Center for Regulatory Effectiveness' ("CRE") Comments on U.S. Environmental Protection Agency's ("EPA") Proposed Interim Decision ("PID") for Atrazine, 85 FR 93 (Jan. 2, 2020), at https://www.govinfo.gov/content/pkg/FR-2020-01-02/pdf/2019-28339.pdf . Comments filed February 29, 2020, at www.Regulations.gov , EPA-HQ-OPP-2013-0266.

I. EXECUTIVE SUMMARY AND REQUESTED ACTIONS

We commend EPA's PID for improved data quality in some respects. In particular, the PID's Community Equivalent Level of Concern ("CELOC') is superior to the grossly flawed CELOC that EPA included in the Agency's Ecological Risk Assessment ("ERA") for atrazine.[1] We assume that the ERA, which has not been changed since proposed for comment, is now considered modified to include the new CELOC. Please correct us if our assumption is mistaken. We request that EPA emphasize in the record that the new 15 ppb CELOC applies to all watersheds. We also request that EPA not use either the new or old CELOC quantitatively or qualitatively for "final effects determinations."

Despite the CELOC improvement, there are still several significant data quality flaws and omissions in the ERA. For example, in the Agency's own words, EPA is considering atrazine amphibian and fish studies

> "with quality concerns and [which] have not been replicated since the original study, despite multiple studies involving the same endpoint."[2]

EPA's reliance on amphibian effects studies that are of poor-quality and demonstrated to be non-reproducible violates the Information Quality Act's ("IQA")

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[1] The PID is available at https://www.epa.gov/sites/production/files/2019-12/documents/atrazine_pid_signed_12_18_19.pdf . EPA's atrazine ERA is available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 . EPA originally described this ERA as "draft" or "preliminary." See https://www.epa.gov/ingredients-used-pesticide-products/draft-ecological-risk-assessments-triazines . EPA apparently now considers its "Revised Ecological Risk Assessment" to be final. See, *e.g.,* PID pages 8-9, and 19.

[2] The quoted EPA language is from page 307 of the atrazine ERA, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 .

accuracy and reproducibility requirements. [3]

We request that EPA not use any non-reproducible studies to assess or regulate atrazine. We also ask that EPA carefully consider evidence in the record indicating that studies advocated by the 2012 Science Advisory Panel ("SAP") are too inaccurate and unreliable to be used to assess and regulate atrazine. [4]

EPA is apparently concerned that it has to use inaccurate, non-reproducible studies just because the 2012 SAP said so.[5] This concern has no basis. EPA has to comply with IQA requirements, not with SAP recommendations.

The ERA violates IQA requirements in several other respects: *e.g.,* use of inaccurate, unvalidated models and inaccurate statements such as 35% bird deaths from atrazine use.[6]

EPA should expect an IQA Request for Correction ("RFC") if the atrazine ERA is not corrected in a timely manner to comply with the IQA. These corrections include but are not limited to use of non-reproducible, inaccurate and unreliable studies to assess and regulate atrazine.

We hope for data quality improvement during EPA's Endangered Species Act ("ESA") review and consultation using new EPA's "Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological

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[3] See, *e.g.,* EPA IQA Guidelines, Section 6.3, page 21 (emphasis added), at https://www.epa.gov/sites/production/files/2019-08/documents/epa-info-quality-guidelines_1.pdf .

[4] This evidence includes but is not limited to Van der Kraak *et al.,* Crit Rev Toxicol. 2014 Dec; 44 Suppl 5:1-66. doi: 10.3109/10408444.2014.967836, at https://www.ncbi.nlm.nih.gov/pubmed/25375889 . The 2012 SAP report in question is at https://www.epa.gov/sites/production/files/2015-06/documents/061212minutes.pdf .

[5] See, *e.g., Atrazine—Environmental Fate and Effects Division's Response to Public Comments*, pages 4-5, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-1267 .

[6] CRE's prior filings discuss these IQA violations in detail. These prior filings include *CRE Alert on IQA Violations in EPA's Ecological Risk Assessment for Atrazine,* at https://www.thecre.com/forum1/?s=iqa+alert ("IQA Alert"); and *CRE Comments on EPA's Atrazine ECO Risk Assessment* , at https://www.thecre.com/forum1/?p=7459 . These CRE filings are incorporated herein by reference, and are part of CRE's comments on the atrazine PID.

