

**CENTER FOR REGULATORY EFFECTIVENESS' ("CRE") COMMENTS ON  
EPA'S DRAFT ECOLOGICAL RISK ASSESSMENT FOR ATRAZINE ("ERA"),  
<https://www.gpo.gov/fdsys/pkg/FR-2016-06-06/pdf/2016-13299.pdf> and  
<https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0794-0005> .  
COMMENTS FILED OCTOBER 4, 2016 at [www.regulations.gov](http://www.regulations.gov),  
DOCKET IDENTIFICATION NUMBER EPA-HQ-OPP-2015-0794**

According to EPA's draft ERA, any level of atrazine exposure causes widespread and devastating harm to plants, birds and fish.<sup>1</sup> 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.<sup>2</sup> The few available field data for plants show no significant adverse effects from atrazine.<sup>3</sup> 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 data and models that EPA uses to predict this nonexistent harm.

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<sup>1</sup> See, e.g., ERA, pages 26 (birds) and 29 (plants), at

<https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315>.

<sup>2</sup> ERA, page 215, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315> .

<sup>3</sup> E.g., Andrus *et al.*, Spatial and Temporal Variation of algal assemblages in six Midwest agricultural streams having varying levels of atrazine and other physiochemical attributes, *Sciences of the Total Environment* 505: 65-89 (2015), at <http://www.ncbi.nlm.nih.gov/pubmed/25310883>; Andrus, *et al.*, Seasonal synchronicity of algal assemblages in Midwestern agricultural streams having varying concentrations of atrazine, nutrients and sediment, *Science of The Total Environment* 125-139 (2013), at <http://www.sciencedirect.com/science/article/pii/S0048969713003744> ; Davies *et al.*, Triazine herbicide contamination on Tasmanian streams: Sources, concentrations and effects on biota, *Marine and Freshwater Research* 45(2):209-226 (January 1994), at [https://www.researchgate.net/publication/248886529\\_Triazine\\_herbicide\\_contamination\\_of\\_Tasmanian\\_streams\\_Sources\\_concentrations\\_and\\_effects\\_on\\_biota](https://www.researchgate.net/publication/248886529_Triazine_herbicide_contamination_of_Tasmanian_streams_Sources_concentrations_and_effects_on_biota) . But see Lakshminarayana, *et al.*, Impact of atrazine-bearing agricultural tile drainage discharge on planktonic drift of a natural stream, *Environ. Pollution* 1992; 76(3): 201-10, at <http://www.ncbi.nlm.nih.gov/pubmed/15091984> (this study is flawed because no samples were taken before atrazine application nor any samples taken from untreated field channels; consequently, it's impossible to trace phytoplankton differences to atrazine or any other single factor).

Part of the problem is EPA's assumption that the ERA's modeling of experimental ecosystem data accurately reflects real-world field effects.<sup>4</sup> This untested assumption will not support regulatory risk assessments. EPA has to compare its modeled experimental effects with field data from the real world.

It is textbook science that

“Field tests are needed to generate site-specific data...for validating formulated hypotheses on ecological interactions.”<sup>5</sup>

Three Science Advisory Panels (“SAP”), the National Academy of Sciences (“NAS”), and two EPA guidance documents emphasize that modeled ecological effects must be compared with field data in order to determine whether the modeled effects are real.<sup>6</sup> This comparison is essential to validating the models for regulatory use.

In its last atrazine ecological risk assessment, EPA agreed with CRE that the Agency cannot use unvalidated experimental tests to assess and regulate amphibian effects.<sup>7</sup> The ERA's dissemination of modeled experimental effects that have never been validated by comparison with real-world field data violates the objectivity requirements of EPA's

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<sup>4</sup> See, e.g., ERA, Appendix I: Proposed Methodology for Specifying Atrazine levels of Concern for Protection of Plant Communities in Freshwater Ecosystem, page 4, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0337>.

<sup>5</sup> Pesticides in Agriculture and the Environment, page 120, at <https://books.google.com/books?id=Svsh-Zf422kC&pg=PA120&lpg=PA120&dq=science+advisory+panel+field+data+validation&source=bl&ots=RpWuj2tFBc&sig=6wQcQb0IoPwPuxfXAhVPfI7aytM&hl=en&sa=X&ved=0ahUKEwif3ff63P3OAhWCKB4KHbquC2cQ6AEIZDAJ#v=onepage&q=science%20advisory%20panel%20field%20data%20validation&f=false>.

