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March 11, 2022

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Regan,

On behalf of the Triazine Network,¹ we write to express our concerns and request a meeting to discuss the potential adoption of a new aquatic ecosystem concentration equivalent level of concern (CE-LOC) for atrazine that could have widespread impacts on the use and effectiveness of atrazine herbicide products that continue to serve as the foundation of weed control programs for farmers across the nation.

We understand that the U.S. Environmental Protection Agency (EPA or the Agency) may announce a new CE-LOC of 3.4 parts per billion (ppb) and require the imposition of significant new label restrictions and mitigation measures. Doing so would reverse the Agency's decision to use a 15 ppb CE-LOC in the September 2020 Atrazine Interim Decision, a determination that was the result of more than a decade of exhaustive scientific and regulatory review. To justify the adoption of a much lower CE-LOC, EPA would rely on invalid studies and questionable conclusions that contradict the exhaustive scientific record, the overwhelming scientific consensus, and repeated findings and recommendations of EPA's own Scientific Advisory Panels (SAPs), not to mention the real-world evidence supplied by more than six decades of safe, on-farm use of atrazine products without observable impacts on aquatic ecosystems.

A. History of the Atrazine CE-LOC

In June 2016, EPA's Environmental Fate and Effects Division (EFED) released a preliminary Ecological Risk assessment as part of the atrazine registration review that proposed a 3.4 ppb CE-LOC. This CE-LOC was never adopted. Instead, in the September 2020 Atrazine Interim Decision, EPA confirmed that its October 2019 "decision to use the concentration of 15 µg/L as a 60-day average for the CE-LOC has not changed."² This decision was the result of a years-long scientific review process and reflected the

¹ The Triazine Network is a coalition of more than twenty grower organizations and individual farmers from across the nation that was established in 1995. The Triazine Network is committed to the use of sound science and established scientific methods to evaluate the potential health and environmental impacts of the triazine herbicides, including atrazine. The Triazine Network shares the concerns of the entire U.S. agricultural community that any regulatory action regarding atrazine be based on a thorough understanding of U.S. farming practices and a comprehensive, scientifically defensible evaluation of the best available scientific data.

² Atrazine Interim Decision (September 2020), available at <https://www.epa.gov/sites/default/files/2020-09/documents/atrazine-id-signed-final.pdf>.

Agency's careful consideration of the extensive scientific record and "significant public comments [and] concerns" received from all stakeholders during the registration review process.³

In August 2021, less than a year later, EPA announced that it was "reevaluating" its atrazine CE-LOC, was considering the adoption of a 3.4 ppb CE-LOC, and planned to complete the review and announce its findings in 2022.⁴ Unlike its previous efforts, EPA has, to date, conducted this review as an entirely internal process.

We understand that Syngenta, the primary atrazine registrant, met with Assistant Administrator Freedhoff and other EPA personnel on March 3, 2022 to discuss the Agency's CE-LOC reevaluation. Syngenta presented its concerns over the current reevaluation, including the history of EPA's atrazine CE-LOC determinations, the scientific consensus in support of a CE-LOC of at least 15 ppb, and the potential widespread impacts of requiring mitigation and label restrictions on a county-wide basis using a 3.4 ppb CE-LOC.⁵ At the meeting, EPA informed Syngenta that it was planning to announce the adoption of a 3.4 ppb CE-LOC. EPA asserted, contrary to the record, that the Agency established two separate CE-LOCs, a 15 ppb "regulatory" CE-LOC and a 3.4 ppb "scientific" CE-LOC, that the Agency had "always" maintained that the 3.4 ppb CE-LOC was the "scientific" CE-LOC, and that the pending adoption of a 3.4 ppb CE-LOC was not a reversal of any scientific position by the Agency.

The Triazine Network is greatly concerned by the lack of transparency and openness in EPA's CE-LOC reevaluation, its attempt to rewrite history and deny that it is changing its position on a scientific and regulatory determination, and a potential decision to adopt a 3.4 ppb CE-LOC that is contrary to the scientific record and scientific consensus and that could lead to mitigation measures and restrictions with substantial negative impacts on farmers' ability to use a critical weed control tool.

B. Scientific Consensus Is Firmly Against a 3.4 ppb CE-LOC

The EPA's CE-LOC reevaluation falls short in several respects of the Assistant Administrator's commitment to "ensure that our activities will be conducted transparently, using the best available scientific information" and that "all our decisions will be well documented, transparently made, and will seek and incorporate input from all stakeholders."⁶

First, the Atrazine Interim Decision clearly confirmed EPA's decision to adopt 15 ppb as "the CE-LOC" that would be used to evaluate the potential need for mitigation measures and label restrictions instead of the 3.4 ppb CE-LOC proposed in the 2016 Draft Ecological Risk Assessment. The record does not support EPA's contention that EPA has maintained separate "scientific" and "regulatory" CE-LOCs. Any decision to reverse a critical Agency determination like the 15 ppb CE-LOC, which was adopted after a years-long registration review process, must be presented and defended in a scientifically robust and straightforward manner. To date, EPA has not done so.

