



March 12, 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-2020-0585

Re: Comments on Registration Review: Glyphosate; Draft Endangered Species Act Biological Evaluations, EPA-HQ-OPP-2020-0585; 85 Fed. Reg. 76071 (November 27, 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 Glyphosate (the Draft Glyphosate BE) 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](mailto:mbasu@croplifeamerica.org) or (202) 296-1585.

Sincerely,

A handwritten signature in black ink, appearing to read "Manojit Basu", with a horizontal line underneath.

Manojit Basu  
Managing Director, Science Policy  
CropLife America

CC: Ed Messina, Acting Director, EPA OPP  
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# **CropLife America Comments on the Draft Biological Evaluation for Glyphosate**

(EPA-HQ-OPP-2020-0585)

**DATE: MARCH 12, 2021**

## 1 EXECUTIVE SUMMARY

The Draft Biological Evaluation for Glyphosate (the Draft Glyphosate BE) was developed under the Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides (the Revised Method), released in March 2020. The Draft Glyphosate BE, like the draft carbaryl and methomyl BEs (collectively the Draft Carbamate BEs) and the draft atrazine, simazine, and propazine BEs (collectively the Draft Triazine BEs), reinforce the fact that the Environmental Protection Agency (EPA or the Agency) has not yet reached a workable, consistent, and sustainable approach to conduct assessments for listed species and their critical habitats.

In the Preamble to the draft Revised Method, the Agency told the public that the pilot method 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 Glyphosate BE, the Agency has made incremental progress, but the major limitations cited as rationale for revising the Interim Approaches for National-Level Pesticide Endangered Species Act Assessments are largely uncorrected, and, in some ways, these deficiencies have compounded.

CLA recommends that the Agency make a significant effort in the final glyphosate BE to reduce the level of compounding conservatism in the assessment, accurately incorporate use and usage information, ensure modeling tools are properly verified, and establish whether pesticide exposure can cause affect that is reasonably certain to occur as described in the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service's (NMFS)(the Services collectively) new Endangered Species Act (ESA) regulation (Consultation Procedures, 2019).

In the Draft Glyphosate BE, 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 incorporate 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 have insufficient

documentation. A thorough review and scientific evaluation of the tools used in the Draft Glyphosate BE should be undertaken prior to their application in the final BE.

The weight-of-evidence approach applied in the Draft Glyphosate BE and as outlined in the Revised Method ignores lines of evidence that should be considered on a species-specific basis. CLA strongly recommends revision of the weight-of-evidence approach in developing the BEs by either removing the “strongest, moderate, or weakest” confidence statement or using them to update an effect determination.

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 Glyphosate BE in November 2020 (EPA, 2020c). The Draft Glyphosate BE applied the Revised Method, a new version of the MAGtool, and the PAT. CLA reviewed the Draft Glyphosate BE 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 Glyphosate BE.

## 3 POLICY CONSIDERATIONS FOR THE AGENCY

### 3.1 Reasonably Certain to Occur

CLA believes that EPA must make significant efforts on the final glyphosate BE to overcome persistent deficiencies in its analyses and meet EPA's own stated expectations for improvements to be delivered by its Revised Method (EPA, 2020j). There is little evidence in the Draft Glyphosate BE, 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 Glyphosate BE. Instead, the implementation of the first Step of the Revised Method simply examines: whether exposure could occur, based on species range data overlap with action area; effect thresholds; and highest estimated exposure concentration (EEC) predicted for the species in the terrestrial and/or aquatic environment. Ultimately, if the EECs exceed the thresholds for direct or indirect effects, then a May Affect determination is made. This deterministic approach is inconsistent with Interagency Cooperation Regulation from the Services and the National Academy of Sciences Panel Report (Consultation Procedures, 2019; National Research Council, 2013).

Without broader consideration of specific individual exposure scenarios for each of the listed species, species life histories, factors that may mitigate exposure, and the probability of exposure occurring given appropriate historical use and usage data in Step 1, 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 the Draft Carbamate and Triazine BEs, EPA's Draft Glyphosate BE fails to reflect the revisions to the regulations for Interagency Cooperation for the Services (CLA, 2020b). The revisions to the regulations for Interagency Cooperation for the Services modified the definition of "effects of the action" in ways fundamental to EPA's BE process. The new definition clarified how EPA must evaluate whether an action

“may affect” 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” (EPA, 2020i). However, this change has not been implemented by EPA in the Draft Carbamate, Triazine, or Glyphosate 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 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, 2020i). Despite the Services’ guidance and EPA’s pledge to implement these changes, EPA failed to base the analysis and conclusions in the Draft Glyphosate BE 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 glyphosate is Not Likely to Adversely Affect (NLAA) an individual for a substantial number of listed species and critical habitats.