<sup>6</sup> 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 122 and 147, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#); Guidance on the Development, Evaluation, and Application of Environmental Models (EPA 2009) (“CREM Guidance”), page vii, at [https://www.epa.gov/sites/production/files/2015-04/documents/cred\\_guidance\\_0309.pdf](https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf); Guidance for Quality Assurance Project Plans for Modeling (EPA 2002), page 41, at <https://www.epa.gov/sites/production/files/2015-06/documents/g5m-final.pdf>.

<sup>7</sup> See [http://www.thecre.com/quality/20030224\\_epa.html](http://www.thecre.com/quality/20030224_epa.html)

for supporting links and a more complete discussion. The documents at this link are incorporated into these CRE comments by reference and are part of CRE's comments.

Information Quality Act Guidelines (“IQA Guidelines”), and violates basic principles of sound science.

EPA agrees with CRE that SAP review is required for the ERA modeled effects, if EPA continues to use them to assess and regulate atrazine.<sup>8</sup> This SAP review should include EPA’s failure to validate its models and ecological risk assessment with field data.

All this necessary work should have been done before EPA disseminated the ERA’s modeled effects. EPA’s failure to perform this work before dissemination violates the pre-dissemination review requirements of the IQA Guidelines.<sup>9</sup>

These and other issues are discussed in more detail below.

### ***HOW SAPs SHOULD REVIEW EPA’S MODELLED EFFECTS***

EPA’s CREM Guidance requires that the ERA models be subjected “to credible, objective peer review.”<sup>10</sup>

EPA stated in response to previous CRE comments on the atrazine risk assessments that “models and standard operating procedures used in risk assessment formulation are reviewed by the FIFRA Scientific Advisory Panel (SAP)...”<sup>11</sup>

SAPs should review the following ERA models, if EPA continues to use them to assess and regulate atrazine:

A) ERA page 26: Terrestrial Investigation Model and Markov Chain Nest Productivity Model and Integrated TIM-McNest Model (beta version)(which includes review of the ERA’s Seedling Emergence Vegetative Vigor endpoints at pages 28-30);

B) WARP (*e.g.*, ERA pages 24 and 32, and development of bias factors at 104-113);

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<sup>8</sup> Atrazine Final Work Plan, Case Number 0062 (EPA 2013), Pages 4-5, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0308> .

<sup>9</sup> *E.g.*, EPA’s IQA Guidelines, pages 3, 29, at <https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf> ; Region 3 Pre-Dissemination Review Checklist, at <https://www.epa.gov/quality/region-3-pre-dissemination-review-checklist> .

<sup>10</sup> CREM Guidance, page vii, at [https://www.epa.gov/sites/production/files/2015-04/documents/cred\\_guidance\\_0309.pdf](https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf) .

<sup>11</sup> Atrazine Final Work Plan, Case Number 0062 (EPA 2013), Pages 4-5, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0308> .

C) Surface Water Concentration Calculator (*e.g.*, ERA page 51);

D) All models listed at ERA page 52; and

E) T-HERPs (*e.g.*, ERA page 27).

SAPs should review these models to determine whether they have been properly validated and calibrated because, as a prior atrazine SAP explained, “Any model should be calibrated and validated.”<sup>12</sup>

This review should charge the SAP with determining whether ERA model predictions accurately reflect real world conditions. As a prior SAP reviewing the PRZM and WARP models for EPA’s atrazine risk assessment explained, “in the end, a meaningful model is only as good as the ability of its assumptions to mirror the real world.”<sup>13</sup>

The paramount goal of validation is to determine whether the models’ predictions correspond with reality. This must be determined by corroborating the models’ predictions with observed data. As a prior SAP explained, “A means of assessing the accuracy of this [atrazine] assessment is needed, such as comparing measured and calculated...atrazine loads in major drainage basins.”<sup>14</sup>

If EPA wants to use models that predict adverse environmental effects from the continued use of an already registered pesticide in accordance with its Label (*e.g.*, atrazine), then EPA must support the models’ predictions with observed field data showing those effects. Otherwise, EPA cannot use those models and their predictions to assess and regulate atrazine’s use.

