EPA-HQ-OPP-2021-0575

October 25, 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-2021-0575

Re: EPA's Draft Endangered Species Act Biological Evaluations for the Registration Review of Clothianidin, Imidacloprid, and Thiamethoxam; EPA-HQ-OPP-2021-0575

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 Endangered Species Act (ESA) Biological Evaluations of Clothianidin, Imidacloprid, and Thiamethoxam (the Draft Neonic 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, Director, EPA OPP
Jan Matuszko, Acting Division Director, EPA EFED
Julie Chao, Acting 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 Clothianidin, Imidacloprid, and Thiamethoxam

(EPA-HQ-OPP-2021-0575)

1 EXECUTIVE SUMMARY

The Draft Biological Evaluations for Clothianidin, Imidacloprid, and Thiamethoxam (the Draft Neonic BEs) developed using the Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides (the Revised Method), reinforce the fact that the Environmental Protection Agency (EPA or the Agency) has not yet reached an efficient, and sustainable approach to assess 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) limited review of the Draft Neonic BEs, 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 been compounded. The public commenting period of 60 days does not allow sufficient time to evaluate each of the Neonic BEs and has impacted our ability to provide extensive comments.

CLA recommends that the Agency make a significant effort in the final neonic BEs to reduce the level of compounding conservatism in the assessment and to adjust the approach to more accurately incorporate use and usage information. This includes revising the usage information and assumptions on poultry litter. CLA provides specific recommendations in the Conclusions section of this document to reduce the vastly overstated potential effects of neonics on listed species.

In the Draft Neonic 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. Furthermore, these models lack transparency;

include problems with quality assurance and control; and provide insufficient documentation. A thorough review and scientific evaluation of the tools used in the Draft Neonic BEs should be undertaken prior to their application in the final BEs.

The weight-of-evidence approach as outlined in the Revised Method is flawed and 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 and removal of the “strongest, moderate, or weakest” confidence statement which is based on faulty methods and serves little purpose.

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, reliant on the best available scientific and commercial data, and is protective of species.

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2 INTRODUCTION

The Agency released the Draft Neonic BEs in August 2021 (EPA, 2021a, 2021c, 2021b). The Draft Neonic BEs applied the Revised Method and a new version of the MAGtool. CLA reviewed the Draft Neonic 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 Neonic BEs.

3 POLICY CONSIDERATIONS FOR THE AGENCY

3.1 BE Executive Summary

Based on prior stakeholder feedback, EPA's communications accompanying its release of the Draft Neonic BEs clarified the early screening role that BEs play in the Endangered Species Act (ESA) consultation process; explaining that EPA's Likely to Adversely Affect (LAA) determination does not mean that a pesticide is putting a species in jeopardy. We very much appreciate this clarity, and EPA's willingness to work with stakeholders to explain the process to the public. However, states and other local agencies have made regulatory determinations and policy decisions from conclusions drawn in the BEs. To improve the scientific integrity and efficiency of the entire consultation process, to lessen the burden on the Services in reviewing overly broad BEs, and since conclusions drawn from the BEs can inadvertently influence policy and publica perceptions on the impact of pesticide use on listed species and their habitats, we encourage EPA to work towards developing accurate and scientifically defensible BEs using real-world product use data from applicator partners along with the most current science.

3.2 Making Efficient 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 Neonic BEs results are an excellent example of this resulting in a high percentage of LAA determinations.

Due to 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, most listed species and critical habitat that moved through the Revised Method, as implemented using the MAGtool, received an 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, the Draft Glyphosate BE, and the BEs on atrazine, simazine, and propazine (collectively the Draft Triazine BEs) (EPA, 2020a, 2020f, 2020e, 2020c, 2020b, 2020d).

Appendix 4-8 in the Draft Neonic 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.

Thus, as previously stated in CLA's comments on the Draft Carbamate BEs, *a priori* informal consultation with the Fish and Wildlife Service (FWS), and National Marine Fisheries Service (NMFS) (collectively referred to as "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's recognition that "the methods applied to BEs will continue to evolve as EPA gains experience and as scientific methods and data improve" (EPA, 2020i). 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 encourage 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 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. In a recent Congressional report, EPA mentioned that they will continue to explore how to put protections in place for listed species earlier in the consultation process by working with stakeholders to identify mitigations for vulnerable species in the short term (EPA, 2021e). The new Office of Chemical Safety and Pollution Prevention quarterly ESA stakeholder meetings are a good first step in establishing more meaningful interaction.