### **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 Glyphosate 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 93% of listed species analyzed will have to be further assessed by the Services. Table 1 summarizes the results from the Draft Glyphosate BE for the total of 1,795 listed species. Step 1 resulted in No Effect determinations solely because the potential use footprint for glyphosate is incorrect. For example, EPA represents the aquatic Use Data Layer (UDL) for glyphosate as “all aquatic area under US jurisdiction” (EPA, 2020c). This assumption is incorrect as glyphosate application is only permitted on emergent vegetation. Further, due to the incorrect use assumptions and a lack of consideration of species-specific information, all species and critical habitats received a May Affect determination, compelling consultation with the services under ESA Section 7. Formal consultation due to the assignment of a May Affect/LAA determination is required for 1676 listed species and 759 critical habitats.

**Table 1. Summary of effect determination results in the Draft Glyphosate BE (From EPA, 2020c – Appendix 4-1)**

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=0	NLAA=45	NLAA=15	NLAA=9 LAA=4	NLAA=45 LAA=2	NLAA=0	NLAA=0	NLAA=5 LAA=1670
Critical Habitats (792)	NE=0	NLAA=19	NLAA=0	NLAA=0 LAA=0	NLAA=14 LAA=2	NLAA=0	NLAA=0	NLAA=0 LAA=757

Throughout the Draft Glyphosate BE there are several incorrect assumptions in the data layers generating unrealistic outcomes. Due to these assumptions, all most all the listed species and critical habitat that moves through the Revised Method as implemented using the MAGtool, receive a LAA determination. Generally, 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); is thought to be extinct (Step 2b); or if the exposure modeling is considered unreliable (Step 2d)(EPA, 2020c). This conclusion is also supported by the results of the Draft Carbamate BEs and the Draft Triazine BEs (EPA, 2020b, 2020d, 2020a, 2020f, 2020e). This approach does not protect listed species or their critical habitats within the context of pesticides because it fails to accurately identify listed species and their critical habitat that may be reasonably certain to be adversely affected by a pesticide.

Appendix 4-8 in the Draft Glyphosate BEs provides 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 and should be applied much earlier in the assessment process. For example, as stated in the Draft Glyphosate BE, no pesticides are applied to the open ocean:

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 glyphosate is not applied directly to the ocean and does not bioaccumulate (EPA, 2020c).

Thus, as previously 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 no possibility of pesticide exposure 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 and 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, 2020j). Such opportunities abound in endangered species assessments and should be addressed, where possible, in the



preparatory stages of BE development. 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. Registrants have broad information about their products, where the best available data are located, and can 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 all the Draft BEs to date demonstrates that we have not yet reached a workable, legally defensible, and sustainable approach to listed species risk assessments (EPA, 2020b, 2020d, 2020a, 2020f, 2020e, 2020c).

### **3.4 Conservation Approaches**

CLA recommends that EPA develop a decision system linking ecological risk assessments with ESA conservation goals. Currently, species conservation is not the focus of the risk assessment. 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. Aligning the risk assessment with the ESA's conservation goals could improve species conservation outcomes (e.g., improved targeting of any voluntary conservation measures that clearly benefit recovery), reduce the complexity of assessments, and present the best path forward to promote biodiversity and conservation.

In developing this decision system to link 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/avoidance 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, 2020j). 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, 2020h). 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 Glyphosate BE, two usage scenarios are applied, a highly conservative scenario based on a maximum PCT, often assumed to equal 100%, 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. The usage data and PCT refinement are intended to improve the distinction between NLAA and LAA species. The usage data as applied in the Draft Triazine, Carbamate, and Glyphosate BEs does not provide the intended refinement because of unrealistic assumptions, miscalculations, and minimization of the most likely usage scenarios (CLA, 2020b, 2021a). One explicit example is how the Agency treated the PCT for the Conservation Reserve Program (CRP). The CRP UDL was assumed to be 100% as glyphosate usage on CRP land was unavailable and coupled with an incorrect footprint for this UDL that resulted in a significant overestimation of co-occurrence with species range and critical habitat. Furthermore, as described in Section 4.3 of Appendix 1-6, an extremely conservative approach was followed for representing the spatial UDL for CRP land (EPA, 2020c). It included all cultivated cropland from the CDL plus the pasture UDL. This represents a massive area treated with glyphosate at maximum label rates. A comparison of the assumed area of the CRP UDL (>700 million acres) in the Draft Glyphosate BE compared to the actual total acres of CRP land based on the USDA's monthly reporting (20,790,541 acres) shows how wildly conservative this assumption is (USDA, 2020).

