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July 16, 2019

Mr. Vaughn Noga
Chief Information Officer
Environmental Protection Agency
William Jefferson Clinton Federal Building
1200 Pennsylvania Avenue, NW Washington, DC 20460

Re: CRE Alert on IQA Violations in EPA's Ecological Risk Assessment for Atrazine

Dear Mr. Noga:

On behalf of the Center for Regulatory Effectiveness (CRE), I am sending you the enclosed Information Quality Act (IQA) Alert. The IQA Alert concerns EPA's preliminary ecological risk assessment for atrazine ("ERA").

The Alert addresses the ERA's IQA flaws and omissions, which include violations of OMB's recent Memorandum Improving Implementation of the Information Quality Act (April 24, 2019). Several of the ERA's IQA violations also violate the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"

The comment period on the preliminary atrazine ERA ended October 5, 2016. We have not seen any EPA response to CRE's comments on the preliminary atrazine ERA or to any other public comments the agency has received. We are concerned that a very flawed and misleading document continues to be publicly disseminated. Consequently we request that EPA respond publicly to CRE's atrazine IQA Alert before EPA issues a proposed Interim Registration Review Decision or takes any other substantive action in the atrazine registration review.

Respectfully,

Director
Center for Regulatory Effectivenes

CENTER FOR REGULATORY EFFECTIVENESS' ("CRE")
INFORMATION QUALITY ACT ("IQA") ALERT ON
PRELIMINARY ATRAZINE ECOLOGICAL RISK ASSESSMENT ("ERA")

I. SUMMARY

The U.S. Environmental Protection Agency ("EPA") publicly disseminated the atrazine ERA at 81 FR 36301 (June 6, 2016), where EPA solicited public comment on it.[1] CRE commented on the ERA.[2] So did 77,284 other individuals, agencies, associations, and companies.[3] Consequently, the ERA is subject to EPA's IQA Guidelines.[4]

EPA's atrazine ERA violates its IQA Guidelines, the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"), and the Administrative Procedure Act ("APA") for the reasons summarized below:

A) EPA's ERA violates the IQA Objectivity Standard because it relies on an inaccurately derived level of concern for atrazine's effects in freshwater systems. This is the ERA's so-called Concentration Equivalent Level of Concern ("CELOC").[5] EPA's CELOC flunked statutorily required peer review by the Science Advisory Panel ("SAP"). EPA's methodology (including models) and cosm database for deriving this CELOC also flunked statutorily required SAP peer review. [6]

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[1] https://www.govinfo.gov/content/pkg/FR-2016-06-06/pdf/2016-13299.pdf.
[2] See http://www.thecre.com/forum1/?p=7459.
[3] See https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0794-0003 (www.regulations.gov states that 77,284 comments were received on EPA's *Federal Register* notice seeking comment on the ERA).
[4] See, *e.g.,* EPA IQA Guidelines, page 42 ("In response to comments regarding information disseminated in rulemakings and other matters subject to public comment, EPA considers that this information would be disseminated within the meaning of the [IQA] Guidelines"), at https://www.epa.gov/sites/production/files/2018-11/documents/epa-info-quality-guidelines_1.pdf; and EPA's Atrazine Final Work Plan, page 5, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0308 (EPA's atrazine risk assessments are reviewed for consistency with EPA's IQA Guidelines)
[5] See, *e.g.,* preliminary ERA page 32 at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 (discussion of CELOC).
[6] For critical review of the CELOC, CELOC methodology and corresponding cosm database, see, *e.g.,* September 11, 2012 SAP Meeting Minutes, page 22, at https://www.epa.gov/sites/production/files/2015-06/documents/061212minutes.pdf.

B) EPA states that it has made changes in its CELOC methodology (including models) and cosm database in response to the SAP's peer review. The Office of Management and Budget's ("OMB") Memorandum *Improving Implementation of the Information Quality Act* requires EPA to have another SAP review its changed CELOC and CELOC methodology (including models) before EPA uses them.[7] This OMB Memorandum states, "When influential information that has been peer reviewed changes significantly (*e.g.,* as a result of the peer reviewer comments, additional agency analysis, or further consideration), the agency should conduct a second peer review." EPA's failure to do so violates the IQA Objectivity requirement.