Second, while the Triazine Network's own science evaluation showed higher acceptable limits,

³ Id.

⁴ Motion for Partial Voluntary Remand Without Vacatur, *Rural Coalition v. U.S. Env't Protection Agency*, 20-73220 (August 30, 2021).

⁵ Syngenta Presentation, EPA Meeting: Atrazine CE-LOC Reconsideration (March 3, 2022), attached as Exhibit A.

⁶ Statement of Michal Freedhoff (May 12, 2021), available at <https://www.epw.senate.gov/public/?cache/files/8/1/81b26daa-ee3b-489c-bbc5-7eb2d8ef95bf/5CB9A1D4F84A9156F051A834CC0D4FB1.05-12-2021-freedhoff-testimony.pdf>.

the 15 ppb CE-LOC is a “scientific” CE-LOC, supported by the best available and most current scientific studies. It reflects the scientific consensus shown by successive SAPs and other peer reviews and incorporates extensive scientific input received during the public comment process. Along with many others, the Triazine Network submitted technical scientific comments in response to the 2016 Ecological Risk Assessment and its proposed CE-LOC of 3.4 ppb. These comments identified issues pertaining to “data quality and selection, errors, hyper-conservative assumptions, inadequate consideration of the best available science, and the procedures used to calculate the level of concern (LOC) for aquatic plants.”⁷ For example, EFED’s analysis relied on Lampert et al. (1989), even though successive SAPs and peer reviewed publications identified a fundamental flaw in the study design, the addition of a solvent (ethanol) in the treatment enclosures that was not present in the controls, which impacted the aquatic plant community and rendered the reported results invalid.⁸ The 2012 SAP and published scientific review articles identified 11 studies that should be excluded as unreliable or invalid or rescored as showing no effect.⁹ EFED ignored those recommendations and continued to rely on invalid studies and results in proposing the 3.4 ppb CE-LOC in the 2016 Ecological Risk Assessment. In 2019, EPA announced that it was adopting a 15 ppb CE-LOC, making clear that, among other things, it was finally adopting and following the recommendations of the 2012 SAP. Now, EPA says it is reversing its position to again rely on these 11 studies to support the 3.4 ppb CE-LOC. The overwhelming scientific consensus, including more recent published peer-reviewed studies, indicates that these studies are not the best available science and should not be used to support the CE-LOC determination and that the science supports a CE-LOC of at least 15 ppb.¹⁰

Third, the current CE-LOC “reevaluation” has not been open nor transparent. EPA convened no public meetings and solicited no public input before reaching its proposed conclusion. Moreover, in deriving its CE-LOC’s, EPA has applied a complex and opaque “uncertainty analyses” which have produced contrary results and results in CE-LOC ranges that are lower than the actual endpoints of the studies relied on. For example, an uncertainty analysis conducted in 2016 using a study set and scoring consistent with the 2012 SAP recommendations resulted in a CE-LOC range of 13.5- 40 ppb and a median of 20.8 ppb, compared to a 2019 analysis using the same studies and methods that resulted in a CE-LOC range of 1.9-26 ppb and a median of 8.5 ppb.¹¹ To understand this discrepancy, we understand

⁷ Moore et. al., Final Report, Review of EPA’s Ecological Risk Assessment for Atrazine (October 4, 2016) submitted by Triazine Network at page 6, available at <https://www.regulations.gov/comment/EPA-HQ-OPP-2013-0266-1035>. The 2012 SAP noted that it was “disappointed to see” that the 1989 Lampert study was still included in the dataset. The 2012 SPA was the third in a row to conclude the study should be excluded because the purported results were caused by the use of a solvent in the treated groups that was not present in the controls. SAP Meeting Minutes (September 2012) at 41-43, available at <https://www.epa.gov/sap/meeting-materials-september-11-14-2012-scientific-advisory-panel>.

⁸ Id. at 14-15.

⁹ Id. at 13-14.

¹⁰Giddings et al., Data quality scoring system for microcosm and mesocosm studies used to derive a level of concern for atrazine, *Integrated Environmental Assessment Management* 14 (4):489–97 (2018), available at <https://doi.org/10.1002/ieam.4050>; Moore, et al, A weight-of-evidence approach for deriving a level of concern for atrazine that is protective of aquatic plant communities, *Integrated Environmental Assessment and Management* 13:686-701 (2017), available at <https://doi.org/10.1002/ieam.1865>; Smith et al., Assessment of risks to listed species from the use of atrazine in the USA: a perspective, *Journal of Toxicology and Environmental Health, Part B*, 24:6, 223-306, DOI: 10.1080/10937404.2021.1902890 (2021), available at <https://doi.org/10.1080/10937404.2021.1902890>; Baxter et al., Atrazine does not affect algal biomass or snail populations in microcosm communities at environmentally relevant concentrations, *Environ Toxicol Chem.* 2011 Jul;30(7):1689-96, available at <https://pubmed.ncbi.nlm.nih.gov/21567448/>.