For glyphosate, other examples of incorrect or unrealistic usage/UDL/PCT assumptions include:

- For agricultural PCTs:
  - Acreage used in calculating treated acres does not account for acres treated more than once in a season, leading 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. A methodology for calculation of PCT must be derived that ensures consistency with annual application rates assumed in the exposure modeling.
  - Ag PCTs and Non-Ag PCTs, the “Maximum/Upper” usage scenario is unreasonably conservative when allocating all state treated acres to occur within every species range/critical habitat. This is the most conservative usage scenario, using the maximum PCT treated acres and assuming all usage in a state occurs within a species range. When the geographic regions representing species ranges/critical habitat are independent (*i.e.*, no overlap), the outcome when looking across multiple species is that treated areas can vastly exceed the intended state-level PCT and associated treated areas for each UDL. This is both unrealistic and unsupportable.
- For non-agricultural uses:
  - The PCT for the Christmas trees UDL was unrealistically assumed to be 100%, leading to an overestimate of co-occurrence with species range and critical habitat. Glyphosate is not used on Christmas trees while actively growing.

The incorporation of usage data into the MAGtool analysis had almost no impact on the outcome of species NLAA/LAA determinations and in refining the confidence calls in the resulting LAA determinations. Of the 1675 species that moved to Step 2f (see Table 1), none were assigned an NLAA determination based on potential exposure and the “maximum/upper” usage scenario. In the weight-of-evidence analysis in Step 2g, 2h, and 2i, when the “average/uniform” PCT scenario is considered, only 5 species out of the 1675 were classified as NLAA, although the less conservative usage data does not appear to be responsible for those NLAA calls. The vast majority of 1676 LAA determinations were classified as moderate evidence (EPA, 2020c).

While bringing usage data into the Draft Glyphosate BE is a strong step in the right direction, the assumptions under which usage data have been analyzed and subsequently incorporated into the MAGtool has led to no refinement in the overall risk assessment. The limited impact to species effect determinations resulting from incorporating usage data into the glyphosate BE is the result of a series of assumptions and miscalculations

resulting in compounding levels of conservatism, many of which were discussed in Section **Error! Reference source not found.** Here, we identify additional factors that contributed to this outcome:

- Determination of NLAA versus LAA is based nearly entirely upon the “worst case” usage scenario while the “Average/Uniform” usage scenario only comes into play in one of the 10 criteria evaluated in the Weight of Evidence analysis.
- The PCT and associated treated area analysis was incorrect, leading to unrealistic MAGtool results.

#### 4.2 Compounding Conservatism

Compounding conservatism in the BE process is a severe weakness and leads to effect determinations that does not meet the ESA standard of “reasonably certain to occur” as described in the Services’ new regulation on consultation procedures (Consultation Procedures, 2019). In Step 1, a No Effect or May Affect determination is partially based on species range/action area overlap, assuming a maximum use rates on the pesticide label 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 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 results in generic unrealistic and highly conservative exposure scenarios for any listed aquatic 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.

Failure to consider spray drift interception causes an overestimate of pesticide exposure for listed species. 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 “glyphosate would have to be transported by wind blowing from the application site toward the beach with little opportunity for interception of spray droplets” (EPA, 2020c). Application of this sort of refined information will result in species-specific effect determinations that are more realistic and reasonable, 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 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 Research Council, 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 that species or its critical habitat has the potential to be exposed to any pesticide.

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

### **4.3 Modeling**

#### **4.3.1 Aquatic Exposure Modeling**

The aquatic exposure modeling conducted in the Draft Glyphosate BE relied on EPA's established regulatory exposure modeling scenarios to represent a wide range of aquatic habitat, with a few relatively new approaches (edge of field and wetland) to represent some habitats. Several aspects of the modeling approach could be improved to better represent some types of aquatic habitat, as well as to produce refined exposure distributions that are relevant to individual species ranges and critical habitat. Examples are listed below:

- The edge of field EECs do not appropriately represent Bin 2 (low flow) water bodies. The edge-of-field concentrations from the Pesticide Root Zone Model (PRZM) were used to represent EECs in these low flow habitats. More refined exposure distributions relevant to individual species ranges and critical habitats need to be generated for these habitats.
- Use of the Index Reservoir for Bin 3 and Bin 4 water bodies does not account for important watershed processes applicable to these flowing water habitats. The aquatic exposure modeling for moderate and high flow water bodies was based on the Index Reservoir scenario. Hydrologically, the Index Reservoir is very different than a free-flowing river. The hydrological data and models are available to refine flowing water body EECs on a species-specific basis.
- For all aquatic bins, the EECs do not account for application timing variability, Percent Cropped Area (PCA) variability, use pattern variability, and actual usage. The aquatic EECs for all habitat bins assume synchronous applications within a watershed, 100% PCA, and 100% PCT. While the use pattern for glyphosate encompasses nearly all possible terrestrial and aquatic land cover within the

US, the use patterns and timing of applications is variable, and combinations of different land cover and crops within a watershed varies as well. The actual PCT for different potential use sites also varies substantially across the relevant glyphosate UDLs. All these factors can be accounted for in parameterizing watersheds associated with all aquatic habitat bins.