The ERA, CLOC, CELOC methodology (including models) and cosm database are "influential information" under the IQA for many reasons, including the FIFRA section 25(e) requirement that they be peer reviewed. EPA's IQA Guidelines state:

> "EPA will generally consider the following classes of information to be influential... **major scientific and technical work products [of which] the Agency has a legal and/or statutory obligation to conduct a peer review**...."[8]

The ERA and much of its contents (including models) are also influential information under the IQA because:

> 1) If left uncorrected, the ERA will impose massive costs (more than $500,000,000 per year) on the agricultural community;
>
> 2) If left uncorrected, the ERA will in effect ban the use of atrazine; and
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> 3) The ERA is of significant inter-agency interest. EPA is statutorily required to "coordinate and cooperate" with the U.S. Department of Agriculture ("USDA") in developing the ERA."[9] The USDA

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[7] See *Improving Implementation of the Information Quality Act* (OMB, April 24, 2019), pages 2 and 4, https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf. For EPA's statement of changes in response to SAP peer review, see, *e.g.,* ERA, pages 104-146, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315.

[8] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, page 20 (emphasis added), at https://www.epa.gov/sites/production/files/2018-11/documents/epa-info-quality-guidelines_1.pdf.

[9] For USDA's statutory role see FIFRA, 7 U.S.C. 136w-3(a), at https://www.agriculture.senate.gov/imo/media/doc/FIFRA.pdf.

> filed comments on the ERA that asked EPA not to go forward with the current ERA and to conduct further peer review of it. [10] The USDA's comments stated that the ERA will
>
> "not serve as an effective guide for risk mitigation. We strongly recommend EPA revisit the recommendations of previous SAPs and revise the risk assessments to reflect their [previous SAPs] well-balanced and thoughtful scientific deliberations."[11]

C) 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, that have not been validated, and which 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. [12]

D) EPA's ERA violates the IQA Objectivity Standard because it relies on the CELOC to assess amphibian effects. The CELOC violates the IQA Objectivity Standard for the reasons stated above and below.

E) 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.

F) 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.

G) For all of the reasons stated above and below, EPA's ERA is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law" under the APA. [13] 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 APA.[14]

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[10] USDA Comments on ERA, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .
[11] USDA Comments, page 2, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .
[12] USDA Comments on ERA, pages 16-18, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .
[13] See APA, 5 U.S.C. 706(2)(A), at https://www.law.cornell.edu/uscode/text/5/706 .
[14] See APA, 5 U.S.C. 706(1), at https://www.law.cornell.edu/uscode/text/5/706 .

In order to comply with FIFRA, the IQA and the APA, EPA must convene a Science Advisory Panel ("SAP") or Panels to peer review many aspects of the ERA before EPA finalizes the ERA and uses it to assess atrazine.

The USDA comments predict hundreds of millions of lost dollars if atrazine is banned, which is the probable result if the ERA is used to assess atrazine.[15]

Syngenta also filed un-rebutted comments on the ERA stating the following economic benefits of atrazine:

> "The U.S. economy benefits from atrazine and other triazine herbicides by an estimated $4.8 billion per year due to increased crop yields and reduced input costs. For many farm families, the productivity boost supplied by atrazine represents the margin between keeping the farm and losing everything.
>
> Atrazine's value extends beyond farmers and the small businesses they support, to the tax base of rural communities, schools, teachers, sheriff deputies, and firemen. In all, atrazine and the triazines account for up to 85,000 American jobs.
>
> Each year, triazine herbicides contribute the following economic benefits to American agriculture:
>
> Sorghum - $343 million
>
> Sweet Corn - $210 million
>
> Sugar Cane - $60 to $120 million
>
> Ethanol Production - $1.2 to $1.5 billion
>
> Meat and Egg Industries - $1.4 to $1.8 billion."[16]