These model validation requirements stem not only from several SAP reports, but also the National Academy of Sciences report “Models in Environmental Regulatory Decision Making (2007).” In this report, which was commissioned by EPA, the NAS advised EPA

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<sup>12</sup> May 12-14, 2009 SAP Minutes, page 59, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0104-0062> . EPA’s risk assessment response to CRE’s IQA RFC on atrazine’s amphibian effects agreed that validated tests are necessary to assess atrazine. See [http://www.thecre.com/quality/20030224\\_epa.html](http://www.thecre.com/quality/20030224_epa.html) for supporting links and a more complete discussion. The documents at this link are incorporated into these CRE comments by reference and are part of CRE’s comments.

<sup>13</sup> Oct. 26, 2011 Minutes for July 26-28, 2011 atrazine SAP, page 35, <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0399-0080>

<sup>14</sup> August 11, 2009 Minutes of May 12-14, 2009 SAP, page 17, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0104-0062> . See also July 20, 2004 Minutes of March 30-31, 2004 Atrazine SAP, page 54, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2004-0005-0071> (SAP explains that models validation requires field trials capable of validating the predictions of the model).

that “[c]omparing model results with observations is a central component of any effort to evaluate models.”<sup>15</sup>

The NAS rendered this advice during its peer review of models guidance being developed by EPA’s Council for Regulatory Environmental Modeling (“CREM”) After NAS review, EPA published final CREM Guidance which explains that evaluation of model quality requires an answer to the following question: “How closely does the model approximate the real system of interest?”<sup>16</sup>

EPA similarly explains in its earlier document *Guidance for Quality Assurance Project Plans for Modeling (EPA 2002)* that:

“models are calibrated by comparing the predictions (output) for a given set of assumed conditions to observed data for the same conditions. This comparison allows the modeler to evaluate whether the model and its parameters reasonably represent the environment of interest....”<sup>17</sup>

Consequently, EPA should not use any of the ERA models to assess and regulate atrazine until and unless EPA takes the following steps:

1) Demonstrate in a public record that all of the ERA models comply with

A) Guidance on the Development, Evaluation, and Application of Environmental Models (EPA 2009) (“CREM Guidance”), at [https://www.epa.gov/sites/production/files/2015-04/documents/cred\\_guidance\\_0309.pdf](https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf) ;

B) Guidance for Quality Assurance Project Plans for Modeling (EPA 2002), at <https://www.epa.gov/sites/production/files/2015-06/documents/g5m-final.pdf> ;

C) National Academy of Sciences, Models in Environmental Regulatory Decision Making (2007) (“NAS Report”), at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#) ; and

D) EPA’s Information Quality Act (“IQA”) Guidelines, at <https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf> .

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<sup>15</sup> National Academy of Sciences, Models in Environmental Regulatory Decision Making (2007) (“NAS Report”), page 122, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#) .

<sup>16</sup> CREM Guidance, page vii, at [https://www.epa.gov/sites/production/files/2015-04/documents/cred\\_guidance\\_0309.pdf](https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf) .

<sup>17</sup> Guidance for Quality Assurance Project Plans for Modeling (EPA 2002), page 41, at <https://www.epa.gov/sites/production/files/2015-06/documents/g5m-final.pdf> .

2) This public record should include an SAP report that EPA has complied with the regulatory requirements for models listed in items 1A-1D above, and that the SAP approves use of the models.

SAP review of the ERA should not be limited to model validation. SAP review should also focus on the dichotomy between EPA's dire predictions of major ecological harm from any level of atrazine use, and the lack of any significant harm in the real world.

The SAPs should also review any other issues identified by EPA and the public during public comment on draft charges to SAP.

There is ample precedent for public comment on draft charges to EPA peer review panels.<sup>18</sup> EPA's own Peer Review handbook endorses public comment on charge questions.<sup>19</sup>

OMB's Peer Review Bulletin requires that, for highly influential scientific assessments like the ERA, EPA must inform peer reviewers "of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws."<sup>20</sup> The Department of Interior's Bureau of Safety and Environmental Enforcement explains in its own peer review manual that

"Per the OMB Bulletin, the Peer Review Leader must inform the peer reviewers of 'applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality.' This includes, but is not limited to, the DOI Information Quality Standards, DOI Department Manual '305 DM 3,' Executive Order 12866, and the OMB Bulletin."<sup>21</sup>

For the atrazine SAPs, EPA should inform reviewers of EPA's IQA Guidelines and other EPA quality requirements, not the DOI the DOI quality requirements.

