounds but, given the language of section 313(a) and 313(g)(2), even if EPA were to attempt to require that all releases from all facilities be reported that would not necessarily mean that every facility would be required to report. Facilities that are not able to make at least a reasonable estimation of toxic chemical quantities do not have to report even if the reporting threshold is zero."

The commenter's statements concerning enforcement of the proposed 0.1 gram reporting threshold would not be solved by requiring all facilities to report or by a zero threshold. Enforcement is dependent on EPA being able to determine that a facility did not report when it exceeded reporting thresholds or in the case of requirement for all facilities to report, that EPA be able to determine that the amounts reported are accurate. These issues do not change no matter what the reporting requirement may be. EPA will use its best information, including the guidance document that will be available for the dioxin and dioxin-like compounds category, to enforce the requirements of EPCRA section 313 at any threshold. The commenter's concerns that a facility will use third party estimations even though they have been discredited are not warranted.

The commenter's statement that because of the concerns discussed here the proposed 0.1 g exemption would not meet the requirement to obtain reporting on a substantial majority of total releases of dioxin-like chemicals at all facilities subject to these requirements are not correct. As discussed elsewhere in these comment responses, the "substantial majority" requirement does not work the way the commenter assumes. The requirement is tied to the releases from facilities currently subject to the requirements of EPCRA section 313; it is not tied to the aggregate national amount of releases from all sources.

Commenter List: C-717 and C-1904

Comment: The commenters stated that significant releases of toxic chemicals are not reported under EPCRA section 313 because the toxic chemicals are by-products.

Response: EPA disagrees. Chemicals that are by-products of manufacturing processes are reported under EPCRA section 313. Such chemicals are considered coincidentally manufactured and must be included in threshold and release calculations.

Commenter List: C-835

Comment: The commenter stated that under the proposed rule many uses of toxic chemicals will still not be reported. The commenter cited the use of mercury by dentists as an example of a use that should be avoided.

Response: EPCRA section 313 does not regulate the usage of toxic chemicals and only facilities that are covered under EPCRA section 313 are required to report. The specific example the commenter cited is not applicable to reporting under EPCRA section 313.

Commenter List: C-1815

Comment: The commenter stated that EPA must take care that guidance, such as existing guidance on the reporting of "non-detect" levels, is modified to take account of the small amounts and low reporting thresholds for PBTs.

Response: EPA will provide guidance that is appropriate to the reporting of PBT chemicals.

Commenter List: C-1809

Comment: The commenter stated that many important source categories such as mobile and area sources are not covered under EPCRA section 313 which limit its utility as a comprehensive air toxics emissions database. The commenter suggested that, just as EPA has provided a discussion of diffuse sources from fertilizer and pesticide use, the data compiled by EPA's Office of Air Quality Planning and Standards (OAQPS) should be made available in the annual public data release documents.

Response: EPA will explore ways to incorporate the data compiled by OAQPS into the TRI annual data release information.

Commenter List: C-1824

Comment: The commenter cited EPA's statement in the preamble that "communities now know which industrial facilities in their area release or otherwise manage as waste listed toxic chemicals" and stated that communities should have this knowledge but don't since the TRI program does not provide it. The commenter stated that EPA should consider using TRI as a tool to encourage reduction in toxic emissions from important sources such as mobile sources including cars, trucks, and buses, and other sources such as airports.

Response: In response to a petition, EPA is considering whether airports should be added to EPCRA section 313. However, mobile sources outside of a facility's grounds may not be covered by the EPCRA section 313 statutory language on facility coverage (see EPCRA section 313(b)).

8.d Other suggested changes to TRI (airports, etc.)

Commenter list: C-063, C-081

Comment: One commenter noticed that the Toxics Release Inventory data is at least two years old, and usually older than that. The commenter stated that right-to-know would mean more if public information on pollution was more up to date. EPA should speed up the disclosure process.

Response: The data reported under EPCRA section 313 is collected during the reporting year, for example, January 1 through December 31, and then reported to EPA by July 1 of the following year. This timing is mandated by statute. However, EPA is working to make the TRI data available to the public more quickly and the Agency's future goal is to release the data in the year in which it is reported.

Commenter list: C-629

Comment: We support the proposal and once again ask that airports and aircraft operations be required to report their emissions.

Response: On April 16, 1997, EPA received a petition from the Natural Resources Defense Council, the Defenders of Wildlife, the national Audubon Society, and the Humane Society of the U.S. requesting EPA to initiate rulemaking to add SIC code 45, transportation by air, to the list of facilities required to report under EPCRA section 313. In response, EPA issued a Notice of Receipt and request for comments in the Federal Register on February 10, 1998. In the notice, the Agency published the full text of the petition and requested comments on 1) whether the use of TRI chemicals would or should be exempt under the Motor Vehicle Maintenance Exemption, 40 CFR 372.38(c), and 2) the practical impacts of requiring airports to report under section 313 of EPCRA. In the proposed rule for PBT chemicals, EPA requested comments on whether the Agency should modify the exemptions at 40 C.F.R. §§ 372.38 (c) (e.g., the laboratory exemption, and the otherwise use exemptions, including the structural component exemption, the routine janitorial or facility grounds maintenance exemption; the personal use exemption, the motor vehicle maintenance exemption, and the intake air and water exemption) such that they will not apply to PBT chemicals. EPA currently is deciding whether to modify any of the exemptions and whether to add SIC code 45 to the list of facilities required to report under EPCRA section 313. If EPA decides to modify the exemptions or add SIC code 45, it will do so through rulemaking and will address the comments received through this rulemaking in that future rulemaking.

Commenter list: C-1406

Comment: The commenter suggests that EPA should revise the Form R to add code/field which would indicate whether or not the EPCRA section 313 release or transfer was in a hazardous or nonhazardous waste. The commenter states that the purpose of this new data field is to allow the agency to track reductions of chemicals found in hazardous wastes separate from nonhazardous wastes. The commenter states that this information, which cannot currently be gleaned from TRI data, is needed for tracking progress in the Waste Management National Plan, which calls for reductions in the amount of toxic constituents contained in RCRA hazardous waste.

Response: EPA's proposal to lower the reporting thresholds for certain PBT chemicals does not contemplate revisions to the Form R to change the way hazardous and nonhazardous wastes are reported for EPCRA section 313 chemicals. At this time, EPA does not plan to make this suggested change to the Form R.

8.e Manufacture-Only Qualifier for Chemicals Other Than Dioxin

Commenter List: C-1420, C-1421, C-1422, C-1424, C-1431, C-1435, C-1438, C-1443, C-1455, C-1457, C-1815, C-1822, C-1841, C-1843, C-1844, C-1845, C-1852, C-1853, C-1858, and C-1865.

Comment: The commenters requested that EPA add a "manufacture only" qualifier to all PBT chemicals, not just the dioxin and dioxin-like compounds category. The commenters asserted that the addition of the manufacture only qualifier to all PBT chemicals would greatly reduce the burden of the rule. Some commenters suggested that at a minimum the manufacture only qualifier should apply to polychlorinated biphenyls (PCBs), since EPA's rationale for applying the qualifier to dioxin and dioxin-like compounds is equally applicable to PCBs. One commenter contends that EPA's statement that the manufacture qualifier is appropriate for chemicals that are "ubiquitous in the environment" because otherwise many facilities would be required to report simply due to background levels in raw materials applies to PCBs as well. Some commenters suggested that unintentionally manufactured by-products such as hexachlorobenzene and octachlorostyrene should also have the

manufacture only qualifier. Some commenters argued that the burden of the rule could be significantly reduced if EPA focused the reporting effort on the manufacturing sector, which should help concentrate EPA's pollution prevention efforts on the sector most likely to be able to make reductions. Some commenters contend that the primary source for PBT chemicals within the EPCRA section 313 reporting sectors is from manufacturing, and these are the sources that should be focused on for tracking PBT chemicals. Some commenters stated that EPA has acknowledged that many chemicals identified as persistent and bioaccumulative are not imported, processed, or otherwise used, but are manufactured as by-products (at 64 FR 715). Commenters stated that they agree that manufacturing is the primary source for environmental loading of PBT chemicals from EPCRA section 313 facilities, and thus the effort for reporting should be concentrated on the sources where PBT chemicals are generated and data can be gathered. Commenters stated that concentration on the manufacturing of PBT chemicals provides an efficient focus for meaningful pollution prevention efforts. Commenters stated that they are concerned that data from the importing, processing, or otherwise use of PBT chemicals will be inaccurate and misleading since processors and users may not have the resources to conduct the analyses required to provide accurate estimates. One commenter contends that the fear of enforcement might motivate those importing, processing or otherwise using PBT chemicals to report "some amount" and that such information is likely to be inaccurate, and will not accurately reflect the true level of concern. Commenters stated that instead of requiring reports from the many sources where effective emissions reductions may not be possible, that the addition of a manufacture only activity qualifier for all PBT chemicals will provide the public with the most accurate information on PBT chemical emissions and the best opportunity to monitor EPCRA section 313-related environmental loading of these chemicals.

Response: EPA believes that in order to obtain any reporting on dioxin and dioxin-like compounds a very low threshold is required, which is several orders of magnitude lower than the thresholds for other PBT chemicals. At such a low reporting threshold it is estimated that thousands of reports could potentially be filed by facilities, mainly food processing facilities, due to the amount of dioxins in the raw materials they process. The dioxins found in the meat and dairy products that food processors handle have been previously released, circulated in the environment, and bioaccumulated in animals, thus these are not additional loadings to the environment but loadings that have already occurred and cycled through the environment due to the persistence and bioaccumulative properties of these compounds. The unique combination of very low thresholds, the number of food processors that would be required to file, and the fact that they would be filing because of the bioaccumulation of previously released material led EPA to add the manufacture only qualifier to the dioxins category. The qualifier was added in response to the unique set of conditions that apply to the reporting of dioxin and dioxin-like compounds. The manufacture only qualifier was added to reduce reporting burden on facilities, mainly in the food processing industry, that results from the unique combination of circumstances related to the reporting for these chemicals and to focus on those activities that add to the loading of dioxins in the environment rather than on activities dealing with previously released and bioaccumulated chemicals. EPA did not conclude and does not believe that the manufacturing activity is the only important source of PBT chemical releases to the environment and believes that other activities such as processing or otherwise using can result in significant releases of PBT chemicals, including chemicals released to the environment for the first time. The unique combination of circumstances that exists for dioxin and dioxin-like compounds does not exist for any of the other PBT chemicals. EPA did not conclude that the manufacture qualifier is appropriate for chemicals that are "ubiquitous in the environment" because otherwise many facilities would be required to report simply due to background levels in raw materials. The full statement was "These dioxin and dioxin-like compounds are ubiquitous in the environment and thus under the very low reporting thresholds necessary to get reports from any sources (see discussion in Unit VII.A.2.), facilities that process raw materials would be required to report simply because the raw material contains background levels of these chemicals" (at 64 FR 710). Clearly EPA made this statement in the context of the "very low reporting thresholds necessary to get reports [for the dioxin and dioxin-like compounds category] from any sources." This statement is consistent with the unique combination of circumstances that exists for dioxin and dioxin-like compounds and was not intended to apply to all PBT chemicals.

EPA does not believe that the manufacturing activity is the activity for which facilities would be most likely to be able to make reductions or that EPA's pollution prevention efforts should focus solely on the manufacturing of PBT chemicals. Commenters provided no basis for such a conclusion and EPA believes that processors or otherwise users of PBT chemicals also have the opportunity to make effective emissions reductions by using less of a PBT chemical, by not using materials that contain PBT chemicals as contaminants, etc. In addition, the purposes of reporting under EPCRA section 313 are not limited to the collection of information from sources where effective reductions in release and other waste management quantities are possible. Data collected under EPCRA section 313 can serve a variety of information purposes that do not depend on how easy it is for the source to achieve reduction in releases and other waste management. The commenter statement that EPA has acknowledged that many chemicals identified as persistent and bioaccumulative are not imported, processed, or otherwise used, but are manufactured as by-products is incorrect. The actual statement was "[m]any of the chemicals identified as persistent and bioaccumulative in today's action are not imported, processed, or otherwise used but are

manufactured as byproducts” (at 64 FR 715, column 1, last paragraph). As the words “today’s action” clearly demonstrate, this statement was not a broad statement about all PBT chemicals but simply an acknowledgment that many of the PBT chemicals in the proposed rule were by-products. In addition, this statement was made in the context of the discussion on the *de minimis* exemption about how removing the exemption for PBT chemicals would affect the chemicals in the proposed rule; it was not a statement made in connection with the discussion on the manufacture only qualifier. EPA also did not state that manufacturing is the primary source for environmental loading of PBT chemicals from facilities covered under EPCRA section 313. The discussion on the loading of chemicals in the environment from manufacturing was in relation to the reporting of dioxin which, as discussed above, presents a unique combination of circumstances that does not apply to all PBT chemicals. EPA disagrees with the statements that data from facilities that import, process, or otherwise use PBT chemicals will be inaccurate and misleading or that such facilities will report some quantity out of fear of enforcement and that such information is likely to be inaccurate, and will not accurately reflect the true level of concern. EPA believes that facilities that import, process, or otherwise use PBT chemicals will be just as able to report as facilities that manufacture PBT chemicals. It is no more difficult to do calculations regarding small numbers than it is to do calculations on larger numbers, so if a facility that imports, processes, or otherwise uses PBT chemicals has information that allows them to make a reasonable estimation of quantities then they should be just as able to report as any manufacturing facility would be able to report on small quantities manufactured as by-products. If facilities that import, process, or otherwise use PBT chemicals do not have data available that allows them to make a reasonable estimation of quantities then they are not required to report. As for fear of enforcement, EPA can take enforcement actions both for under reporting and over reporting so facilities should not report an amount of a PBT chemical just in order to avoid an enforcement action.