¹¹ Exhibit A at 6.

that Syngenta requested that EPA produce the records supporting the 2019 analysis, but EFED could not produce the records necessary to reproduce or assess the 2019 analysis.¹²

C. Conclusion

The Triazine Network is concerned about the significant potential implications – for growers, registrants, States, and other stakeholders – if EPA were to adopt the 3.4 ppb CE-LOC and require additional label mitigations and restrictions on that basis. Doing so would be a substantial step backwards in EPA’s commitment to transparency and the use of the best available science and would result in scientifically unsupported and unnecessary mitigation measures that could have significant negative effects on growers, the agricultural economy, and the nation’s food supply. At a minimum, before taking such a step, EPA should submit any new proposed CE-LOC for review by a SAP and should incorporate any recommendations resulting from such independent scientific review before adopting the CE-LOC.

Sincerely,



Greg Krissek, Co-Chair
Triazine Network

Cosigners:

National Corn Growers Association and its state affiliates

National Grain Sorghum Producers Association

Florida Fruit and Vegetable Association

And many other agricultural organizations who are involved with the Triazine Network.

cc: Michal Freedhoff, Assistant Administrator, OPPSC, EPA
Rod Snyder, Senior Agricultural Advisor, EPA
Thomas Vilsack, Secretary of Agriculture, USDA
Kimberly Nesci, Director, Office of Pest Management Policy, USDA
Cameron Douglass, Agronomist (Weed Scientist), OPMP, USDA

¹² Follow up to Response to FOIA Request (February 11, 2022), attached as Exhibit B.



EPA Meeting: Atrazine CE-LOC Reconsideration

March 3, 2022

Proposed Agenda

1. Introductions*
2. Discussion on the CE-LOC and the uncertainty analysis.
 - The Interim Decision CE-LOC of 15 ppb is protective of environmental health and should be maintained.
3. Unintended consequences of potential label mitigation associated with lowering the CE-LOC: Watershed vs. County example
4. Discussion

* Syngenta meeting attendees:

- John Abbott, North America Head of Regulatory and Stewardship
- Richard Brain, Principal Scientist – Environmental Safety
- Monty Dixon, Regulatory Team Lead – Herbicides
- Charles Pearson, US Head Regulatory Portfolio
- Mark White, Sr. Stewardship & Regulatory Portfolio Manager

Key points

- In the Atrazine Regulatory Update (Oct 2019) and the Atrazine Interim Registration Review Decision (Sept 2020), EPA confirmed the atrazine aquatic plant CE-LOC of 15 ppb on a 60-day rolling average basis.

EPA Response: The Agency appreciates the commenters' input. However, the Agency's decision to use the concentration of 15 µg/L as a 60-day average for the CE-LOC has not changed. As discussed in the PID, in response to significant public comments, concerns, and

Atrazine Interim Decision, September 2020, pg. 9

- The 15ppb CE-LOC is scientifically valid, conservative and highly protective of aquatic plant communities.
- Syngenta and other stakeholders submitted detailed public comments and scientific critiques over invalid, mis-scored, and low-quality studies, which were used by EPA EFED to derive its draft, proposed CE-LOC of 3.4 ppb in 2016. This proposed CE-LOC relied on flawed studies showing purported effects at low exposure levels that successive SAPs (2007, 2009, and 2012) had made clear should have been excluded from consideration or rescored from "effects" to "no effects." To date, EPA has not responded or addressed these comments and critiques.

Key points (continued)

- Through a recent FOIA request, we've confirmed that EPA EFED's "uncertainty analyses" in 2019 were not transparent or reproducible and are inconsistent with a similar alternate analysis in the 2016 Ecological Risk Assessment further undermining confidence in EFED's science position.
- There would be significant concerns with the potential implications, if EPA were to establish a new CE-LOC of 3.4 ppb as a "science-based" or "regulatory-based" level for determining whether there have been any "exceedances" and for requiring additional label mitigation or monitoring for atrazine products.
- EPA should not adopt a lower CE-LOC.
- If EPA proposes a lower CE-LOC then EPA should seek the advice of another SAP, so that the scientific basis (if any) for lowering the CE-LOC and for requiring additional label mitigation can be vetted by an independent panel of scientific experts.



