February 19, 2021

Ms. Tracy Perry
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

via regulations.gov: EPA-HQ-OPP-2020-0514

Re: Comments on the Draft Biological Evaluations for Atrazine, Simazine, and Propazine, EPA-HQ-OPP-2020-0514; 85 Fed. Reg. 71071 (November 6, 2020)

Dear Ms. Perry:

Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States. CLA represents the interests of its registrant member companies by, among other things, monitoring legislation, federal agency regulations and actions, and litigation that impact the crop protection and pest control industries and participating in such actions when appropriate. CLA's member companies produce, sell, and distribute virtually all the crop protection and biotechnology products used by American farmers.

CropLife America (CLA) appreciates the opportunity to comment on the Draft National Level Listed Species Biological Evaluations for Atrazine, Simazine, and Propazine (the Draft Triazine BEs) produced by the Environmental Protection Agency's (EPA or the Agency). Our comments, provided below, contain an Executive Summary, Policy Considerations, Technical Comments, and Conclusions. Should you have any questions or comments, please feel free to contact me at mbasu@croplifeamerica.org or (202) 296-1585.

Sincerely,

Manojit Basu
Managing Director, Science Policy
CropLife America

CC: Ed Messina, Acting Director, EPA OPP
Jan Matuszko, Acting Division Director, EPA EFED
Sheryl Kunickis, Director, USDA OPMP
Gina Shultz, Deputy Assistant Director, USFWS
Cathy Tortorici, Division Chief, NMFS Office of Protected Resources

CropLife America Comments on the Draft Biological Evaluations for Atrazine, Simazine, and Propazine

(EPA-HQ-OPP-2020-0514)

DATE: FEBRUARY 19, 2021

1 EXECUTIVE SUMMARY

The Draft Biological Evaluations for Atrazine, Simazine, and Propazine (collectively the Draft Triazine BEs) were developed under the Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides (the Revised Method), which was released in March 2020. The Draft Triazine BEs continue to demonstrate that the Environmental Protection Agency (EPA or the Agency) has not yet reached a workable, consistent, and sustainable approach to assessments for listed species.

In the Preamble to the draft Revised Method, the Agency told the public that the pilot method previously used by EPA had the following major limitations:

> (1) The method did not meaningfully distinguish species that are likely to be exposed to and affected by the assessed pesticides from those that are not likely; (2) The level of effort was too high for EPA to sustain for all pesticides; and (3) The amount of documentation produced was too great for the public to review and comment upon in a reasonable timeframe (Pesticides; Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides, 2019).

Based on CropLife America's (CLA) careful review of the Draft Triazine BEs, the Agency has made incremental progress, but the major limitations cited as rationale for revising the interim method are largely uncorrected and, in some ways, these deficiencies have been compounded.

CLA recommends that the Agency must make a significant effort in the final triazine BEs to reduce the level of compounding conservatism in the assessment, adjust the approach to more accurately incorporate use and usage information, and strive to better establish whether pesticide exposure can cause affect that is reasonably certain to occur as described in the Services' new Endangered Species Act (ESA) regulation (Consultation Procedures, 2019). CLA provides specific recommendations in the Conclusions section of this document to reduce the vastly overstated potential effects of triazines on listed species.

In the Draft Triazine BEs, the Agency applied an overly complex system of new tools and models, including the Magnitude of Effect Tool (MAGtool) and Plant Assessment Tool (PAT) that incorporates spatial data, effects thresholds, new exposure models, and the probabilistic methods to evaluate the potential for risk to listed species and their critical habitats. The Public Comment period (including the extension) does not allow sufficient time to adequately evaluate these complex tools. Furthermore, these models lack transparency; are confusing (*e.g.*, model versions); have problems with quality assurance and control; and has insufficient documentation.

Finally, CLA recommends that the Agency and its federal partners facilitate more engagement with a broad range of stakeholders, including the pesticide industry, grower groups, other agricultural groups, and nongovernmental organizations. The input from these stakeholders and organizations can lead to the development of a nationwide evaluation of pesticide risks to listed species that is efficient, scientifically defensible, and reliant on the best available scientific and commercial data. For example, the Agency should convene stakeholder meetings before the deadline for the Congressionally required progress reports so that the Interagency Working Group (IWG) has enough time to consider stakeholder comments on the consultation process as it drafts reports to Congress and as EPA considers further refinements to the Revised Method.

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2 INTRODUCTION

The Agency released the Draft Triazine BEs concurrently in November 2020 (Atrazine, Simazine, and Propazine Registration Review; Draft Endangered Species Act Biological Evaluations, 2020; EPA, 2020f). These Draft Triazine BEs applied the final Revised Method and a new version of the MAGtool. CLA reviewed the Draft Triazine BEs and provides the comments below highlighting policy considerations for the Agency to establish an efficient and legally defensible BE process. We also share our concerns on technical aspects of the Draft Triazine BEs.

3 POLICY CONSIDERATIONS FOR THE AGENCY

3.1 Reasonably Certain to Occur

CLA believes that EPA must make significant efforts in the final triazine BEs to overcome persistent deficiencies in its analyses and meet EPA's own stated expectations for improvements to be delivered by its Revised Method (EPA, 2020f). There is little evidence in the Draft Triazine BEs, that establishes effect due to pesticide exposure is reasonably certain to occur as described in the revised ESA implementation regulations (Consultation Procedures, 2019).

Based on the Revised Method, CLA believes a May Affect determination should reflect whether an effect is "reasonably certain to occur." However, that standard has not been met in the Draft Triazine BEs. Instead, the implementation of the first Step of the final Revised Method simply examines: (a) whether exposure would occur, based on species range data overlap with action area; (b) effect thresholds; and (c) highest estimated exposure concentration (EEC) predicted for the species in the terrestrial and/or aquatic environment. Ultimately, if the EECs exceed the effect thresholds, then a May Affect determination is made. This deterministic approach is inconsistent with Interagency Cooperation Regulation from the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS)(the Services collectively) (Consultation Procedures, 2019).