EPA does not believe that the unique combination of circumstances that exists for dioxin and dioxin-like compounds exists for any of the other PBT chemicals in this rule nor does EPA believe that reduced burden or any of the other reasons suggested by the commenters provide a sufficient reason to focus on manufacturing activity only for the other PBT chemicals in this rule. Therefore, EPA does not believe that it is appropriate to add a manufacture only qualifier to any of the other PBT chemicals in this rule.

8.f. How to Handle No Detects (Half Detection Limit or Zero)

Commenter List: C-1434, C-1864, C1352

Comment: The commenters inquire as to how to report for PBT chemicals that they believe to be in covered streams but which are not measured above detection limits. One commenter (C-1434) recommends that facilities report under a code which indicates the chemical is not detectable or to report a level of zero when it is present in levels less than it can be detected. However, they contend that regardless of how facilities report, either using the commenter’s suggestion or by conservatively reporting at a level equal to the threshold level, the information will have no accuracy or value. They further argue that if all facilities report conservatively because they do not know for sure that they are emitting the chemical, the public fear that all facilities are emitting the chemicals at unhealthy levels will be needlessly and erroneously raised. Another commenter (C-1864) urges EPA to develop a *de minimis* concentration level below which facilities would need not consider the PBT chemical for calculating a threshold quantity. They argue that this will prevent “protective reporting” by a facility that may not have factual information on certain chemicals. The commenter provides the following example. A covered facility processes about one million tons of coal each year to produce coke. Mercury occurs naturally in many coals. The normal quantification limit for mercury in soil is 0.1 mg/kg (parts per million, ppm). If the company were to analyze the coal brought into its facility for mercury and all of the analytical results were below the limits of quantification, all the company would know for purposes of determining the threshold is that mercury was processed at a concentration less than 0.1 ppm and at a rate less than 2,000 pounds per year. This detection limit dilemma places the company in a tenuous situation. Should the company report a release of mercury as a protective measure, even if the reported value is speculative? How can the company perform an engineering estimate with no quantifiable factual basis? They argue that the same situation exists with waste streams, where the concentration of a trace chemical is below the detection limit. Yet another commenter (C-1352) argues that while detection limits for dioxin and dioxin-like compounds may be available at very low levels, this may not be true for other PBT chemicals.

Response: EPA has already established a policy for reporting toxic chemicals that covered facilities monitor for but that are tested below the detection limit. Specifically, EPA has explained in the *1998 EPCRA Section 313 Questions and Answers* document that a:

facility must use reasonable judgment as to the presence and amount of the listed *toxic chemical* based on the best readily available information. An indication that a reportable chemical is below detection is not equivalent to stating that the chemical is not present. If the reportable Section 313 chemical is known to be present, a concentration equivalent to half the detection limit should be used. The *facility* should not estimate *releases* based solely on monitoring devices, but the facility should also rely on its knowledge of specific conditions at the plant. (Q&A #497)

For example, a covered facility manufactures fluoromethanes. As a result of the facility's manufacturing activities, it generates the RCRA wastestream K021 (aqueous spent antimony catalyst waste from fluoromethanes production), which is listed in part because it may contain carbon tetrachloride. The facility monitors this waste for carbon tetrachloride. Sometimes the facility's tests come back indicating that there is carbon tetrachloride in the waste stream, and sometimes the chemical is not detected. The facility consistently uses the same manufacturing process to generate this waste. In this case, the facility could reasonably assume that there is carbon tetrachloride in their waste at below detection limits. Therefore, this facility would consider half the detection limit for carbon tetrachloride for release and other waste management calculations. Contrast that with another example where a covered facility monitors their waste stream for toxic chemical A. Chemical A has never been found in the waste stream and the facility has no other indication that this chemical is present. In this instance, the facility may determine that non-detection test results for Chemical A are more accurately represented as zero rather than one half the detection limit.

EPA's general guidance on the use of one half of the detection limit is intended to apply to circumstances when, based on its site-specific knowledge about its processes, a facility knows that a reportable chemical is present but that the detection method being used is not sensitive enough to detect the chemical. This discourages facilities from using insensitive detection methods just to avoid reporting under EPCRA section 313. It is also consistent with the fact that monitoring data alone may not always be the best available information for making reasonable estimations.

As explained elsewhere in these responses to comment, there may be methods of detection for dioxin and dioxin-like compounds for which a non-detection value is more accurately represented as zero. EPA will be developing reporting guidance for this chemical category in the near future, such guidance will be consistent with the methods used to detect and quantify amounts of dioxin and dioxin-like compounds.

Further, EPA disagrees that it should develop a concentration level below which facilities would need not consider the PBT chemical for calculating a threshold quantity. The commenter does not provide a specific level for such an exemption nor a reason not to use one half the detection limit for quantities known to be present but that have not been detected. As explained in previous responses to comment, even minimal releases of PBT chemicals may result in elevated concentrations in the environment or in an organism and can reasonably be anticipated to result in significant adverse effects. Therefore, as EPA has explained elsewhere in these response to comments, covered facilities: 1) Are not required to perform additional monitoring; 2) are not required to consider concentrations of toxic chemicals for which they have no information; and 3) need only consider readily available data. Thus, EPA disagrees that there should be an exemption for activities involving mixtures containing small concentrations of PBT chemicals.

Commenter List: C-1443, C1815

Comment: Commenters urge EPA to revisit its guidance on the practice of using half the limit of detection for non-detects. They assert that with the lower thresholds, non-detect values should be considered to be zero. They contend that the practice of reporting non-detects at half the detection limit will overstate PBT chemical emissions at the source. One commenter argues that the practice of reporting non-detects as zero is consistent with EPA Region 6 policy (*The Use of Minimum Quantitation Levels (MQLs) in Water-Quality Based Permits* (EPA Region 6, July 1, 1991)) as well as in EPA's draft national guidance on water effluent limitations (*National Guidance for the Permitting, Monitoring, and Enforcement of Water-Quality-based Effluent Limitations Set Below Analytical Detection/Quantitation Levels* (March, 1994)). Another commenter argues that using one half of the detection limit is a problem for matrices such as solid wastes for which the detection limit may be much higher than for cleaner matrices such as water or gaseous streams. They argue that using one half of the detection limit would indicate relatively high emissions, which do not truly exist. They further contend that the use of one half of the detection limit is appropriate in situations such as risk assessments where very conservative assumptions are used to determine the maximum risk which may be associated with a particular activity, but it is not appropriate in reporting actual emissions to the public. They further argue that this would provide incorrect and misleading information, which is inconsistent with EPA's mission to provide meaningful, accurate information to the public about actual emissions and the associated risks in their neighborhoods.

Response: EPA disagrees that non-detects should be considered to be zero across the board for PBT chemicals. In some instances, an indication that a reportable chemical is below detection is not equivalent to stating that the chemical is not present. It simply means that the analytical method used is not sufficiently sensitive to determine the presence of the chemical. Because most of the PBT chemicals addressed in this rulemaking have been shown to persist and bioaccumulate, EPA has lowered substantially the thresholds for these chemicals. At these lower thresholds, even very small quantities can contribute to these lower threshold determinations. As explained at length in the proposal, even small releases of PBT chemicals have the potential to pose human health and significant adverse effects on the environment over a long period of time. EPA believes that for the purposes of reporting under EPCRA section 313, in instances where a covered facility has a sufficient indication that a chemical is present, the practice of using one half of the detection limit in lieu of zero or the value of the detection limit, it is an acceptable compromise.

EPA disagrees that using one half the detection limit will necessarily provide incorrect and misleading information. As EPA explained in the previous response to comment, facilities are not required to use one half the detection limit if a toxic chemical is not detected and the facility has no indication or other reason to believe that the toxic chemical is in the monitored stream.

Rather, covered facilities are expected to use their best readily available data, which may include monitoring data, to make reasonable estimates. In some cases monitoring data may be known to be non-representative. As EPA stated in the *1998 EPCRA Section 313 Questions and Answers* document:

469. Section 313(g)(2) of EPCRA states that the owner or operator of a facility may use readily available data. In some cases, the available data may be known to be non-representative and reasonable estimates offer more accurate release information. Would EPA, in this instance, favor use of the estimates rather than data?

Yes, it is preferable to use reasonable estimates using the best readily available information if available data (including monitoring data) is known to be non-representative.

Therefore, covered facilities should not be using monitoring data when they have other information which would contribute to more accurate reporting.

In addition, the commenter indicates that using one half of the detection limit will only over-report emissions and therefore, is overly conservative for reporting under EPCRA section 313. However, in some cases, using one half the detection limit could significantly under-represent the quantity of the toxic chemical involved. In some in some instances, it may be more accurate to report the value of the detection limit. However, EPA believes that in cases where the facility knows that a toxic chemical is present in a stream but the analytical testing method is not sensitive enough to detect the chemical's presence, and the facility has no other information regarding the concentration of this chemical in the stream, it is appropriate to use one half the detection limit rather than zero.

Further, contrary to assertions by the commenter, EPCRA section 313 does not require the collection of quantitative risk data nor does the statute require that risk data be disseminated to the public. Rather TRI data provide communities, governments, researchers with information on releases and other waste management quantities. TRI data cannot, in themselves, provide information on quantitative risks to individual communities. A determination of the potential risk that a chemical release may pose is dependent upon a number of factors, including the toxicity of the chemical, the physical-chemical properties of the chemical, the specific media to which the chemical is released, and site-specific information that will determine the estimated exposures. While TRI data are not in themselves measures of risk, they are an important input that local communities can use along with the factors described in this section to determine potential risks to themselves, their children, their communities, and their environment that may result from releases of toxic chemicals.

Commenter List: C-1815

Comment: One commenter argues that requiring facilities to report non-detects for PBT chemicals will make it virtually impossible for a facility to demonstrate any further progress in emissions reductions, once the level of detection has been reached.

Response: EPA disagrees. As explained in other responses to comment, non-detects should not always be considered as one half of the detection limit. In some instances, it will be appropriate to report something other than one half of the detection limit if the covered facility has more representative information than monitoring data. For example, because of the processes

used, a facility knows that it manufactures dioxin and dioxin-like compounds when combusting fuel. The facility is using a method in which non-detections are considered to be one half the detection limit. The facility then changes its process to stringently control fuel composition, flow times, temperature, and other conditions in order to eliminate the incidental manufacture of dioxins during their combustion process. In this instance, although the monitoring data the facility now has still indicates non-detect, because the facility altered its process, it now believes that zero is a better indicator of how much dioxin they produce.

8.g. Characterization of releases/definition of release

Commenter list: C-1406

Comment: Commenter suggests that the most beneficial improvement that could be made to Form R would be to add a new data category which would differentiate between different types of releases. Commenter states that this was a primary recommendation of the Toxics Data Reporting Committee (TDRC) of the National Advisory Council on Environmental Policy and Technology (NACEPT). Commenter adds that the committee determined that a major problem is that Form R is deficient in being able to make distinctions between releases which are made directly to the air and water and hence find their way immediately into the air or water, and those releases which are managed and controlled on the land.

Commenter presented a proposal to help rectify this perceived deficiency. Commenter suggests that EPA adopt a Release Attenuation Factor (RAF) as a new Form R data element. Commenter states that the RAF is a single number representative of the management practices associated with a given chemical in a given waste. Commenter adds that the number is, in essence, the equivalent of the Design Attenuation Factor (DAF) developed as part of the EPA Industrial Non-Hazardous Solid Waste Management Practices Initiative. The commenter describes the DAF as basically a single number which represents the type of waste management system used, the local soil and other site conditions, and particular waste characteristics. Commenter further states that DAFs have been established for landfills, waste piles, surface impoundments, and land management units, and indicate the fractional amount of a chemical "release" that actually finds its way to surface or ground water from each of these units.

The commenter states that the RAF approach offers a number of advantages to the Agency, the public, and the generator: 1) RAF-adjusted "release" data would be more representative of actual releases to the environment without losing the data of the total release to the waste management unit; 2) actual environmental release data would more accurately describe real risks to human health and the environment; and 3) the availability of the RAF would encourage unit operators to analyze their operations for release potential, which the current concept of release does not encourage.

Response: EPA's proposal to lower the reporting thresholds for certain PBT chemicals does not contemplate revisions to the Form R to change the way releases are reported for EPCRA section 313 chemicals.

