



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Greg Krissek
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Dear Mr. Krissek:

Thank you for writing and sharing your concerns about triazine herbicides and the aquatic ecosystem concentration equivalent level of concern (CE-LOC). We appreciate your perspective on this issue.

The CE-LOC is a 60-day average concentration of atrazine that, when exceeded, presents a greater than 50% chance of negatively affecting community structure or function of an aquatic environment. The CE-LOC is based on effects to aquatic plant communities; however, by ensuring protection of primary producers, the CE-LOC is intended to also provide protection for the entire aquatic ecosystem, including fish, invertebrates, and amphibians.

EPA acknowledges the recent confusion over the CE-LOC, its determination in the 2016 atrazine ecological risk assessment, and the communication in the 2019 atrazine regulatory update and, ultimately, in the September 2020 interim decision. The value of 15 $\mu\text{g/L}$ as a 60-day average in the regulatory update represented a policy decision, made by the prior administration, to identify a value above the CE-LOC as the basis for determining the need for potential regulation of atrazine to protect aquatic plant communities during regulation review. To date, EPA has received no new data or information that would change the analyses it presented in the 2016 risk assessment. Throughout this process, EPA's scientific determination of the CE-LOC remained at 3.4 $\mu\text{g/L}$ as a 60-day average. The scientific basis for the 3.4 $\mu\text{g/L}$ CE-LOC is well described in the [2016 risk assessment](#), which includes an in-depth description of the method for determining the level of concern for aquatic plant communities. This letter offers additional discussion regarding concerns raised in your March 11, 2022 letter and in recent meetings with the Agency regarding derivation of the CE-LOC and its application in registration review.

EPA will continue to work with the grower community to ensure that the benefits of atrazine, including its use in no-till farming, are maintained while we mitigate ecological risks and protect the aquatic ecosystem.

2016 ecological risk assessment addresses recommendations made at the 2012 Scientific Advisory Panel meeting

The Triazine Network has raised concerns regarding whether EPA adequately considered and incorporated recommendations from a 2012 Scientific Advisory Panel (SAP) when deriving the CE-LOC. As described below, EPA has carefully considered and incorporated feedback from the 2012 SAP where appropriate.

One of the charge questions EPA asked the 2012 SAP was:

“The cosms were comprised of natural communities of periphyton/phytoplankton; in some cases, vascular plants, invertebrates and vertebrates present in those communities were included in the study. These sources were generally described as streams, lakes, reservoirs, and springs, and are considered to be representative of the structure and function of aquatic plant communities in such water bodies. Given the diversity of sources and the described communities, please comment on the extent to which these cosm studies taken together provide useful and reasonable physical models of the natural aquatic plant communities exposed to atrazine in the U.S.”

The other panelists assigned to this question answered with comments on the factors or criteria that can make cosm studies, in general, more useful as a physical model of the natural environment exposed to atrazine. The lead panelist on this question, however, went beyond the charge and discussed where he believed EPA had mis-scored individual cosm studies or endpoints. This was done without the benefit of the panelists having access to EPA’s evaluations of each individual cosm study, which were not in the docket for this SAP meeting because EPA did not ask about individual cosm studies. This panelist stated that some of the cosm studies were invalid and some of the endpoints used should have been scored as “no effect.” Because these recommendations were outside the scope of the charge questions, the recommendations were essentially the opinion of a single panelist that were not afforded robust discussion by the larger group of experts. Nonetheless, EPA carefully considered these recommendations, and the 2016 ecological risk assessment includes detailed analyses of the microcosm and mesocosm (cosm) studies that the [2012 SAP meeting](#) identified as warranting a re-evaluation. The 2016 risk assessment addresses each one of the studies and endpoints in question, beginning on page 200.

Expanding on the specific example of Lampert et al. (1989) mentioned in your letter, EPA provided a detailed analysis of this study and the supporting evidence for its inclusion in the cosm dataset starting on page 200 of the 2016 risk assessment. The use of this study was brought up at the 2012 SAP meeting and the panel pointed out that the use of a solvent, ethanol, could have resulted in some effects on the aquatic community. EPA considered this input and noted that the solvent was administered once, in small amounts, and likely disappeared rapidly. A theoretical “worst case” analysis of potential solvent effects was also discussed in the 2016 risk assessment. Overall, EPA’s reasoning for including this study was based on several factors, including the timing of the observed effects, the description of how the solvent was administered, the quick dissipation and degradation of the solvent, and a theoretical “worst case” analysis of solvent effects. EPA has not received data rebutting our re-evaluation and analysis of the potential impact of ethanol on this study.