In or prior to Step 1, without broader consideration of specific individual exposure scenarios for each of the listed species, species life histories, factors that may mitigate exposure (*e.g.*, landscape, behavior), and the probability of exposure occurring given appropriate historical use and usage data, it is not possible to establish if registration action would be reasonably certain to cause an effect on a listed species. CLA has submitted a Step-Zero white paper to the Agency outlining an approach which could assist in meeting the reasonably certain to occur standard and make the BE process more efficient (CLA, 2020a).

As with its Draft BEs for Carbaryl and Methomyl (the Draft Carbamate BEs), EPA's Draft Triazine BEs fail to reflect the revisions to the regulations for Interagency Cooperation for the Services (CLA, 2020b). Those changes modified the definition of "effects of the action" in ways fundamental to EPA's BE process. By changing the prior definition of "effects of the action," the Services clarified how EPA must evaluate whether an action "may effect" an endangered species. EPA acknowledged in its response to comments in 2020: "[b]ased on [the] language of [50 C.F.R. § 402.02], a May Affect determination considers whether an effect is reasonably certain to occur" (Endangered and Threatened Wildlife and Plants; Regulations for Interagency Cooperation, 2019). However, this change has not been implemented by EPA in the Draft Carbamate and Triazine BEs. EPA should apply the correct legal standard when conducting a BE, which will lead to accurately measuring what is reasonably likely to occur.

Additionally, the Services have now established a framework to guide both the action agencies and the Services when determining whether an effect is reasonably certain to occur. These revised consultation regulations state that "[a] conclusion of reasonably certain to occur must be based on clear and substantial information, using the best scientific and commercial data available" (Consultation Procedures, 2019). The regulation thus requires both the action agency and the Services to apply this standard. The Services made this change because "[e]xperience has taught [them] that the failure to provide a definition and parameters to the term 'reasonably certain to occur' left the concept vague and occasionally produced determinations that were inconsistent or had the appearance of being too subjective" (EPA, 2020e). Despite the Services' guidance and EPA's pledge to implement these changes, EPA failed to base the analysis and conclusions in the Draft Triazine BEs on clear and substantial information. The Agency did not use the best scientific and commercial data available to develop realistic conclusions about whether an individual of a species is likely to be affected. If it had done so, EPA would have concluded that the triazines are Not Likely to Adversely Affect (NLAA) an individual for a substantial number of listed species and not likely to cause adverse modification to the critical habitat on which they depend. In addition, EPA also should have provided the Services with realistic usage data on the limited uses authorized by registered labels and commitment letters from the registrant to modify labels, but it did not.

3.2 Making Efficient and Scientifically Defensible Effect Determinations

The efficiency of the BE process and how the Revised Method is implemented using the MAGtool remains a major issue for several reasons. The draft atrazine BE results are an excellent example of this as described below.

Despite several years of effort on an incredibly well-studied pesticide, EPA concludes that virtually100% of listed species analyzed in the contiguous United States will have to be further assessed by the Services. Table 1 summarizes the results from the draft atrazine BE for the total of 1,795 listed species. Step 1 resulted in high numbers of No Effect determinations solely because commitment letters from the registrant removed all areas outside of the contiguous states from the draft BE. Moreover, most species in the contiguous states are assessed as LAA, setting up the requirement for formal consultation.

Table 1. Summary of effect determination results in the draft BE for atrazine								
Entity (Starting Number)	**Step 1**	**Step 2A**	**Step 2B**	**Step 2C**	**Step 2D**	**Step 2E**	**Step 2F**	**Step 2G/H/I**
Species Ranges (1795)	NE=676	NLAA=36	NLAA=8	NLAA=4 LAA=2	NLAA=27 LAA=2	NLAA=3	NLAA=21	NLAA=7 LAA=1009
Critical Habitats (792)	NE=412	NLAA=11	NLAA=0	NLAA=0 LAA=0	NLAA=7 LAA=2	NLAA=1	NLAA=27	NLAA=6 LAA=326

Due to the significant issues with compounding conservatism, flawed application of usage data, lack of an appropriate weight-of-evidence approach, and other concerns identified in these comments, any listed species that moves through the Revised Method, as implemented using the MAGtool, will receive a LAA determination. A different outcome can only be expected if, the listed species has no possibility of exposure (Step 1a); has an unlikely exposure pathway (*e.g.*, ocean species)(Step 2a); or is thought to be extinct (Step 2b)(EPA, 2020f). This conclusion is also supported by the results of the Draft Carbamate BEs (EPA, 2020b, 2020c). This approach does not protect the listed species within the context of pesticides, not only from a time and resources perspective, but also by failing to accurately identify listed species and their critical habitat that may be reasonably certain to be impacted by a pesticide.

Appendix 4-8 in the Draft Triazine BEs provide qualitative evidence regarding listed species that are unlikely to be exposed due to incomplete exposure pathways and whether the exposure modeling applied is appropriate for the listed species. This section adds limited but needed realism to the assessment, which should be applied much earlier in the assessment process. For example, for most pesticides, application to the open ocean is very unlikely as stated in the draft atrazine BE:

> Exposures to species that predominantly occur in the open ocean (*e.g.*, whales) or rely on ocean species (*e.g.*, seabirds) are reasonably expected to be *de minimis*. This is because atrazine is not applied directly to the ocean and does not bioaccumulate (EPA, 2020a).