Commenter List: C-1844, C-1849

Comment: Commenter states that TRI releases as defined by EPA are not the same as ambient releases to the environment which may result in public exposure. Commenter argues that because other kinds of activities such as recycling and approved waste disposal are incorporated into reported volumes, the TRI reported releases will likely be substantial overestimates of the actual quantities released to the ambient environment. Commenter believes that the information may be useful to source reduction efforts, but the commenter believes the merging of reporting requirements under §313 of EPCRA and §6607 of the Pollution Prevention Act (PPA) of 1990 has resulted in information which is misleading to the public's desire to know what actual exposures are occurring.

The commenter states that another example of misleading information in the TRI is including recycled material as a release. Recycled chemicals are not released to the environment and do not lead to human exposures. Conversely, recycling makes beneficial use of the material and prevents it from being released into the environment.

Response: EPA does not agree with the commenters regarding their description of the term "TRI releases." First, the commenters appear to misunderstand how recycling and other waste management quantities are reported under EPCRA section 313. The commenters state that,

because other kinds of activities such as recycling and approved waste disposal are incorporated into reported volumes, the TRI reported releases will likely be substantial overestimates of the actual quantities released to the ambient environment.

Recycling activities and other waste management quantities are included in what EPA calls "total production-related waste managed" but are not included as "releases." EPA includes all quantities disposed of on- or off-site as "releases" [i.e., sections 5, 6.1 (metals and metal compounds only), and 6.2 (disposal) of the Form R] but does not include quantities reported on the Form R as recycled, combusted for energy recovery, or treated on- or off-site as "releases." Consequently, EPA disagrees with the commenter that quantities reported under EPCRA section 313 as "releases" are likely to be substantial overestimates.

Additionally, the commenters imply that the term "releases" should capture only what the commenters refer to as "quantities released to the ambient environment which may result in public exposure." However, EPA's proposal to lower the reporting thresholds for certain PBT chemicals does not contemplate revision of EPA's interpretation of "release" or other interpretations of definitional terms under EPCRA section 313 or section 6607 of the PPA. Neither did EPA propose revisions to the Form R to change the way releases are characterized for EPCRA section 313 chemicals. As explained elsewhere, comments relating to EPA's interpretation of these reporting elements and public release of information regarding the same were addressed by the Toxics Data Reporting (TDR) Committee in its report titled Report on the Toxics Release Inventory Program ("TDR Report") dated December 15, 1998. EPA is not addressing issues raised in the TDR Report in this rulemaking. Issues and recommendations raised in the TDR Report will be addressed as part of a separate effort.

However, commenter's statement regarding the merging of reporting requirements under §313 of EPCRA and §6607 of the Pollution Prevention Act (PPA) of 1990 merits some clarification. Commenter statements that this merging has resulted in information which is misleading to the public's desire to know what actual exposures are occurring. As described elsewhere, EPA believes that the commenter has misunderstood the difference between the term "releases" and "production-related waste managed" as they are used in the TRI Program. The commenter also believes that because EPA uses the word "release," TRI data will mislead the public into thinking that a reported EPCRA section 313 "release" necessarily results in an actual exposure of people or the environment to a toxic chemical. Although EPA provides clear descriptions of TRI data for public use, the Agency recognizes that the potential exists for the data in TRI to be mischaracterized and/or misunderstood. For example, on pages 1-6 and 1-7 of the 1997 TRI Public Data Release includes the following language.

TRI reports reflect releases and other waste management activities of chemicals, not exposure of the public to those chemicals. Release estimates alone are not sufficient to determine exposure or to calculate potential adverse effects on human health and the environment. Although additional information is necessary to assess exposure and risk, TRI data can be used to identify areas of potential concern. Furthermore, TRI data, in conjunction with other information, can be used as a starting point in evaluating exposures that may result from releases and other waste management activities of toxic chemicals. The determination of potential risk depends upon many factors, including the toxicity of the chemical, the fate of the chemical after it is released, the locality of the release, and the human or other populations that are exposed to the chemical after its release.

EPA does not believe that the potential for mischaracterization and/or misunderstanding justifies not collecting and making information available to the public about PBT chemicals. EPA will continue to attempt to provide the public with the means for correctly interpreting the TRI data.

Commenter List: C-1844, C-1846, C-1859, C-1863

Comment: Several commenters state that the new thresholds proposed by EPA for PBT chemicals may require metal mining facilities to report inordinately large amounts of "releases" of naturally-occurring metals and metal compounds, when what those facilities have been doing is no more than moving dirt and rock from one place to another. Commenters argue that these high numbers will give the public an inaccurate picture of the situation. The commenters state that reported values will not reflect concentrated materials but, in fact, low concentration of constituents that are naturally occurring within and not being "released" from the waste rock. They argue that placing such material on the land in the same form that it was when it was excavated does not increase the risk to the community or create a "release" as the public understands that term. Commenters further argue that the movement of these materials at a typical surface metal mine does not result in a "release" of the waste rock, as would occur where there is a discharge to air or water. Rather, they contend that earthen material is deposited within the permit boundary in compliance with applicable federal, state, and local requirements resulting in non-existent risk to the community. Commenters also state that reporting these inflated, non-release values does not provide the

public with a better understanding of what is occurring in their community. In fact, they contend that the contrary will occur. Commenters believe the public will be provided with less understanding and be highly misled as to what is occurring.

Another commenter adds that, for many chemicals, the TRI implies that there are higher exposures from facilities subject to the TRI reporting requirements than actually exist. For example, the commenter states that wastes that are land disposed or injected into deep wells are considered releases. Under current regulations, the amount of chemical present in a waste must be reduced to a safe level before it is disposed in a landfill. The commenter argues that today's landfills are engineered structures designed to contain the chemicals. Similarly, the commenter believes that use of an injection well results in no human exposure and that these are not releases to the environment.

Commenters also state that the more appropriate means of providing useful TRI data to the public is to revise Form R and the way in which EPA disseminates these data to explain to the public what the TRI data actually means from a risk or non-risk standpoint, especially related to metal mines. They argue that, in the case of naturally-occurring metals and metal compounds, rather than lowering the thresholds for such EPCRA section 313 substances EPA could better serve the public's right-to-know by making long overdue revisions to the TRI Form R to convey more accurately how industry manages EPCRA section 313 chemicals. In addition, commenters further state that EPA could further serve the public's right-to-know by providing a more accurate and realistic context for TRI data when the Agency issues its annual TRI report to the public. Commenters state that if the Agency wishes to improve the utility of TRI data to the public, then it should heed the advice offered by its Toxics Data Reporting (TDR) Committee in that Committee's December 15, 1998, Report on the Toxics Release Inventory Program ("TDR Report"). They state that the TDR Committee report is permeated with legitimate concerns that the current TRI program fails to provide the public with reasonably accurate information on exposure to, and thus risk from, TRI chemicals. By way of example, commenters cite the following:

Neither the TRI Form R nor the agency's annual public data release ("PDR") of TRI information distinguishes between actual releases to the environment and placement of materials into containment structures designed, and permitted, for that purpose. TDR Report, p.3

The PDR requires a "prominent cautionary statement (beyond what is currently contained in the PDR)" as to the limitations of data presented and the need for site-specific evaluation of the data. TDR Report, p.9 EPA should use, in press releases and the PDR, appropriate data qualifiers (validity, quality, level of accuracy) and disclose to the public the data quality assurance methods the agency employed. TDR Report, p. 11

The commenters believe that these are concrete steps that can be taken pursuant to the Vice President's initiative to improve the utility of TRI data to the public while streamlining the reporting process and reducing the reporting burden on facilities. Instead, the commenters argue that the agency is proposing to expand reporting obligations to include data that is less reliable than that which is already reported.

Finally, several commenters add that these naturally-occurring metals and metal compounds at mines are not susceptible to "source reduction" short of limiting or ceasing operations, which is an unrealistic goal given the country's need for minerals.

Response: The commenter raises several issues that have been addressed by EPA in previous rulemakings and that were not reopened as part of this rulemaking. For example, commenters express concern about reporting as a "release" those toxic chemicals in mining waste rock and toxic chemicals that are injected into underground injection wells. EPA addressed this issue in a separate rulemaking. 62 FR 23834, 23853 (May 1, 1997) EPA's proposal to lower the reporting thresholds for certain PBT chemicals did not contemplate revision of EPA's interpretation of "release" or other interpretations of definitional terms under EPCRA section 313 or section 6607 of the PPA. Neither did EPA propose revisions to the Form R to change the way releases are characterized for EPCRA section 313 chemicals. As explained elsewhere, comments relating to EPA's interpretation of these reporting elements and public release of information regarding the same were addressed by the TDR Committee in its report.

The commenters cite the TDR Committee report of December 15, 1998 as containing "advice" and "concrete steps" that the Agency can take if it wishes to improve the utility of TRI data and reduce burden. First, EPA disagrees with the commenter's characterization of the TDR Committee report. The commenter implies that there is more agreement behind the ideas presented in the report than is true. The introduction of the report clearly explains that "the Committee did not reach consensus on most issues." The report goes on to say that "[t]he Committee, therefore, chose to present the various solutions put forth during discussion as "ideas" without an indication of the level of support for the idea." (Toxics Data

Reporting Committee report, December 15, 1998. p. 1) In addition, the examples cited by the commenter are not direct quotes from the report and cannot be fully understood without reading the merits and concerns listed after each idea discussed in the report. Therefore, EPA disagrees with the commenter's implication that the examples cited from the TDR report are concrete steps that the Agency should take. Finally, EPA is not addressing issues raised in the TDR Report in this rulemaking. EPA has reviewed the TDR report and is addressing several of the actions suggested by the Committee as part of a separate effort.

The commenters appear to raise an issue with regard to the definition of the term "waste rock." On December 22, 1998, EPA received a petition from the National Mining Association pursuant to the Administrative Procedures Act requesting the EPA change the current EPCRA section 313 definition of overburden to include consolidated and unconsolidated overburden. Through the petition process, EPA will address the issue of the definitions of consolidated overburden, unconsolidated overburden and waste rock.

Several commenters imply that because EPCRA section 313 does not include exposure or risk considerations the data on PBT chemical releases will be misleading to the public by indicating risks where none exist. EPCRA section 313 is not a risk-based reporting system, therefore, EPA disagrees with the commenter's implication that EPCRA section 313 should include exposure or risk considerations. EPA believes that a risk-based approach to EPCRA section 313 reporting is at odds with the overriding purpose of EPCRA section 313, which is to get information about the use, disposition, and management of toxic chemicals into the public domain, enabling the users of this information to evaluate the information and draw their own conclusions about risk. One goal for reporting is to move the determination of which risks are acceptable from EPA to the communities in which the releases occur. This basic, local empowerment is a cornerstone of the right-to-know program. EPCRA section 313 establishes an information collection and dissemination program. It provides the public with information that can be used with other site-specific factors to determine if releases into their communities result in risks that the community determines warrant further action given other factors, such as economic and environmental conditions, or particularly vulnerable human or ecological populations. In addition, EPA will continue to improve its annual public data release as well as its outreach and education efforts to assist users in understanding the data. Consequently, EPA disagrees with the commenters that EPCRA section 313 should be risk-based or that the information reported on releases and other waste management of PBT chemicals will be misleading to the public. For these reasons, EPA also disagrees with the commenter's suggestion that the Agency revise the Form R and the way in which EPA disseminates these data to explain to the public what the TRI data actually means from a risk or non-risk standpoint.

Several commenters state that naturally-occurring metals and metal compounds at mines are not susceptible to "source reduction" short of limiting or ceasing operations, and that therefore, lowering thresholds for PBT chemicals at mine sites does not serve the purposes of the PPA. EPA disagrees with the commenter. EPCRA section 313 and PPA section 6607 are tools to collect and disseminate information regarding the releases and other waste management of toxic chemicals. This information is then used to inform the public about such activities, assist government agencies, researchers and other interested parties in conducting research and data gathering, and aid in the development of regulations, guidelines, and standards. These statutes do not require changes in toxic chemical waste management. They simply provide information to permit the public to make informed decisions about toxic chemicals. This is important for PBT chemicals because these chemicals can remain in the environment for a significant amount of time and can bioaccumulate in organisms, such that even relatively small releases of these chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. Therefore, EPA disagrees with commenters because EPA believes that the availability of information on PBT chemicals is a critical component of the public's right-to-know and it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals.

8.h. Delay implementation of the rule

Commenter List: C-1353

Comment: The commenter stated that reporting of dioxins under EPCRA section 313 is not appropriate until it can be determined whether coal-fired combustion systems equipped with hot-side ESPs, like municipal waste combustors equipped with hot-side ESPs, generate dioxin and dioxin-like compounds. The commenter also stated that they have concerns about how EPA will require reporting of emission measurements below minimum detection limits. The commenter also stated that EPA has set guidelines and procedures for the utility industry to collect information on mercury in coal and flue gas under an Information Collection Request (ICR) and that EPA wants to collect this information to address inconsistencies in and lack of

accurate mercury inventories for the utility industry. The commenter stated that this data base would lead to more accurate emission modification factors for these categories of air pollution control devices and that when the data are evaluated, EPA will have a better knowledge base with which to set thresholds. The commenter stated that EPA should not set thresholds for mercury until the data collected under the utility ICR are evaluated and that until this is completed, the burden of a 10 pound/year reporting threshold under the TRI does not appear to be justified.