This Alert is not limited to a single pesticide registration. EPA did not disseminate the ERA in the course of an individual registration, permit or licensing proceeding. There are multiple atrazine registrants and even more registered

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[15] USDA Comments, pages 40-49, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 . For the preliminary ERA constituting a de facto ban, see, *e.g.*, https://www.agri-pulse.com/articles/7563-farm-groups-urge-epa-to-modify-atrazine-assessment

[16] http://www.atrazine.com/benefits/benefits-of-atrazine-economic-development.aspx .

atrazine products.[17] EPA's atrazine ERA is a general risk assessment of national scope that was developed through its own public notice and comment proceeding. The ERA applies to and affects all FIFRA registrations and all of atrazine's many uses and applications. The ERA will be applied to all of them in separate, subsequent individual registration proceedings. The ERA will also be used and disseminated by the U.S. Fish and Wildlife Service ("FWS") in FWS' review of atrazine under the Endangered Species Act.

Throughout this IQA Alert, we demonstrate that the ERA predicts environmental harm that does not exist in the real world. Atrazine has been safely used for over 60 years. If finalized without major correction, the ERA will likely prohibit the use of atrazine for no good reason. That prohibition will violate the IQA, FIFRA and APA, as well as basic principles of sound risk assessment and regulatory science.

We next provide a brief discussion of IQA Alerts. Then we provide a more detailed discussion of some of the ERA's IQA and FIFRA violations. Finally, we request that EPA take the specific actions necessary to correct these violations.

II. IQA ALERTS

CRE is one of the original advocates and supporters of the IQA. 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 tests. EPA agreed.[18]

CRE is now filing an IQA Alert, which notifies a federal agency that if the contents of a proposed information dissemination remain unchanged, then final dissemination of the information will be subject to an IQA Request for Correction; in this instance one to be filed by CRE and perhaps others.

In contrast to an IQA alert, an IQA Request for Correction is a formal petition demanding a change(s) in a document disseminated by a federal agency that

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[17] Atrazine technical registrants include Syngenta Crop Protection LLC; Drexel Chemical Company; Agan Chem. Mfg. Ltd., and Oxon Italia S.P.A. See, *e.g.*, EPA's Atrazine Final Work Plan, page 2 at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0308 .

[18] CRE's 2002 IQA RFC is at https://www.epa.gov/sites/production/files/2019-02/documents/2807.pdf . EPA's response is at pages 18-19, https://www.epa.gov/sites/production/files/2016-03/documents/2807Response_03_27_03.pdf .

violates the IQA. A RFC is considerably more controlling than a petition filed solely pursuant to the Administrative Procedure Act in that the IQA establishes deadlines by which the recipient agency must act, and the substance of the response is governed by regulations issued by both EPA and OMB pursuant to the IQA.[19]

OMB requires that EPA amend EPA's current IQA Guidelines by July 23, 2019, to be consistent with OMB's recent memorandum to all agencies entitled Improving *Implementation of the Information Quality Act.*[20] Among other changes, OMB's memorandum tells EPA to revise EPA's IQA Guidelines to ensure that EPA's response to an IQA RFC contains

> "a point-by-point response to any data quality arguments contained in the RFC and should refer to a peer review that directly considered the issue being raised, if available."[21]

OMB also requires EPA to revise EPA's IQA Guidelines to ensure that EPA

> "share[s] draft responses to RFCs and appeals with OMB prior to release to the requestor for assessment of compliance with the above norms."[22]

This requirement is consistent with the Department of Justice's notification of the courts that OMB has the authority to make the ultimate decision on an RFC if it wishes to do so.[23]

III. IQA, FIFRA AND APA VIOLATIONS

A) EPA's ERA has to be Peer Reviewed

Section 25(d) of FIFRA establishes the SAP as a FIFRA peer reviewer.[24]

Section 25(e) of FIFRA requires that the SAP or some other qualified external panel review EPA's CELOC, corresponding cosm database and methodology, and

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[19] EPA's current procedures for filing and IQA Request for Correction are set forth at pages 31-35, https://www.epa.gov/sites/production/files/2018-11/documents/epa-info-quality-guidelines_1.pdf .