Thus, as stated in CLA's comments on the Draft Carbamate BEs, *a priori* informal consultation with the Services should be pursued to agree upon a list of species with these types of circumstances so that they do not have to be independently investigated in future BEs (CLA, 2020b). For any conventional active ingredient, it should be possible to address a significant number of listed species prior to initiating the Agency BE process. This would save time, resources, and make the BE process more efficient in the future. Finding these opportunities fits with the Agency recognition that "the methods applied to BEs will continue to evolve as EPA gains experience and as scientific methods and data improve" (EPA, 2020f). Such opportunities abound in endangered species assessments and should be addressed, where possible, in the preparatory stages of BE development (EPA, 2020f). CLA has documented some of these opportunities in a recent white paper (CLA, 2020a).

3.3 Collaboration

CLA members recognize the importance of collaboration among EPA, the US Department of Agriculture (USDA), and the Services on listed species issues, and strongly encourages collaboration with the individual registrants as part of this process in the future. Registrants have broad information about their products, where the best available data is located, and can potentially provide expertise and knowledge on product use, sales, and other information that may be important to EPA evaluations. It is critical to all interested parties that there be a manageable, efficient, and defensible process to share information to maintain regulatory certainty and protect the listed species and critical habitats.

3.3.1 Meaningful Interaction

CLA advocates for a more meaningful interaction with EPA on topics associated with pesticide products. CLA represents a wide variety of interests in agriculture that can bring significant knowledge to the table on pesticide usage, integrated pest management, and many other topics. CLA can provide scientific expertise, agricultural knowledge, and relevant information to assist EPA in establishing the scientific foundation for their pesticide regulatory decisions.

Although the final Revised Method is an overall improvement to the process of developing a BE, its application in the Draft Triazine BEs demonstrates that we have not yet reached a workable, legally defensible, and sustainable approach to listed species risk assessments.

3.4 Conservation Approaches

CLA recommends that EPA develop a decision system linking risk ecological risk assessments with ESA conservation goals. Current risk assessments are not designed with the intention of conserving listed species under the ESA as the goal. For example, the assessments are typically based on individual level endpoints, but the ESA conservation goals may be described in a recovery plan in terms of species population numbers, distribution, or conservation of specific habitat. Subsequently, the endpoints require additional translation before they are directly relevant to the jeopardy/adverse modification analysis. Improving the risk characterization so that it is relevant to the ESA conservation goals that reduce the complexity of assessments and improve species conservation outcomes (*e.g.*, improved targeting of any voluntary conservation measures that clearly benefit recovery) is the best path forward to promote biodiversity and conservation.

Registrants for triazines made significant concessions regarding labelled uses (*i.e.,* restricting the label to the contiguous U.S.), mitigations (spray drift buffers, etc.), and conservation efforts (net conservation offsets, etc.). However, many of the label restrictions, mitigations, and conservation efforts were not considered in the Draft Triazine BEs.

In developing this decision system, linking risk ecological risk assessments with ESA conservation goals, CLA recommends that EPA's analysis incorporate existing conservation areas within the agricultural landscape and registrant-initiated conservation mitigation. For example, USDA conservation programs are supported by an estimated $6 billion expenditure in FY 2020. Recognition of these existing protections and conservation efforts in the EPA assessment process, and alignment with the Services on how these existing protections can inform the pesticide assessment process, could allow the Agency to work with its IWG partners to leverage ongoing conservation efforts and maximize benefits to listed species.

4 TECHNICAL COMMENTS

4.1 Pesticide Usage Data

The application of pesticide usage data is intended to refine the BEs by quantitatively accounting for the reality that not all potential pesticide use sites are treated with a specific active ingredient. This approach was introduced in the Revised Method (EPA, 2020f). EPA assumes the percent crop treated (PCT) is within the area where use patterns and species ranges, or critical habitat area overlap. This ignores the fact that a pesticide could be applied anywhere within a state and not just within the species range or critical habitat area, making this assumption unrealistic and not reasonably certain to occur. The justification for this assumption is that it is conservative and intended to address inherent uncertainty in the usage data (EPA, 2020d). However, it is far more likely that any pesticide application would occur unevenly throughout a state, particularly given the availability of other pesticides in the market. How usage is distributed within a state should therefore be estimated using probabilistic methods (Budreski et al., 2016).

In the Draft Triazine BEs two usage scenarios, a highly conservative scenario based on a maximum PCT and usage focused within a species range, and an alternative usage scenario based on an average treated PCT and usage uniformly distributed across a state are applied. The usage data and PCT refinement are intended to improve the distinction between species not likely to be affected by use of a pesticide from those likely to be affected. The usage data as applied in the Draft Triazine and Carbamate BEs does not provide the intended refinement because of unrealistic assumptions, miscalculations, and minimization of the most likely usage scenarios (CLA, 2020b). Primary examples include:

- For agricultural uses:
    - The acreage used in calculating treated acres does not account for the likelihood of multiple applications per season. EPA assumes that all acres are treated at the same time. This leads to overly conservative PCT estimates.

  - The methodology used in calculating a PCT is inconsistent with the exposure modeling which assumes applications to use sites at maximum annual label rates.
  - The methodology for creating Use Data Layers (UDLs) is based on a multi-year composite of Cropland Data Layer (CDL) crop footprints, combined with the PCT estimation approach. This results in an over-prediction of treated acres.
  - For multi-crop UDLs, including "Vegetables and Ground Fruit" and "Other Orchards", the "Maximum/Upper" usage scenario may substantially over-predict treated acres within a species range.
- For non-agricultural uses:
  - The maximum PCT calculated for all non-Ag uses is unreasonably conservative as it represents use of all herbicides on these use sites, not just triazines.
  - The total treatable acres used in calculating non-Ag PCTs are inconsistent with the acres associated with the non-Ag UDLs.
- The "Maximum/Upper" usage scenario is unreasonably conservative when allocating all state treated acres to occur within every species range/critical habitat.
- Determination of NLAA versus Likely to Adversely Affect (LAA) is based nearly entirely upon the "worst case" usage scenario.
- The "Average/Uniform" usage scenario only comes into play in one of the 10 criteria evaluated in the Weight of Evidence analysis.
- The overall PCT and associated treated area analysis are flawed, leading to unrealistic MAGtool results and conclusions.