Response: EPA disagrees with the commenters statements, there is no reason to delay the reporting on dioxin or mercury for the reasons the commenter has stated. The ongoing work the commenter mentions may provide better guidance on how to report air releases under EPCRA section 313 but whether a facility has better guidance on how to report has nothing at all to do with setting the reporting thresholds. In addition, these additional data only deal with air releases; there are other releases such as direct releases to water that are also of concern. The concerns the commenter has for the reporting of dioxin and dioxin-like compounds, such as how to handle emission measurements below minimum detection limits, will be addressed in a guidance document that EPA will provide for reporting on this category.

Commenter List: C-1406

Comment: The commenter stated that they are not opposed to the lowering of reporting thresholds for PBT chemicals but that they believed it is premature to expand the TRI at this time for the following reasons: 1) The Agency is not managing the data that it currently collects; 2) the TRI is increasingly being called upon to implement a growing number of outside programs; 3) the TRI and Form R suffer from a number of problems requiring remedy; and 4) the TRI, as an important external cost internalization (ECI) mechanism, must first be retooled vis-a-vis ECI objectives.

Response: EPA disagrees with the commenter's statements: the Agency is managing the data it currently collects; the TRI program is not being called upon to implement a "growing number of outside programs." While there may be improvements that can be made in the TRI program and the Form R, there are no significant problems with either the program or the Form R; certainly none that would impact the lowering of reporting thresholds for PBT chemicals. Finally, the TRI program does not need to be "retooled vis-a-vis ECI objectives." Even if EPA agreed with any of these comments these are not a basis for not lowering the EPCRA section 313 reporting thresholds for PBT chemicals and denying the public the important information that will be collected on PBT chemicals.

Commenter List: C-1443

Comment: The commenter stated that EPA should withdraw the proposed rule until the development of the Agency PBT criteria and the single Agency-wide list of PBT chemicals. The commenter stated that if EPA should decide to go forward with this rule at the present time, then EPA should work to resolve issues other than those of the list itself, with a supplemental public comment period of 30 days once the list is final, before promulgation of a final rule. The commenter stated that in that way, the regulated community will have full knowledge of its obligations (including which data to gather on what particular chemicals) before this rule goes into effect.

Response: EPA does not believe that there are any issues that need to be resolved by providing an additional comment period and that there is no reason to delay the final rule. The issues of Agency-wide PBT criteria and a single Agency-wide list of PBT chemicals are addressed elsewhere in these comment responses.

Commenter List: C-1814

Comment: The commenter stated that the proposed rule leaves many unanswered questions about how facilities will estimate dioxin emissions; therefore, companies are uncertain of how they will be impacted by the proposed rule. The commenter stated that although EPA promised to develop guidance documents to address these difficult questions, the promise of future guidance is not reassuring. The commenter stated that EPA should not finalize the addition of dioxins to the TRI until appropriate guidance is developed to help facilities comply with the reporting requirements and that EPA should seek industry input in its efforts to develop such guidance.

Response: EPA does not believe that the final rule should be delayed in order to develop reporting guidance. After finalization of the PBT rule, EPA will provide updated guidance documents, will prepare and provide, in those cases where it is appropriate, chemical specific guidance documents, and will continue to offer training in order to assist facilities in reporting to TRI.

Commenter List: C-1820

Comment: The commenter stated that they are an industry sector only recently required to report under the EPCRA section 313 and that they are concerned that the electric utility industry sector as a whole has not followed, and is not aware of, the impact of the proposed rule. The commenter stated that, because of this, EPA will not be afforded the expert scientific knowledge, and resulting comments, that the industry could offer. The commenter suggested that the EPA withhold finalizing the proposed rule and work to more fully involve the regulated community in commenting on the proposed changes.

Response: EPA disagrees. EPA believes that sufficient notice has been provided to the electric utility industry sector and that sufficient comments have been received from this industry sector. A number of commenters from this industry sector, including major trade associations as well as individual utility companies, provided comments on the proposed rule. EPA believes that the regulated community has been provided with sufficient opportunity to comment on the issues raised in the proposed rule and does not believe that the final rule should be delayed to allow time for more comments.

Commenter List: C-1835

Comment: The commenter requested that EPA delay final rulemaking until such time when it can determine that those releases pose a health threat or risk to the public and to effectively address their concerns.

Response: As discussed elsewhere in these comment responses, EPCRA section 313 is not a risk based statute. The development of risk assessments is not required in order to lower the EPCRA section 313 reporting thresholds; thus, there is not a basis for delaying the final rule in order to determine risks. In fact, without the additional data on PBT chemical releases it may not be possible to accurately determine what the risks are in a particular community or to the nation as a whole.

Commenter List: C-1428 and C-1836

Comment: The commenters stated that EPA should wait for the final release of its dioxin reassessment before adding the dioxin and dioxin-like compounds category to the EPCRA section 313 list of toxic chemicals. One of the commenters stated that EPA should wait for any approval of the newly proposed World Health Organization (WHO) TEQ factors before promulgating EPCRA section 313 reporting requirements for dioxin and dioxin-like compounds.

Response: EPA has stated previously (in the dioxin proposed rule) that there is nothing in the dioxin reassessment that will change the conclusion that dioxin and dioxin-like compounds meet the listing criteria of EPCRA section 313 or that they are persistent and bioaccumulative chemicals. Therefore, there is no basis for not adding them to the EPCRA section 313 list or lowering the reporting thresholds to ensure that facilities will file reports. TEQ factors are a method for determining relative toxicities of dioxin-like compounds but EPA is not using them to make any determinations under EPCRA section 313 so there is no reason to wait for finalization of the newest WHO TEQ factors, which can change over time anyway.

Commenter List: C-1857

Comment: The commenter stated that EPA needs to defer promulgating new TRI thresholds for well-studied PBT chemicals such as mercury. The commenter stated that, instead, EPA should develop a carefully constructed national strategy to address such chemicals, particularly for PBTs in fossil fuels. The commenter stated that EPA should evaluate existing data, ongoing data collection activities, and the national nature of likely responses to reconsider whether additional TRI reporting adds value.

Response: EPA does not believe that there is any reason to defer the reporting of well-studied PBT chemicals including mercury. The fact that a PBT chemical is well-studied does not mean that the information that would be collected under EPCRA section 313 is available or that the information is not important. Under the Agency's PBT strategy EPA is developing national action plans for mercury and other PBT chemicals and the Agency's strategy includes the use of data on PBT chemicals collected under EPCRA section 313 as well as other relevant data that may be available.

8.i. Extend the comment period

Commenter List: C-003, C-0019, C-027, C-029, C-030, C-037, C-307, C-308, C-309, and C-310. Additional requests to extend the comment period were submitted by: American Cyanamid Company, Borden Chemicals and Plastics, CMA

Brominated Flame Retardant Industry Panel, CMA Polychlorinated Biphenyls Panel, Dow Chemical Company, Eastman Chemical Company, Georgia Gulf Corporation, International Cadmium Association, PPG Industries, and General Motors Corporation.

Comment: Fourteen of the commenters requested that EPA extend the commenter period on the January 5, 1999 (64 FR 688) proposed rule by 60 days while 5 other commenters requested a 90 extension. The commenters stated that the original 60 day comment period was too short and cited a number of reasons for needing more time including: the proposed rule raises complex issues that they need additional time for consideration, the potential for significant impacts on their industry, the overlap with other Agency PBT activities, and the public meetings that EPA had scheduled on the proposed rule.

Response: EPA responded to these request by extending the comment period on the proposed rule by 30 days from March 8, 1999 to April 7, 1999 (64 FR 9957, March 1, 1999). As EPA stated in the **Federal Register** notice that extended the comment period:

“EPA has received requests from a number of groups to extend the comment period for the January 5, 1999 proposed rule. These groups include the American Cyanamid Company, American Forest & Paper Association, American Portland Cement Alliance, Chemical Manufacturers Association, Chlorine Chemistry Council, Eastman Chemical Company, National Mining Association, and the Pentachlorophenol Task Force. These groups have requested additional time to review relevant information and prepare comments on the proposed rule. EPA has considered these comments and has determined that extending the comment period is an appropriate action that will not cause a significant delay in the evaluation of the proposed rule. Therefore, EPA is extending the comment period on the January 5, 1999 proposed rule and the February 23, 1999 action by 30 days until April 7, 1999.”

8.j. Facilities don't have the information to meet the rule

Commenter Number: C1865

Comment: The commenter questions the quality of data to be provided under the lower thresholds. They assert that facilities are much less likely to have actual release measurements for the potential releases under the lower reporting thresholds; thus, there will be increased reliance on estimation and EPA guidance.

Response: EPA disagrees that the data that will be provided under the lower thresholds will be any less accurate than under the 10,000 and 25,000 pound thresholds. Since the program's inception, facilities have never been required to perform any additional monitoring or testing. As stated in EPCRA section 313 (g)(2):

[i]n order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation.

Therefore, if facilities have monitoring data, they can use it. Oftentimes, monitoring data is calibrated for very low concentrations. Therefore, EPA believes that it is no more likely that covered facilities will have monitoring or testing data for these chemicals at the lower thresholds than they do for other toxic chemicals at the higher thresholds.

In addition, EPA believes that there are several sources of high quality guidance concerning low concentrations of PBT chemicals available to covered facilities to help them make threshold determinations and release and other waste management calculations. For example, EPA has published guidance documents for the regulated community (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)) and trade associations provide guidance documents to their members (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). In addition, many facilities have access to the Internet to find relevant information. For example, the United States Geological Survey's U.S. Coal Quality Database which contains information about toxic chemicals contained in coal from across the country, has been made available on the Internet. (<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>)

Further, EPA believes that in some instances, estimates may be more accurate than monitoring data. As EPA stated in the 1998 EPCRA Section 313 Questions and Answers document:

469. Section 313(g)(2) of EPCRA states that the owner or operator of a facility may use readily available data. In some cases, the available data may be known to be non-representative and reasonable estimates offer more accurate release information. Would EPA, in this instance, favor use of the estimates rather than data?

Yes, it is preferable to use reasonable estimates using the best readily available information if available data (including monitoring data) is known to be non-representative.

Therefore, covered facilities have been guided to not use monitoring data when they have other information which would contribute to more accurate reporting.

Finally, as discussed more fully elsewhere in these responses to comment, EPA has eliminated range reporting for PBT chemicals and has revised its policy on reporting significant digits such that facilities should report releases and other waste management quantities greater than 0.1 pound (except dioxins) as precisely as possible given the accuracy and the underlying data on which the estimate is based, supports this level of precision. These added measures also will provide improved data accuracy.

Commenter Number: C1352, C-1458

Comment: The commenters argue that it may not be possible for facilities to estimate releases. One commenter (C-1352) argues that the extremely low thresholds will compel facilities to compile chemical data with much greater sensitivity than would be required simply for product specification guarantees, waste disposal, or for some other type of sampling required by regulation. They argue that given that: 1) the *de minimis* exemption has been eliminated for PBT chemicals; 2) products are not analyzed to the sensitivity of the lowered thresholds; and 3) PBT chemicals are not analytes of interest, since the anticipated concentration (if believed present) would not approach a level of operational or regulatory concern, a facility owner or operator would be unable to provide a "reasonable estimate" related to these chemicals. Therefore, they argue, the concept of "readily available data" outlined under section 313(g)(2) does not apply to this rule. Likewise, "reasonable estimates" as applied to these chemicals would be virtually impossible. Another commenter (C-1458) argues that this problem is intensified by the fact that EPA proposes to eliminate range reporting and whole number reporting for PBT chemicals.

Response: EPA strongly disagrees with the commenter's assertions that the concept of "readily available data" does not apply to PBT chemicals and that owners/operators will not be able to provide reasonable estimates. The reporting requirements of EPCRA section 313 apply to facilities that meet certain criteria. Specifically, EPCRA Section 313 (b) states:

Covered Owners And Operators Of Facilities.--

(1) In General. --

(A) The requirements of this section shall apply to owners and operators of facilities that have 10 or more full-time employees and that are in Standard Industrial Classification Codes 20 through 39 (as in effect on July 1, 1985) and that manufactured, processed, or otherwise used a toxic chemical listed under subsection in excess of the quantity of that toxic chemical established under subsection (f) during the calendar year for which a release form is required under this section.

Facilities that meet these criteria are subject to the reporting requirements of EPCRA section 313 (a). Covered facilities that exceed either the default thresholds established in EPCRA section 313(f)(1) or alternate thresholds established by the Agency, must comply with the basic reporting requirements of EPCRA section 313 (a). Specifically, section 313(f)(2), provides that EPA:

may establish a threshold amount for a toxic chemical different from the amount established by paragraph (1). Such revised threshold shall obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements of this section. The amounts established by EPA may, at the Administrator's discretion, be based on classes of chemicals or categories of facilities.

To comply with these reporting requirements, section 313 (g)(2) states that:

[i]n order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation.

Therefore, EPCRA section 313 is clear that covered facilities that exceed the applicable thresholds must comply with the reporting requirements and “may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved.” EPCRA section 313 does not, however, provide any exemption from the practice of using readily available data to comply with the reporting requirements of EPCRA section 313.

