

**COMMENTS BY THE CENTER FOR REGULATORY EFFECTIVENESS ON
THE ATRAZINE ENVIRONMENTAL FATE AND EFFECTS RISK ASSESSMENT
(DOCKET CONTROL NUMBER OPP-34237C)**

INTRODUCTION

The Center for Regulatory Effectiveness (“CRE”) has the following primary comments on the Environmental Fate and Effects Chapter of EPA’s Registration Eligibility Science Chapter for Atrazine (“*Environmental Risk Assessment*”).

First, EPA’s *Environmental Risk Assessment* “concluded that the major effects from atrazine use are indirect effects on fish and invertebrate populations....” At the same time, EPA correctly admitted “that there is ‘inadequate data’ on indirect effects to assess risk...”; and that “[c]urrently, there is no methodology...which can model and statistically analyze indirect effects.” *EFED Review of Public Comments in Response to the EPA EFED Revised Environmental Risk Assessment for Atrazine*, p. 3(April 10, 2002)(“*Comment Response*”). EPA also correctly admitted that there are substantial uncertainties regarding the field and laboratory standards used to support the *Environmental Risk Assessment*’s conclusion of indirect effects: *e.g.*, lack of reproducibility and lack of transparency. *Environmental Risk Assessment*, pp. 63-64. Given these admissions, EPA obviously cannot publicly disseminate a conclusion that atrazine causes indirect effects. Any such conclusion would violate the objectivity and utility standards of the Data Quality Act amendments to the Paperwork Reduction Act, 44 U.S.C. § 3516 statutory and historical notes (“Data Quality Act”). Consequently, EPA’s *Environmental Risk Assessment* should be revised to delete any conclusion that atrazine causes indirect effects on wildlife.

Second, the *Environmental Risk Assessment* should be revised to state that EPA cannot use or rely on the Hayes Frog Studies because those studies do not comply with the Data Quality Act for the following and other reasons:

- The Hayes Frog Studies results cannot be reproduced; and
- There are no validated test methods for aromatase induction, which is the hypothesized mode or mechanism of action underlying the Hayes Frog Studies.

Third, the *Environmental Risk Assessment* should be revised to state that there is no acceptable evidence of wildlife endocrine disruption from atrazine because there are no validated test methods for endocrine disruption. The objectivity and utility standards of the Data Quality Act preclude any conclusion or suggestion of adverse endocrine effects until and unless there are properly validated test methods.

Fourth, the quotient method EPA used in the *Environmental Risk Assessment* is arbitrary and lacks utility. Consequently, any conclusions based on the quotient method violate the utility and objectivity standards of the Data Quality Act. EPA should defer any conclusions about the environmental effects of atrazine until EPA has developed a reliable probabilistic risk assessment method for adverse environmental effects.

These and other comments are discussed in more detail below.

EPA'S ENVIRONMENTAL RISK ASSESSMENT CANNOT ASSESS INDIRECT EFFECTS

EPA's *Environmental Risk Assessment* determined that the only major environmental risk from atrazine use was indirect effects, not direct effects: *e.g.*,

- “[T]he Agency has concluded that the major effects from atrazine use are indirect effects on fish and invertebrate populations....” *Comment Response, p. 3.*
- “[T]he atrazine effects of concern are indirect effects on the aquatic community due to the loss of vegetative habitat.” *Comment Response, p. 3.*
- “[T]he Agency identified the endpoints of greatest concern as indirect effects on aquatic communities due to loss of species sensitive to atrazine and resulting in changes in structure and functional characteristics of the affected communities, and reductions in populations of aquatic macrophytes, invertebrates and fish.” *Environmental Risk Assessment, p. 3.*
- “[T]he Agency notes that the results of the agency’s preliminary risk assessment shows that Levels of Concern (LOCs) are not exceeded for most of the direct acute and chronic effects on aquatic organisms.” *Environmental Risk Assessment, p. 12.*

Paradoxically, EPA also admits in its *Comment Response* the Agency is unable to assess indirect environmental effects for atrazine or any other pesticide:

- “EFED contends that there is ‘inadequate data’ on indirect effects to assess risk....” *Comment Response, p. 3.*

- “Currently, there is no methodology...which can model and statistically analyze indirect effects.” *Comment Response*, p.3.

EPA’s inability to assess indirect environmental effects is not a new phenomenon. EPA acknowledged this flaw in its risk assessment process over ten years ago:

Although the Agency believes that long-term, indirect effects of pesticide use on aquatic ecosystems may be important, the Agency does not have a testing scheme in place to accurately measure such effects within the time specified for Reregistration. *Decisions on the Ecological, Fate, and Effects Task Force*, Linda J. Fisher, EPA Assistant Administrator, Attachment: Program Guidance on Ecological Risk Management, p. 1 (Oct. 29, 1992).