- The spatial resolution of exposure scenarios at the Hydrologic Unit Code (HUC) 2 scale is insufficient to characterize species-specific exposure. A single PRZM landscape scenario per crop group, and either one or two weather stations, are selected to represent exposure in each HUC2. Because of their large size, HUC2 watersheds cover very diverse climatological regions. Particularly in the western contiguous US HUC2s, a species range may be constrained to drier or wetter portions of the HUC2. As precipitation is one of the most important parameters required to estimate aquatic exposure magnitude, it is important that climate inputs to PRZM simulations reflect that of a species range or critical habitat.

We understand that aquatic exposure modeling is complex and needs to be significantly refined particularly at Step 2. CLA recommends EPA to organize a joint workshop with all stakeholders for identifying existing models (e.g., Soil and Water Assessment Tool), and scenarios to capture the magnitude of exposure more realistically for aquatic species.

#### 4.3.2 Magnitude of Effect Tool

A software tool that will be used in the regulatory environment, such as the MAGtool must be transparent, scientifically well supported, and must provide some measure of confidence in the output. Otherwise, regulatory decisions based on the output of the tool could be considered arbitrary and capricious. It is important that the Agency provide all information required to operate and understand the MAGtool.

There are numerous issues with the MAGtool documentation that make evaluation difficult. For example:

- In the Draft Glyphosate 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, 2020c). However, the documentation indicates it is version 2.1. In addition, the reader must read large sections of the BE to determine how MAGtool v2.2 differs from the former version and get limited instructions on how to operate the updated tool.
- In the *Mag\_TerrTool\_v2.2.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\_v2.2.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 glyphosate, thus leading the reader to question the validity of the model for use with glyphosate.

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 (e.g., CDL) or third-party software (e.g., ESRI ArcGIS) that are required for the pre-processing tools to operate nor does it capture the post-processing scripts required to collect and format MAGtool results.