Therefore, as explained above, facilities have a variety of sources available to help them comply with these reporting requirements. EPA considers production records, monitoring or analytical data, EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Facility Generating Facilities* (EPA 745-B-99-003)) and trade association guidance documents (e.g., National Council of the Paper Industry and Stream Improvement (NCASI) Technical Bulletins and NCASI’s *Handbook of Chemical Specific Information for SARA Title Section 313 Reporting*) and reasonable judgement on the part of the facility’s management all to be readily available data that covered facilities use to make their calculations.

In addition, one commenter argues that the lower thresholds will require covered facilities to compile chemical data with much greater precision than would be required simply for product specification guarantees, waste disposal, or for some other type of sampling required by the program. However, since the inception of the program, covered facilities have always been required to use their best readily available data to comply with the requirements of EPCRA section 313. EPA has never instructed facilities to ignore sources of data nor to only consider large releases in determining thresholds and making release and other waste management calculations. In fact, there are reports contained in the database for which facilities have reported one pound of releases. Therefore, EPA disagrees that compiling information for the lowered thresholds should be any more onerous than compiling the information for other toxic chemicals used at the facility.

Furthermore, as EPA explained more fully in other responses to comment contained in this document, although the *de minimis* exemption is being eliminated for PBT chemicals, EPA believes that given that facilities: 1) are not required to perform additional monitoring; 2) are not required to consider concentrations of toxic chemicals for which they have no information; and 3) need only consider readily available data, the elimination of the *de minimis* exemption for PBT chemicals will not vastly increase the extent of effort required to comply with EPCRA section 313.

Finally regarding the use of whole numbers and range reporting, EPA believes that the information available to the typical EPCRA section 313 reporter is generally greater and/or more accessible than it was 10 years ago. With the improved estimation techniques and tools that are available to the current EPCRA section 313 reporter, EPA believes that many facilities will be able to accurately estimate releases and other waste management amounts of section 313 PBT chemicals with more precision than whole numbers. Further, because of this improved information availability, EPA believes that many facilities will be able to accurately estimate releases and off-site transfers for further waste management of PBT chemicals in quantities of less than 1,000 pounds without the use of range codes. Although it may be true that some facilities will be better able to make those estimates than others, EPA does not believe this justifies not collecting the more specific and useful information from those facilities that can provide it.

Commenter Number: C-1405

Comment: One commenter contends that contrary to EPA’s assertion that information such as Material Safety Data Sheets (MSDSs) can provide facilities with adequate information concerning hazardous constituents in materials used, adequate information is often insufficient to enable facilities to meet EPA’s proposed regulation in the absence of the current *de minimis* exemption. They argue that a common source of information to users of materials with hazardous constituents are MSDSs but that OSHA only requires manufacturers of materials in commercial use to report hazardous constituents at 1.0 or 0.1 percent. Thus MSDS may not have sufficient information regarding materials which contain PBT chemicals at concentrations below these levels. In addition, there may not be any readily available sources of information for some potential sources of PBT chemicals (including structural components). They further argue that although EPA states in the proposed rule that additional sampling would not be required of reporting facilities, in the absence of pre-existing data, the only alternative is

sampling. This would present an unreasonable burden on any facility that is, or might be, subject to EPCRA Section 313 reporting requirements as proposed in this rule.

Response: EPA disagrees with the commenters' assertions. The Agency believes that since reporting first began in 1988, many new sources of information, in addition to MSDSs, have become available to covered facilities to use to determine concentrations of toxic chemicals in mixtures. As explained above, some of these sources of information include EPA guidance documents and trade association guidance documents. In addition, relevant information has become much more accessible to covered facilities over the past ten years. For example, although the United States Geological Survey's U.S. Coal Quality Database has been in existence since the mid 1970s, only more recently has it been made available on the Internet. (<http://energy.er.usgs.gov/products/databases/UScoal/index.htm>). Further, the Agency believes that it underestimated how much information covered facilities had available to them in 1988 regarding small concentrations of toxic chemicals in mixtures. However, as EPA explained in the preamble to the final rule:

"[i]n the event that the person does not know the specific concentration or the upper bound concentration than the person is not required to further estimate or otherwise factor that chemical in that mixture or product into threshold or release calculations." (February 16, 1988; 53 FR 4511)

Therefore if the *only* source of information on a toxic chemical in a mixture is from an MSDS, and the MSDS does not indicate if the chemical is contained in the mixture, the facility is not required to consider the toxic chemical towards threshold determinations or release and other waste management calculations.

Further, as stated in EPCRA section 313 (g)(2):

[i]n order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. *Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation.* ... (emphasis added)

Therefore, under EPCRA section 313, facilities are not required to perform any additional monitoring or analysis of production, process or use other than that already collected under other requirements. However, if a facility is required to monitor toxic chemicals under another statute, this data must be considered in determining thresholds and release and other waste management calculations under EPCRA section 313. EPCRA section 313(g) requires that facilities use readily available data, or in absence of such data, facilities are required to use reasonable estimates. If no monitoring data are available, the facility should use other readily available information in making threshold determinations and release and other waste management calculations.

8.k. Releases - generation of waste vs. management of waste

Commenter List: C-1456, C-1849

Comment - The commenters assert that because activities such as recycling, approved waste disposal, and treatment are incorporated into reported volumes, the EPCRA section 313 reported releases will be substantial overestimates of the actual quantities released to the ambient environment. One commenter (C-1849; TNRCC) argues that TRI releases as defined by EPA are not the same as ambient releases to the environment which may result in public exposure. They further argue that although this information may be useful to source reduction efforts, merging of reporting requirements under §313 of EPCRA and §6607 of the Pollution Prevention Act (PPA) of 1990 has resulted in information which is misleading to the public's desire to know what actual exposures are occurring. Another commenter (C-1456; NIPSCO) asserts that by requiring electricity generating facilities to report transfers off-site for treatment and disposal of PCBs from transformers, EPA has established a disincentive to properly dispose of PCB transformers and remove them from use. They argue that most PCB wastes transferred to off-site facilities are destroyed in regulated units which destroy at least 99.9999% of the PCBs and the small amount of PCB materials not destroyed are placed in carefully regulated chemical waste landfills. Further, they argue, that by removing the fluids from service and destroying PCBs they are reducing the risk of public exposure to these chemicals. However, they believe that the amount reported as "Off-site transfer" is added to other reporting quantities and the total is

reported as "releases". They are concerned that because the casual reader may conclude additional "releases" of PCBs to the environment have occurred, companies would have a disincentive to voluntarily remove PCBs. They further argue that programs like EPCRA section 313 cause covered facilities to report PCB removals as a "release" creating a strong disincentive to participate in proactive programs for their removal.

Response: The commenters are incorrect in stating that EPCRA section 313 release quantities include recycling and treatment amounts. Under EPCRA section 313, if a chemical activity threshold is met for the chemical, covered facilities are required to report the quantity of the toxic chemical entering each environmental medium, this includes "releases." The definition of release pursuant to EPCRA section 329(8) means:

any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles) of any hazardous chemical, extremely hazardous substance, or toxic chemical.

There is no language in this definition, anywhere else in the EPCRA statute, or in the regulations promulgated pursuant to EPCRA section 313, that limit this definition to ambient releases to the environment which may result in public exposure. In fact the definition specifically includes disposing of toxic chemicals as well as the abandonment of closed receptacles. In addition, neither the statute nor the regulations limit this definition to on-site releases. Therefore, the definition of release under EPCRA section 313 is significantly broader than the commenter seems to believe.

In addition to release reporting, under section 6607(b)(1) of the PPA, if a covered facility meets the reporting thresholds under EPCRA section 313, the facility is required to report the "quantity of the chemical entering any wastestream (or otherwise released to the environment)..." This quantity includes amounts of the toxic chemical released, treated, and recycled. However, this quantity does not include:

[t]he amount of any toxic chemical released into the environment which resulted from a catastrophic event, remedial action, or other one time event, *and is not associated with production processes during the reporting year.* (PPA 6607 (b)(7)) (emphasis added)

Therefore, the quantity of the toxic chemical entering the wastestream as collected under section 6607(b)(1) of the PPA, is the amount of the toxic chemical in production related waste. Covered facilities currently report the amount of the toxic chemical in production related waste as quantities of the toxic chemical released, treated, combusted for energy recovery and recycled. These quantities are collected as separate data elements in section 8 of the Form R. Further, facilities report the ultimate disposition of toxic chemicals in waste such that these quantities (*i.e.*, amounts released, treated, combusted for energy recovery, and recycled) are mutually exclusive. Collectively, then, these quantities are the amount entering the waste stream or the quantity of the toxic chemical in production related waste. For example, a covered facility transfers 1,000,000 pounds of PCBs to an incinerator for treatment. The covered facility knows that 999,999 pounds are destroyed in the incinerator and the remaining one pound is disposed in a landfill. The facility reports 999,999 pounds as transferred off-site for treatment and one pound as transferred off-site for disposal. These two quantities are reported as separate data elements on the Form R. The quantity reported as disposed off-site is considered released because, as explained previously, disposal is a type of release. The entire quantity (1,000,000 pounds) is the amount of production related waste.

Once collected, EPA presents the TRI data to the public in a number of formats. In its annual data release documents, EPA highlights different aspects of the quantities of toxic chemicals released and otherwise managed as waste. For example, EPA presents total on-site releases and, as subsets, presents the quantities released to air, surface water, underground injection and on-site land releases. (See *1997 Toxics Release Inventory* (EPA 745-R-99-003) Figure 2-3 "TRI On-site Releases") EPA also presents the quantity of total releases in the public data release. As discussed earlier, under EPCRA section 313, release quantities are not limited to quantities released to the ambient environment. Therefore, total releases, as presented in the public data release include both on and off-site releases as well as a variety of disposal methods. For example, in Table 2-20A of the 1997 public data releases, EPA presents TRI on-site and off-site releases by chemical and type of release (*e.g.*, air emissions, underground injection, etc.) (*1997 Toxics Release Inventory*, EPA 745-R-99-003).

In addition to TRI release data, EPA presents production related waste quantities in the public data release. Because production related waste includes releases, EPA includes release quantities with other waste management quantities. However, in this document, the Agency generally distinguishes quantities of the toxic chemical released from other types of

waste management. In other words, EPA does not count the quantities of toxic chemicals treated, combusted for energy recovery or recycled as quantities released. (See, for example, *1997 Toxics Release Inventory* (EPA 745-R-99-003) Table 2-20A "TRI On-site and Off-site Releases, by Chemical, 1997" and Table 2-20B "TRI Chemicals in Waste, by Chemical, 1997")

Further, EPA does not believe that the TRI program provides a disincentive for the proper and safe handling of PCBs in transformers managed as waste. As explained, covered facilities are required under EPCRA section 313 and section 6607 of the PPA to report quantities of toxic chemicals released or otherwise managed as waste if they meet a chemical activity threshold. Quantities of toxic chemicals sent off-site for treatment are described as such. These transfers are not included as releases. In addition, EPA disagrees that quantities of PCBs sent off-site for treatment will be misunderstood by the public because these quantities are accurately represented in the TRI database and in the public data release as a separate type of waste management.

Commenter List: C-1436

Comment: The commenter asserts that there is no benefit to the public in lowering the reporting threshold for pendimethalin to encourage waste minimization because adequate incentives and requirements already exist. Specifically, they argue that current market and regulatory requirements such as the pesticide formulation, packaging, and repackaging (PFPR) rule that includes substantial pollution prevention (P2) requirements already provide a high level of incentive for waste minimization. In addition, they argue that because a registered pesticide is the actual product being manufactured, there is adequate incentive to minimize the loss of these materials to waste. Further, they add that other factors and EPA programs already place it at the highest level for any manufacturing plant. They explain that in addition to manufacturing waste minimization efforts, specific pesticide formulator and packager effluent guidelines include waste minimization provisions. Pesticide formulators mix active ingredients with inert substances or carriers and packagers package formulated materials in to salable packages. Waste minimization provisions are included in pesticide formulating, packing and repacking regulations. In addition, EPA's waste water discharge regulations require facilities to choose to meet either "zero pollutant discharge" requirements or implement certain P2 practices. The commenter explains that this rule applies to all PFPR of essentially all pesticide active ingredients. Requirements of this rule are extensive and include certification statements of P2 practices, treatment method requirements to meet pesticide manufacturing effluent guidelines, and on-site compliance paperwork implementation of P2 practices.

Response: EPA disagrees that there is no benefit to the public in lowering the reporting threshold for pendimethalin to encourage waste minimization. Under EPCRA section 313 and PPA section 6607(b), covered facilities are required to report quantities of toxic chemicals released or otherwise managed as waste if the facility exceeds certain chemical activity thresholds. EPA then provides this release and other waste management information to the public. EPCRA and PPA simply provide for reporting mechanisms of the waste management of toxic chemicals. Neither require facilities to perform any pollution prevention activities, but rather require covered facilities to report on any such activities they have performed during the course of the reporting year. Making this information publically available encourages facilities to perform pollution prevention activities. EPA believes that pesticide manufacturers have many other incentives to perform pollution prevention activities on toxic chemicals they use during production and TRI is one of the best ways to showcase these activities.