EFED's CE-LOC Uncertainty Analyses

EPA's "Uncertainty Analyses" Are Inconsistent With Each Other and the Underlying Studies

	2016 Ecological Risk Assessment	2016 Ecological Risk Assessment (alternate) ¹	2019 Regulatory Update & 2020 Interim Decision ²
Cosm Study Database	includes 11 studies that SAPs determined were <u>invalid</u> or <u>were wrongly scored as showing effects</u>	<u>excludes invalid studies</u> and <u>rescores studies</u> consistent with SAP findings and Giddings (2012)	<u>excludes invalid studies</u> and <u>rescores studies</u> consistent with SAP findings
Range	0.4 – 16.1 ppb	13.5 – 40.5 ppb	1.9 – 26 ppb
Median	3.4 ppb	20.8 ppb	8.5 ppb

Outcomes rely on outlier low endpoints from studies multiple SAPs found invalid (e.g., use of solvent in treatment groups not present in control)

Outcomes roughly consistent with actual endpoints of rescored underlying studies

Inconsistent results from analyses using same method, models, and database

Outcomes significantly lower than actual endpoints of rescored underlying studies, which show no effects below ~10-15 ppb

¹ 2016 Ecological Risk Assessment p. 212 (alternate uncertainty analysis using scoring methodology of Giddings (2012)); September 11, 2012 SAP Meeting Minutes at 19 (finding that “rescoring by the [SAP] of this subset of studies agreed with that of Giddings (2012)).

² 2019 Regulatory Update at 3 (uncertainty analysis conducted “[u]tilizing the cosm study scoring and study exclusions recommended by the 2012 SAP”)

History of Atrazine Aquatic Plant Community LOC

- 2004 - 2011** Existing LOC **18 ppb**. SAPs (2007 and 2009) evaluate potential atrazine aquatic plant community impacts and LOC using CASM model calibrated with cosm study results.
- September 2011** OPP announces estimated LOC **10 ppb (60 days)**, based on PATI model calibrated with cosm study results.
- 2012** SAP evaluates cosm endpoints and PATI model, finds EPA's updated proposed LOC of **4-7 ppb (60 days)** relies on invalid studies and improper scoring; agrees with the cosm scoring in Giddings et al. 2012; and recommends conduct of a higher-tiered simulated stream study.
- January 2016** Peer-review publication of higher-tiered study by King et al. using simulated streams, no effects of pulsed exposures **up to 150 ppb (30 ppb for 60 day average)**
- June 2016** Draft Ecological Risk Assessment suggests CE-LOC of **3.4 ppb (60 days)**
- October 2016** Detailed comments by Syngenta and others on science supporting significantly higher CE-LOC, including published scientific analyses.
- November 2016** Peer-review publication of weight of the evidence and data quality analysis by Moore et al., supports LOC of approximately **20 ppb**.
- April 2018** Peer-review publication of updated weight of the evidence and data quality analysis by Giddings et al. supports LOC of approximately **20 ppb**.

History of Atrazine Aquatic Plant Community LOC (continued)

- October 2019** Regulatory update by EPA adopts cosm scoring and study exclusions recommended by 2012 SAP, applies uncertainty analysis, revises CE-LOC to **15 ppb (60 days)**.
- January 2020** Atrazine PID confirms CE-LOC of **15 ppb (60 days)**. EPA provides minimal responses to public comments and more recent studies and commits to responding fully as part of Biological Evaluation process. EFED's cosm scoring database and PATI simulations were not provided for review.
- March 2020** Detailed comments by Syngenta and others on science, including published scientific analyses, confirming **15 ppb (60 days)** is highly conservative.
- September 2020** Atrazine ID states that the Agency's decision to use the concentration of **15 ppb** as a 60-day average for the CE-LOC has not changed.
- November 2020** EPA issues draft biological evaluation, does not discuss or apply CE-LOC.
- July 2021** Peer-review publication of assessment of potential atrazine risks to endangered species by Smith et al., supports LOC of **50 ppb**.
- August 2021** EPA files motion for remand, announcing agency reconsideration of CE-LOC with a timetable for completion by January 2022.



**Unintended Consequences of
Potential Label Mitigation
associated with lowering the
CE-LOC: Watershed vs. County
example**