Nothing has changed since, as acknowledged by EPA in its atrazine *Comment Response*.

Moreover, EPA used the quotient method in its *Environmental Risk Assessment*, and EPA admits: “The quotient method cannot evaluate secondary effects.” 61 FR 47552, 47594 (Sept. 9, 1996). EPA defines the term “secondary effects” as

an effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest (synonymous with indirect effects...). *Id.* at 47615.

EPA cannot inform the public that atrazine use causes indirect effects when EPA admits that “there is no methodology...which can model and statistically analyze indirect effects”; and “that there is ‘inadequate data’ on indirect effects to assess risk...” *Comment Response*, p. 3. EPA’s *Environmental Risk Assessment* violates the Data Quality Act’s objectivity and utility requirements because EPA’s conclusion that atrazine has adverse indirect effects has no factual or scientific basis. Consequently, this conclusion is not accurate and reliable; nor is it useful to its intended users. 67 FR 8452, 8453 (Feb. 22, 2002)(OMB’s government-wide Data Quality guidelines).

With regard to indirect effects, EPA also relied on some field and laboratory studies. With regard to the quality of these studies, EPA admitted:

This refined assessment, while providing a greater certainty of adverse effects on aquatic life than that based on modeled exposure and typical laboratory toxicity values, also contains inherent uncertainties. Two important sources of uncertainty can be attributed to the monitoring data and the laboratory (including laboratory data on the major degradates) and field study data themselves. The monitoring data were not collected for the purpose of supporting an ecological risk assessment. Thus, the spatial and temporal distributions of the monitoring data do not match those for the laboratory toxicity studies or the field studies.

The laboratory and field study data for the most part are taken from published literature. The EPA scientists did not have access to the raw data necessary to evaluate some of these studies as is typically done for data submitted by registrants to support registration. Also, while a majority of the laboratory and field toxicity data indicated similar exposure levels, there were some studies that showed no effects at similar exposure levels. In addition, while the laboratory toxicity data indicate adverse effects to certain species of organisms, we cannot determine with certainty that impacts on these or similar species would result in a loss of ecological function or important changes in community structure in natural systems.

Detrimental effects on plants are rapid are rapid and appear to increase as both the atrazine concentration exposure increases. Prolonged exposure results in starvation and ultimately death of plants. Rapid recovery of oxygen evolution (within hours) is observed in aquatic plants if atrazine exposure is removed. Plant recovery and resistance are two complicating issues which add uncertainty to any risk assessment on atrazine, and there is insufficient information to do more than report that both occur.

Environmental Risk Assessment, pp. 63-64.

These field and laboratory studies do not meet the Data Quality Act's objectivity and utility standards. EPA itself admits that "the laboratory toxicity data" do not allow the Agency to "determine with certainty that impacts on these or similar species would result in a loss of ecological function or important changes in community structure in natural systems." Moreover, the laboratory and field toxicity tests showing adverse effects are not reproducible: "some studies... showed no effects at similar exposure levels"; and neither EPA nor the public has access to the underlying data. It is also inaccurate to compare monitoring data with field and laboratory data when their "spatial and temporal distributions... do not match." In addition, EPA acknowledges, "Plant recovery and resistance are two complicating issues which add uncertainty to any risk assessment on atrazine, and there is insufficient information to do more than report that both occur." In sum, based on the current data base, and based on the risk assessment methods used by EPA, there is too much "uncertainty" regarding atrazine's indirect environmental effects to reach any accurate, reliable, unbiased and useful conclusion regarding those effects. Consequently, any conclusion regarding those effects cannot meet Data Quality Act standards.

THE HAYES FROG STUDIES DO NOT MEET DATA QUALITY STANDARDS

The *Environmental Risk Assessment* suggests that the Hayes Frog Studies show that atrazine

use causes endocrine disruption in frogs at very low concentrations, in particular with regard to reproductive development. The Hayes Frog Studies do not meet the Data Quality Act objectivity and utility requirements for at least two reasons.

First, other laboratories have been unable to reproduce them. Attached as Exhibit A to CRE's comments are a written report and slides from a presentation to EPA by Dr. James A. Carr of Texas Tech University. Dr. Carr was unable to reproduce Dr. Hayes' test results. In addition, CRE understands that Dr. John Giesy, of Michigan State University, has been unable to reproduce Dr. Hayes' test results. Test results that have been shown not to be reproducible do not meet the Data Quality Act's objectivity and utility standards because they are not accurate, reliable or useful.

Second, Dr. Hayes hypothesizes that atrazine can cause adverse endocrine effects in frogs because atrazine induces aromatase in the frogs. *Environmental Risk Assessment*, p. 90. There are no validated test methods for aromatase induction. Any mode or mechanism of action that relies on unvalidated test methods does not meet the Data Quality Act's objectivity and utility standards because the unvalidated test methods have not been demonstrated to be accurate, reliable and useful.

