

June 13, 2022

Michal Freedhoff, Ph.D.
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U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Dr. Freedhoff,

Thank you for responding to our March 11, 2022 letter to the Agency. Unfortunately, the Agency's response in the June 2, 2022 letter contains statements and claims that we know to be untrue. Many of us who lead the Triazine Network have been involved in this issue for many years. We strongly question the statements about the history of the CE-LOC and so-called "confusion" about EPA's use of dual CE-LOCs. The statements about the 2012 SAP are simply incorrect. The 3.4 ppb CE-LOC is at best, based on shaky scientific evidence derived through a process that has not been transparent. Atrazine is a vital tool for farmers across the nation, and it is especially important to farmers who implement conservation tillage, or no-till farming which plays a significant role in carbon sequestration. Our farmers are committed to carbon-smart farming. However, if farmers are unable to effectively use atrazine, many acres will return to tillage and our carbon savings will be greatly impacted. Please consider our response below.

We write now to reply to your June 2, 2022 letter and again urge the Agency to reconsider its plan to propose a new aquatic ecosystem concentration equivalent level of concern (CE-LOC) for atrazine of 3.4 parts per billion (ppb or ug/L). For the reasons stated in our March 11, 2022 letter, the Agency should not adopt a CE-LOC that relies on invalid studies; rejects the conclusions of a years-long, robust scientific review process; and would have significant, real-world negative impacts.

We are concerned that the June 2, 2022 letter mischaracterizes the CE-LOC history and the Scientific Advisory Panel (SAP) process and outcomes, undermining the integrity of the Agency's CE-LOC process and the public's ability to rely on the Agency's scientific and regulatory decisions in the pesticide program and beyond. We are also concerned that the letter refers to the current 15 ppb CE-LOC as "a policy decision, made by the prior administration." This statement further mischaracterizes the CE-LOC history and record, as reflected in our March 11 letter and this reply letter.

We understand that EPA intends to present its CE-LOC re-evaluation for review and comment and will use the opportunity to address the substantive grounds EPA provides in support of its position at that time. This response focuses on the lack of transparency in EPA's process and corrects the history of EPA's atrazine CE-LOC determinations.

A. The record on EPA’s decision to adopt a 15 ppb CE-LOC is well supported and compelling.

The June 2, 2022 letter refers to “recent confusion” over the CE-LOC, but the confusion, if any, is caused by EPA’s attempts to recharacterize its recent CE-LOC determination. The letter claims that EPA made a “policy decision” in 2019 and 2020 “to identify a value above the CE-LOC” to determine the need for potential regulation of atrazine, but that EPA’s “scientific determination of the CE-LOC remained at 3.4 ug/L.” The letter further asserts that “EPA has received no new data or information that would change the analyses it presented in the 2016 [preliminary ecological risk] assessment.”

By its own terms, the October 2019 Regulatory Update “memorializes EPA’s decision to use the concentration of 15 ug/L” as the CE-LOC “for the purposes of determining the need for any potential mitigation to protect aquatic plant communities.”¹ It describes the Agency’s “[r]e-evaluation of . . . the CE-LOC” in response to scientific critiques of the 3.4 ppb CE-LOC EPA had proposed “in the 2016 preliminary risk assessment,” including that the 3.4 ppb CE-LOC relies on “numerous fundamentally flawed, inconsistent and misinterpreted” studies and “ignores recommendations made by the 2012 FIFRA Scientific Advisory Panel.”² As a result, EPA decided to use 15 ppb as “the CE-LOC,” relying in part on an analysis that adopted the SAP’s 2012 recommendations.³ The September 2020 Atrazine Interim Decision responded to comments regarding the CE-LOC and confirmed that EPA’s October 2019 “decision to use” 15 ppb as “the CE-LOC” has not changed.⁴ There is no suggestion that 15 ppb is a policy number “above the CE-LOC” or is not a science-based determination, and no reference to retaining 3.4 ppb as “the scientific CE-LOC.”