[20] This OMB Memorandum is available at https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf .

[21] *Id.*, page 10.

[22] *Id.*, page 10.

[23] See, *e.g.*, http://www.thecre.com/oira/?p=4124 .

[24] 7 U.S.C. 136w(d), at https://www.agriculture.senate.gov/imo/media/doc/FIFRA.pdf .

many of the ERA models.[25] Section 25(e) requires

> **"peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this Act [FIFRA] ...."**[26]

This language is clearly broad enough to encompass EPA's CELOC and its corresponding cosm database and methodology, as well as any significant computer model that EPA uses or relies on in the ERA. The ERA is a "major scientific study." Left unchanged, it will have a huge and adverse economic impact on American agriculture because it will probably put atrazine out of business.

EPA agrees that much of the ERA must be peer reviewed. In response to CRE's comments, EPA stated in its *Atrazine Final Work Plan* that

> "models and standard operating procedures used in risk assessment formulation [like the atrazine ERA] are reviewed by the FIFRA Scientific Advisory Panel (SAP), which is composed of biologists, statisticians, toxicologists and other experts who provide independent scientific advice to the EPA on a wide-range of health and safety issues related to pesticides."[27]

SAP review of atrazine "models and standard operating procedures" helps implement the FIFRA Section 25(e) peer review requirements. It also helps implement the IQA Guidelines.

Because FIFRA 25(e) section requires peer review, the ERA's CELOC, CELOC Methodology, CELOC cosm database, and models are automatically classified as influential information under EPA's IQA Guidelines, which state:

> "EPA will generally consider the following classes of information to be influential... **major scientific and technical work products [of which] the Agency has a legal and/or statutory obligation to conduct a peer review**...."[28]

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[25] 7 U.S.C. 136w(e), at https://www.agriculture.senate.gov/imo/media/doc/FIFRA.pdf (emphasis added).
[26] *Id.*
[27] EPA's Atrazine Final Work Plan, page 5, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0308 .
[28] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, page 20 (emphasis added), at https://www.epa.gov/sites/production/files/2018-11/documents/epa-info-quality-guidelines_1.pdf .

Consequently, the OMB Peer Review Bulletin also requires peer review. [29]

Finally, EPA's *Peer Review Handbook* states that environmental regulatory models should be peer reviewed:

"3.5.11. Should Environmental Regulatory Models Be Peer Reviewed?

In general, the answer is yes." [30]

B) EPA's CELOC, CELOC Methodology and Corresponding COSM Database Flunked Statutorily Required Peer Review, and EPA's Dissemination of Them Violates the IQA Objectivity Standard

EPA's preliminary Atrazine ERA includes a CELOC that establishes a level of concern for atrazine effects on "aquatic plant community primary productivity, structure and function" in freshwater systems. This CELOC is set at such a low atrazine concentration that it will effectively bar use of atrazine if EPA assesses atrazine based on it.[31]

EPA based its CELOC on a Plant Assemblage Toxicity Index Model ("PATI") and on a proposed micro/mesocosm data set.[32] Multiple SAPs criticized EPA's poor scoring quality and relevance.[33]

In contrast to the Integrated TIM/Mcnest model (which has never been peer reviewed), a 2012 FIFRA SAP reviewed and rejected EPA's CELOC, cosm database, and methodology (including the PATI Model).[34] The SAP report stated:

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[29] See OMB Peer Review Bulletin, page 2, at https://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf .

[30] EPA Peer Review Handbook (4th Edition, 2015), page 52 at https://www.epa.gov/sites/production/files/2015-10/documents/epa_peer_review_handbook_4th_edition_october_2015.pdf (emphasis part in the original and part added).