Commenter List: C-1352

Comment: The commenter asserts that most of the PBT chemicals in waste are either not regulated under the waste regulations or would be present at such low concentrations as to not exceed a regulatory action level. They further argue that the proposed rule will not encourage waste minimization. First, they insist, no facility is willing or able to perform sophisticated process design simply on the basis of guidance documents or "reasonable estimates". Therefore, they argue that the rule will require analysis for PBT chemicals in order for meaningful process design to be performed. Second, because production at a facility occurs at high volumes and the proposed rule is concerned with low concentrations and low reporting thresholds, a PBT reporting threshold could be exceeded even if the concentration of the respective chemical was just barely above the limit of detection. They assert that although industry has made substantial minimization gains, the technology is not available to treat/remove chemicals of concern from manufactured products or generated waste (prior to generation) at such low concentrations and that any improvements that may be possible now or in future years would be enormously expensive due to the low concentrations that would likely be involved. Therefore, they argue, EPA's expected process improvement gains outlined in the preamble will not occur.

Response: The commenter is confused. In the preamble to the proposed rule, EPA does not assert that covered facilities will begin performing waste minimization activities as a direct result of this rulemaking. Rather, the Agency states that the PBT chemical rulemaking will provide data on PBT chemicals to EPA, industry and the public. Several EPA offices have ongoing projects and programs that are dealing with issues concerning PBT chemicals. EPA has established the PBT planning group which is a coordinating body consisting of representatives from various program offices throughout EPA that are dealing with PBT chemicals. This group has developed a strategy to reduce pollution from PBT chemicals through the application of regulatory and non-regulatory authorities, with a strong emphasis on pollution prevention. The availability of that data, in turn, can allow all parties to identify and track releases of PBT chemicals and monitor the progress of the programs designed to reduce the amount of PBT chemicals entering the environment. The data will also allow EPA and others to design prevention strategies that are focused and effective.

Further, EPA disagrees that the rule will require analysis for PBT chemicals. As explained in previous comments, EPCRA section 313 does not require facilities to test or monitor for toxic chemicals but rather it requires, under EPCRA section 313 (g)(2), that covered facilities make reasonable estimates using their best readily available data. A facility's readily available data may include production records, monitoring or analytical data, EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745-B-99-003)), trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Section 313 Form R Reporting*) and reasonable judgement on the part of the facility's management to make these determinations. If a covered facility does have information regarding the concentration of a toxic chemical in a mixture or trade name product, as in the case the commenter presented where the chemical is in concentrations above the detection limit, the facility must consider all non-exempted sources of the chemical for threshold determinations.

In addition, EPA disagrees with the commenter's last assertion that "the technology is not available to treat/remove chemicals of concern from manufactured products or generated waste (prior to generation) at such low concentrations and that any improvements that may be possible now or in future years would be enormously expensive due to the low concentrations that would likely be involved." Although there are some processes that might not, at present, be amenable to source reduction in terms of PBT chemicals, some processes may be. For example it may be possible to stringently control fuel composition, flow times, temperature, and other conditions in order to substantially reduce or even eliminate the incidental manufacture of dioxins during combustion processes. Therefore EPA continues to believe that in some cases, opportunities for pollution prevention will present themselves resulting from information reported under EPCRA section 313.

8.I. Releases - There is already sufficient information on releases on mercury and dioxin

Commenter Number: Chrome Coalition (C1431); SSINA (C1431a); Copper and Brass Fabricators Council, Inc. (C1435); Mercatus Center at George Mason University (C1448); Steel Manufacturers Association (C1858); American Petroleum Institute (C1865)

Comment: Some commenters contend that EPA should not lower the reporting thresholds for PBT chemicals because there is already sufficient information available on the releases of PBT chemicals. They contend that the information in the dioxin assessment, Clean Air Act section 112(c)(6) inventory, and the 1997 mercury inventory completed by EPA's Office of Air Quality Planning and Standards can provide the public and government with the information necessary to understand the environmental consequences of PBT chemical releases. Therefore, reporting would yield data which are either duplicative or unnecessary.

Response: EPA recognizes that there are some other data available on PBT chemicals but these data are not comparable to EPCRA section 313 data. These data are often not facility based estimates. For example the mercury inventory is based on EPA estimates based on typical facilities. Because these data do not represent actual facility estimates, they cannot provide the site-specific release information that is of use to communities and, thus, cannot function as an adequate substitute for TRI data. Further much of these data are media-specific, e.g., the Clean Air Act section 112(c)(6) inventory and the mercury inventory provide information on only air releases, and thus provide the public with only part of the picture on releases into the environment. The TRI data base is a multimedia data base and thus provides more comprehensive information about releases to air, water, and land including underground injection. Further, these other information sources do not create the same incentives to implement pollution prevention measures that TRI does. Currently available non-TRI sources of information cannot provide release and other waste management information or pollution prevention data with the scope and level of detail as data currently included in TRI. Therefore, EPA believes that the data sources identified by the commenters cannot provide the

public, researchers, public interest groups, government and industry with the information on PBT chemicals that the TRI data base can.

8.m. Interpretive Guidance Issues

Commenter List: C-2102

Comment - The commenter inquires as to the applicability of EPCRA section 313 to POTWs and whether or not POTWs manufacture or process dioxin or dioxin-like compounds. They explain that sewage sludge can be land applied or landfilled and they inquire as to whether either of these uses qualify as manufacturing or processing of dioxins.

Response - Currently POTWs, in themselves, are not included on the list of SIC codes covered by EPCRA section 313. However, some POTWs may be part of a covered facility and would therefore be required to report as part of that facility. Each facility must determine its primary SIC code to determine coverage under EPCRA section 313. If the primary SIC code of the facility, which may consist of more than one establishment, is an EPCRA section 313 covered SIC code (*i.e.*, major group codes 10 (except 1011, 1081, and 1094), 12 (except 1241), or 20 through 39; industry codes 4911 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); 4931 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4939 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4953 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. section 6921 et seq.), or 5169, or 5171, or 7389 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis)) and if the facility as a whole has more than 10 full time employees or the equivalent thereof, then the facility is covered if it exceeds an activity threshold for a listed toxic chemical. If a POTW is part of a covered facility, the application of toxic chemicals to land may be an otherwise use of the toxic chemical subject to the 10,000 pound threshold or to a lower threshold if the chemical is a PBT chemical as part of this rulemaking. For example, if the POTW receives the toxic chemical from off-site for the purposes of further waste management and subsequently disposes of the chemical by landfilling it onsite, this would be an otherwise use of the toxic chemical. In addition, if the toxic chemical is not received in waste from off-site but rather is created at the facility as a result of managing a waste from off-site, and the facility subsequently disposes the toxic chemical by landfilling it onsite, this would also be an otherwise use of the toxic chemical. Further, it is unclear what the commenter means by land applied, but this could, in itself, be an otherwise use of the toxic chemical. For example, if the toxic chemical is applied to the land to enrich the soil, this would be an otherwise use of the toxic chemical.

Finally, EPA has limited the dioxin listing with the qualifier “manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical.” Therefore, not all processing or otherwise use activities of this PBT chemical must be considered towards the facility’s threshold determinations. However, if a covered facility exceeds a threshold for dioxin elsewhere at the facility, any quantities of this toxic chemical that are subsequently landfilled on-site would be reported as released on the Form R.

Commenter List: C-1405

Comment - The commenter asserts that covered facilities will be required to locate and inventory every device that contains mercury, including thermometers, and record every release including each instance of thermometer breakage. They argue that such a requirement seems excessive and would provide little real value-added to the reduction of the use of PBT chemicals or their presence in the environment.

Response - EPA disagrees that little real value would be added by the reporting of releases of mercury from broken thermometers or that reporting these releases is excessive. Currently, if a covered facility exceeds a chemical activity threshold for mercury, the facility is required to report on all non-exempt releases and other waste management of mercury at the facility provided that they cannot take the article exemption⁷. While it is likely that they can take the article exemption, if

⁷Thermometers may be eligible for the article exemption. The article exemption applies if a toxic chemical in an item meets all of the following three criteria. The item must: 1) be formed to a specific shape or design during manufacture; 2) have an end use function dependent in whole or in part upon its shape or design during end use; and 3) not release a toxic chemical under the normal circumstances of processing or otherwise use of the item at the facility.

not exempt, the use of mercury in a thermometer would be considered an otherwise use of the toxic chemical. If a covered facility manufactures, processes or otherwise uses more than 10 pounds of mercury, the facility must report all non-exempt releases and other waste management of this toxic chemical. This could include releases of mercury from a thermometer. Nothing in this rule would change the reportability of such a release.

In addition, because PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. For example, mercury releases are of particular concern for the Great Lakes area. As explained in the EPA/Environment Canada document entitled "Background Information on Mercury Sources and Regulations" for the Binational Great Lakes Toxics Strategy:

[w]hen released to the environment, even in small quantities, [mercury] bioaccumulates, reaching dangerous levels in fish at the top of the aquatic food chain. Fish consumption advisories throughout Great Lakes waterbodies are testament to the health risks caused by mercury present in the Great Lakes ecosystem.

At the thresholds of 10,000 and 25,000 pounds/year, many facilities that are releasing mercury but do not exceed these thresholds, are not reporting any releases to the TRI database. EPA is lowering the chemical activity threshold for mercury to 10 pounds to capture more of these releases. Under this lower chemical activity threshold, more releases and other waste management activities are expected to be reportable under EPCRA section 313 because more covered facilities will likely exceed this lower threshold.

Commenter List: C-1863

Comment: The commenter asserts that it is inappropriate to lower reporting thresholds for the PBT chemicals used in mining, particularly when applied to metal mining. They argue that when EPA issued a final rule in May, 1997, adding coal and metal mining to the list of industries subject to EPCRA section 313, EPA exempted "overburden" from EPCRA section 313 release threshold and release and other waste management calculations. The commenter claims that the Agency defined "overburden" unrealistically and far too narrowly. That definition is the subject of an NMA petition for rulemaking (see December 21, 1998, NMA letter to Maria Doa from NMA Deputy General Counsel Roderick T. Dwyer). The commenter argues that in contrast to "overburden", EPA considers TRI chemicals in "waste rock" to be subject to EPCRA section 313 release calculations, assuming the chemical threshold is triggered elsewhere at the facility. The metal mining sector moves vast quantities of waste rock, and that waste rock virtually always contains trace amounts of many different metals and metal compounds, perhaps including in some instances, mercury and/or cobalt. Assuming that the EPCRA section 313 thresholds are triggered elsewhere at the facility, metal mining facilities may be required to report large amounts of "releases" of naturally-occurring metals and metal compounds, when, the commenter asserts, what those facilities have been doing is no more than moving dirt and rock from one place to another.

Response: EPA disagrees with the commenter's assertion that it is inappropriate to lower thresholds for PBT chemicals used in metal mining because these facilities are doing no more than moving dirt and rock from one place to another. Because even minimal releases of PBT chemicals may result in elevated concentrations in an organism and can be reasonably anticipated to cause an adverse affect, EPA believes that all releases of these chemicals may be of concern. For example, mercury releases are of particular concern for the Great Lakes area. As explained in the EPA/Environment Canada document entitled "Background Information on Mercury Sources and Regulations" for the Binational Great Lakes Toxics Strategy:

Although a thermometer may meet these criteria, if the thermometer is broken, there could reasonably be expected to be a release of greater than one half pound from the thermometer that would negate the exemption. If the mercury is recycled or reused, however, the third criterion would not be negated.

[w]hen released to the environment, even in small quantities, [mercury] bioaccumulates, reaching dangerous levels in fish at the top of the aquatic food chain. Fish consumption advisories throughout Great Lakes waterbodies are testament to the health risks caused by mercury present in the Great Lakes ecosystem.

In addition, several mining sites are listed on the National Priorities List (the Superfund list) because of mercury contamination. However, at the thresholds of 10,000 and 25,000 pounds/year, many facilities that are releasing mercury but do not exceed these thresholds, are not reporting any releases to the TRI database. EPA is lowering the chemical activity thresholds for PBT chemicals such as mercury to capture more of these releases. Under these lower chemical activity thresholds, more releases and other waste management activities will be reported under EPCRA section 313 because more covered facilities will likely exceed this lowered threshold.

In addition, under EPCRA, the statutory definition of release means:

any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles) of any hazardous chemical, extremely hazardous substance, or toxic chemical. (EPCRA section 329(8))

Use metal mining facilities release toxic chemicals when they remove waste rock from the earth, they must report these activities on Form R. Further, metal mining generates large quantities of waste rock that typically contain heavy metals (copper, arsenic, etc.). These previously buried materials are exposed to the elements upon excavation and become susceptible to leaching by wind and snow. Ultimately, the leaching process of these metals and other toxic chemicals can lead to ground and surface water contamination. Therefore, EPA disagrees that it is inappropriate to lower thresholds for PBT chemicals used in metal mining because: 1) minimal releases of persistent bioaccumulative toxic chemicals may result in significant adverse effect; 2) waste rock may contain significant levels of PBT chemicals; and 3) the disposal of waste rock meets the statutory definition of release under EPCRA section 313.

Commenter List: C0446

Comment: The commenter urges EPA to clearly address issues involving threshold determinations for contaminants or minor constituents in incoming fuel.