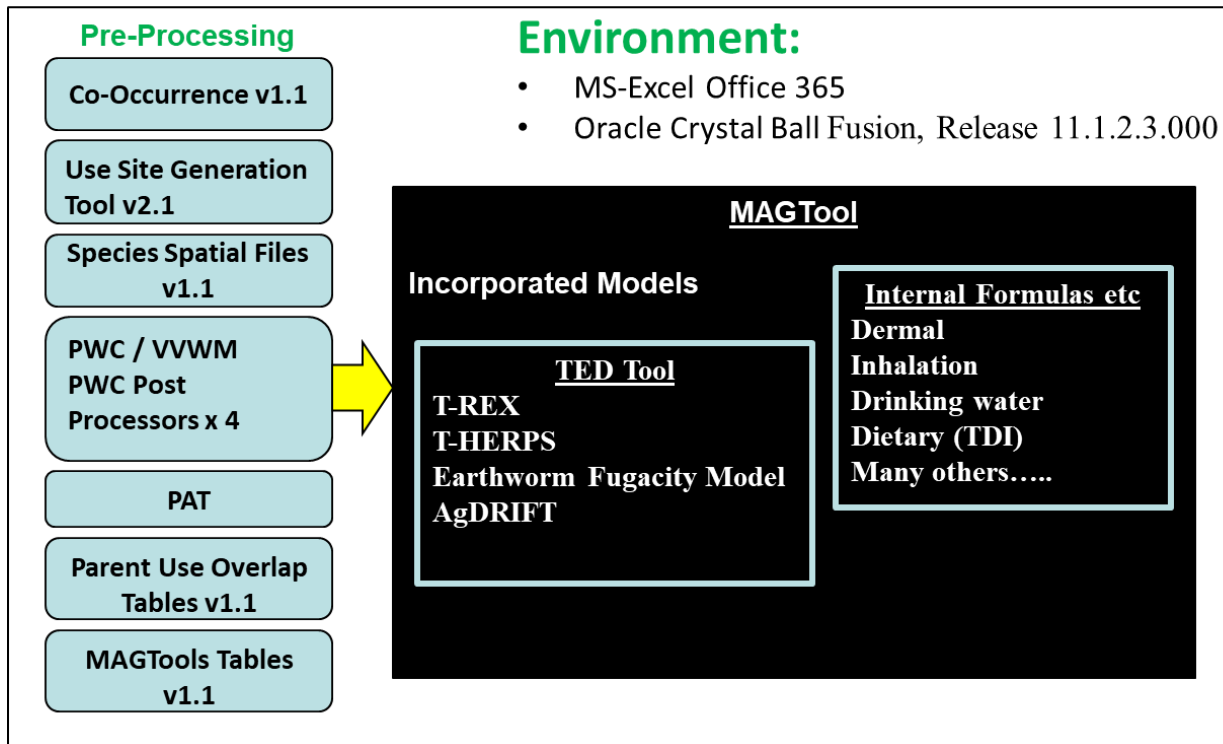


Figure 1. MAGtool v2.2. generalized architecture.

The MAGtool requires 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. In a limited manner, EPA does document 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 for Python coding), Excel workbook and worksheet design and development, error checking, and other QA processes. There is no documentation on QC approaches for each version and/or chemical where the MAGtool has been applied. The lack of a formal QC process is

evidenced by the many errors detected in the Draft Glyphosate BE. For example, the endpoints for terrestrial monocots and dicots are as follows:

- Monocot – Wheat (*Triticum aestivum*) = MATC = 0.086 lb a.i./A
- Dicot – Radish (*Raphanus sativus*) = MATC = 0.07 lb a.i./A [MRID 49639102]

However, in the MAGtool (*Mag\_TerrTool\_v2.2.xlsm* - 'Inputs' worksheet), EPA reversed these values. This is a critical error which invalidates the effect determination conclusions for all listed terrestrial monocot and dicot plant species.

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



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).

	Mortality	Sublethal	Indirect		Species Taxa	Indirect Taxa
Test species for endpoint	NA	Lettuce, oat, onion	#N/A	Incidents Reported?	Yes	#N/A
Pollinator/Dispersal/Habitat taxa used to assess indirect risk:	#N/A		Obligate relationship?	#N/A		
Effects Determination	#N/A			Additional discussion of Effects Determination	#N/A	
Confidence	#N/A				#N/A	
Factor influencing confidence call	Increase or Decrease in in confidence?	Explanation				
Impacts to Mort/Sublethal/Indirect	#N/A	#N/A				
Impact of PCT/Acres Distribution (base assumptions)	#N/A	#N/A				
Impact of alternative assumptions for population, rates and toxicity data	#N/A	#N/A				
Range Data Quality	#N/A	#N/A				
Species Surrogacy	#N/A	#N/A				
Usage Data Reliability	#N/A	#N/A				
Incidents Reported	#N/A	#N/A				
Habitat and Exposure model	#N/A	#N/A				
Drift contribution to impact	#N/A	#N/A				

**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 and other errors reduce confidence in the MAGtool outputs and ultimately the findings of the Draft Glyphosate BE. These errors must be addressed prior to finalizing the glyphosate BE and providing the output to the registrant and Services for their review and analysis. Development of comprehensive documentation and presentation of formal QA/QC results for the MAGtool would be a significant step in untangling issues with the tool.