[31] See, *e.g.,* https://www.agri-pulse.com/articles/7563-farm-groups-urge-epa-to-modify-atrazine-assessment .

[32] For EPA's dissemination of the CELOC, see, *e.g.,* ERA, page 32, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 .

[33] See, *e.g.,* CRE's Atrazine IQA alert, footnote 5 *supra.*

[34] "The FIFRA SAP serves as a primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention and is structured to provide scientific advice, information, and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment." See EPA at https://www.epa.gov/pesticides/epa-requests-comments-prospective-candidates-fifra-scientific-advisory-panel-epas .

> "[T]he Panel could not validate the 4 to 7 µg/L CE-LOC [sic] due to a number of concerns with the methodology previously described in responses to charge questions 6 and 7. In brief, the Panel had concerns with the selection process of the final cosm dataset. Furthermore, each step in the multi-step LOC methodology is associated with inherent error, and then propagated along each step so that the accumulated error in the CE-LOC will likely be quite large. As a result, the Panel expressed minimal confidence in the calculated CE-LOC."[35]

The USDA concurred with the SAP's rejection of the CELOC in USDA's comments to EPA on the ERA: *e.g.*,

> "The EPA risk assessment paints a very dire picture of the effects of atrazine on aquatic plant communities, which is surprising given the results of several studies showing no adverse effects on aquatic plant communities. EPA should reconcile the results of its modeling effort with the results of these studies."[36]

EPA's dissemination of its CELOC, corresponding cosm database, and methodology (including the PATI model) in the preliminary Atrazine ERA violates the IQA Objectivity requirement, which requires demonstrated accuracy and reliability.[37] This critical part of EPA's ERA is not accurate and reliable because it flunked statutorily required peer review.

OMB recently told EPA and other federal agencies that they have to update their IQA Guidelines by July 23, 2019 to state:

> "When influential information that has been peer reviewed changes significantly (e.g., as a result of the peer reviewer comments, additional agency analysis, or further consideration), the agency should conduct a second peer review."[38]

Neither the SAP nor anyone else has peer reviewed the CELOC or its methodology and corresponding cosm database since the SAP rejected them in 2012. If EPA thinks that that it has made sufficient changes in them to satisfy the

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[35] September 11, 2012 SAP Meeting Minutes, page 22, at https://www.epa.gov/sites/production/files/2015-06/documents/061212minutes.pdf .

[36] USDA Comments, page 18 (emphasis added), available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .

[37] EPA IQA Guidelines, page 15, at https://www.epa.gov/sites/production/files/2018-11/documents/epa-info-quality-guidelines_1.pdf.

[38] *Improving Implementation of the Information Quality Act* (OMB, April 24, 2019), page 4, at https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf .

SAP and meet IQA requirements, then FIFRA Section 25(e) and the IQA require that EPA obtain a new and positive SAP review before EPA uses its new CELOC, database and methodology (including models) to assess atrazine.

Using an invalid CELOC methodology and cosm database to assess atrazine is also arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law under the APA.[39]

C) 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)

In its preliminary atrazine ERA, EPA used the Integrated TIM/MCnest model to assess atrazine's effects on birds.[40] 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 used 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."[41]

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.[42]

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[39] 5 U.S.C. 706(2)(A), at https://www.law.cornell.edu/uscode/text/5/706 .

[40] 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 .

[41] https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments. This EPA statement is 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 aren't reviewed and acceptable for use for atrazine.

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

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.[43]

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 APA.[44]

EPA's use of TIM/MCnest without the mandatory peer review also constitutes "agency action unlawfully withheld or unreasonably delayed" under the APA.[45]

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").[46] 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.

D) 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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[43] IQA Guidelines, page 15 definition of Objectivity, at https://www.epa.gov/sites/production/files/2018-11/documents/epa-info-quality-guidelines_1.pdf .