Evaluations of Pesticides"("EPA's new ESA procedures").[7] EPA's ESA and other atrazine review should be consistent with the quality standards identified in CRE 's filings with the Agency on the issue.[8]

We discuss and expand upon these comments below.

II. EPA Should Clarify that the PID's 15 ppb CELOC Applies to all Watersheds, and EPA Should Not Use the CELOC Quantitatively or Qualitatively in "final effects Determinations"

The PID's 15 ppb CELOC should be applied to all watersheds. The PID as currently written could be interpreted as allowing a range of 1.9 to 26 ppb. This interpretation would not be justified because anything below 15 ppb for any watershed would not meet IQA standards, would be unsupported factually and scientifically, and could not be supported through cost benefit analysis. Consequently, EPA should clarify the PID and all relevant documents to unambiguously state that the PID's 15 ppb CELOC should be applied to all watersheds.

EPA states that it will not use the CELOC during atrazine ESA review and consultation. In the Agency's own words, "quantitative use of the CELOC will not be the basis for final effects determinations."[9] We ask that EPA confirm this statement in its response to CRE's comments on the PID and in other prominent spots.

We also ask that EPA not use the CELOC quantitatively **or** qualitatively for final effects determinations. If EPA does intend to use the CELOC in any way during final effects determinations, then we ask that EPA explain how the Agency intends to use it. This explanation should be included in EPA's response to CRE's comments on the PID and in other prominent spots.

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[7] EPA's new ESA procedures are available at https://www.epa.gov/endangered-species/draft-revised-method-national-level-endangered-species-risk-assessment-process .

[8] CRE's filings on the issue include *CRE Alert on IQA Violations in EPA's Ecological Risk Assessment for Atrazine,* at https://www.thecre.com/forum1/?s=iqa+alert ("IQA Alert"); and *CRE Comments on EPA's Atrazine ECO Risk Assessment* , at https://www.thecre.com/forum1/?p=7459 . These CRE filings are incorporated herein by reference, and are part of CRE's comments on the atrazine PID.

[9] EPA Memorandum to File, page 5, at http://www.thecre.com/forum1/wp-content/uploads/2019/11/EPA-HQ-OPP-2013-0266-1260.pdf .

III. EPA Should Not Use or Rely on Amphibian and Fish Effects (or any other) Studies that Are Not Reproducible and Do Not Meet All Other IQA Standards

In the Agency's own words, EPA is using or relying on considering amphibian and fish studies

> "with quality concerns and [which] have not been replicated since the original study, despite multiple studies involving the same endpoint." [10]

EPA's reliance on poor-quality and non-reproducible studies violates the Information Quality Act's accuracy and reproducibility requirements because, *inter alia,* EPA has to "ensure" the reproducibility of the atrazine effects studies that the Agency disseminates.

CRE has a history on this issue. In 2002, CRE submitted one of the first IQA Requests for Correction ("RFC") to EPA. This RFC requested correction of information disseminated in an earlier EPA ecological risk assessment for atrazine. CRE's RFC argued that EPA needed to support its atrazine amphibian effects disseminations with properly validated, reproducible tests. EPA agreed.[11]

Reproducibility is required before EPA's action can be based on science. The National Academies of Science, Engineering and Medicine explains:

> "In science, explanations are limited to those based on observations and experiments that can be substantiated by other scientists."[12]

In other words, it is impossible for non-reproducible atrazine effects studies to be the "best available science" because they are not even science.

For Influential Scientific Information, such as the ERA and its atrazine amphibian and fish effects studies, EPA's Information Quality Guidelines require that EPA

> "**ensure reproducibility** for disseminated original and supporting data

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[10] The quoted EPA language is from page 307 of the atrazine ERA, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 .

[11] CRE's 2002 IQA RFC is at https://thecre.com/pdf/petition-atrazine2B.pdf . EPA's response is at https://www.thecre.com/quality/20030224_epa.html .

[12] National Academy of Sciences, Science and Creationism: A View from the National Academy of Sciences, Second Edition (Washington, DC: National Academy Press, 1999), p.1, at https://www.nap.edu/catalog/1886/science-and-creationism-a-view-from-the-national-academy-of .

according to commonly accepted scientific, financial, or statistical methods."[13]

For several reasons, the atrazine studies are "influential" and subject to the IQA requirement that EPA ensure their reproducibility before using or relying on them.