Also, as part of the discussion at the 2012 SAP meeting about the body of cosm studies, the panel suggested that another cosm study could be designed that would meet all the criteria the panel thought would be most important for a highest quality cosm study to answer remaining questions about at what level atrazine begins to cause adverse effects on aquatic plant communities. The idea was that perhaps

another well run cosm study could address some of the remaining uncertainties in the overall cosm study database. The panel did not suggest replacing the entire body of cosm studies with just a single cosm study. And during that discussion, EPA confirmed that the panel recommended that any additional studies be added to the currently available information, not to replace the body of current cosm studies. There was considerable discussion on what would make a “perfect” cosm study and apparent agreement that another study could be useful. Ultimately, the lead panelist recommended that EPA first go back and re-evaluate the cosm studies he identified as being mis-scored (discussed in the previous paragraph). He said that he suspected that a re-evaluation would raise the CE-LOC to approximately 20 µg/L, at which point he noted a new cosm study may not be needed. Other panelists disagreed that conducting a new cosm study should depend on the value of the CE-LOC. While not required by EPA, Syngenta ultimately submitted a study that they co-authored and believed met the criteria that reflected this panel’s discussions, referred to as “the Baylor Study.”

In summary, in response to feedback and recommendations provided at the 2012 SAP meeting on the CE-LOC, for the 2016 atrazine ecological risk assessment, EPA:

- 1) separated studies using flowing waters from studies using still waters,
- 2) investigated bias in choice of plant species in laboratory and cosm studies,
- 3) removed studies with endpoints from exposure durations and magnitudes that are not environmentally relevant,
- 4) evaluated the uncertainties inherent in the available cosm dataset and evaluated and quantified the cumulative error in the CE-LOC estimation,
- 5) re-reviewed studies with effects below 30 ppb, including the 11 cosm studies identified in the meeting as warranting re-review, and
- 6) reviewed additional studies identified in the literature.

In the re-review of cosm studies with effects below 30 ppb, EPA did not find any errors in our interpretation of those studies or endpoints.

Consideration of public comment on the 2016 risk assessment including the 5-point scoring system and incorporation of the Baylor study

Stakeholders, including registrants, grower groups, environmental NGOs, and other members of the public, submitted more than 100,000 comments on the 2016 atrazine ecological risk assessment. EPA does not typically respond point-by-point to each concern raised in each public comment. Instead, EPA synthesizes comments to address substantive new information, corrections, concerns, etc. and responds with the level of detail needed to inform risk management decisions. EPA provided detailed responses to substantive comments raised by Syngenta and the Triazine Network in the response to comments on the 2016 ecological risk assessment. The atrazine biological evaluation further addressed and incorporated certain relevant feedback and information from the 2016 ecological risk assessment public comments. As a matter of policy, OPP does not generally republish updated risk assessments, unless changes due to public comments are significant and substantive and are needed to support the risk management preliminary or interim decision.

In EPA’s most recent meeting with the Triazine Network, it had raised concerns that EPA had dispensed with a 5-point scoring system and instead attributed equal weight to all studies using a binary scoring system. In particular, the Network noted that using this approach the Baylor study would meet the highest standard. EPA notes that the system it took to the 2012 SAP for scoring of the cosm studies did not include weighting factors. In that methodology, the endpoints from all of the

scientifically valid studies were used in the development of the CE-LOC with no study given higher weight than others. After the SAP, Syngenta proposed a different methodology where some studies, including the Baylor study, would have more weight than others. EPA did not adopt Syngenta's proposed methodology in the 2016 risk assessment, as EPA did not have a basis for discounting or diminishing the results of the other studies. EPA did evaluate the Baylor study (also published as King, et. al., 2016) and agreed that it was high quality and relevant and, consistent with the methodology that EPA took to the SAP. EPA included it as part of the overall database of cosm studies used to determine the CE-LOC in its 2016 risk assessment.