[44] 5 U.S.C. 706(2)(A), at https://www.law.cornell.edu/uscode/text/5/706.

[45] APA, 5 U.S.C. 706(1), at https://www.law.cornell.edu/uscode/text/5/706 .

[46] 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/ .

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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 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." [47]

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.[48]

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

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[47] 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 .

[48] See, *e.g.*, Page 35, Oct. 26, 2011 Minutes for July 26-28 atrazine SAP, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0399-0080 ; August 11, 2009 Minutes for May 12-14, 2009 SAP, page 17, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0104-0062 ; July 20, 2004 Minutes for March 30-31, 2004 SAP, page 54, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2004-0005-0071 ; National Academy of Sciences, Models in Environmental Regulatory Decision Making (2007), pages 114, 122 and 147, at http://www.nap.edu/download.php?record_id=11972# ; and Guidance on the Development, Evaluation, and Application of Environmental Models (EPA 2009) ("CREM Guidance"), page vii, at https://www.epa.gov/measurements-modeling/guidance-document-development-evaluation-and-application-environmental-models. For the IQA's accuracy requirements, see, *e.g.*, NAS ESA Report, Pages 68-69, at http://www.nap.edu/download.php?record_id=11972# ; and EPA IQA Guidelines, page 15, at https://www.epa.gov/sites/production/files/2018-11/documents/epa-info-quality-guidelines_1.pdf .

The ERA models predict that any level of atrazine exposure causes widespread and devastating harm to plants, birds and fish.[49] 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. [50]

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.[51] 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 use is not common.[52]

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."**[53]

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.[54]

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.[55]

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

[50] *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 .

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

[52] 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.

[53] 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 .

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

In sum, EPA should follow the SAP's recommendations and 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.

E) EPA's Dissemination of an ERA Using the CELOC to Assess Atrazine Effects on Amphibians Violates the IQA Because the CELOC Violates the IQA Objectivity Standard

The ERA uses the CELOC to assess atrazine effects on amphibians.[56] EPA states:

> "Based on the available amphibian toxicity data, the CELOC is protective for a majority of the observed direct effects to amphibians, and this endpoint also provides protection from indirect effects to amphibians through impacts to aquatic plant communities." [57]

The ERA's amphibian effects information disseminations violate IQA requirements because, for the reasons stated above and below, the CELOC violates the IQA Objectivity Standard.

When EPA corrects this IQA violation and reassesses atrazine amphibian effects, EPA must remember its response to CRE's 2002 IQA Request for Correction ("RFC"), which successfully sought correction of EPA's earlier risk assessment disseminations about atrazine's amphibian effects. CRE argued in its 2002 IQA RFC that EPA needed to support its disseminations with properly validated tests, and EPA agreed.[58]

Consequently, any EPA risk assessment of atrazine's potential amphibian effects must be based on properly peer reviewed and validated protocols. Otherwise, they will violate the IQA Objectivity Standard because they cannot be presumed accurate and reliable.

We are aware of only one properly peer reviewed, validated, and IQA-

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

[56] See, *e.g.*, ERA, page 143, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 , for these disseminations.

[57] ERA, page 308, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315.

[58] CRE's 2002 IQA RFC is at https://www.epa.gov/sites/production/files/2019-02/documents/2807.pdf . EPA's response is at pages 18-19, https://www.epa.gov/sites/production/files/2016-03/documents/2807Response_03_27_03.pdf .

compliant atrazine amphibian effects test: the Kloas *et al.* DCI study.[59]

F) The ERA's Water Database Has Quality Control and Methodological Errors that Cause Large Overestimates of Aquatic and Terrestrial Exposure, and which Violate the IQA Objectivity Standard

The ERA relies on errors in reporting; on duplication of entries; on infilling errors for time periods when samples were not available; and on use of non-detect samples with levels of detection much higher than the ERA's proposed LOC. The proposed ERA's overestimates depend on modeled exposure concentrations that are up to 260 times higher than corresponding monitoring data.[60] These inaccurate and unreliable data result in part from use of models that have never been properly peer reviewed, validated and peer reviewed.[61]