In short, EPA’s 2019 re-evaluation was conducted in response to substantive critiques the Agency continued to receive from SAPs and other scientists and stakeholders on the study inclusion, scoring, and other methods that led to the 3.4 ppb CE-LOC proposed in 2016. As a result of this scientific peer-review feedback, as stated in the Regulatory Update and confirmed in the Interim Decision, EPA updated its analyses and adopted the 15 ppb CE-LOC. The assertion that the CE-LOC “remained” at 3.4 ppb all along is unsupported and undermines the integrity and transparency of EPA’s latest “re-evaluation” and the entire years-long CE-LOC regulatory process.

B. The record is clear that the 2012 SAP’s critiques of the CE-LOC EPA proposed at the time (4-7 ppb) were made by the full panel.

The June 2, 2022 letter suggests that the 2012 SAP recommendations were the opinions of a single panelist and were beyond the 2012 SAP’s charge. That is incorrect.

¹ Regulatory Update on the Registration Review of Atrazine (October 22, 2019) at 1, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2013-0266-1260>. The Regulatory Update was signed by Rick Keigwin, then the Director of EPA OPP, who now serves as the Assistant Administrator for OCSPP.

² *Id.* at 2.

³ *Id.* at 7 and Appendix A.

⁴ Atrazine Interim Decision (September 2020) at 9, available at <https://www.epa.gov/sites/default/files/2020-09/documents/atrazine-id-signed-final.pdf>. The Atrazine Interim Decision was signed by Elissa Reaves as Acting Director of EPA OPP PRD, who continues in that role as the Director.

Dr. Jim Fairchild, who served for many years as a Research Aquatic Ecologist for the United States Geological Survey, took the lead for the 2012 SAP panel in assessing EPA’s inclusion and scoring of the studies that supported EPA’s proposed CE-LOC, which was 4-7 ppb at the time. He was eminently qualified for the task, with a focus on pesticides, metals, and risk assessment and over 80 peer-reviewed scientific publications.⁵ Dr. Fairchild served on eight SAPs and as journal editor for Environmental Toxicology.⁶ The opinions that EPA’s 4-7 ppb CE-LOC relied on invalid and mis-scored studies and the recommendations to correct these issues were not his alone. The other panel members, themselves distinguished scientists, heard and assessed the critiques by Dr. Fairchild and numerous other scientists and stakeholders.⁷ The Meeting Minutes reflect that the recommendations were uniformly adopted as the consensus opinion of the full Panel.⁸ These opinions were also consistent with and shared by previous SAP’s.⁹ The ongoing scientific consensus, including three peer-reviewed scientific articles published since 2016, align with the SAP recommendations and support 15 ppb as a scientific and highly conservative CE-LOC.¹⁰

The June 2, 2022 letter’s assertion that the SAP’s critiques of EPA’s study inclusion and scoring “went beyond the charge” also misses the mark. It would be inconsistent with an open scientific peer review process to expect the Panel to assess “the extent to which these cosm studies taken together provide useful and reasonable physical models” without also noticing and assessing whether EPA had addressed recommendations by previous SAPs to change and improve study inclusion and scoring. The Panel noted that “EPA had responded to the 2009 SAP’s advice to expand the number of cosm studies in this analysis by addition of twenty or so new cosm

⁵ Dr. James Fairchild LinkedIn Profile, available at https://www.linkedin.com/in/fairchild-james-5b668030/?trk=public_profile_browsemap.