In the draft atrazine BE, an example of the impact of the faulty usage assumptions can be seen in the analyses of Sonoma alopecurus (*Alopecurus aequalis var. sonomensis*). This species is a native perennial grass found only in marshes, wetlands, and other riparian areas in two mid-coastal counties north of San Francisco. The draft atrazine BE concluded that the species was likely to be adversely affected by the "Open Space Developed" use pattern for atrazine, according to Appendix 1-4 and Appendix 1-6, that includes two turfgrass use patterns (EPA, 2020a). The primary registrant, Syngenta, has no active registrations for atrazine in California and only five other atrazine products remain registered in California, once cancelled products are excluded (California Department of Pesticide Regulation, 2020a). Evaluation of the California Pesticide Use Reporting (PUR) database indicates that atrazine use in California has been low, *i.e.*, ~20,000 lbs between 2017-2019, which represents less than 0.03% of the amount annually applied nationally. In addition, the average PCT for atrazine turfgrass is <1% (EPA, 2020d). Finally, most of the recent use in California has been primarily in the Imperial Valley near the border of Mexico and is expected to decrease as existing stocks decline (California Department of Pesticide Regulation, 2020b). Given these factors, atrazine usage and Sonoma alopecurus habitat are highly unlikely to overlap. Yet, the MAGtool predicts that atrazine impacts 22% of the Sonoma alopecurus population each year (EPA, 2020a). This conclusion is almost certainly a function of the faulty application of usage data in the draft atrazine BE, combined with MAGtool automation without appropriate review and consideration of refined data.

4.2 Compounding Conservatism

Compounding conservatism in the BE process is a severe weakness. In Step 1, a No Effect or May Affect determination is partially based on species range/action area overlap, assuming full pesticide label rates are applied to 100% of crop and non-crop area. The UDLs generated by EPA overestimate actual use due to lumping of use patterns from all registered labels from multiple registrants together, including both agricultural and non-agricultural uses. The geographic ranges of listed species are imprecise, highly conservative, and expressed only at the county level in most cases. Application of usage data at Step 2 at the state level within the species ranges is also highly conservative (see Section 4.1).

The current application of usage data also leads to unrealistic conservatism within the exposure modeling approaches themselves. For example, the UDLs and usage data inform pesticide inputs into the exposure models. The aquatic exposure modeling is very conservative itself. For example, using variable field sizes depending on whether standard pond, index reservoir, or edge-of-field were being used as species aquatic habitat bin surrogates. The results are generic and represent unrealistic and highly conservative exposure scenarios for any listed species. For terrestrial listed species, the usage data and UDLs inform the exposure concentrations and residues predicted for off-field drift, but the off-field drift component does not account for the habitat where a species may be found. This is an important line of evidence especially since edge of field habitats may indeed already be managed for agricultural production.

Another example of unrealistic conservatism is not accounting for spray drift interception. Not considering spray drift interception causes an overestimate of pesticide exposure for listed species where the assumption of no interception is not reasonable. Spray drift interception and direction was one line of evidence used qualitatively by EPA to evaluate the potential for risk for pinnipeds using beaches for basking and other purposes. Specifically, EPA states “atrazine would have to be transported by wind blowing from the application site toward the beach with little opportunity for interception of spray droplets.” (EPA, 2020a). Application of this sort of refined information will result in species-specific effect determinations that are more realistic than predominately occurs in all BEs to date.

Step 2, as applied, does little to address compounding conservatism, as a refined step in a hierarchical Ecological Risk Assessment (ERA) process should do. More information on this refined process can be found in guidelines and framework from EPA and the National Academies of Science (EPA, 1992, 1998; National Academies of Science, 2013). The way the MAGtool is applied is entirely prescribed with default inputs and little to no flexibility. This is particularly problematic in a tiered risk assessment framework because there is no mechanism to incorporate or consider higher-tier data. Given that Step 1 already identifies most species as May Affect, the usage data as applied in Steps 2f and 2g then makes it extremely likely that a listed species will receive a LAA determination, whether a listed species or critical habitat has the potential to be exposed to a pesticide.

Overall, CLA believes that a thorough review of the compounding conservatism of the BE within the context of the usage data application and impacts on the likelihood of exposure is urgently needed.

4.3 Modeling

4.3.1 Magnitude of Effect Tool

When preparing a software tool, such as the MAGtool, that is to be used in the regulatory environment, it is critical that the tool is transparent, scientifically well supported, and provides some measure of confidence in the output. Without these qualities, any regulatory decisions based on the output of the tool could be considered arbitrary and capricious. To this end, it is important that the Agency provide all information required to operate and understand the MAGtool. Unfortunately, this is not the case with the MAGtool version used to support the Draft Triazine BEs. Examples of this are provided below.

The Agency did not clearly indicate which version of the MAGtool was used for that Draft Triazine BEs and the specific differences between the versions (Atrazine, Simazine, and Propazine Registration Review; Draft Endangered Species Act Biological Evaluations, 2020). The version of the MAGtool used for the Draft Triazine BEs appears to be version 2.2. However, documentation included with the atrazine MAGtool indicates it is version 2.1. In the draft atrazine BE, Chapter 1, the Agency indicates that version 2.2 was used: "For exposure in terrestrial habitats, the MAGtool (version 2.2) is used (additional details in Attachment 1-1 and tool documentation)" (EPA, 2020a). In addition, the reader must read large sections of the BE to determine how MAGtool v2.2 differs from the former version and how to operate the updated tool.