In light of the above concerns, the *Environmental Risk Assessment* should be revised to state that EPA will not use or rely on the Hayes Frog Studies because they do not meet Data Quality Act standards.

EPA CANNOT REACH ANY CONCLUSION ABOUT ENDOCRINE DISRUPTION UNTIL AND UNLESS THERE ARE VALIDATED TEST METHODS

EPA's *Environmental Risk Assessment* at page 90 states:

Atrazine has been reported to cause sub-lethal effects in aquatic organisms and amphibians. These include endocrine effects in frogs at -0.1 Fg/L and in largemouth bass at -50 Fg/L, as well as olfactory effects in salmon at -50 Fg/L. In addition some studies have been conducted where these effects were not demonstrated.

At pages 90-93, the *Environmental Risk Assessment* contains an extensive discussion of the relevant studies which suggests that some of them support the conclusion that atrazine causes wildlife endocrine effects.

EPA has also acknowledged:

The Endocrine Disruptor Screening program has proposed a number of test protocols for identifying endocrine effects in wildlife species. Some of these protocols are currently in round-robin testing. As of this date, none of them have been approved for regulatory testing.

EFED Review of Comments from Syngenta and its Contractors about the EPA Revised Environmental Risk Assessment for Atrazine, p. 22. (April 22, 2002).

The *Environmental Risk Assessment* in its current state violates the Data Quality Act's objectivity and utility standards because it indicates that atrazine does cause endocrine effects in wildlife based on studies using unvalidated test methods. EPA should revise its *Environmental Risk Assessment* to clearly state that EPA cannot reach any conclusions about wildlife endocrine effects from atrazine until and unless there are properly validated test methods for those effects.

THE QUOTIENT RISK ASSESSMENT METHOD IS ARBITRARY AND LACKS UTILITY

As in the case of most if not all pesticides, EPA used the quotient method to assess atrazine's environmental risks:

The standard method used in the EPA Office of Pesticide Programs (OPP) to characterize ecological risk is the ratio or quotient method. "Typically, the ratio (or quotient) is expressed as an exposure concentration divided by an effects concentration: (U.S. EPA, Part A, Section 5.1.3). A risk quotient (RQ) is the ratio of the estimated environmental concentration of a chemical to a toxicity test effect level for a given species. It is calculated by dividing an appropriate exposure estimate (e.g., EEC or estimated environmental concentration) by an appropriate toxicity test effect level (e.g. LC50). Thus, the RQ is an index (an indicator or measure of a condition) of the potential adverse effects. As an index, the risk quotient needs some reference point or bearing to have meaning. Thus, the Agency has established Levels of Concern (LOCs) in order to identify when the potential adverse effects are of concern to the Agency (See Appendix XVI, Table 1). LOCs are criteria used to indicate potential risk to nontarget organisms and the need to consider regulatory action. When an LOC is exceeded, it means that a pesticide, when used as directed, has the potential to cause adverse effects on nontarget organisms.

Environmental Risk Assessment, p. 5

The referenced Appendix Table contains the LOCs that EPA has established for all pesticide environmental risk assessment. These LOCs do not vary from pesticide to pesticide.

EPA's refined risk assessment for atrazine's environmental effects consisted primarily of computer modeling of atrazine concentrations in various surface waters based on the available monitoring data. The model results were then compared to the LOCs. *Environmental risk assessment, pp. 4-5, 7-8, 16.*

EPA's Office of Pesticide Programs has explained on its website that the quotient risk assessment method lacks utility (emphasis added):

The [SAP] panel suggested that the current test methodologies and specific endpoints used by OPP in its model assessments were designed to support the relative simplistic process of hazard assessment, not risk assessment. The Panel indicated that the current approach has a number of limitations, *and its utility in risk assessments is of questionable value*. They also pointed out that gaps in the current methodologies must be filled to accomplish effective and comprehensive risk assessments. As a result, they strongly urged OPP EFED to conduct probabilistic assessments (risk assessments) to evaluate the ecological impacts from pesticides.

The SAP has emphasized its concern “with the notion that the frequency of LOC exceedances is a useful measure.” The SAP concluded that the LOC-exceedance standard is “essentially an arbitrarily selected threshold.” *FIFRA Scientific Advisory Panel, Final Report on a Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Methodology for Conducting Comparative Ecological Risk Assessments*,” p. 9 (SAP Report No. 99-01A, Jan. 22, 1999).

EPA’s use of the quotient method in the *Environmental Risk Assessment* violates the Data Quality Act’s utility and objectivity requirements because this method is not accurate, reliable or useful in assessing the indirect or other environmental effects of atrazine.

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Attachment