⁶ *Id.*

⁷ Dr. Stephen Klaine from Clemson University described Dr. Fairchild’s review as “unbelievably detailed” and stated that he “agree[d] with all of his assessments.” Transcript of June 2012 SAP Meeting at 411, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2012-0230-0219>. Dr. Klaine expressed his concern that EPA was “less discriminating regarding which cosm studies they accepted compared to the criteria used for accepting the amphibian studies” and that his “biggest problem is with the cosm data.” *Id.* at 411, 433. Robert Gilliom from the U.S. Geological Survey summarized “what I am hearing from my colleagues” as a consensus that EPA could proceed with the existing studies “as long as they are sifted through once more” and that the database would be “further improved by adding some improved studies.” *Id.* at 424. Dr. John Rodgers from Clemson University made the point that “many of the studies” EPA was relying on are “getting pretty old,” that “our ability to design these studies has improved significantly over the past decades” and “[w]e’ve got better instrumentation . . . [and] techniques that are orders of magnitude more sensitive.” *Id.* at 421. Consistent with the SAP process, these viewpoints expressed at the meeting coalesced into the consensus position of the Panel presented in the Meeting Minutes.

⁸ 2012 SAP Meeting Minutes (September 11, 2012) at 19-20, available at <https://www.epa.gov/sites/default/files/2015-06/documents/091112minutes.pdf> (“The Panel recommended that the cosm studies at concentrations less than 30 ug/L . . . be re-evaluated and re-scored.” “The Panel’s re-evaluation of this subset of cosm studies identified 11 cosm studies mis-scored by the EPA as having ‘effects,’ when they should have been rescored as having ‘no effect.’” “The Panel suggested that these studies be re-scored and/or dropped from the dataset.”); *Id.* at 41 (“The Panel focused on major concerns with the Agency’s scoring process of effect/no effect of the cosm studies listed in Appendix D.”).

⁹ *Id.* at 41 (“The 2009 SAP flagged a number of the same studies for the same reasons”); *id.* at 43, Table 1, n. 1 (identifying seven studies that been identified as flawed by the 2009 SAP); *id.* at 42 (“The Panel was disappointed to see [the Lampert] study still included in the cosm dataset since the 2007 and 2009 SAPs indicated that it be dropped due [to] solvent bias.”).

¹⁰ March 11, 2022 Triazine Network Letter at 3 & n. 10 (citing sources).

studies,” updated its own analysis to incorporate those new studies, and expressed its ongoing “major concerns” with EPA’s study inclusion and scoring.¹¹

C. EPA’s “uncertainty analyses” remain opaque.

In 2016 and 2019, EPA presented the results of various “uncertainty analyses” to support its CE-LOC determinations. These uncertainty analyses, including the Agency’s decision of which analyses to follow, provide the primary scientific basis for EPA’s CE-LOC determinations. Despite serving such a critical purpose, they remain entirely opaque.

In our March 11, 2022 letter to EPA, we noted that EPA conducted uncertainty analyses in 2016 and 2019 that each incorporated the SAP recommendations but produced very different outcomes.¹² The June 2, 2022 letter attributes this difference to the fact that EPA used the approach described in Giddings 2012 for the 2016 analysis, including the use of split endpoints, and used the 2012 SAP recommendations in 2019, without splitting endpoints. However, according to the Meeting Minutes, the 2012 SAP agreed with Giddings’ study scoring approach and recommended it be adopted.¹³ Moreover, analyses in recent peer-reviewed publications that follow the SAP’s inclusion and scoring recommendations, without splitting endpoints, point to a CE-LOC of at least 20 ppb.¹⁴

The June 2, 2022 response only underscores the opacity of EPA’s uncertainty analyses. The Network’s March 11, 2022 letter pointed out that, in response to a recent FOIA request, the Agency was unable to produce the records necessary to reproduce or assess its 2019 uncertainty analyses.¹⁵ The June 2, 2022 letter does not explain or dispute the lack of support for its uncertainty analysis outcomes. Without access to the datasets, it is impossible to recreate the 2019 uncertainty analysis, to understand how EPA implemented the SAP recommendations in the various scenarios run to generate the reported ranges of CE-LOC outcomes, and to assess to what extent the difference in outcomes is attributable to splitting versus not splitting endpoints as EPA now contends.