There are numerous additional transparency issues with the MAGtool v2.2 that make evaluation difficult. For example:

- In the *Mag_TerrTool_v2.xlsm* workbook, the 'Habitat' worksheet refers to the Terrestrial Plant Model (TerrPlant) and SWCC (Surface Water Concentration Calculator) as being the exposure model(s) used to evaluate exposure for terrestrial and wetland plant species. This appears to be no longer the case in the MAGtool v2.2.
- In the *Mag_TerrTool_v2.xlsm* workbook, the "README" worksheet describes how the "tool is currently only set to run for either carbaryl or methomyl." No mention is made of atrazine, simazine, nor propazine, thus leading the reader to question the validity of the model for use with the triazines.
- In the *Atrazine WoE Input Parameters.xlsx* workbook, the "README" worksheet indicates "information below provides instructions", yet no instructions are provided.

The MAGtool relies on a group of pre- and post-processing tools to operate from start to completion (see Figure 1 for a simplified version of the MAGtool v2.2 architecture). Figure 1 does not capture the datasets, CDL or other software that are required for the pre-processing tools to operate.

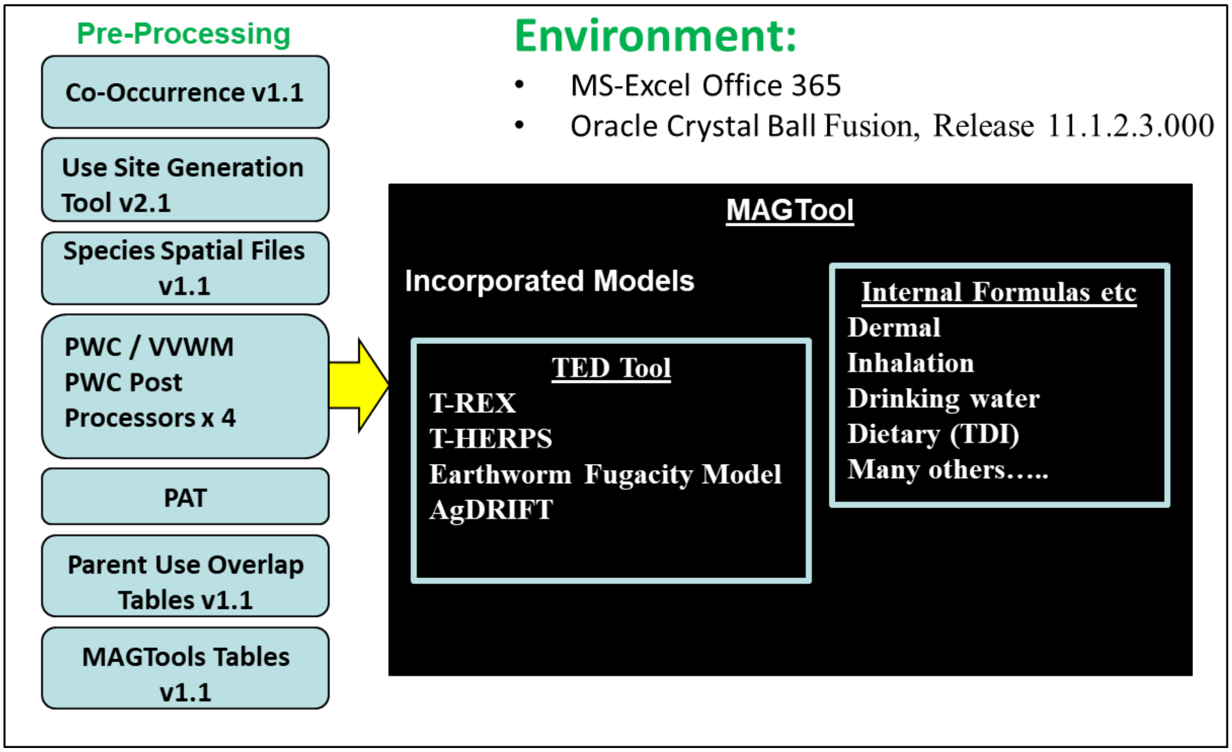

Figure 1. MAGtool v2.2. generalized architecture.

One of the key requirements for operating the MAGtool is the need for specific versions of Microsoft Excel and Crystal Ball. Although the Agency provides information on Crystal Ball, it does not indicate that Excel 2019 or higher is required to operate the MAGtool, which has some updated functions that make the tool incompatible with older versions.

There are no quality control (QC) and quality assurance (QA) processes designed specifically for the MAGtool in any of the documentation. EPA does document, in a limited way, some of the QA processes used to review data intended for use in the MAGtool. However, there is no documentation on MAGtool development QA (*e.g.*, for Visual Basic for Applications or Python coding), Excel workbook and worksheet design and development, error checking, and other QA processes. There is no documentation on quality control approaches for each version and/or chemical where the MAGtool has been applied. The lack of a formal QC process is visible in the many errors detected in the draft atrazine BE. For example, the endpoints for terrestrial monocots and dicots are as follows:

- Monocot – Onion (*Allium cepa*) = IR15 = 0.018 lb a.i./A [MRID 49639102]
- Dicot – Soybean (*Glycine max*) = IR15 = 0.0011 lb a.i./A [MRID 49639102]

However, in the MAGtool, EPA reversed these values such that the monocot IR15 was 0.0011 lb a.i./A and the dicot IR15 was 0.018 lb a.i./A. This is a critical error which invalidates the effects determination conclusions for all listed terrestrial monocot and dicot plant species.

Many other errors and issues were also observed in the MAGtool in all the Draft Triazine BEs. The names of the steps in the MAGtool output files do not correspond with what was defined in the EPA's Revised Guidance. For instance, the Revised Method defines Step 2a as "Is the exposure pathway incomplete?" but the same step in the MAGtool output is listed differently, as "Step 2a (<1% overlap) - NLAA results" (EPA, 2020a).