Response: Contaminants or other minor constituents in fuel are treated in the same manner as any other toxic chemical in a mixture for purposes of reporting under EPCRA section 313. As explained in the *EPCRA Section 313 Industry Guidance for Electricity Generating Facilities* (EPA 745-B-99-003), all EPCRA section 313 chemicals contained in fuels combusted for energy production are regulated otherwise used. The facility must consider the quantity of non-PBT chemical constituents of the fuel towards the 10,000 lb threshold. For example, in the instructions to the Form R (*Toxic Chemical Release Inventory Forms and Instructions 1998 Edition*) (EPA 745-K-99-001)) EPA specifically lists toxic chemicals in fuels as an example of toxic chemicals otherwise used.

Contaminants in fuels are sometimes eligible for the *de minimis* exemption if the toxic chemical is not a PBT chemical. Many of the EPCRA section 313 chemicals contained in commonly used fuels exist in below *de minimis* concentrations. As a result, facilities do not have to apply non-PBT chemicals present in fuels that exist below *de minimis* levels towards the otherwise use activity thresholds. Appendix A is a list of chemicals commonly found in fuels in the guidance document cited above. However, it is important to note that new chemicals may be manufactured as a result of combustion. These new toxic chemicals are not eligible for the *de minimis* exemption because they are manufactured by-products.

GENERAL COMMENTS IN OPPOSITION TO THE RULE

Commenter List: C-1453, C-1864, C-1813

Comment: Some commenters have general concerns with the PBT rulemaking. One commenter argues that the EPCRA section 313 reporting requirements are already too complex, overly burdensome, and wrought with uncertainty. They contend that the changes proposed by EPA only add to that problem. Another commenter argues that the problems in the proposed rule are so serious and numerous that the only reasonable course of action for EPA is to withdraw the proposal. They argue that EPA is adopting a "ready, fire, aim" approach to addressing PBT chemicals, instead of a careful and coordinated strategy.

Response: EPA strongly disagrees with these comments. The reporting requirements under EPCRA section 313 are not too complex, overly burdensome nor wrought with uncertainty. Compared with other environmental regulations (e.g., RCRA and CAA), EPCRA section 313 is one of the least complicated and most straightforward programs. The law does not require any additional monitoring or any other limitations or restrictions with regards to a covered facility's activities, rather, covered facilities are simply required to file forms containing information on the facilities' releases and other waste management of listed toxic chemicals.

As EPA explained in the proposed rule, review of existing data leads the Agency to believe that, as a general matter, the release to the environment of toxic chemicals that persist and bioaccumulate is of significantly greater concern than the release of toxic chemicals that do not persist or bioaccumulate. Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. EPA believes that the availability of information on PBT chemicals is a critical component of a community's right-to-know. Therefore, it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals.

Further, with respect to the comment that the Agency is adopting a "ready, fire, aim" approach to addressing PBT chemicals as well as elsewhere in these responses to comments, instead of a careful and coordinated strategy, EPA also disagrees. As explained at length in the PBT proposal, EPA carefully considered the latest activities of the national and international groups interested in addressing PBT chemicals and, guided by the goals and criteria of EPCRA section 313, proposed an initial list of toxic chemicals that persist and bioaccumulate in the environment. Some of these chemicals were already on the EPCRA section 313 list while others EPA proposed to add to this list. Despite the presence of these chemicals on lists the Agency used as an initial screen for persistence and bioaccumulation, EPA independently evaluated each chemical's persistence and bioaccumulation characteristics against the criteria delineated in the proposed rule. Furthermore, all of the chemicals in this final rule have been independently evaluated for their toxicity and shown to meet the relevant EPCRA section 313(d)(2) criteria. The Agency then proposed well thought out carefully devised thresholds based on the purposes of EPCRA section 313 and the chemicals' potential to persist and bioaccumulate, while keeping in mind burden considerations. See Unit IV. EPA is, therefore, finalizing the addition of the new chemicals to the EPCRA section 313 list of toxic chemicals and is lowering the reporting thresholds for all of the identified PBT chemicals on this list.

Commenter List: C-1422b:

Comment: Upon reviewing the petition of Communities For A Better Environment (CBE) of August 24, 1996, which formed the basis for the 1997 dioxin and dioxin-like compound proposal, the commenter identified the specific subject of the petition as "dioxin compounds emitted in the petroleum refining industry." The commenter asserts that the very beginning of that petition read "[E]mission of dioxin in the petroleum refining industry has emerged as an issue meriting immediate attention." They further argue that the petition did not involve the organic chemical industry generally but rather only oil refineries and the emissions believed to come from oil refineries. They contend that EPA has not explained the reasons for expanding the scope of its review beyond the citizen petition to address the entire organic chemical industry.

Response: EPA did not expand the scope of the CBE petition to add dioxins and dioxin-like compounds to the list of toxic chemicals under EPCRA section 313. CBE's petition clearly states that:

...through this Petition, we urge: i) inclusion of all dioxin and dioxin like compounds in the list of toxic chemicals for which a toxic chemical release form is required to be submitted by industries manufacturing, processing, or using them; (pg. 3 of petition)

CBE did not limit its petition to petroleum refineries and, therefore, EPA did not expand on the original petition's application. However, had CBE limited its petition, at the Agency's EPCRA section 313 provides the Agency with discretion to add chemicals meeting the section 313(d)(2) criteria and/or lower reporting thresholds pursuant to 313(f)(2), on its own initiative. EPA certainly may have expanded it.

Commenter List: C-1851

Comment: The commenter argues that the proposed rule is fundamentally flawed in its underlying principles and analysis, does not have any broader application other than for a few unique chemicals and circumstances, and appears to suffer from being placed on a fast track without full analysis. The commenter recommends that EPA revisit its approach in a more deliberative manner and develop a data management plan, use of sound science, and evaluate issues of characterization of data to be developed under a PBT system.

Response: EPA disagrees with the commenter's characterization of the PBT proposal. In fact, as explained in other sections of these responses to comment, the Agency did use sound science, employ data management considerations and evaluate issues of data characterization for this rulemaking. In developing this rule, EPA employed generally accepted scientific principles. Furthermore, as stated elsewhere in this document, EPA believes that even small releases of PBT chemicals are of significant concern and would not agree with the commenter's characterization of the rule as applying only to a "few unique chemicals and circumstances." Information reported pursuant to the lower reporting thresholds will be valuable; for instance, such data will allow the public to evaluate releases in their local communities and serve to assist local and federal government agencies, researchers, and other persons in the conduct of research and data gathering. EPA, therefore, is finalizing the PBT rulemaking.

Commenter List: C-1812

Comment: The commenter asserts that EPA incorrectly assumes that requiring additional electric utilities to report chemical release data will further the purposes of the Pollution Prevention Act. They argue that as a practical matter, electric utilities cannot reduce the amount of section 313 chemicals released without changing the type of fuel used or without adding emission control devices that are far beyond those already required by the Clean Air Act. They contend that because many facilities are limited in fuel choices by the physical design of the facility, reductions in combustion by-products can only be achieved by reducing the amount of coal or oil consumed. The commenter believes that it is inappropriate for EPA to influence fuel switching and energy policy through EPCRA and PPA. The commenter also believes that EPA should not use EPCRA and PPA to second-guess the effectiveness of the Clean Air Act in setting the levels of emission control deemed necessary to protect public health and the environment.

Response: EPA disagrees with the commenter's assertion that the PBT rule does not further the purposes of the PPA and EPCRA, and that the Agency is trying to use EPCRA and the PPA to second guess the effectiveness of the Clean Air Act. EPCRA section 313 and PPA section 6607 are tools to collect and disseminate information regarding the releases and other waste management of toxic chemicals. This information is then used to inform the public about such activities, assist government agencies, researchers and other interested parties in conducting research and data gathering, and aid in the development of regulations, guidelines, and standards. These statutes are not designed to, nor does EPA expect them to be used to directly affect changes in toxic chemical waste management at the facility level. Neither of these statutes was designed to create a "command and control" approach to affecting the use or management of toxic chemicals at the facility level. EPA, however, is aware that some facilities may have used information collected pursuant to the EPCRA section 313 reporting requirements to make changes in their production or waste management processes resulting in fewer releases or less use of toxic chemicals. (Ref. 67). However, the fact that a facility, or class of facilities, may be unable at this time to make process changes resulting in fewer releases, or decreased usage of the chemicals subject to this rule, does not undermine the value of the information that will be collected at the lower reporting thresholds. The commenter seems to indicate that because of the claim that facilities subject to the lower reporting thresholds may not be able to eliminate or reduce releases of these toxic, persistent, and bioaccumulative chemicals, the public should therefore be denied information on the presence and release of these chemicals in their communities. EPA strongly disagrees. PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, such that even relatively small releases of these chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. Therefore, EPA believes that the availability of information on PBT chemicals is a critical component of a community's right-to-know and it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals.

The commenter is correct that PBT chemicals may be used or manufactured in combustion processes and that such use or coincidental manufacture may be unavoidable. However, the mere presence of these chemicals will not guarantee releases or other waste management activities will occur. For example, there are well documented conditions that favor the formation of dioxins during combustion, and in some cases it may be possible to stringently control fuel composition, flow times, temperature, and other conditions in order to substantially reduce or eliminate the incidental manufacture of dioxins during combustion processes.

Commenter List: C-1868

Comment: This commenter requests EPA to reject the proposed rule altogether and instead use the current TRI reporting system as a vehicle for collecting information on PBT chemicals. They argue that EPA could then use other more appropriate programs for establishing strategies to address reductions of PBT chemicals.

Response: EPA disagrees that the current EPCRA section 313 reporting requirements are sufficient to capture useful release and other waste management information on PBT chemicals. EPA strongly believes that increased reporting on PBT chemicals will improve the usefulness of the data on these chemicals. There are currently very few reports for some of the PBT chemicals, such as mercury, mercury compounds and PCBs. For some of the chemicals being added by this rule, such as the dioxin and dioxin compound category, EPA believes that no reports would be submitted at the higher thresholds. The currently available data provide a distorted picture of potential exposures to humans and the environment, because at the current thresholds only a fraction of the releases that could be captured from facilities in the SIC codes subject to EPCRA section 313 are being reported. From EPCRA section 313 covered facilities are reported. This limited reporting results in a significant underestimation of the actual releases from the industry sectors covered by subject to EPCRA section 313. As such, the current data are of limited use for evaluating the potential exposures to humans and the environment of toxic chemicals that persist and bioaccumulate. Expanding the picture of potential exposures will increase the utility of all the TRI data on these chemicals. EPCRA is not a mechanism by which EPA actively attempts to regulate a reduction in chemical releases. EPA, however, believes the information reported pursuant to EPCRA is highly useful, for instance, such information assists local communities, government agencies, and researchers, among others, perform research and gather data. The information that will be collect on PBT chemicals at these lower reporting thresholds will be comprehensive and easily accessible by the public and others.

Commenter List: C-1409, C-1871, C-059, C-063, C-081, C-1787, C-2240, C-1830, C-793

Comment: Several commenters urge EPA to expand the reporting requirements of EPCRA section 313 and PPA section 6607 to include chemical use information. One commenter argues that by focusing efforts at the "end of the pipe," a chance is lost to reduce the use of toxic chemicals up front. They argue that by requiring chemical use information, the public can hold facilities accountable for reductions in emissions, and the public can determine if the reductions are due to true pollution prevention efforts or just changes in production levels. Another commenter asserts that tens of millions of Americans are exposed to toxic chemicals on a daily basis in their homes, workplaces and communities, but are kept in the dark about these exposures. Chemical use reporting, they assert, gives the public greater access to information and encourages companies to voluntarily reduce their use of toxins and generation of hazardous wastes, helping companies save millions of dollars in the process. Another commenter argues that their research in New Jersey confirms that many industrial products contain PBT chemicals. In fact, they argue, these products contain many more pounds of industrial chemicals than are generated as waste. This commenter determined that 2.9 billion pounds of 32 known or suspected PBT chemicals reported by industrial facilities in New Jersey in 1996 were shipped as (or in) products (accounting for 90 percent of the total use of those substances in that year). Yet another commenter argues that the toxics data that companies are currently required to disclose to the public are creating a major incentive for them to reduce toxic chemical emissions. Reporting chemical uses would give companies further incentive to promote pollution prevention more effectively.

Response: In this rulemaking, EPA did not request comment on collecting chemical use or materials accounting information. EPA has considered collecting this type of information under EPCRA section 313 and the PPA (See 61 *FR* 51322; Oct. 1, 1996) but is not actively pursuing this option at the present time. Therefore, EPA is not responding in detail to the merits of these comments.

9. General Comments in Opposition to the Rule

Commenter List: C-1453, C-1864, C-1813

Comment: Some commenters have general concerns with the PBT rulemaking. One commenter argues that the EPCRA section 313 reporting requirements are already too complex, overly burdensome, and wrought with uncertainty. They contend that the changes proposed by EPA only add to that problem. Another commenter argues that the problems in the proposed rule are so serious and numerous that the only reasonable course of action for EPA is to withdraw the proposal.

They argue that EPA is adopting a "ready, fire, aim" approach to addressing PBT chemicals, instead of a careful and coordinated strategy.