CLA strongly supports recent collaborations between registrants and FWS to refine and complete the draft malathion Biological Opinion (BiOp) and encourages similar meaningful interactions throughout the process. Active engagement between the action agency (EPA), the Services, and registrants in the development of the BiOp, common in the BiOp process involved in other types of federal actions, will allow for a better outcome for species protection while recognizing the need for pesticide application by growers, public health officials, and other users. CLA has further details on these process improvements in their draft BiOp comments (CLA, 2021c).

3.4 Conservation Approaches

CLA recommends that EPA develop a decision system linking ecological risk assessments with ESA conservation goals. Current risk assessments are not designed with listed species recovery 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 reduces the complexity of assessments and improve species conservation outcomes (*e.g.*, allowing for improved targeting of voluntary conservation measures that can benefit recovery).

In developing this approach 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 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 Interagency Working Group (IWG) partners to leverage ongoing conservation efforts and maximize benefits to listed species.

As outlined in the Frequently Asked Questions for the Draft Neonic BEs, EPA is considering additional mitigation measures, which may inform the final BE or the BiOp, including measures that are tailored to individual species (EPA, 2021d). This should include product labels (*i.e.,* drift mitigation, buffers, droplet size), application timing, equipment (*i.e.,* nozzles, hooded sprayers), best management practices, integrated pest management, conservation offsets, and refinement tools (*i.e.* species sequencing, refined range mapping). Programs exist to promote these actions and are supported by registrants[1]

[1] BeSure Campaign from Growing Matters: https://growingmatters.org/besure

4 TECHNICAL COMMENTS

4.1 Pesticide Usage Data

4.1.1 Usage Proximity to Species

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, 2020i). 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. 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 addition to usage data, the Agency should refine its risk assessments for the Neonic BEs using the most current species maps. While we acknowledge the time constraints the Agency was under to complete the draft BEs, for the neonic consultation process we encourage the Agency to rerun its spatial analysis and effect determinations to incorporate the new maps for some species that were uploaded to the FWS website in 2021. For future ESA consultations, we encourage the Agency to always incorporate the most current available maps into its assessments the best available scientific and commercial data.

While bringing usage data into the 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 compared to having ignored usage data and assumed 100% PCT for all neonic potential use sites. The limited impact to species effects determination resulting from incorporating usage data into the neonic BEs are 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 Not Likely to Adversely Affect (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 flawed, leading to unrealistic MAGtool results.

4.1.2 Seed Treatments

No usage information for seed treatments is presented in the National and State Summary Use and Usage Matrix (SUUM memo). For each listed seed treatment use, it is indicated “site not surveyed at the national level.” While it is true that seed treatment usage estimates are not available from the data sources utilized to construct the SUUM memos (*e.g.*, Kynetec Agrotrak, California Pesticide Use Reporting [PUR] data, Kline), it should be noted that seed treatment usage estimates are available from Context Market Research (2021 US & Canada Seed Treatment Study, (Context Network)). Context tracks information from surveys of seed treating companies, including the amount of liquid product used to treat seed. This information can be combined with seeding rates to obtain acreage estimates, which can be further combined with National Agricultural Statistics Service (NASS) planted acres data to obtain PCT estimates for seed treatments. The raw data contain information that is product- and company-specific; however, aggregate data requests can be made to preserve data confidentiality. Since the estimates are based on data from seed treating facilities (and do not reflect where the seed is planted) the usage estimates from Context are currently only valid on a national scale. However, as the Context data are the only known source of information on seed treatment usage, CLA strongly encourages EPA to develop methods to incorporate these estimates into the BEs. This would align with the Agency’s stated mission of using the best available data for endangered species risk assessment. Alternatively, CLA could work with EPA and market intelligence companies such as Context to explore survey methods that will allow for obtaining seed treatment usage estimates at the state-level.