They are influential because they are precedential and controversial.[14] They will set the controversial precedent that it is ok to assess and regulate on the basis of poor-quality and non-reproducible studies, just because a SAP says to.

They are also influential because they have been subject to multiple peer reviews.[15]

These atrazine studies are also "influential" because they "have a clear and substantial impact on important public policies or private sector decisions."[16] FIFRA and ESA review, which will be based in part on EPA's disseminations regarding atrazine amphibian and fish effects, will go a long way to determining whether growers have access to the atrazine they need to grow their crops.

The atrazine studies, and EPA's atrazine assessment and review, are also influential because they are "Agency actions that are likely to have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, Tribal, or local governments or communities."[17]

These atrazine studies are also "influential" because they are "major scientific and technical work products" that "have a major impact, involve precedential, novel, and/or controversial issues…." [18]

The atrazine amphibian effects issue is very controversial. It began with a court case:

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[13] EPA IQA Guidelines, Section 6.3, page 21 (emphasis added), at https://www.epa.gov/sites/production/files/2019-08/documents/epa-info-quality-guidelines_1.pdf .

[14] EPA IQA Guidelines, Section 6.2, page 20 (emphasis added), at https://www.epa.gov/sites/production/files/2019-08/documents/epa-info-quality-guidelines_1.pdf .

[15] *Id.*

[16] *Id.*

[17] *Id.* See, *e.g.,* CRE's IQA Alert, pages 2-3, at https://www.thecre.com/forum1/?s=iqa+alert (discussion of economic impact).

[18] *Id.*

"Under an amended consent decree entered in to conclude litigation between the Environmental Protection Agency (EPA) and the Natural Resources Defense Council (NRDC), the Agency issued an Interim Reregistration Eligibility Decision (IRED) for atrazine on January 31, 2003. The decree further stipulated that EPA would issue a revised IRED on October 31, 2003 that considers studies conducted prior to February 28, 2003 on the effects of atrazine on amphibians. After developing a paper that addressed the significance of the amphibian risk data, the Agency agreed, under the consent decree, to seek external peer review of its evaluation of these studies from a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP). In June 2003, the SAP reviewed a White Paper prepared by EPA (USEPA 2003) that critically evaluated the collective available data from 17 laboratory and field studies, discussed the nature of remaining uncertainties in evaluating the potential effects of atrazine on amphibian development, and outlined the nature of future studies that could address these uncertainties."[19]

ESA review of atrazine is governed by still another court case/settlement:

"Atrazine is one of the chemicals in stipulated partial settlement agreement in the case of Center for Biological Diversity et. al., v. United States Environmental Protection Agency et al., No. 3:11 cv 0293 (N.D. Cal.). Among other provisions, this agreement sets an August 14, 2021, deadline for EPA to complete nationwide ESA section 7(a)(2) effects determination for atrazine and, as appropriate, request initiation of any ESA section 7(a)(2) consultations with the Services that EPA may determine to be necessary as a result of those effects determinations." [20]

The atrazine amphibian effects issue has been the subject of multi-page articles in the *New York Times*, *Washington Post*, and *New Yorker.* [21]

Atrazine's amphibian effects are as controversial as it gets for purposes of being "influential." For that and other reasons, EPA's disseminations about them are subject to IQA reproducibility requirements.

In light of the above, the IQA requires that EPA "ensure reproducibility" for the information that EPA disseminates regarding atrazine's amphibian and fish

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[19] Page 5, at https://archive.epa.gov/scipoly/sap/meetings/web/pdf/2007_amphibian_white_paper.pdf .
[20] PID, page 57, at https://www.epa.gov/sites/production/files/2019-12/documents/atrazine_pid_signed_12_18_19.pdf .
[21] See, *e.g.,* https://thecre.com/post/ ; and https://thecre.com/quality/20030425_washpost.html ; and https://www.newyorker.com/magazine/2014/02/10/a-valuable-reputation .

effects. EPA is violating this IQA requirement by using, relying on, and disseminating amphibian and fish "studies with quality concerns and [which] have not been replicated since the original study, despite multiple studies involving the same endpoint." [22]

EPA apparently believes that a 2012 Science Advisory Panel ("SAP") report requires EPA to use and rely on all amphibian effects studies, no matter how flawed and non-reproducible the studies and effects are.[23] This belief is incorrect.