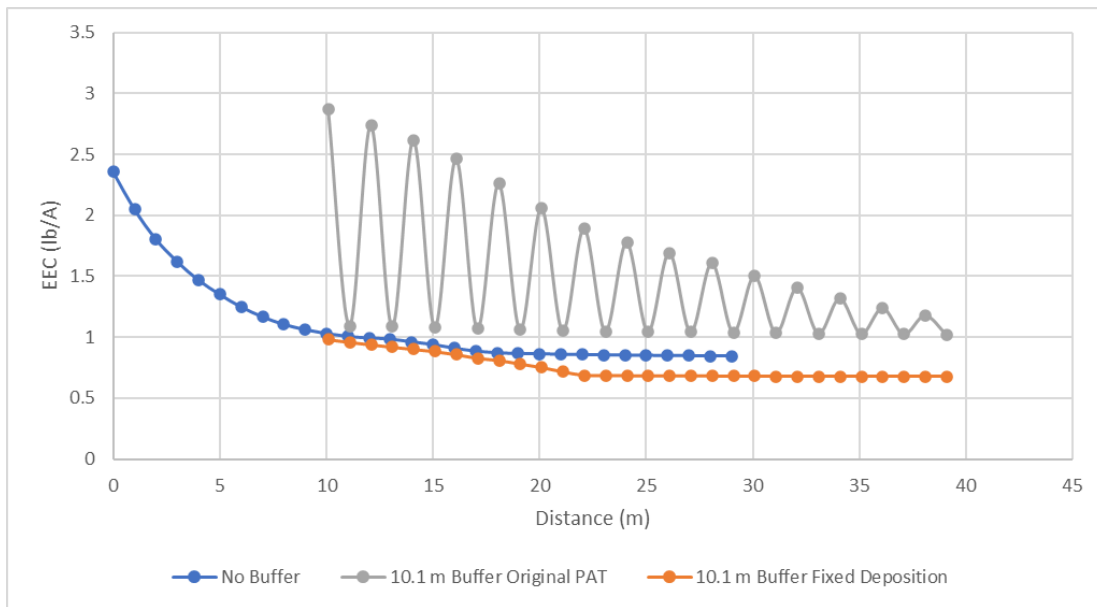
### 4.3.3 Plant Assessment Tool

The PAT replaced TerrPlant in the MAGtool v2.2 that was used for the Draft Triazine BEs and the Draft Glyphosate BE. Specific concerns about the PAT and the technical approaches used in the Terrestrial Plant Exposure Zone (T-PEZ), and Wetland Plant Exposure Zone (W-PEZ) modules are discussed herein.

#### 4.3.3.1 PAT and Glyphosate

There are several issues that have been identified in our evaluation of the PAT tool, as distributed by EPA, with the Draft Glyphosate BE. Many of these involve issues of transparency although there are some technical concerns and errors as identified in the bullets below:

- In the manual, PAT is described as a stand-alone model that uses existing algorithms from the PRZM and the Variable Volume Water Model. AgDRIFT is used to calculate off-target spray deposition to areas adjacent to the treated field. The individual components of the model must be setup and run before PAT can be executed. This can lead to user errors because the user must point PAT to the required individual files. In addition, PAT uses drift curves exported by AgDRIFT, but the algorithms themselves are not used for calculating off-target spray deposition. Instead, PAT uses its own erroneous function to calculate spray deposition (see comment below). Therefore, PAT is not a stand-alone model and needs a thorough scientific review.
- The PAT uses several external libraries. For transparency and to facilitate making results reproducible, the version numbers of the external libraries should be provided.
- The function “get\_sdf” is coded in an overly complicated manner and yields incorrect results for buffer distances greater than 0 m. For buffer distances that are not integers, the calculated deposition oscillates between the 1-m increments resulting in deposition values and EECs that are more than factor 2 higher than the results obtained with a 0 m setback distances. An example of the impact of the output is shown in Figure 3. It is not clear to what extent setback distances were used in the Draft Glyphosate BE. However, this error could have a significant impact on the NLAA/LAA determination. The error emphasizes the lack of a thorough QA/QC review nor a scientific-technical review. Other parts of PAT such as the T-PEZ pesticide transport and fate calculations are more complicated to review. A thorough review and evaluation is required prior to use of PAT use in pesticide risk assessments and BEs.



**Figure 3. 1-IN-10 Annual Maximum EECs Using No Buffer, A Buffer of 10.1m with the PAT Default Code, and a Buffer of 10.1 m with a Fixed Spray Drift Deposition Algorithm.**

4.3.3.2 Terrestrial Plant Exposure Zone

The T-PEZ conceptual model is intended to represent a non-target terrestrial plant community adjacent to a treated field, that is exposed to pesticide via spray drift and runoff. The vegetation zone itself may consist of various plants. There are several concerns with how the T-PEZ module is used to generate exposure estimates. These include:

- The model assumes that all runoff from the field enters the T-PEZ as sheet flow and does not account for many influential site-specific factors, such as slope, surface roughness, and flow path length (as acknowledged in the PAT manual). These factors may vary greatly among application sites (e.g., row crops, vegetables, orchards, hay, pasture). PAT does not account for site specific field management practices (e.g., terracing, contour farming, runoff and erosion controls, irrigation/drainage ditches, rills, and creeks) which may significantly reduce sheet flow runoff into the T-PEZ.
- Section 3.1 of the PAT manual has contradictory statements regarding the location of the T-PEZ relative to a treated field. The buffer/setback parameter in PAT has no impact on runoff loadings (EPA, 2020g). Based on the contradictory statements, it is not clear whether the T-PEZ is always assumed to be immediately adjacent to a field or if there can be a buffer between the treated field and the exposure zone. This requires clarification.