4.1.3 Poultry Litter

The poultry litter assessment for imidacloprid suffers from flaws in the assumed usage footprint as well as application rate and frequency. Rather than develop a new UDL for the poultry litter assessment, EPA combined existing UDLs. For the Contiguous United States (CONUS) assessment, appendix 1-6 reports 8 pre-existing UDLs were combined for the poultry litter UDL. However, EPA lists nine pre-existing UDLs when describing what was combined for the creation of the CONUS poultry litter UDL in the same appendix. The pre-existing UDLs combined for the CONUS poultry litter UDL were selected on the basis that they include any of the 24 crops included in the nutrient assimilation capacity calculations of USDA Reports (Kellogg et al., 2000). As a result of the breadth of crops in these pre-existing UDLs that are not expected to receive a poultry litter amendment, the spatial footprint of the poultry litter UDL is overestimated. The attempt to refine the spatial footprint at the county layer further inflated the footprint as counties with acreage defined by any of the pre-existing UDLs were included in the assessment if the NASS Ag census either reported poultry production or no poultry production. In Appendix 1-6, EPA acknowledges the over-estimation associated with inclusion of counties with no-reported data stating, “Counties with no data probably contain developed area and have a lesser change to have poultry production” (EPA, 2021c). The issues with the spatial footprint of poultry litter assessment are further exacerbated with EPA's assertion that 100% of the defined spatial footprint is treated (i.e., 100% PCT). As a result of this compounding conservatism the assessment predicts application to a land area in many cases that is not even feasible. For example, Washington DC has an area of ~21,802 acres once impervious, open water, wetland, and forest areas are subtracted (~50% of total area of 43,705.6 acres). The poultry liter UDL analysis in the draft BE is based on the assumption that this entire area (~21,802 acres) receives poultry liter applications.

4.2 Quantitative Assessment of Seed Treatments

EPA did not conduct a quantitative risk assessment for seed treatment uses in the Draft Neonic BEs. Instead, EPA notes that foliar or soil treatments are considered protective of seed treatment uses. However, in terms of environmental receptors, the exposure potential of a seed treatment use is significantly different than for a foliar or ground spray. Just as EPA would separately assess aerial versus ground spray application because of the difference in offsite drift potential, seed treatment uses should be assessed separately. This will result in separate LAA/NLAA determinations for seed treatment uses compared to other use patterns. In this way, seed treatment uses will be recognized in areas where offsite exposure potential is reduced and will be properly assessed where exposure to certain taxa is expected. A separate quantitative assessment for seed treatments will result in a more accurate risk assessment and greater transparency in risk characterization across all use patterns, both for registrants and the public.

4.3 Seed Treatment and Species Biology

In the most recent ecological risk assessments for imidacloprid, EPA identified seed eating birds and mammals as taxa of concern for seed treatment uses. In the BEs, EPA simply identified granivorous (i.e., seed eating) birds and mammals whose habitats overlapped with the geography of where neonic treated seeds could be planted (i.e., the Action Area). However, the EPA did not consider individual species biology and factors such as proportion of seeds in the animal's diet, the time of year that a given animal would eats seeds, and whether a given species would forage in a newly planted agricultural field. When these factors are considered, several of the granivorous bird and mammal species identified by EPA as LAA would have low to no potential of consuming a freshly planted, treated seed. This is an excellent example of how qualitative data can be used to complement and enhance the quantitative data. A few examples are provided in Table 1.

Table 1. Use of Species Biology to Evaluate Likelihood of Treated Seed Consumption				
Species	**Diet**	**Habitat**	**Migration**	**Source(s)**
Red-Cockaded Woodpecker (*Picoides borealis*)	Mostly insects with some fruit and seeds. Only forages in trees.	Mature pine forests, preferably longleaf pine.	Non-migratory	(FWS, 2020)
Eastern Black Rail (*Laterallus jamaicensis jamaicensis*)	Small aquatic and terrestrial invertebrates and small seeds. Seeds consist of aquatic plants such as cattails and bulrush.	Salt marshes, shallow freshwater marshes, wet meadows, and flooded grassy vegetation.	Partial	(Eddleman et al., 2020)
Beach Mice[2]	Small invertebrates and small seeds of beach-growing grasses (*i.e.,* sea oats, dune panic grass, and ground cherry)	Coastal dunes, including the frontal dunes and adjacent inland scrub dunes.	Non-migratory	(FWS, 1983, 1987, 2010)