G) The ERA Violates the IQA Objectivity Standard Because the ERA Lowers the Fish Endpoint 12-Fold Based on a Study that is Not IQA-Compliant

The ERA relies on Papoulias et al. (2014) to lower the fish endpoint.[62] EPA's own Data Evaluation Record (DER) concludes that this study has serious deficiencies in its execution, and data analyses found no concentration-response. This IQA non-compliant study conflicts with a more-recent IQA compliant study and with other fish studies conducted by EPA itself. [63]

The DER for Papoulias *et al.* (2014) states, "the study is of sufficient quality to include qualitatively in the risk assessment"; therefore, it is not of sufficient quality to be used quantitatively. In contrast, the DER for a study submitted by one of the registrants, which repeated Papoulias et al. (2014), and which was conducted in

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[59] https://www.ncbi.nlm.nih.gov/pubmed/19008211 .

[60] Examples of these IQA noncompliant disseminations are the ERA cover, and ERA pages 2, 23-33, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 .

[61] These errors and omissions are discussed in detail in USDA's ERA Comments, pages 18-29, https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 ; CRE's ERA Comments, at http://www.thecre.com/forum1/wp-content/uploads/2017/01/pest-atrazine-eco-comments-10.pdf ; and Syngenta's ERA Comments, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0925.

[62] This inaccurate dissemination occurs at, *e.g.*, ERA, page 2, https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315 .

[63] These errors and omissions are discussed in detail at, *e.g.*, Syngenta's ERA comments, pages 10-11, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0925 .

accordance with OPPTS and OECD guidelines, describe the registrant study as "scientifically sound."

Other studies have found no harm to fish from atrazine.[64]

III. REQUESTED CORRECTIONS

CRE requests that EPA withdraw its preliminary atrazine ERA and revise it to correct the IQA and FIFRA violations discussed above and below. EPA should provide SAP review as an essential part of this correction process. The proposed scope and proposed charges for this SAP review should be subject to public notice and comment before they are finalized.

USDA filed comments on the ERA that request similar corrective action by EPA for similar reasons.[65]

We also request that EPA:

A) Replace the proposed CELOC with a standard that is supported by the record and that is IQA and FIFRA-compliant.

B) Replace the inaccurate proposed overestimates of aquatic and terrestrial exposures with estimates based on IQA and FIFRA-compliant data and models.

C) Replace the inaccurate proposed NOEL for birds with NOELs supported by IQA-compliant data and models.

D) Replace the inaccurate proposed lowered fish endpoint with an endpoint that is supported by IQA and FIFRA-compliant data and models.

E) Replace the proposed surrogates for amphibian effects with a regulatory standard that is supported by the (Kloas et al. 2009) DCI study.

F) Not disseminate a final atrazine ERA until EPA explains and certifies in the administrative record that the ERA complies with the IQA. This explanation and certification must include the corrections requested in items (A) through (E) above. This explanation and certification must be supported by materials identified in the administrative record.

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[64] Hosmer *et al.*, "Fish short-term reproduction assay with atrazine and the Japanese medaka (*Oryzias latipes*)," *Environ Toxicol Chem* 2017;36:2327–2334, at https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.3769 .

[65] USDA Comments on ERA, *e.g.*, Transmittal Letter and pages 1, 3-4, 16-22, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826 .

G) Provide public notice and opportunity to comment on all the corrections requested in (A) through (F) above.