Watershed Level Mitigation vs. County Level Mitigation

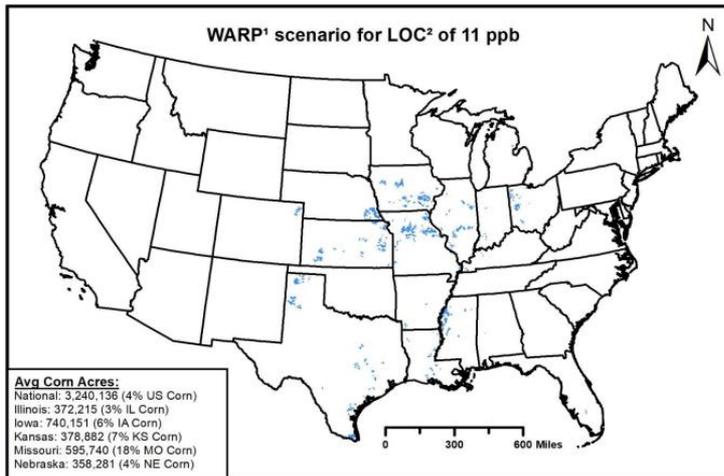
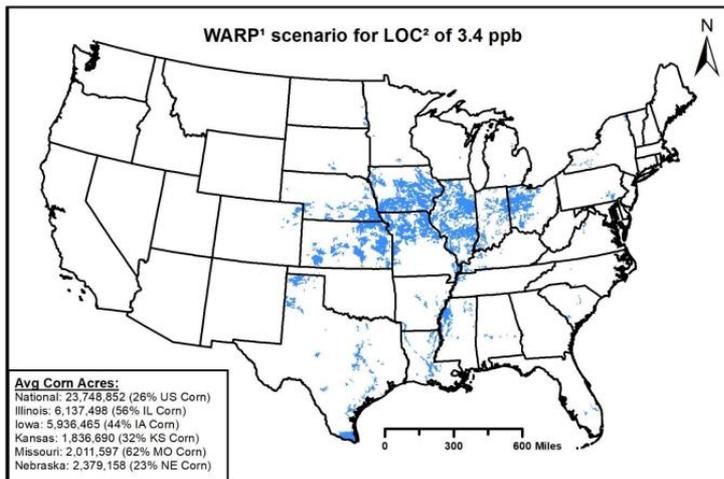
With a 3.4 ppb LOC:

- **23,748,852** average corn acres (2017-2020) intersect the WARP HUC12 watersheds exceeding 3.4 ppb, nationally.
- The average corn acres in the counties that intersect these same WARP HUC12 watersheds, nationally, is **55,942,643**.
- Therefore **32,193,791** additional average corn acres would be negatively impacted if regulated by the county vs. WARP HUC12 watersheds, nationally.

With a 11 ppb LOC:

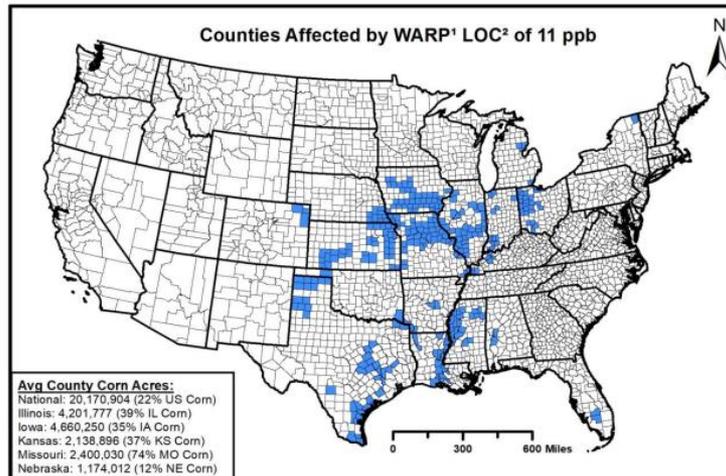
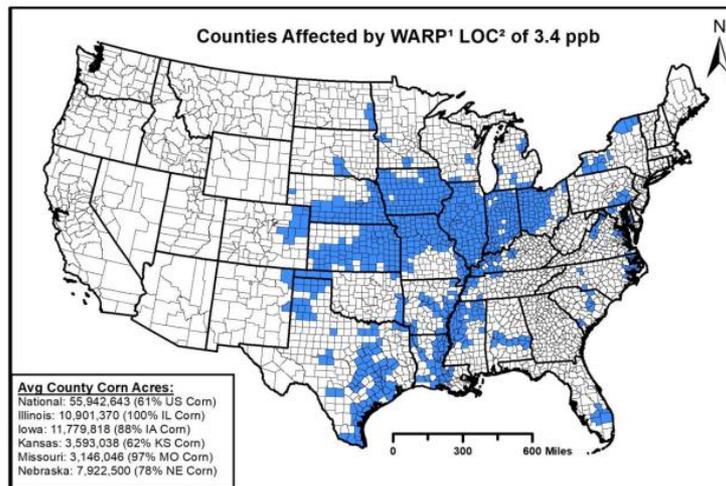
- **3,240,136** average corn acres (2017-2020) intersect the WARP HUC12 watersheds exceeding 11 ppb, nationally.
- The average corn acres in the counties that intersect these same WARP HUC12 watersheds, nationally, is **20,170,904**.
- Therefore **16,930,768** additional average corn acres would be negatively impacted if regulated by the county vs. WARP HUC12 watersheds, nationally.