D. EPA received ample information and analyses that support not adopting the 3.4 ppb CE-LOC proposed in 2016.

The June 2, 2022 letter attempts to justify EPA’s planned adoption of the 3.4 ppb CE-LOC by contending that it has “received no new data or information that would change the analyses it presented in its 2016 risk assessment,” in which EPA rejected the SAP’s recommendations on study scoring and inclusion. This ignores the more recent, peer-reviewed articles providing further scientific support for the SAP approach and a far higher, yet still conservative, CE-

¹¹ *Id.* at 41.

¹² March 11, 2022 Triazine Network Letter at 3 (the 2016 analysis resulted in a CE-LOC range of 13.5-40 ppb and a median of 20.8, while the 2019 analysis resulted in a range of 1.6-26 ppb and a median of 8.5 ppb.).

¹³ 2012 SAP Meeting Minutes (September 11, 2012) at 19 (“The Panel noted that EPA would not have to re-evaluate this subset of cosm studies if they adopted the scoring of Giddings (2012). This would be appropriate since the rescoring by the Panel of this subset of studies agreed with that of Giddings (2012).”)

¹⁴ March 11, 2022 Triazine Network Letter at 3 & n. 10; *id* Ex. A at 7-8.

¹⁵ *Id.* at 4 & Exhibit B at 2 (the EPA scientist who conducted the analyses confirmed he did not have records of the various datasets that were run to produce the 2019 uncertainty analysis, and acknowledged that “at the time of the regulatory update I was running several different datasets for different purposes and it is possible that I overwrote this version with a different dataset.”)

LOC.¹⁶ It also ignores that the 2016 assessment was only a preliminary assessment and that the Agency *did* change its analyses and approach in the 2019 Regulatory Update and 2020 Interim Decision.¹⁷

We will respond to EPA’s substantive arguments in support of the planned 3.4 ppb CE-LOC after they are presented for comment in the proposed decision. For now it is sufficient to note that in its determination to support the lower CE-LOC, EPA stands alone against scientific consensus.¹⁸ EPA continues to rely on studies that the successive SAPs and other scientists identified as invalid, unreliable, or misscored due to fundamental issues such as improper study design or lack of documentation;¹⁹ continues to reinterpret study results contrary to the findings of the study’s authors;²⁰ and rejects the notion that studies that are more sophisticated, better designed, and/or better documented should be given any greater weight.²¹

E. Adoption of a scientifically unsound and overly conservative 3.4 ppb CE-LOC would have significant impacts.

EPA has not shared what additional mitigation measures it may propose in connection with a 3.4 ppb CE-LOC. The Network understands that the Agency is withholding this information until it releases its proposed decision for public comment, and intends to respond with detailed comments at that time.

However, it is important to understand that a 3.4 ppb CE-LOC would have significant negative implications for growers, registrants, States, and other stakeholders, regardless of the severity of

¹⁶ *Id.* at 3.

¹⁷ In November 2019, EPA’s Environmental Fate and Effectives Division (EFED) responded to scientific comments on the 2016 3.4 ppb CE-LOC by stating that EPA had “re-evaluated the CE-LOC” and referring to the 2019 Regulatory Update “for a complete discussion of this re-evaluation and impact on the CE-LOC for regulatory purposes.” Atrazine—Environmental Fate and Effect Division’s Response to Public Comments, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2013-0266-1604>. The Response is signed by Dana Spatz, EFED’s Branch Chief; Rosanna Louie-Juzwiak, the Risk Assessment Process Leader; Senior Chemist Dr. Rochelle Bohaty; and Senior Biologist Dr. Colleen Rossmeisl.