Another example is a misdirect error in a formula affecting the determination of whether incident reports were available in the weight-of-evidence analysis template (Figure 2).

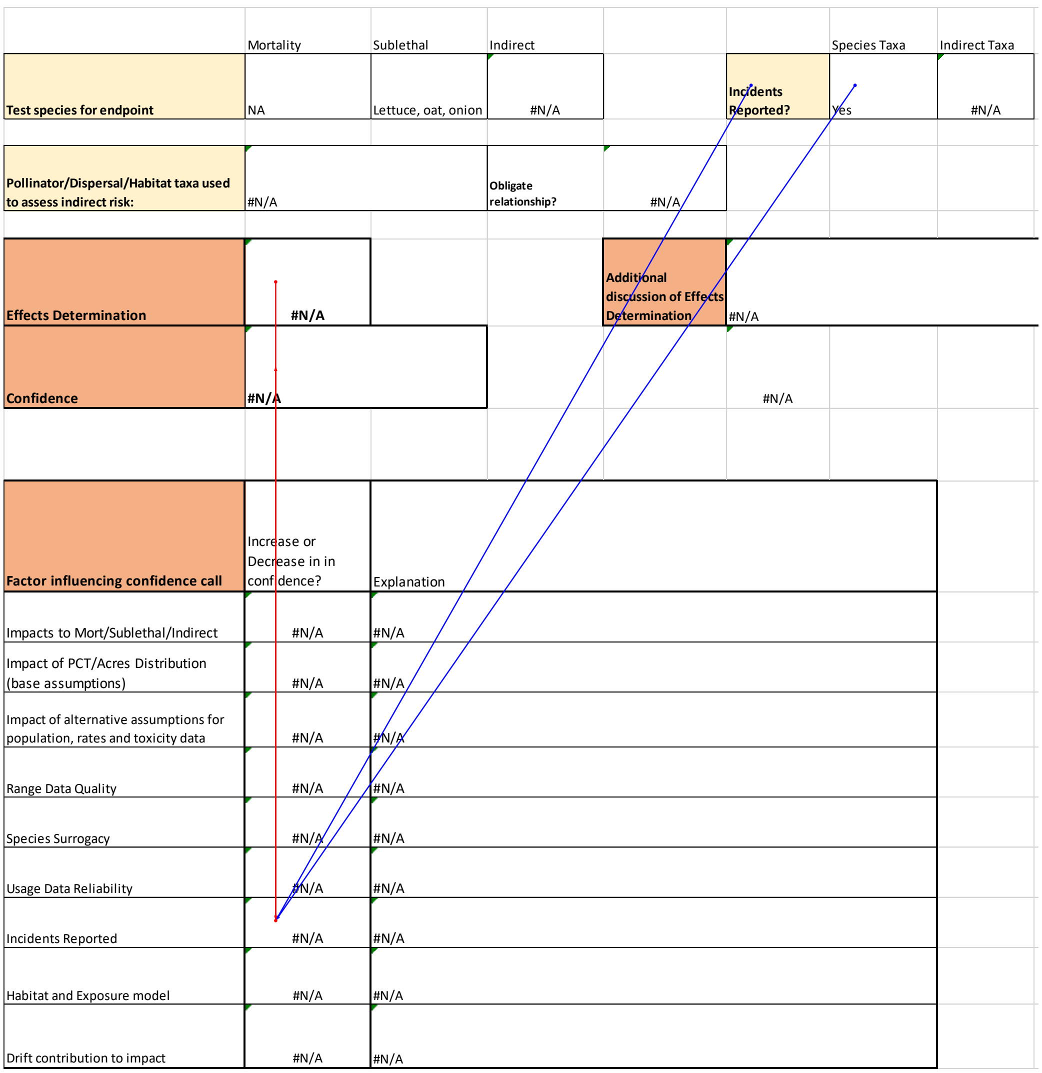

Figure 2. Excel precedents (red arrow) and dependents (blue arrows) for Cell C49 in the "CB output template_Terr Plants_Effects determinations" workbook in the "Output by Species" worksheet.

These, among other errors reduce confidence in the MAGtool outputs and ultimately the findings of the Draft Triazine BEs. These errors must be addressed prior to finalizing the Triazine BEs and providing the output to the Services for their review and analysis. It is clear from the above comments that the development of comprehensive documentation, and the presentation of formal QA/QC results for the MAGtool would be a significant step in untangling issues with the tool and make its results reproducible and defensible.

4.3.2 Plant Assessment Tool

The Plant Assessment Tool (PAT) replaced TerrPlant in the MAGtool v2.2 that was used for the Draft Triazine BEs. The PAT model considers runoff and spray drift exposure to terrestrial and wetland environments using mechanistic representations of fate and transport. The documentation provided with the PAT model does not necessarily correspond to the version of PAT used in the Draft Triazine BEs. EPA provides a copy of a document user guide for Version 1.0, but other documents suggest that the PAT model is version 2.0. It is unclear whether there have been changes from version 1.0 to version 2.0 of the PAT model and what those may have been, and which was applied in the Draft Triazine BEs.

Since the PAT is not integrated into the MAGtool and requires other EPA models and processors to function, learning how to use the PAT model to prepare inputs necessary for the MAGtool v2.2 is complex and time-consuming. Significant time and resources are required to generate, quality control and quality assure the results. This was not possible within the public comment period, given that the PAT tool output is applied within the significantly more complex MAGtool. CLA recommends an up-to-date and comprehensive documentation of the model that would allow for a more rigorous and efficient evaluation.