Response: EPA strongly disagrees with these comments. The reporting requirements under EPCRA section 313 are not too complex, overly burdensome nor wrought with uncertainty. The law does not require any additional monitoring or any other limitations or restrictions with regards to a covered facility's activities, rather, covered facilities are simply required to file forms containing information on the facilities' releases and other waste management of listed toxic chemicals.

As EPA explained in the proposed rule, review of existing data leads the Agency to believe that, as a general matter, the release to the environment of toxic chemicals that persist and bioaccumulate is of significantly greater concern than the release of toxic chemicals that do not persist or bioaccumulate. Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. EPA believes that the availability of information on PBT chemicals is a critical component of a community's right-to-know. Therefore, it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals.

Further, with respect to the comment that the Agency is adopting a "ready, fire, aim" approach to addressing PBT chemicals, instead of a careful and coordinated strategy, EPA also disagrees. As explained at length in the PBT proposal, EPA carefully considered the latest activities of the national and international groups addressing PBT chemicals and, guided by the goals and criteria of EPCRA section 313, proposed an initial list of toxic chemicals that persist and bioaccumulate in the environment. Some of these chemicals were already on the EPCRA section 313 list while others EPA proposed to add to this list. Despite the presence of these chemicals on lists the Agency used as an initial screen for persistence and bioaccumulation, EPA independently evaluated each chemical's persistence and bioaccumulation characteristics against the criteria delineated in the proposed rule. Furthermore, all of the chemicals in this final rule have been independently evaluated for their toxicity and shown to meet the relevant EPCRA section 313(d)(2) criteria. The Agency then carefully devised thresholds based on the purposes of EPCRA section 313 and the chemicals' potential to persist and bioaccumulate, while keeping in mind burden considerations. See Unit IV. EPA is, therefore, finalizing the addition of the new chemicals to the EPCRA section 313 list of toxic chemicals and is lowering the reporting thresholds for all of the identified PBT chemicals on this list.

Commenter List: C-1422b:

Comment: Upon reviewing the petition of Communities For A Better Environment (CBE) of August 24, 1996, which formed the basis for the 1997 dioxin and dioxin-like compound proposal, the commenter identified the specific subject of the petition as "dioxin compounds emitted in the petroleum refining industry." The commenter asserts that the very beginning of that petition read "[E]mission of dioxin in the petroleum refining industry has emerged as an issue meriting immediate attention." They further argue that the petition did not involve the organic chemical industry generally but rather only oil refineries and the emissions believed to come from oil refineries. They contend that EPA has not explained the reasons for expanding the scope of its review beyond the citizen petition to address the entire organic chemical industry.

Response: EPA did not expand the scope of the CBE petition to add dioxins and dioxin-like compounds to the list of toxic chemicals under EPCRA section 313. CBE's petition clearly states that:

...through this Petition, we urge: i) inclusion of all dioxin and dioxin like compounds in the list of toxic chemicals for which a toxic chemical release form is required to be submitted by industries manufacturing, processing, or using them; (pg. 3 of petition)

CBE did not limit its petition to petroleum refineries and, therefore, EPA did not expand on the original petition's application. However, had CBE limited its petition, EPCRA section 313 provides the Agency with discretion to add chemicals meeting the section 313(d)(2) criteria and/or lower reporting thresholds pursuant to 313(f)(2), on its own initiative.

Commenter List: C-1851

Comment: The commenter argues that the proposed rule is fundamentally flawed in its underlying principles and analysis, does not have any broader application other than for a few unique chemicals and circumstances, and appears to suffer from being placed on a fast track without full analysis. The commenter recommends that EPA revisit its approach in a more deliberative manner and develop a data management plan, use of sound science, and evaluate issues of characterization of data to be developed under a PBT system.

Response: EPA disagrees with the commenter's characterization of the PBT proposal. In fact, as explained in other sections of these responses to comment, the Agency did use sound science, employ data management considerations and evaluate issues of data characterization for this rulemaking. In developing this rule, EPA employed generally accepted scientific principles. Furthermore, as stated elsewhere in this document, EPA believes that even small releases of PBT chemicals are of significant concern and would not agree with the commenter's characterization of the rule as applying only to a "few unique chemicals and circumstances." Information reported pursuant to the lower reporting thresholds will be valuable; for instance, such data will allow the public to evaluate releases in their local communities and serve to assist local and federal government agencies, researchers, and other persons in the conduct of research and data gathering.

Commenter List: C-1812

Comment: The commenter asserts that EPA incorrectly assumes that requiring additional electric utilities to report chemical release data will further the purposes of the Pollution Prevention Act. They argue that as a practical matter, electric utilities cannot reduce the amount of section 313 chemicals released without changing the type of fuel used or without adding emission control devices that are far beyond those already required by the Clean Air Act. They contend that because many facilities are limited in fuel choices by the physical design of the facility, reductions in combustion by-products can only be achieved by reducing the amount of coal or oil consumed. The commenter believes that it is inappropriate for EPA to influence fuel switching and energy policy through EPCRA and PPA. The commenter also believes that EPA should not use EPCRA and PPA to second-guess the effectiveness of the Clean Air Act in setting the levels of emission control deemed necessary to protect public health and the environment.

Response: EPA disagrees with the commenter's assertion that the PBT rule does not further the purposes of the PPA and EPCRA, and that the Agency is trying to use EPCRA and the PPA to second guess the effectiveness of the Clean Air Act. EPCRA section 313 and PPA section 6607 are tools to collect and disseminate information regarding the releases and other waste management of toxic chemicals. This information is then used to inform the public about such activities, assist government agencies, researchers and other interested parties in conducting research and data gathering, and aid in the development of regulations, guidelines, and standards. Neither of these statutes was designed to create a "command and control" approach to affecting the use or management of toxic chemicals at the facility level. EPA, however, is aware that some facilities may have used information collected pursuant to the EPCRA section 313 reporting requirements to make changes in their production or waste management processes resulting in fewer releases or less use of toxic chemicals. (Ref. 67). However, the fact that a facility, or class of facilities, may be unable at this time to make process changes resulting in fewer releases, or decreased usage of the chemicals subject to this rule, does not undermine the value of the information that will be collected at the lower reporting thresholds. The commenter seems to indicate that because of the claim that facilities subject to the lower reporting thresholds may not be able to eliminate or reduce releases of these toxic, persistent, and bioaccumulative chemicals, the public should therefore be denied information on the presence and release of these chemicals in their communities. EPA strongly disagrees. PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, such that even relatively small releases of these chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. Therefore, EPA believes that the availability of information on PBT chemicals is a critical component of a community's right-to-know and it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals.

The commenter is correct that PBT chemicals may be used or manufactured in combustion processes and that such use or coincidental manufacture may be unavoidable. However, the mere presence of these chemicals will not guarantee releases or other waste management activities will occur. For example, there are well documented conditions that favor the formation of dioxins during combustion, and in some cases it may be possible to stringently control fuel composition, flow times, temperature, and other conditions in order to substantially reduce or eliminate the incidental manufacture of dioxins during combustion processes.

Commenter List: C-1868

Comment: This commenter requests EPA to reject the proposed rule altogether and instead use the current TRI reporting system as a vehicle for collecting information on PBT chemicals. They argue that EPA could then use other more appropriate programs for establishing strategies to address reductions of PBT chemicals.

Response: EPA disagrees that the current EPCRA section 313 reporting requirements are sufficient to capture useful release and other waste management information on PBT chemicals. EPA strongly believes that increased reporting on PBT chemicals will improve the usefulness of the data on these chemicals. There are currently very few reports for some of the PBT chemicals, such as mercury, mercury compounds and PCBs. For some of the chemicals being added by this rule, such as the dioxin and dioxin compound category, EPA believes that no reports would be submitted at the higher thresholds. The currently available data provide a distorted picture of potential exposures to humans and the environment, because at the current thresholds only a fraction of the releases that could be captured from facilities in the SIC codes subject to EPCRA section 313 are being reported. This limited reporting results in a significant underestimation of the actual releases from the industry sectors subject to EPCRA section 313. As such, the current data are of limited use for evaluating the potential exposures to humans and the environment of toxic chemicals that persist and bioaccumulate. Expanding the picture of potential exposures will increase the utility of all the TRI data on these chemicals. EPCRA is not a mechanism by which EPA actively attempts to regulate a reduction in chemical releases. EPA, however, believes the information reported pursuant to EPCRA is highly useful, for instance, such information assists local communities, government agencies, and researchers, among others, perform research and gather data. The information that will be collect on PBT chemicals at these lower reporting thresholds will be comprehensive and easily accessible by the public and others.

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Response: In this rulemaking, EPA did not request comment on collecting chemical use or materials accounting information. EPA has considered collecting this type of information under EPCRA section 313 and the PPA (See 61 *FR* 51322; Oct. 1, 1996) but is not actively pursuing this option at the present time. Therefore, EPA is not responding in detail to the merits of these comments.

10 GENERAL COMMENTS IN SUPPORT OF THE RULE

Commenter List: C-011, C-033, C-056, C-072, C-073, C-100, C-109, C-141, C-1892, C-2235, C-2262, C-262, C-369, C-484, C-490, C-502, C-520, C-605, C-362, C-1879, etc.

Comment: Several commenter support EPA's proposal to add PBT chemicals to the list of EPCRA section 313 toxic chemicals and to lower the reporting thresholds for these chemicals for a host of reasons. These commenters specifically argue that the public has a right to know about releases and other waste management of these chemicals.

Response: EPA agrees with these commenters. As EPA explained in the proposed rule, review of existing data leads the Agency to believe that, as a general matter, the release to the environment of toxic chemicals that persist and bioaccumulate is of greater concern than the release of toxic chemicals that do not persist or bioaccumulate. Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment. EPA believes that the availability of information on PBT chemicals is a critical component of a community's right-to-know. Therefore, it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals.

Commenter List: C-193

Comment: This commenter asserts that it is essential for the public to be informed of the release of any toxic substances, not by some chance discovery by the media or a whistle blower who risks his job, but immediately, when such releases occur. They argue that the public has an absolute right to this information and the commenter urges EPA to take action to see that severe penalties are imposed upon those who fail to inform both the public and the regulatory agencies concerned.

Response: EPA does not believe that EPCRA section 313 is the appropriate tool for this commenter's suggestion. As explained in EPCRA section 313(a), covered facilities are required to submit reports concerning their releases of toxic chemicals for the entire calendar year on July 1 of the following year. The specific statutory requirement is:

(a) Basic Requirement. - The owner or operator of a facility subject to the requirements of this section shall complete a toxic chemical release form as published under subsection (g) for each toxic chemical listed under subsection (c) that was manufactured, processed, or otherwise used in quantities exceeding the toxic chemical threshold quantity established by subsection during the preceding calendar year at such facility. Such form shall be submitted to the Administrator and to an official or officials of the State designated by the Governor on or before July 1, 1988, and annually thereafter on July 1 and shall contain data reflecting releases during the preceding calendar year.

Further, EPCRA section 313(i) states that "[t]he Administrator may modify the frequency of submitting a report under this section, but the Administrator may not modify the frequency to be any more often than annually." Therefore, the language of EPCRA section 313 constrains the Agency from collecting this type of information any more frequently than annually.

EPA believes that better mechanisms to require facilities to report their releases of chemicals immediately would be EPCRA section 304 (40 CFR 355.40) and CERCLA section 103(a) (40 CFR Part 302).

Miscellaneous Comments

Commenters: C-1889

Comment: The commenter stated that industry has asked EPA not to consider the injection of untreated toxic waste into "open-ended deep wells" or the burial in the Earth itself as a release to the environment. The commenter states that for EPA to even cradle such an idea is absurd and asks "if injecting untreated hazardous waste or burying it in the Earth itself is not a release to the environment – then, what is?" The commenter also states that in the case of injection wells, TRI should include reports of spillage on the ground at the injection site which the commenter states has proven to be one of the most significant sources of contamination to the environment from these facilities.

Response: EPA did not raise, address, request comment on, or in any way reopen issues related to underground injection or the definition of release in the proposed rule. Therefore, EPA declines to respond to this comment.

Commenter Number: C- 1422

Comment: The commenters assert that EPA cited several documents in the proposed rule which are either not complete or are not available to the public. Draft documents should not be used to substantiate a Proposed Rule. This is particularly important when these documents represent EPA initiatives that have not been reviewed or responded to, or will be

implemented over periods of many years. Similarly, substantiating a rule with articles that are "in press" is unfair, since those interested in commenting do not have the benefit of determining the merits of the references listed.

Response: EPA strongly disagrees with these commenters' assertions. In the proposal, EPA cited to two documents that were in press at the time of publication of the proposal. These documents were: Meylan, W.M., Howard, P.H., and Boethling, R.S., "Improved Method for Estimating Bioconcentration Factor from Octanol/Water Partition Coefficient." *Environ. Toxicol. Chem.*, and Webster, E., Mackay, D. and F Wania, F, "Evaluating Environmental Persistence." *Environ. Toxicol. Chem.*, (1998). Although these documents, as of the publication date of the proposed rule, had not been published, they had been accepted for publication and press ready copies were included in the public docket of the proposed rule. Therefore, anyone interested in commenting on the rule certainly had an opportunity to review all of the references listed. Further, EPA believes that the draft documents cited in the proposed rule were sufficiently complete to add support to the issues that they addressed.