¹⁸ EPA’s proposed 3.4 ppb CE-LOC was also the subject of highly critical comments from federal and state regulatory partners that rely on the issuance of an accurate and effective CE-LOC. USDA stated that “[t]here should be no surprise that USDA has significant concerns regarding the ecological risk assessments,” that “the results described in these risk assessments do not translate to what is occurring in the real world,” and that “[i]t is puzzling to read the recommendations from the SAPs and EPA’s re-registration decision – and end up with these ecological risk assessments.” USDA letter to EPA (October 5, 2016), available at <https://www.regulations.gov/comment/EPA-HQ-OPP-2013-0266-0826>. USDA “strongly recommend[ed]” that “EPA revisit the recommendations of previous SAPs and revise the risk assessments to reflect their well-balanced and thoughtful scientific deliberations.” *Id.* The National Association of State Departments of Agriculture (NASDA) objected to the premature, unauthorized posting of the 2016 preliminary risk assessment and to its “substantive scientific shortcomings,” asked the Agency to correct its reliance on “‘studies’ not conducted in accordance with the Agency’s scientific guidelines as required under FIFRA,” and requested “a written explanation on the Agency’s justification for utilizing the studies deemed flawed by EPA’s 2012 Scientific Advisory Panel.” NASDA letter to EPA (May 27, 2016), available at <https://www.nasda.org/letters-comments-testimony/nasda-letter-on-epas-preliminary-ecological-risk-assessment-on-atrazine>. NASDA reiterated those concerns and requests after EPA failed to address them in re-releasing the 2016 preliminary risk assessment. NASDA letter to EPA (October 5, 2016), available at <https://www.regulations.gov/comment/EPA-HQ-OPP-2013-0266-0962>.

¹⁹ June 2, 2022 EPA Letter at 2.

²⁰ *Id.* at 4.

²¹ *Id.*

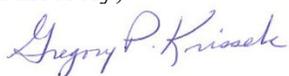
any new label mitigation measures proposed and ultimately adopted by EPA. These impacts would include:

- requiring additional mitigation measures for 24 million acres of corn, sorghum, sugarcane and imposing additional costs, complexity and uncertainties on the nation's farmers and food supply;
- defeating climate smart policy and imposing negative environmental impacts by requiring more tillage, increased soil erosion, and more fossil fuel usage;
- generating numerous reports of "exceedences," alarming the public and burdening regulators based on a CE-LOC that lacks scientific support and practical relevance;
- creating the potential for state and federal regulators to adopt the 3.4 ppb CE-LOC for other purposes, such as setting water quality standards and requirements, despite the lack of scientific support and practical relevance;
- undermining the transparency and reliability of the administrative record and process, by reversing a recent scientific and regulatory determination while claiming that the Agency's underlying position never actually changed; and
- calling into question EPA's overall methods and approach to conducting ecological risk assessments and regulating all pesticides by adopting a CE-LOC contrary to overwhelming scientific consensus and the Agency's own prior determinations.

F. Conclusion

We reiterate our request that the Agency not adopt the 3.4 ppb CE-LOC, which would have significant, real-world negative impacts, negating benefits of climate-smart farming practices. We also reiterate our request that EPA submit any new proposed CE-LOC for review by a SAP and incorporate any recommendations resulting from their scientific review before changing the current 15 ppb CE-LOC.

Sincerely,



Greg Krissek, Co-Chair



Gary Marshall, Co-Chair

cc: Michael S. Regan, Administrator, EPA
Rod Snyder, Senior Agricultural Advisor, EPA
Jake Li, Deputy Assistant Administrator for Pesticide Programs, EPA
Thomas Vilsack, Secretary of Agriculture, USDA
Kimberly Nesci, Director, Office of Pest Management Policy, USDA
Cameron Douglass, Agronomist (Weed Scientist), OPMP, USDA
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Debbie Stabenow, Chair, Senate Agriculture Committee
John Boozman, Ranking Member, Senate Agriculture Committee
David Scott, Chair, House Agriculture Committee
G.T. Thompson, Ranking Member, House Agriculture Committee