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<sup>18</sup> *E.g.*,

<https://www.epa.gov/sites/production/files/documents/pavillionchargecommentstewartencana.pdf>.

<sup>19</sup> U.S. Environmental Protection Agency Peer Review Handbook (3rd Edition) pages 58-59, at [https://www.epa.gov/sites/production/files/2015-09/documents/peer\\_review\\_handbook\\_2006\\_3rd\\_edition.pdf](https://www.epa.gov/sites/production/files/2015-09/documents/peer_review_handbook_2006_3rd_edition.pdf). The public has a guaranteed right to present oral and written comments to the SAP. *Id.*, page 74; 5 U.S.C. App.2 § §10(a), 10(b).

<sup>20</sup> OMB Peer Review Bulletin, page 25, at <https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>.

<sup>21</sup> Bureau of Safety and Environmental Enforcement, "Peer Review Process Manual," page 60, at <https://www.bsee.gov/sites/bsee.gov/files/research-guidance-manuals-or-best-practices/oil-spill-response/bsee-peer-review-process-manual.pdf>

**AMPHIBIAN EFFECTS DATA MUST MEET IQA AND OTHER  
OMB/EPA QUALITY STANDARDS  
BEFORE EPA CAN USE THEM TO REGULATE**

EPA states in the ERA that conflicting study results persuaded the Agency to regulate atrazine's amphibian effects (if any) through regulation of fish and plants, and not directly.<sup>22</sup>

These conflicting studies may result from not using validated tests. EPA should regulate only on the basis of validated tests. This was the point of CRE's IQA Request for Correction regarding EPA's proposed use of amphibian effects tests in the current atrazine ecological risk assessment. EPA agreed with CRE.<sup>23</sup>

At this point in time, only the DCI study (Kloas 2009) has been validated and is, therefore, acceptable for use in regulating atrazine's effects on amphibians (if any).<sup>24</sup> Before EPA uses any other tests to regulate atrazine's amphibian effects, then those tests should be reviewed by SAPs to determine whether they have been validated in accordance with EPA's CREM Guidance and the other validation requirements discussed above.

EPA should inform the SAPs of these validation requirements (including the IQA guidelines and CREM Guidance) before their review.

**ALL DATA MUST MEET IQA AND OTHER  
OMB/EPA QUALITY STANDARDS  
BEFORE EPA CAN USE THEM TO REGULATE**

All data that EPA uses to assess and regulate atrazine must meet the validation, IQA and other quality standards discussed above. Amphibian effects are discussed above. We have not found any records demonstrating compliance with these quality standards for any of the other organisms assessed in the ERA: *e.g.* fish, plants, invertebrates, and birds.

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<sup>22</sup> ERA, page 31, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315>.

<sup>23</sup> See [http://www.thecre.com/quality/20030224\\_epa.html](http://www.thecre.com/quality/20030224_epa.html) for supporting links and a more complete discussion of CRE's IQA Request for Correction and EPA's response.

<sup>24</sup> The DCI study is discussed at page 174 of the ERA, <https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0315>.

If EPA wants to assess and regulate these or any other taxa, then EPA should ask SAPs to review the models and studies that the Agency proposes to use. The SAPS should determine whether those models and studies meet the required quality standards. SAPS should also determine whether real world field data support EPA's modeled assumptions based on experimental data.

### ***RECOMMENDED EPA ACTIONS***

There are no field data--no real-world data--supporting the ERA's modeled effects. EPA should revise its ERA to be consistent with this fact.

If EPA still believes that some change in the current ecological assessment and regulation of atrazine may be necessary, then EPA should first take the following actions:

- 1) Validate the ERA models in accordance with the principles discussed above;
- 2) Develop field data supporting any changes proposed by EPA;
- 3) Have SAPs review EPA's model validations, field data, and any EPA conclusions based on the models and data;
- 4) Allow public comment on EPA's charges to the SAPs; and
- 5) Inform the SAPs of the data quality, model validation and other requirements that apply to the SAPs' review, as discussed above.

We thank you for the opportunity to submit these comments. We look forward to EPA's response to our comments, and to the SAP proceedings reviewing the ERA.

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