- The function calculating spray drift deposition automatically sets drift deposition to zero beyond a setback distance of 997 ft. This prevents the assessment of aerial applications for terrestrial habitats that are expected to be further away than 997 ft.
- A more realistic water balance algorithm needs to be implemented into the PAT terrestrial module. This algorithm should acknowledge that runoff and infiltration are dependent of soil saturation and many other factors (e.g., soil hydraulic conductivity, slope, surface roughness). In addition, other processes essential to the water balance such as evapotranspiration need to be considered.
- All pesticide mass coming from the treated field is instantaneously distributed across the T-PEZ. This is problematic because runoff out of the T-PEZ and infiltration below the T-PEZ active root zone only occurs if the incoming water volume exceeds the available T-PEZ holding capacity, or the T-PEZ is already at its holding capacity. In both cases a significant amount of runoff and loadings will move through the T-PEZ without the potential to interact with the plants. Thus, the run-off deposition is overestimated in cases where the T-PEZ is already at or close to saturation.
- All sediment is assumed to be deposited within the T-PEZ. All incoming erosion from the treated field is assumed to stay in the T-PEZ. Depending on the magnitude of the runoff event and many other parameters (e.g., slope, soil saturation) not all sediment will deposit in the T-PEZ and a fraction of the sediment and sorbed pesticide mass will therefore not interact with the T-PEZ. This pesticide mass should be accounted for.

#### 4.3.3.3 Wetland Plant Exposure Zone

The Wetland Plant Exposure Zone (W-PEZ) conceptual model is intended to represent a non-target wetland plant community that is exposed to pesticide via overland flow and spray drift. The wetland has a variable volume, can dry out (which leads to concentrating pesticide) and has a maximum volume defined by a maximum water depth of 15 cm. PAT converts all pesticide in water to a terrestrial concentration (lb/A). A terrestrial concentration or endpoint does not apply when there is standing water and terrestrial concentrations should only be considered when the water depth is below 0.5 cm (which is the threshold when aquatic concentrations are ignored).

- The W-PEZ conceptual model assumes that all runoff and its loadings from a treated field, which is more than 10 times the size of the wetland itself, enters the wetland water body. The assumption that 100% runoff and pesticide load from field enters the water body becomes increasingly unrealistic if there is a buffer between the field and the wetland. Even a small buffer distance will decrease runoff and pesticide losses due to infiltration and sedimentation (as assumed by the T-PEZ conceptual model) and contributions of flow from untreated areas.

We understand that the PAT used for the Draft Triazine BEs and the Draft Glyphosate BE are complicated and the Agency has made several unrealistic assumptions. CLA recommends EPA to organize a joint workshop with all stakeholders for identifying scenarios to address the concerns raised in our comments.

#### 4.4 Probabilistic Methods

CLA continues to advocate for probabilistic methods in the development of BEs. Screening-level deterministic methods are used in Step 1 in the Revised Method to identify listed species that are potentially at risk (*i.e.*, May Affect or No Effect) from exposure to a pesticide active ingredient (EPA, 2020j). The methods are overly conservative to reduce the likelihood of Type II errors (failure to reject a false null hypothesis of *de minimis* risk), but they 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 determination of May Affect for large numbers of listed species and critical habitats 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 and the Draft Triazine BEs, CLA highlighted many of the flaws with the approach to weight-of-evidence assessment in the Revised Method (CLA, 2020b, 2021a). Those comments are also applicable to the Draft Glyphosate BE. Our comments highlight the importance of considering other lines of evidence in Steps 1 and 2 prior to making effect determinations. The applications of the Revised Method in the BEs to date have clearly demonstrated three main points, which are detailed in this section.

The Agency employs a spatial overlay analysis (co-occurrence – Step 1a) and modeling lines of evidence (Steps 1b, 1c2f, and 2g) as the main determinants in effect determinations for all listed species and critical habitats evaluated. This process does not consider the many other lines of evidence available for listed species that may strongly support, or strongly refute the results of the modeling lines of evidence. The other lines of evidence include mesocosm studies, field studies, incident reports, species-specific life histories, and monitoring data, among others. 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 illustrating how lines of evidence, including this from modeling, are incorporated into the risk characterization to inform the effect determinations (Clemow et al., 2018; Moore et al., 2016; Whitfield-Aslund et al., 2017).

Adjusting the modeling lines of evidence to account for alternative assumptions (Steps 2h, i) does not significantly contribute to the weight-of-evidence approach given that it is the same models being applied somewhat probabilistically. The alternate analysis cannot help but reinforce the single modeling line of evidence on which the original effect determination was made because the models applied are designed to be highly conservative and unrealistic. Step 2i should make alternative assumptions for population size, toxicity surrogacy, habitat, and migration. But all of these factors should be considered in the problem formulation prior to initiation of Step 1 to increase the efficiency of the process (CLA, 2020a). For example, species that only occur on beaches or in old growth forest can be readily removed from further consideration in a BE if a minimal effort can demonstrate that, for a particular pesticide, exposure is unlikely.