Although our initial impression is that the PAT model represents an advancement over the simplistic TerrPlant model, it is clearly a new EPA model. It should undergo review by the Scientific Advisory Panel as is normal practice before use in a significant regulatory assessment. We strongly recommend that such a review be conducted before finalizing the Draft Triazine BEs to ensure transparency and that the model is scientifically defensible and functions properly.

4.4 Probabilistic Methods

CLA continues to advocate for probabilistic methods in the development of biological evaluations. Screening-level deterministic methods are used in Step 1 in the Revised Methods to identify listed species that are potentially at risk (*i.e.*, May Affect or No Effect) from exposure to an active ingredient (EPA, 2020f). The methods are deliberately and overly conservative to reduce the likelihood of Type II errors (failure to reject a false null hypothesis of *de minimis* risk), but correspondingly increase Type I errors (falsely reject a null hypothesis of *de minimis* risk). However, this approach does not allow for an evaluation of whether exposure or effect was discountable, insignificant, or reasonably certain to occur. As implemented, Step 1 leads to large numbers of listed species and critical habitats receiving a May Affect determination requiring consultation with the Services rather than prioritizing listed species that may be adversely affected by the specific pesticide. This reduces the likelihood that pesticide-related federal actions (*e.g.*, registrations, registration review) can proceed in a timely manner. The approach immediately places the resource and administrative burden on the Services, which have fewer resources and less expertise than the Agency on pesticide issues. CLA has submitted extensive comments documenting the benefits of using probabilistic methods (CLA, 2020a).

4.5 A Robust Weight-of-Evidence Approach

In our comments on the Draft Carbamate BEs, CLA highlighted many of the flaws with the approach to weight-of-evidence in the Revised Method (CLA, 2020b). Those comments are also applicable to the Draft Triazine BEs. Therefore, it is critical that other lines of evidence are considered in Steps 1 and 2 to provide appropriate context prior to making effect determinations. There is considerable documentation available on conducting qualitative and quantitative weight-of-evidence analyses for regulatory decision making (Hall et al., 2017; Linkov et al., 2009; Lutter et al., 2015; Society of Environmental Toxicology and Chemistry, 2018). Risk assessments on listed species have also been conducted with a weight-of-evidence component and illustrate how lines of evidence, including the modeling lines of evidence, are incorporated into the risk characterization to inform the effect determinations (Brain et al., 2015; Clemow et al., 2018; Moore et al., 2016).

EPA's reliance on the MAGtool precluded incorporation of the many available higher tier refined studies in the weight-of-evidence assessment for atrazine. For example, numerous microcosm and mesocosm studies have been conducted to determine the effects of atrazine on aquatic plant communities. These studies have been the subject of many reviews by EPA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panels and others (FIFRA Scientific Advisory Panel; Notice of Public Meeting, 2012; Giddings et al., 2018; Moore et al., 2017). Yet, as far as we could determine, no mention was made of these studies in the draft atrazine BE, nor were they considered in the weight-of-evidence assessments for listed plant species or other listed species that depend upon aquatic plants for habitat or food.

Another example of not applying higher tier refined studies involves the preclusion of field studies that estimate spray drift effects. EPA's standard approach for estimating spray drift effects to downwind plant communities, as applied in the MAGtool for atrazine, overestimated impacts measured in a real-world field study (Brain et al., 2019). While the study was clearly conducted under worst-case conditions, EPA dismissed it as relevant only to the location and conditions under which it was conducted (EPA, 2020a). Incorporation of this information into the atrazine BE would represent a significant improvement to the weight-of-evidence assessments for listed terrestrial plant species and to listed species that depend on terrestrial plants for habitat and food.

Since 2004, EPA has overseen the Atrazine Ecological Monitoring Program (AEMP). This program conducts frequent sampling of atrazine concentrations targeting the most vulnerable watersheds in corn, sorghum, and sugarcane growing areas of high atrazine use. The program has determined worst-case exposure with minimal uncertainty of missing peak concentrations. EPA did mention the AEMP in the draft atrazine BE (EPA, 2020a), but did not use the available monitoring data to evaluate model performance, other than a simple comparison of model-predicted ranges to observed monitoring data ranges. Despite the availability of this comprehensive AEMP dataset for atrazine, EPA relied exclusively on their standard Pesticide in Water Calculator (PWC) exposure modeling system to predict atrazine concentrations in aquatic bins of varying pesticide concentrations in the draft BE. EPA failed to take advantage of the extensive, targeted monitoring dataset for atrazine in surface waters of the Midwest, which represents an exclusion of best available data in the draft atrazine BE weight-of-evidence analysis.

4.6 Uncertainty

The Agency applied numerous conservative assumptions to account for perceived uncertainties in the Draft Triazine BEs. The documentation of uncertainty and directional implications of these assumptions is important. In the absence of data, or in the presence of naturally variable data, a risk assessment must use reasonable and conservative assumptions that account for this uncertainty. This is a requirement of the ESA regulations, to ensure that any evaluation of exposure that could achieve a level causing adverse effects is reasonably certain to occur (Consultation Procedures, 2019). Compounded conservative assumptions throughout the Draft Triazine BEs lead to unrealistic exposure estimates that are not reasonably certain to occur. It is critical to communicate in a transparent way how each of the conservative assumptions and the combined assumptions alone and in combination affect the magnitude and direction of the risk estimates.

Table 2 lists assumptions excerpted from an Agency FIFRA risk assessment illustrate how the Agency could tabulate sources of uncertainty in the draft atrazine BE and future BEs (EPA, 2015).