If a SAP tells EPA to act in a manner that violates the IQA, then EPA has to reject the SAP's advice.

The IQA requires that EPA ensure reproducibility of all the atrazine amphibian and fish effects information the Agency disseminates, regardless of what the SAP recommends. The IQA imposes accuracy and reliability requirements on all the atrazine amphibian and fish effects information the Agency disseminates, regardless of what the SAP recommends.

The 2012 atrazine SAP is peer review of a "Highly Influential Scientific Assessment." [24] Consequently, the *OMB IQA Peer Review Bulletin* requires EPA to inform the SAP reviewers "of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws." [25] EPA did not comply with this IQA requirement.

At this point in time, CRE knows of one atrazine amphibian effects study that meets IQA requirements. That is an atrazine amphibian gonadal effects study that everyone agrees is properly validated, accurate and reliable. This study showed no

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[22] The quoted EPA language is from page 307 of the atrazine ERA, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 .

[23] See, *e.g., Atrazine—Environmental Fate and Effects Division's Response to Public Comments*, pages 4-5, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-1267 .

[24] The ERA involves significant interagency interest: *e.g.,* EPA is statutorily required to coordinate and cooperate with the USDA in regulating atrazine, and USDA filed statutorily required and critical comments on the ERA. Moreover, EPA's atrazine disseminations could have a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than $500 million in any one year…." *Compare OMB IQA Peer Review Bulletin,* page 20, at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/inforeg/peer_review041404.pdf *with* CRE's IQA Alert, pages 2-3, at https://www.thecre.com/forum1/?s=iqa+alert .

[25] *OMB IQA Peer Review Bulletin,* page 22, at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/inforeg/peer_review041404.pdf .

adverse atrazine effects on amphibians at environmentally relevant concentrations.[26] These test results are consistent with two subsequent and comprehensive literature studies.

The first is a 2019-2020 study that uses a Quantitative Weight of Evidence ("QWoE") to review the body of available company reports and peer reviewed literature regarding the effects of the atrazine on fish, amphibians, and reptiles in company reports and the peer reviewed literature since 2014. This "QWoE analysis concluded that atrazine does not adversely affect fish, amphibians, and reptiles, at environmentally relevant concentrations (<100 µg atrazine/L)." [27]

This conclusion is consistent with a 2014 study using the same QWoE [28]

EPA has not yet responded to the 2019-2020 study. EPA has, however, stated that the 2014 study is "inconsistent with the opinion of the [2012] SAP"[29] because

> "Regardless of the underlying methodology for performing a weight of evidence analysis, the Panel did not agree with excluding the results of the open literature studies, either due to relevance of endpoints or quality of the studies. The weight of evidence analysis conducted by the registrant Syngenta, and submitted in the public comment period, excludes these endpoints either through scoring the relevance or the quality of the data endpoints as low, such that the registrant concluded that there is no impact to amphibians (or any other aquatic species), which is inconsistent with the opinion of the SAP."[30]

EPA's ERA had relied on the 3.4 ppb CELOC to assess and regulate atrazine effects on amphibians. That CELOC is now abandoned, and it is not clear how EPA

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[26] This test, its origin, and its results are discussed in detail at https://archive.epa.gov/scipoly/sap/meetings/web/pdf/2007_amphibian_white_paper.pdf .

[27] Hanson, ML *et al.* , *Effects of atrazine on fish, amphibians, and reptiles: update of the analysis based on quantitative weight of evidence* Crit Rev Toxicol. 2019 Sep;49(8):670-709. doi: 10.1080/10408444.2019.1701985. Epub 2020 Jan 15, at https://www.ncbi.nlm.nih.gov/pubmed/31939690 .

[28] Van der Kraak *et al.,* Crit Rev Toxicol. 2014 Dec; 44 Suppl 5:1-66. doi: 10.3109/10408444.2014.967836, at https://www.ncbi.nlm.nih.gov/pubmed/25375889 .

[29] *Atrazine—Environmental Fate and Effects Division's Response to Public Comments*, page 5, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-1267 .

[30] *Id.*

intends to assess assessing and regulate atrazine effects on amphibians. [31] It is, however, clear that EPA's assessment and regulation cannot be based on non-reproducible studies or on any other information that does not meet the IQA's accuracy and other data quality requirements.