Watershed Level



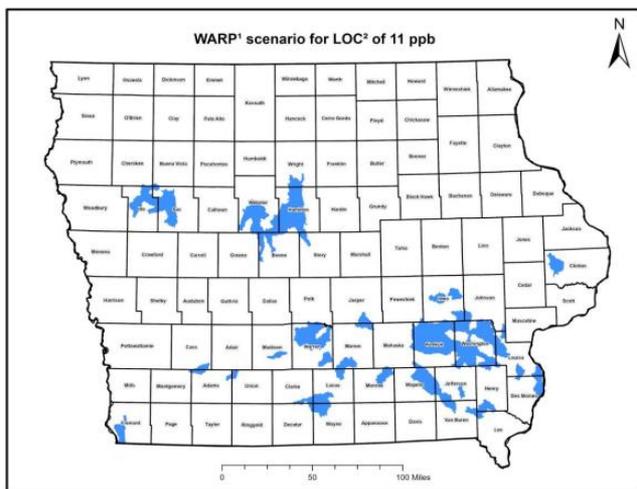
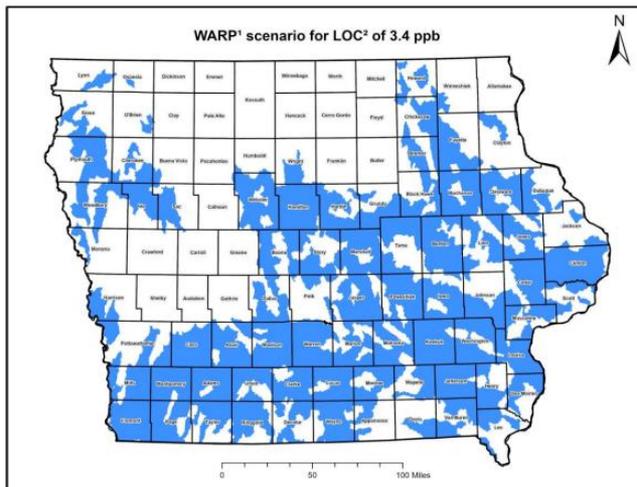
¹Watershed Regressions for Pesticides
²Level of Concern

County Level



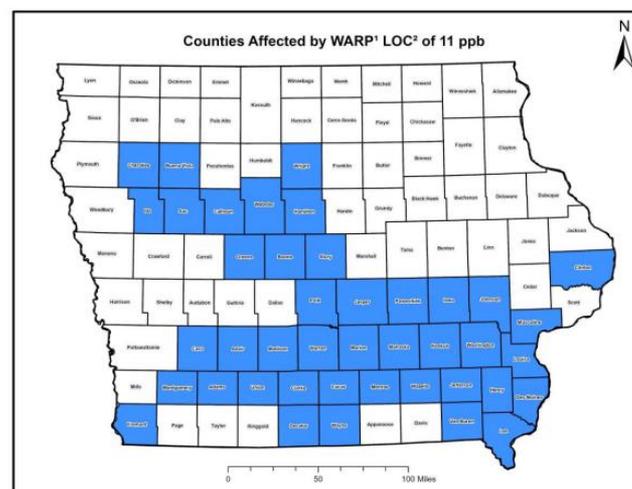
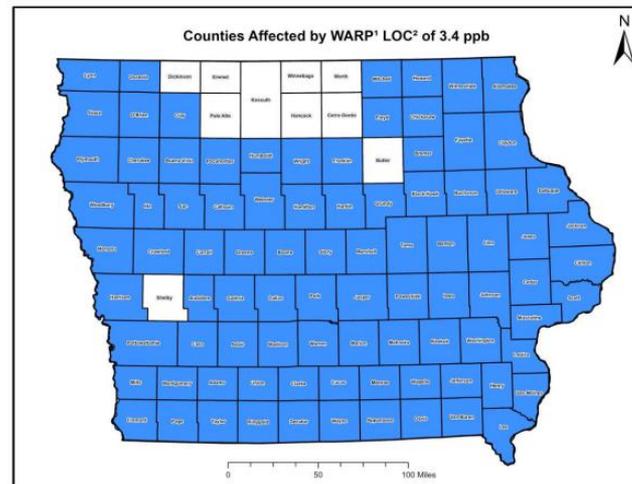
¹Watershed Regressions for Pesticides
²Level of Concern

Watershed Level



¹Watershed Regressions for Pesticides
²Level of Concern

County Level



¹Watershed Regressions for Pesticides
²Level of Concern

Conclusions

- EPA should not adopt a lower CE-LOC.
- If EPA proposes a lower CE-LOC then EPA should seek the advice of another SAP, so that the scientific basis (if any) for lowering the CE-LOC and for requiring additional label mitigation can be vetted by an independent panel of scientific experts.
- EPA should not impose additional label mitigations.
- The consequences of any proposed mitigations should consider the economic impact on farmers and the implications on food security. For example, mitigations imposed at the county level are overly broad and include over a 42% increase in affected corn acres nationally.