The Agency provides a confidence statement as either strongest, moderate, or weakest for each weight-of-evidence conclusion. CLA does not see the relevance, value, or utility of the confidence statement, particularly because so few lines of evidence were incorporated into the weight-of-evidence approach and the approach itself is lacking. CLA also questions the utility to the Services of the confidence statement during a formal or informal consultation.

CLA strongly recommends revision of the weight-of-evidence approach in developing the BEs and removal of the confidence statement which is based on faulty methods and thus serves little purpose. Instead of the “strongest, moderate, or weakest” confidence statements, we request the Agency to explore the possibility of using the lines of evidence as means to raise or lower the determinations among No Effect, NLAA, and LAA.

#### **4.6 Uncertainty**

The Agency applied numerous conservative assumptions to in the Draft Glyphosate BE to account for perceived uncertainties. 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 Glyphosate BE leads to unrealistic exposure estimates that are not reasonably certain to occur. It is critical to communicate in a transparent way how the conservative assumptions separately and in combination, affect the magnitude and direction of the risk estimates.

Table 2 lists assumptions excerpted from a FIFRA risk assessment to illustrate how the Agency could tabulate sources of uncertainty in the draft BEs (EPA, 2015a).

<b>Table 2. Examples of uncertainty sources and their impact on risk estimates for sulfonylurea pesticides (from EPA, 2015)</b>	
<b>Assumption</b>	<b>Directional Implications</b>
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 <sub>50</sub> 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 Glyphosate BE but provided an incomplete picture of their impact. For example, in Chapter 4:

Non-agricultural use rates. For some non-agricultural uses, the single application rates were calculated at rates up to 40 lbs a.e./A. These higher rates of 40 lbs a.e./A are calculated by extrapolating up from a smaller area as is expressed on the label. These rates were interpreted to be relevant for a wide variety of non-crop areas where total vegetation control is desired. These

calculated rates were selected for modeling and may be a potential area for label refinement in the future (EPA, 2020c).

The Agency did not explain how uncertainty in the extrapolated applications rates affects the characterization of risk and effect determinations for each of the listed species and critical habitats. In this case, the predicted exposure concentrations are vastly overestimated based on how the products are used. The assumptions EPA has made over the spot treatment extrapolation to the “per acre” rate is based on language on a ready-to-use (RTU) product (a consumer concentrate) label. From Appendix 1-4 of the Draft Glyphosate BE, a footnote note presented below Table 3 in the appendix identifies specifically the RTU product label 228-713 that uses are applicable for small areas (up to 150 sq ft). In the glyphosate preliminary ecological risk assessment for registration review, the Agency acknowledged that the rate was not a realistic value in practice for residential uses, thus the extrapolated rates would not be applied (EPA, 2015b).

Therefore, the extrapolation has an exceptionally large impact on the magnitude and direction of the risk characterization and subsequent effect determinations. CLA requests the Agency to communicate and clarify with the registrants before making these assumptions.

In addition, the 40 lb/A glyphosate use rate in the Draft Glyphosate BE comes only from labels for total vegetation control products. As the Agency develops the final Glyphosate BE, it should review again all registered uses of glyphosate. Any newly registered uses of glyphosate should be added, and all cancelled uses and products should be removed from the final BE. The Agency should take this approach in all future BEs to ensure that only actively registered uses are captured.

There are many other examples that are not documented by EPA in the Draft Glyphosate BE. Because these assumptions and their impact are not discussed in a transparent way in the Draft Glyphosate 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, 2021b). 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 Glyphosate BE does not include best available data (e.g., usage data, application rates), uses incorrect drift curves and software tools (e.g., MAGTool, PAT), and improperly implements the weight-of-evidence approach. These errors lead to an outcome that fails to adequately (or appropriately) define the risk (or lack thereof) that would allow the Services to interpret how to advance the risk assessment process. The final Glyphosate BE requires significant 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 and improvement opportunities in the overall BE process and the Draft Glyphosate BE:

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 and their critical habitats.
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. Both 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. Without consideration of these factors, the identification and development of further risk mitigations are impeded.
5. EPA should re-visit the approach to their weight-of-evidence analysis and remove the confidence statement from the BE process as it has little if any utility.
6. Refined data are ignored or marginalized and inadequately considered as available lines of evidence, thus limiting confidence in species-specific effect determinations.
7. Usage data and UDLs require significant adjustment to reflect glyphosate use more accurately.
8. 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.

9. New and revised complex tools and models employed by the Agency to implement the Revised Method lack adequate peer review, documentation, and QA/QC procedures, reducing confidence in the findings.

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