IV. *CONCLUSION:* THE ERA IS WRONG; THERE IS NO ENVIRONMENTAL HARM FROM ATRAZINE UNDER CURRENT USE REQUIREMENTS

CRE's comments on the ERA told EPA:

> "According to EPA's draft ERA, any level of atrazine exposure causes widespread and devastating harm to plants, birds and fish. This is obviously not the case, and the ERA's predicted harm is obviously not real. It does not mirror the real world.
>
> Atrazine is not a new product. It has been used very widely for over 50 years, and few products have been studied as much. If the ERA's predicted environmental harm were real, then the harm would have been obvious long ago. In fact, much of the U.S. would be a desert littered with dead fish and birds, and it's not. The ERA is inaccurate and unreliable.
>
> EPA admits that there is a 'lack of documented incidents' of harm from atrazine. The available field data for plants show no significant adverse effects from atrazine. No field data support the ERA's modeled effects, which are contradicted by decades of widespread atrazine use with no observed harm. There is obviously something wrong with the inaccurate data and models that EPA uses to predict harm that does not in reality exist."[66]

The USDA filed similar comments. [67]

Recent studies further rebut the ERA's prediction of widespread (but never observed) environmental harm from atrazine use. For example, the high levels of primary production and accumulation of algal biomass in all streams indicate that effects of pulses of atrazine at environmentally relevant concentrations are transient and do not represent ecologically significant adverse outcomes to periphyton, phytoplankton, and aquatic macrophytes, particularly in agricultural streams subjected to high nutrient loads.[68]

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[66] CRE's comments are available at http://www.thecre.com/forum1/wp-content/uploads/2017/01/pest-atrazine-eco-comments-10.pdf .

[67] USDA's comments are available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0826.

[68] King *et al.*, "Effects of pulsed atrazine exposures on autotrophic community structure, biomass, and production in field-based stream mesocosms," *Environ Toxicol Chem* 2016; 35:660–675, https://www.ncbi.nlm.nih.gov/pubmed/26292195 .

In another study, reproduction assays with fathead minnows and Japanese Medaka show no evidence of impaired fecundity from atrazine exposure.[69]

In another study, a quantitative weight of evidence analysis of atrazine exposure to fish, amphibians and reptiles demonstrated that any effects were not translated to adverse outcomes in terms of apical endpoints.[70]

Another study demonstrated that EPA used an incorrect and inaccurate dermal route equivalency factor in the ERA. Use of a correct and accurate dermal route equivalency factor results in greatly reduced modeled atrazine risk to birds than previously reported in the ERA using TIM. [71]

As one final example, the ERA's CELOC is based on a database that includes inaccurate, unreliable, and irrelevant cosm studies that do not meet IQA standards. IQA-compliant use and analysis of the available cosm studies results in a much higher CELOC.[72]

Our preceding discussion explains what's wrong with the ERA. It also identifies the corrective actions necessary to produce an accurate atrazine ecological risk assessment that complies with FIFRA, the IQA, and the APA.

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[69] Brain *et al.*, "Extended fish short term reproduction assays with the fathead minnow and Japanese medaka: No evidence of impaired fecundity from exposure to atrazine," *Chemosphere* 2018; 205: 126-136, https://www.sciencedirect.com/science/article/pii/S0045653518307161 .

[70] Van Der Kraak *et al.*, "Effects of atrazine in fish, amphibians, and reptiles: an analysis based on quantitative weight of evidence," Crit Rev Toxicol. 2014 Dec; 44 Suppl 5:1-66, https://www.ncbi.nlm.nih.gov/pubmed/25375889 .

[71] Maul *et al.*, "Derivation of avian dermal LD50 values for dermal exposure models using in vitro percutaneous absorption of [^{14}C]-atrazine through rat, mallard, and northern bobwhite full thickness skin," *Science of The Total Environment 2018; 630: 517-525,* https://www.sciencedirect.com/science/article/pii/S0048969718306053

[72] Giddings et al., "Data quality scoring system for microcosm and mesocosm studies used to derive a level of concern for atrazine," *Integr Environ Assess Manag.* 2018; 14(4): 489-497, https://www.ncbi.nlm.nih.gov/pubmed/29663627 ; and Moore *et al.*, "A weight-of-evidence approach for deriving a level of concern for atrazine that is protective of aquatic plant communities," *Integr Environ Assess Manag.2016;* 13(4): 686-701, https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.1865