The Syngenta logo is positioned on the right side of a dark green horizontal bar. It consists of the word "syngenta" in a white, lowercase, sans-serif font, with a small green leaf icon above the letter 'g'.

syngenta

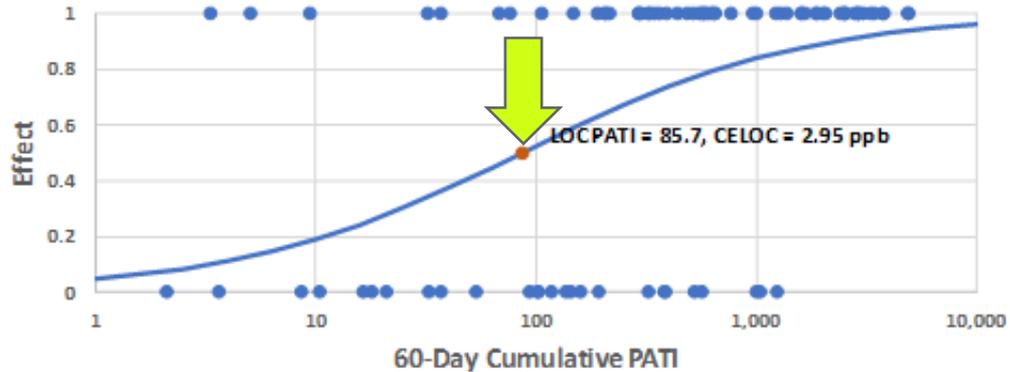
CE-LOC Analysis

PATI and Direct Cosm Regression Analysis Based on Appendix G from EPA, 2016 and Appendix A from Keigwin, 2019

PATI and Direct Cosm Regression Analysis Based on Appendix G from EPA, 2016 and Appendix A from Keigwin, 2019							
Alternative	Scenario description relative to 2016 EPA Base Case (Scenario 0)	# of Cosms in Cosm Set	LOCPATI (%Effect-Day)	CELOC	60-D LOCppbd (PPB-D)	CELOC (PPBD)	% Increase over EPA Base Case
Scenario 0	EPA, 2016 - Base Case	86	85.7	2.95	176.8	2.95	NA
Scenario 1	EPA, 2016 - Base Case Excluding Cosm ID# 58b	85	107.0	3.72	224.1	3.74	127
Scenario 2	Keigwin Memo, Appendix A, Exclude IDs #58 and 58b (same as EPA 2016-L)	84	128.8	4.50	273.0	4.55	154
Scenario 3	Keigwin Memo, Appendix A, Classify ID #s 1, 2, 3, 4, 5, 41, 42, 52 as No Effect	86	98.5	3.42	190.3	3.17	108
Scenario 4	Keigwin Memo, Appendix A, Exclude ID #s 1, 2, 3, 4, 5, 41, 42, 52	78	87.1	3.01	180.0	3.00	102
Scenario 5	Keigwin Memo, Appendix A, Exclude ID #s 22, 23, 24, and 25	82	104.6	3.65	222.2	3.70	126
Scenario 6	Keigwin Memo, Appendix A, Classify ID #s 28 and 44 as No Effect	86	112.7	3.93	239.4	3.99	135
Scenario 7	Keigwin Memo, Appendix A, Classify ID #s 83, 84, 85, 86, and 87 as No Effect	86	128.5	4.50	279.8	4.66	158
Scenario 8	Scenarios, 2, 4, and 5 (Exclude only)	72	161.8	5.64	352.7	5.88	199
Scenario 9	Scenarios 3, 6, and 7 (Classify as No Effect only)	86	259.2	8.95	574.8	9.58	325
Scenario 10	Scenarios 2, 4, 5, 6, and 7 (Exclusions and Classify as No Effect combined)	72	297.9	10.30	668.7	11.15	378
Scenario 11	2012 SAP - Exclude ID#s 58, 58b, 22, 23, 24, 25 & Classify ID#s 1, 2, 3, 4, 5, 28, 41, 42, 44, 52, 83, 84, 85, 86, and 87 as No Effect	80	452.9	15.24	1064.9	17.75	602

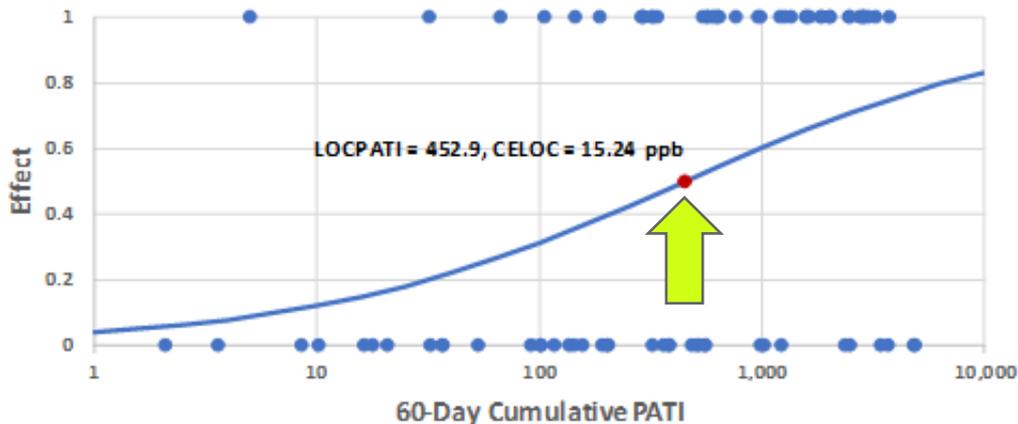
CE-LOC Comparison of EPA, 2016 Base Case and 2012 SAP Recommendations