Table 2. Examples of uncertainty sources and their impact on risk estimates for sulfonylurea pesticides (from EPA, 2015)

Assumption	Directional Implications
100% efficiency of applications	Assumption that 100% of applications reach soil and are subject to runoff and partially drift away from field inflates the assumed level of off-site exposure.
Most sensitive species endpoint used	Likely to overestimate the potential for effect because there is no evidence that listed species are generally more sensitive than tested species.
Runoff and drift are uniform dispersing from the target area	Assumption overestimates the actual level and significance of potential exposure because dispersion is understood to occur in a gradient from treated area and will become more sporadic at greater distances.
Adsorption desorption and degradation kinetics	The assumed soil or water DT_{50} and soil absorption coefficient used in modeling off-site movement of chemical is a conservative value obtained from laboratory studies. The potential for leaching, or off-site movement of chemical may be over-estimated. The range in measured values was *x*, the value used in modeling was *y*, if the least conservative measured values were used the estimate would be *z*. There is uncertainty because not all soils are tested.
No degradation is assumed in runoff or drift	For some chemicals with more rapid degradation kinetics this assumption may overestimate exposure.
Test species exposure is representative of field exposure	Actual exposure may be reduced or increased by animal behavior. In field exposure, there is greater choice of food items. There may be repellency or attraction to food items intentionally or unintentionally treated with a chemical.
Maximum rates used	Likely to overestimate exposure potential. Where a use rate range is stipulated on the label, the highest rates are normally used only in instances of high severity of pest infestation or for difficult to control pests. This situation would almost never occur simultaneously in every field and on every crop.
Wind is blowing at maximum speed perpendicular to plant exposure zone. There is no interception of spray by near-field vegetation.	Likely to overestimate exposure potential at greater distances from the edge of a treated field. Wind is not constant in speed and the wind conditions for spraying legally are stipulated on the label. The wind direction relative to a treated field will vary. Wind breaks adjacent to a treated field will intercept spray drift and reduce potential exposure further downwind.
Default half-life of 35 days is used for foliar dissipation.	Likely to overestimate potential for chronic exposure. Many substances are known to degrade at a faster rate, the emergence of new vegetation will dilute the chemical residue on treated foliage.

The Agency did endeavor to identify sources of uncertainty in the Draft Triazine BEs but provided an incomplete picture of their impact. For example, in Chapter 4 of the draft atrazine BE:

> There are uncertainties in the spatial footprint associated with the non-agricultural uses (*e.g.*, turf uses) of atrazine and there are limited data available to inform the extent of usage in any given area for these types of uses. Another important uncertainty is that the available range data for some listed species are at the sub-county level, with boundaries that are biological in nature, while others follow geopolitical boundaries, such as county or state lines. Species with overly broad ranges that include habitats the species would not utilize lead to uncertainties in effects determinations (EPA, 2020a).

The Agency did not explain how uncertainty in the spatial data resolution affects the characterization of risk and effect determinations for each of the listed species and critical habitats. In many cases, the potential for exposure was vastly overestimated at Step 1a, triggering the Services consultation due to the automatic May Affect determination.

Another example involves the application of usage data:

> Usage data are available at the state, region, or national level while species' range or critical habitat information are at the sub-state level. To address the difference in scale, we made several assumptions with respect to where pesticide-treated acres could occur relative to a species' habitat (*e.g.*, all treated acres occur within the habitat, evenly dispersed throughout the state, or primarily outside of a species habitat)(EPA, 2020a).

Again, EPA did not explain how this uncertainty affected the risk characterization and effect determination. In this case, the assumption that all treated acres occur within the species habitat significantly overestimates exposure for each species evaluated. Unfortunately, EPA appears to have based most of their NLAA or LAA determinations on this assumption.

There are many other examples that are not documented by EPA in the Draft Triazine BEs. Because these assumptions and their impact are not discussed in a transparent way in the BE, the results and conclusions cannot be evaluated or considered as "reasonable" within the context of the ESA regulations. In a recent study commissioned by CLA (manuscript in prep) on uncertainties in risk assessments, the following recommendations and conclusions were identified:

- A plan for assessing uncertainty should be established within the problem formulation of the ecological risk assessment,
- The effort put into an uncertainty analysis should be progressive relative to the nature and tiers of the ecological risk assessment,

- Prioritize major uncertainties by determining those sources most likely to impact the assessment, and
- Qualitative and quantitative methods are necessary to account for uncertainty depending on its nature.

Risk managers are better equipped to use a risk characterization for informed decision making if uncertainty is conveyed along with risk assessment conclusions (CLA, 2021). As noted in the document conclusions, risk characterizations presented without appropriately characterizing the impact of uncertainties leave ecological risk assessments vulnerable to scientific criticism and legal challenges. They also greatly diminish the ability to prioritize advanced assessment of the mitigation strategies to protect potentially vulnerable species.

5 CONCLUSION

The Draft Triazine BEs require revisions to address the identified errors and issues as reported in these comments. The relatively short comment period means additional shortcomings may yet be identified. We note the following overarching concerns:

1. Refined data are ignored or marginalized and inadequately considered as available lines of evidence, thus limiting confidence in species-specific effect determinations.
2. Highly conservative assumptions are used to address uncertainty at each Step, leading to compounding conservatism throughout the BE and thus unrealistic exposure and effect characterizations.
3. New and revised complex models employed by the Agency to implement the Revised Method lack adequate peer review, documentation, and QA/QC procedures, reducing confidence in the findings.

Overall, the review of the Draft Triazine BEs lead to the following conclusions:

1. The Revised Method process as implemented by the Agency is not a workable, legally defensible, or sustainable approach to risk assessments for listed species.
2. The process fails to identify listed species and their critical habitat that may reasonably be expected to be adversely impacted by a pesticide and therefore impedes the identification and development of appropriate corresponding risk mitigations.
3. The MAGtool and PAT should be reviewed by the Scientific Advisory Panel as is normal practice before use in a significant regulatory assessment.
4. EPA should consider label restrictions, state and federal requirements, mitigation practices, and conservation approaches during the BE process which benefit the listed species. This lack of inclusion impedes the identification and development of further risk mitigations.

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