4.4 Indirect Effects

4.4.1 Habitats and Proximity to Use Patterns

Many listed species have habitat requirements that are not conducive to growing crops or other uses for which thiamethoxam or other neonics may be applied (e.g., field nurseries, soil amendments with poultry litter). As a result, the ranges of such species are not sufficiently proximal to treated crop and other use pattern footprints to result in exposure. Examples are listed in Table 2:

[2] Listed beach mice include Alabama Beach Mouse (*Peromyscus polionotus ammobates*), Anastasia Island Beach Mouse (*P. p. phasma*), Choctawhatchee Beach Mouse (*P. p. allophrys*), Perdido Beach Mouse (*P. p. trissyllepsis*), Southeastern Beach Mouse (*P. p. niveiventris*), and St. Andrew Beach Mouse (*P. p. peninsularis*)

Table 2. Use of Habitat Requirements and Proximity to Use Patterns to Evaluate Indirect Effects		
Species	Habitat	Source(s)
Alameda whipsnake (*Masticophis lateralis euryxanthus*)	local variations of chaparral, which have low nutrient levels and range from deep, weakly developed soils to shallow, rocky soils. Temperatures often exceed 100°F.	(FWS, 2021)
Salt marsh harvest mouse (*Masticophis lateralis euryxanthus*)	Emergent wetlands of San Francisco Bay and its tributaries. Generally restricted to saline or brackish marsh habitats around the San Francisco Bay Estuary.	(Bias & Morrison, 1999)
Fragrant prickly-apple (*Harrisia fragrans)*	Sand pine scrub habitat and in xeric hammock, coastal strand, and coastal hammocks along the Atlantic Coastal Ridge	(FWS, 2021)

For each of these listed species, however, in the draft Thiamethoxam BE, the Agency assumed that their dietary items (for the animals) or pollinators (for the plant) were present on treated fields and other treated areas during thiamethoxam applications. However, based on proximity analyses for the agricultural use patterns deemed LAA in the draft BE for indirect effects to these three listed species, none were found in close proximity to the species ranges. The Agency provided no scientific rationale in the Draft Neonic BEs for their assumption that dietary items or pollinators of listed species would be present on treated fields even though the habitat requirements of these receptor groups are generally similar to those where the listed species are found. Had the Agency accounted for proximity of thiamethoxam use patterns to the habitats where listed species are found and adjusted exposure accordingly using a spray drift model, many LAA conclusions for indirect effects would have been NLAA.

4.4.2 Unique Species Diets

The MAGtool is an automated tool designed to automate and improve the efficiency of the difficult task of assessing over 1800 listed species and over 800 critical habitats for a wide variety of use patterns, application methods, and formulations. However, the current models used in the BEs fail to consider critical species-specific foraging behaviors, diets, and habitats, many of which are highly specialized. For example, the Alameda whipsnake has a near obligate dependency on western fence lizards for its diet (FWS, 2021). The current implementation of the MAGtool, however, only considers terrestrial insects in estimating the effects of pesticides, including thiamethoxam, to the prey of the Alameda whipsnake. Terrestrial insects are infrequently consumed by this species, and the EPA provided no evidence that reduced availability of insect prey would have any impact on even one individual snake.

In the case of the Everglade snail kite (*Rostrhamus sociabilis*), the model correctly considered aquatic invertebrates as the major receptor group upon which the kite species depends for food. However, the kite has an obligate dependency on apple snails, a unique dietary requirement that was not considered in the Draft Neonic BEs (Reichert et al., 2020). Although thiamethoxam is toxic to aquatic insects, it is non-toxic to aquatic snails including apple snails even at the upper bound concentrations estimated to occur by the EPA in habitats of the Everglade snail kite (see Figure 1).