EPA, 2016 - Base Case



PATI-Derived CE-LOC = 2.95 ppb

2012 SAP - Exclude ID#s 58, 58b, 22, 23, 24, 25 & Classify ID#s 1, 2, 3, 4, 5, 28, 41, 42, 44, 52, 83, 84, 85, 86, and 87 as No Effect



PATI-Derived CE-LOC = 15.24 ppb

February 11, 2022

VIA E-MAIL

Gibbs Moore
Government Information Specialist
Public Information and Record Retention Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. (Mail Code 3204A)
Washington, D.C. 20004

Re: Response to Freedom of Information Act Request EPA-2022-000686

Dear Mr. Moore:

Thank you for your February 3, 2022 email and prompt attention in responding to our February 2 letter regarding EPA's response and production of materials with regards to our FOIA request for records relating to the atrazine aquatic plant community concentration-equivalent level of concern ("CE-LOC") analysis and figures provided in EPA's October 22, 2019 Atrazine Regulatory Update.¹

As explained in our February 2 letter, understanding the process, scenarios, inputs, and outcomes used to generate the 2019 uncertainty analysis is important because that analysis was provided as part of the scientific basis for establishing the 15 µg/L atrazine CE-LOC that the Agency is now reevaluating. As we noted, the values reported from the 2019 uncertainty analysis skew significantly lower than the actual effects scores of the underlying cosm studies, if assessed and scored as the Scientific Advisory Panel recommended. They are also significantly lower than the reported results of an uncertainty analysis conducted in the 2016 risk assessment using an equivalent cosm scoring approach and the same version of the PATI model.

According to your email, we understand that EPA has no further responsive records to produce that would help assess or reproduce the 2019 uncertainty analysis and the CE-LOC range, median, and percentile values that were reported. Based on comments included in the email from an unidentified "subject matter expert" who conducted the 2019 uncertainty analysis and collected the records in response to the FOIA request we further understand that:

- The version of the PATI model used in the 2019 uncertainty analysis is the same version used in EPA's 2016 draft risk assessment.

¹ Regulatory Update on the Registration Review of Atrazine (October 22, 2019), available at <https://www.regulations.gov/document/EPA-HQ-OPP-2013-0266-1260>.

- There is “no single executable or GUI” for the PATI model, instead it is made up of the “series of executable files” that EPA provided. However, those files produce an error message and will not run.
- There is no “user guide” for the PATI model used to generate the 2019 uncertainty analysis. The PATI model is “not very intuitive and is fairly tedious” to run, and the unidentified respondent “worked directly with” the author of the 2016 risk assessment (Frank Faruggia) to learn how to run the model.
- The model developer (Russell Erickson) “has retired” and the respondent does not believe that the Agency “is continuing to develop the ‘PATI’ model or associated documentation.”
- In response to the request for the specific cosm dataset and study scoring and inclusion determinations that were used to generate the different scenarios that created the range of CE-LOC’s in the 2019 uncertainty analysis, the respondent indicated that “I do not have a spreadsheet version or selection table like the one Syngenta requests.” The only document produced in response to this request is the “cosmeffects.dat” file. The respondent “acknowledge[d] 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.” The “cosmeffects.dat” file contains only a single list of cosm endpoint IDs, exposure levels, and effect/no effect scores and does not indicate the various scenarios the Agency ran to generate the range of CE-LOC values.

These explanations, coupled with the position that no additional responsive records exist to be produced, confirm that the Agency either did not create or did not maintain the record necessary for any third party, or the Agency itself, to assess or reproduce the 2019 uncertainty analysis. If this is not correct, please provide any clarifications, additional records, or further information by February 16, 2022, so that Syngenta can knowledgeably assess whether to file a formal appeal of the response to the FOIA request.

We also reiterate that Syngenta would be happy to meet directly with the EPA personnel that conducted the 2019 uncertainty analysis to further understand how it was conducted and the reproducibility of EPA’s process. We would welcome the opportunity to meet with the “subject matter expert” who provided the comments and conducted the uncertainty analysis.

Although such measures will hopefully not prove necessary, Syngenta again reserves the right to take formal action if needed to compel a complete response and production of requested records, including through pursuing a formal FOIA appeal.

Sincerely,



David A. Barker
Counsel for Syngenta Crop Protection, LLC

cc: Edward Messina, Director, Office of Pesticide Programs (OPP)
Elissa Reaves, Director, OPP Pesticide Re-Evaluation Division
John Abbott, Mark White, Richard Brain, Syngenta Crop Protection, LLC