The Baylor study (MRID 49535501) concluded that atrazine had a negative impact on some components of the communities and these effects did not recover to control conditions by the end of the study. Despite these effects, the authors concluded that atrazine did not impact the community structure at the end of the study. EPA reviewed the available information and concluded that atrazine did affect the aquatic community in this study. The study shows that atrazine treatment reduced the level of dissolved oxygen and reduced the biomass of an important component of the aquatic community, metaphyton, across all test concentrations. Metaphyton is a general term for filaments of green algae that grow in mats in fresh water, which provide food and habitat for many aquatic animals. Further discussion of the study is available in the 2016 DRA and the data evaluation record (DER) for MRID 49535501.

Summary of uncertainty analyses discussed in the 2016 ecological risk assessment and 2019 regulatory update

EPA completed an uncertainty analysis within the 2016 ecological risk assessment that examined potential sources of error in calculating the CE-LOC, including alternative assumptions on the scoring and interpretation of cosm studies. The 2016 uncertainty analysis included what the CE-LOC would be if EPA had agreed with the base set of cosm studies and endpoint scores described in Giddings 2012, which had Syngenta's support. A major difference between recommendations made in Giddings and those made at the 2012 SAP meeting is that Giddings "split" cosm study endpoints, which the SAP did not recommend, as not all panelists agreed that splitting endpoints is sound science. Splitting endpoints looks at effects on individual parts of the community rather than on the entire community (i.e., one effect/no effect score per test concentration). By splitting endpoints, Giddings counts "no effect" endpoints multiple times for components of the community that are less sensitive to atrazine.

The 2019 uncertainty analysis, which was included in the 2019 regulatory update, generated a CE-LOC range and median value that differed from the 2016 uncertainty analysis. The results differ because each of these analyses looked at different scenarios. Unlike the 2016 analysis described above, the 2019 analysis used the cosm study classifications and scoring recommended by one panelist at the 2012 SAP meeting (as described in the earlier section). The purpose of the 2019 analysis was to demonstrate what the CE-LOC would have been if that panelist's recommendations were followed. EPA often uses alternative assumptions to be transparent on the effect of a different approach.

While EPA presented uncertainty analyses in both the 2016 risk assessment and in the 2019 regulatory update for transparency purposes, EPA continues to conclude that the alternative approaches for each of these analyses are inappropriate. Splitting endpoints effectively disregards community-level effects by allowing adverse effects on one portion of the community to be canceled out by no effects on another portion of the community. Rather, consistent with the 2012 SAP, EPA considers an effect on one or more parts of the community to be an effect on the entire community. Similarly, as discussed previously,

EPA did not conclude the classifications and scoring system that are the basis of the 2019 uncertainty analysis are appropriate because EPA did not agree with the panelist's conclusions regarding the results of the 11 cosm studies or the reliability of the studies for use in regulatory decision-making. To date, no new data or information has been submitted that would change EPA's determination of the CE-LOC presented in the 2016 risk assessment. As such, EPA has concluded that the assessment establishing a CE-LOC of 3.4 µg/L is still supported by the best available science.

Basis of the 2019 Atrazine Regulatory Update and 2020 Atrazine Interim Decision

In the 2019 regulatory update, EPA discussed the underlying science for the CE-LOC, highlighted some of the uncertainties in the assessment, and discussed the benefits to growers that atrazine provides. Ultimately, EPA announced a risk management approach to mitigating potential risk to aquatic plant communities at a regulatory level of 15 µg/L. As described above, the value of 15 µg/L was not determined based on an analytical assessment nor did it represent a change in the CE-LOC.

As you are aware, in *Rural Coalition, et al., v. U.S. Environmental Protection Agency, et al.*, Case No. 20-73220 (9th Cir), EPA sought and was granted a voluntary remand to reevaluate the regulatory determination that the concentration of 15 µg/L triggers required monitoring and/or mitigation to protect the aquatic ecosystem. EPA intends to issue a proposed revised decision as it relates to the issue on remand and provide a public comment period. EPA encourages the Triazine Network to participate in that process.

Sincerely,

Michal Freedhoff, Ph.D.
Assistant Administrator