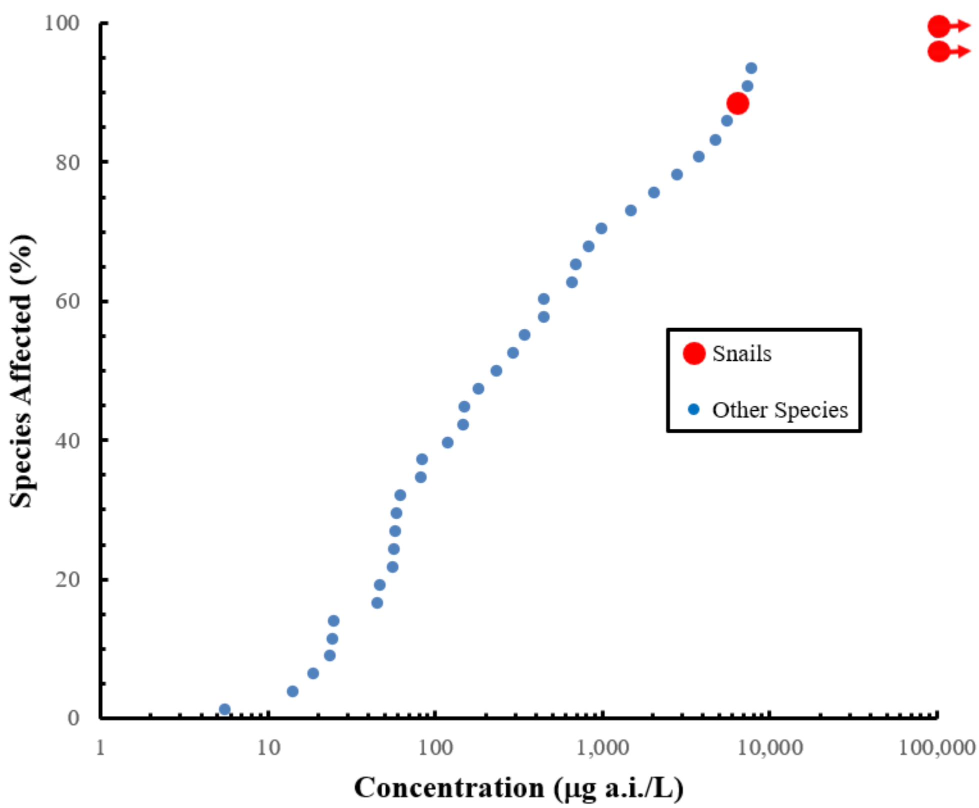

Figure 1. Acute species sensitivity distribution for aquatic invertebrate species exposed to thiamethoxam. Arrows indicate unbounded EC/LC50s. Data from (**Miles et al**., **2017**; **PMRA**, **2021**)

The lack of species specificity regarding the dietary requirements of listed species led to the EPA concluding that use of thiamethoxam would adversely affect the availability of prey upon which listed species depend for numerous use patterns. Had the unique dietary requirements of listed animal species been considered, there likely would have been significantly fewer LAA conclusions. We recommend that the EPA modify the MAGtool to estimate exposure and risk to the major dietary items upon which each listed species depends We further recommend that the EPA model typical diets for listed species that have multiple dietary items rather than modeling each dietary item assuming that it constitutes 100% of the diet.

4.5 Compounding Conservatism

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 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.

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; NRC, 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 any pesticide or not.

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

4.6 Modeling

4.6.1 Magnitude of Effect Tool

When preparing a software tool that will be used in the regulatory environment, such as the MAGtool, 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. 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 Neonic BEs. There are numerous transparency issues with the MAGtool that make the evaluation difficult and CLA has critiqued the lack of transparency within the MAGtool in our previous comments (CLA, 2020b, 2021a, 2021b).

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 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 evidenced by the many errors detected in the Draft Neonic BEs. Providing the original MAGtool workbooks and the Crystal Ball output template will help the public better understand how EPA chose values and derived conclusions for this important step in the ESA process.

These, among other errors, reduce confidence in the MAGtool outputs and ultimately the findings of the Draft Neonic BEs. These errors must be addressed prior to finalizing the neonic BEs and providing the output to the registrant and 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.

4.6.2 Plant Assessment Tool

The Plant Assessment Tool (PAT) is a mechanistic model written in Python that estimates pesticide concentrations in terrestrial, wetland, and aquatic plant habitats. It is comprised of three modules: Terrestrial Plant Exposure Zone (T-PEZ), Wetland Plant Exposure Zone (W-PEZ), and Aquatic Plant Exposure Zone (A-PEZ). Specific concerns about the PAT and the technical approaches used in the T-PEZ and W-PEZ modules are discussed herein.