Consequently, we ask that EPA not review, assess and regulate atrazine on any non-reproducible studies. We also ask that EPA carefully consider the 2014 study, the 2019-2020 study, and all other relevant parts of the record, and determine (in the written record) which studies do not meet IQA standards and, therefore, should not be used to review, assess and regulate atrazine.

IV. The Atrazine ERA Contains Other FIFRA and IQA Errors That Must Be Corrected in a Timely Manner

In addition to the above–discussed IQA violations, EPA's ERA violates the IQA Objectivity Standard and FIFRA Section 25(e) because the ERA relies on models developed by EPA that are inaccurate, have not been validated, and have not been peer reviewed.

EPA's inaccurate, unvalidated, non-peer reviewed models include but are not limited to the Integrated Terrestrial Investigation Model ("TIM")/ Markov Chain Nest Productivity ("MCnest") model. USDA's comments on the ERA identified significant problems with the TIM/MCnest model and stated that this model should not be used until and unless it has been adequately and positively peer reviewed. [32]

EPA's ERA violates the IQA Objectivity Standard because the ERA's water database has quality control and methodological errors that cause large and inaccurate overestimates of aquatic and terrestrial exposure.

EPA's ERA Violates the IQA Objectivity Standard because the ERA lowers the fish endpoint 12-Fold based on an inaccurate study. Syngenta repeated the EPA study twice but accurately. Syngenta got the same results both times, and those results contradict EPA's inaccurate study results. Because EPA's fish endpoint study cannot be reproduced, it cannot be used.

In addition, EPA's ERA uses the TIM/MCnest and other models to assess atrazine without the peer review required by FIFRA Section 25(e). This constitutes "agency action unlawfully withheld or unreasonably delayed" under the Administrative Procedure Act ("APA").[33]

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[31] See atrazine PID, page 21, at https://www.epa.gov/sites/production/files/2019-12/documents/atrazine_pid_signed_12_18_19.pdf .
[32] See, *e.g.,* USDA ERA comments on ERA, pages 16-18, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .
[33] See APA, 5 U.S.C. 706(1), at https://www.law.cornell.edu/uscode/text/5/706 .

The models' flaws are discussed in more detail below.

A) EPA's Use of Its Un-Validated Integrated TIM/MCnest and other Models in the ERA, and EPA's Failure to Have These Models Peer Reviewed by the SAP or Anyone Else, Violate The IQA Objectivity Standard and FIFRA Section 25(e)

The atrazine ERA uses the Integrated TIM/MCnest model to assess atrazine's effects on birds.[34] This model violates Section 25(e) of FIFRA because the FIFRA SAP never peer reviewed them. Nor has any other external peer review panel.

EPA uses this model in the ERA despite the fact that EPA does not even consider TIM/MCnest to be final for use. It is still being beta tested. EPA explains,

> "This is a pre-release beta version of the integrated TIM/MCnest model. This model and the species library have not yet been subject to review and results should be considered provisional and subject to revision."[35]

This EPA statement specifically applies to organophosphate pesticide risk assessments, but EPA is using the same models for the atrazine ERA, and there is no agency statement that these models are reviewed and acceptable for use for atrazine. There is no such statement because these models are not reviewed and acceptable for use for atrazine.

During EPA's public comment period on the ERA, the USDA told EPA that the Agency "should review the TIM/MCnest models before using them in a final risk assessment to estimate avian risk." USDA's comments to EPA document significant problems with the TIM/MCnest model. These problems preclude relying on the TIM/MCnest model's accuracy and reliability. USDA urges EPA to provide further expert review of these models before using them.[36]

For the preceding and other reasons, the ERA's use of the TIM/MCnest model violates FIFRA Section 25(e), which requires peer review before use, and the IQA Objectivity Standard, which requires demonstrated accuracy and reliability.[37] EPA's use of TIM/MCnest to assess atrazine is also arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law under the

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[34] For EPA's dissemination of the TIM/MCnest model's predicted atrazine effects, see, *e.g.*, ERA, page 26, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315.

[35] https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments .

[36] USDA Comments on ERA, pages 16-18, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .

[37] IQA Guidelines, page 15 definition of Objectivity, at https://www.epa.gov/sites/production/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf .

APA.[38]

EPA's use of TIM/MCnest without the mandatory peer review also constitutes "agency action unlawfully withheld or unreasonably delayed" under the APA.[39]

This issue is not limited to the atrazine registrations. The TIM/MCnest model is used to assess other products/substances, in other regulatory contexts (e.g., the Endangered Species Act), and by other agencies: e.g., the U.S. Fish and Wildlife Service ("FWS") and the U.S. National Marine Fisheries Service ("NMFS").[40]

Resolution of these model issues in the ERA will be precedential and affect these model issues when presented by the assessment or regulation of other products, under other statutes, in other regulatory contexts, and by other agencies.

B) EPA's Use of TIM/MCnest and Other Models in the Atrazine ERA Violates the IQA Objectivity Standard Because the Models Have Not Been Validated by and Conflict with Real-World Field Data

While neither the SAP nor anyone else has ever peer reviewed the integrated TIM/MCnest model, in 2004 the SAP did peer review TIM and some other models that EPA intended to use for pesticide terrestrial risk assessment. The 2004 SAP emphasized in its peer review report that EPA needed to validate TIM and other model results with real world "'field' data":

> "More troubling is the appearance that there is no intention to obtain appropriate data to improve parameter estimation and to validate model outcomes. The Panel strongly recommends that the Agency obtain data that validate critical modules within existing models and that can be used to refine distributions that will be needed in higher levels of the risk assessment process."
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> "Additional Data Needs. The Agency has made significant progress in developing its approach to probabilistic risk assessment and is to be commended for its efforts. However, while the analyses have become more sophisticated and the data sources more varied, there appears to be little change in the amount of 'field' data to support the analyses. Data gaps identified previously have not been fulfilled. Instead new ways of applying

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[38] 5 U.S.C. 706(2)(A), at https://www.law.cornell.edu/uscode/text/5/706 .
[39] APA, 5 U.S.C. 706(1), at https://www.law.cornell.edu/uscode/text/5/706 .
[40] See, *e.g.*, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment ; https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments; https://blog.epa.gov/2014/02/14/mcnest-fly-away-home/ .

existing data/other models to estimate unavailable data have been identified and applied. Although this approach can serve to advance the development of probabilistic models in the short term, it will increase uncertainties and reduce the Agency's ability to validate/refine models in the future.... The absence of appropriate data is noted throughout Chapter 3, and the Panel would encourage the Agency to rapidly fill these data gaps." [41]

This need to corroborate and validate model results with real world "'field data" is well established. It is a fundamental principle of regulatory model validation and use.

The ERA models are not corroborated by field data. In fact, field data conflict with the ERA model results.

The ERA models predict that any level of atrazine exposure causes widespread and devastating harm to plants, birds and fish.[42] The real world data rebuts the ERA's conclusions of widespread ecological damage from atrazine use. Comments on the ERA identify many instances when ERA model projections are contradicted by real-world field data. [43]

For example, the ERA models incorrectly estimate that atrazine use results in more than 35% of birds dying. These estimates conflict with real world observations that show no bird deaths. Even EPA admits that there is a "lack of documented incidents" of harm from atrazine.[44] Other high-quality studies show no significant difference in bird population decline between high-intensity agricultural areas where pesticide use is common, and non-agricultural areas where pesticide

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[41] SAP Report No. 2004-03, MEETING MINUTES, FIFRA Scientific Advisory Panel Meeting, March 30-31, 2004, held at the Sheraton Crystal City Hotel, Arlington, Virginia, "A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Refined (Level II) Terrestrial And Aquatic Models -- Probabilistic Ecological Assessments For Pesticides: Terrestrial, pages 12 and 54, available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2004-0005-0071 .

[42] See, *e.g.,* ERA, pages 25-29 available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 .

[43] *E.g.,* Comments Submitted by Syngenta Crop Protection, LLC, Concerning the Registration review of Atrazine Draft Ecological Risk Assessment, page 7, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-1040 ; Response to EPA's Draft Ecological Risk Assessment of Atrazine for Wildlife, Syngenta, pages 7 and 9, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0925 ; and USDA Comments on ERA, pages 18-22, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .

[44] ERA, page 215, available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 .

use is not common.[45]

USDA's comments on the ERA correctly emphasize, "the results described in these risk assessments do not translate to what is occurring in the real world."[46]

USDA advises EPA to "[c]onsider whether modeled results are realistic given real-world observations," and cites page after page of study abstracts and links that show no harm from atrazine under its current label.[47]

USDA's comments also explain in detail the problems with EPA's use of the WARP model and the TIM/MCnest model. USDA recommends that these models not be used in the atrazine ERA.[48]

In sum, EPA should only use models that have been peer reviewed and validated as consistent with real world data. The ERA models have not been peer reviewed and are inconsistent with real world data. Consequently, they violate the IQA's Objectivity standard.

V. EPA Should Comply with Information Quality Standards During EPA's Endangered Species Act Review and Consultation and During the Agency's Use of New ESA Procedures

The atrazine PID must comply with EPA's IQA Guidelines and with OMB's Government-wide IQA Guidelines and Guidance. Information disseminated through EPA's proposed new ESA Procedures (atrazine-related or otherwise) must also comply with EPA's IQA Guidelines and with OMB's Government-wide IQA Guidelines and Guidance.

CRE made these points and discussed them in detail in several previous filings with EPA: *e.g.,* CRE's atrazine IQA Alert;[49] CRE's Comments on EPA Proposed Revised Method for National Level Endangered Species Risk Assessment Process for

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[45] See Belden et al., "Relative Abundance Trends of Bird Populations in High Intensity Croplands in the Central United States," Integr Environ Assess Manag 2018; 14:692–702, at https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/ieam.4083 .

[46] USDA Comments Transmittal letter, page 1 (emphasis added). This letter and the USDA comments are available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .

[47] See, *e.g.,* USDA Comments, pages 18-22, available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .

[48] USDA Comments, *e.g*., pages 8-10, 16-18, available at https://wwC.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .

[49] Available at https://www.thecre.com/forum1/?s=iqa+alert .

Biological Evaluations of Pesticides; [50] and CRE's Comments on EPA's Draft Ecological Risk Assessment for Atrazine. [51]

These previous CRE filings are still relevant and are incorporated by reference into CRE's IPD comments. EPA has not yet responded to many of the points and arguments made in these previous CRE filings.

EPA states that it intends to use its proposed new ESA Procedures to finish the atrazine re-registration review, including effects determination and Biological Evaluation.[52] We once again ask EPA to acknowledge that the Agency's information disseminations during atrazine re-registration review (including effects determinations, Biological Evaluation, and ESA consultation) must comply with the IQA.

They cannot comply with the IQA until EPA conforms its IQA Guidelines to the requirements of OMB's Memorandum for the Heads of Executive Departments and Agencies: *Improving Implementation of the Information Quality Act* ("*OMB IQA Memorandum.*" The *OMB IQA Memorandum* states:

> The purpose of this Memorandum is to reinforce, clarify, and interpret agency responsibilities under the Information Quality Act (IQA)."[53]

The OMB IQA Memorandum specifies changes to federal agencies' IQA Guidelines and "directs agencies to update their guidelines within 90 days" to include these OMB changes.[54] The OMB IQA Memorandum is dated April 24, 2019. Consequently, EPA's updated IQA guidelines were due July 25, 2019.

Other federal agencies have made these required IQA Guideline changes.[55] We have seen no evidence of EPA's making these required IQA Guideline changes. EPA cannot comply with IQA until it makes these changes.

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[50] Available at https://thecre.com/pdf/pst%20esa%20ipd%20july%201%20comments.pdf .
[51] Available at https://www.thecre.com/forum1/?p=7459 .
[52] See, *e.g.,* EPA Memorandum to File, page 5, at http://www.thecre.com/forum1/wp-content/uploads/2019/11/EPA-HQ-OPP-2013-0266-1260.pdf
[53] OMB IQA Memorandum, page 1, at https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf .
[54] *Id.,* page 2.
[55] See, *e.g*., U. S. Department of Justice ("OMB M-19-15 is in effect"), at https://www.justice.gov/information-quality ; U.S. Department of Energy, at https://www.federalregister.gov/documents/2019/10/04/2019-21662/interim-report-implementing-updates-to-the-department-of-energys-information-quality-act-guidelines ; and U.S.D. A. , at https://www.ocio.usda.gov/policy-directives-records-forms/information-quality-activities .

Consequently, we ask that EPA make these required IQA Guideline changes as soon as possible.

We thank you for this opportunity to comment. We look forward to your timely response to our comments.

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