4.6.2.1 <u>T-PEZ</u>

The Terrestrial Plant Exposure Zone (T-PEZ) conceptual model is intended to represent a non-target terrestrial plant community immediately adjacent to a treated field that is exposed to pesticide via spray drift and runoff. Runoff is assumed to move through the exposure zone as a continuous film of non-channelized water. 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 T-PEZ conceptual model assumes that all runoff from the field enters the T-PEZ as sheet flow and does not account for many site-specific factors which have an impact on the occurrence of runoff into the T-PEZ. Factors influencing runoff may vary greatly between different application sites. PAT does not account for site specific characteristics and field management practices which may result in less opportunity for 100% 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 and the buffer/setback PAT input parameter has no impact on runoff loadings (EPA, 2020g). 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, which should be clarified.

- The function calculating spray drift deposition automatically sets drift deposition to 0 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. 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. However, 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.

4.6.2.2 W-PEZ

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. A critique of the wetland plant exposure zone conceptual model and its potential impacts on the outcome of the assessment for each species are listed below.

- PAT converts all pesticide in water to a terrestrial concentration (lb/A). A terrestrial concentration and endpoint do not apply when there is standing water and terrestrial concentrations should only be considered when the water depth is below 0.5 cm.

- The W-PEZ conceptual model assumes that all runoff and its loadings from a treated field, which is more than 10 times larger than the wetland itself, enters the wetland water body. This assumption y becomes increasingly unrealistic if there is a buffer between the field and the wetland. Even if there is only with a small buffer distance, there will be runoff and pesticide losses due to infiltration and sedimentation and contributions of flow from untreated areas.

4.6.3 Modeling Conclusions

PAT and the MAGtool should go through a Science Advisory Panel (SAP) review. In addition, the scientific community and all stakeholders should get the opportunity to review and test PAT before it is being used in BEs supported by the EPA. An SAP review will help ensure that the model is correctly identifying adverse effects on listed species and their critical habitat while using the best available data. This is not to diminish their utility in providing an effective mode to communicate that EPA is working on a new tool with specific functions.

4.7 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 Methods to identify listed species that are potentially at risk (*i.e.*, May Affect or No Effect) from exposure to an active ingredient (EPA, 2020i). 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 or insignificant. As implemented, Step 1 leads to large numbers of listed species and critical habitats receiving May Affect determinations 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).

4.8 A Robust Weight-of-Evidence Approach

In our comments on previous BEs, CLA highlighted many of the flaws with the approach to weight-of-evidence assessment in the Revised Method (CLA, 2020b, 2021b). Those comments are also applicable to the Draft Neonic BEs. In short, these comments highlight the need for other lines of evidence be considered 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 (Step 1b,c; Step 2f,g) as the main determinants in making 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. These lines of evidence may include mesocosm studies, field studies, incident reports, species-specific life histories, monitoring data, and many more possible lines of evidence. 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 (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 the same models are being applied somewhat probabilistically. The alternate analysis cannot help but reinforce the one line of evidence (modeling) 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. All these factors should be considered well before the last step in the process. In fact, the analyses for toxicity surrogacy, habitat and migration should be undertaken 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. Unfortunately, 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 of the confidence statement as information for the Services during a formal or informal consultation.

CLA strongly recommends revision of the weight-of-evidence approach in developing the BEs and removal of the “strongest, moderate, or weakest” confidence statement which is based on faulty methods and thus serves little purpose. Revision of this approach is vital to the integrity of this and future BEs, especially considering that many species and habitat effects outlined in the Draft Neonic BEs are indirect. 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.

4.9 Uncertainty

The Agency applied numerous conservative assumptions to account for perceived uncertainties in the Draft Neonic 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. 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 3 lists assumptions excerpted from an Agency FIFRA risk assessment illustrate how the Agency could tabulate sources of uncertainty in the draft BEs moving forward (EPA, 2015).

Table 3. 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 not explain how uncertainty in applications rates affect 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. Therefore, the extrapolation has a very large impact on the magnitude and direction of the risk characterization and subsequent effect determinations.

In a recent study commissioned by CLA (manuscript in prep) on uncertainties in risk assessments, the following recommendations and conclusions were identified for addressing uncertainties:

- 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, 2021d). As noted in the conclusions of the document, 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 Neonic 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. In several cases usage data and UDLs were overestimated, and significant adjustment is required to reflect actual neonic use.
3. Species biology and other qualitative information should be used to complement the quantitative data used in the BEs.
4. Highly conservative assumptions are used to address uncertainty at each Step, leading to compounding conservatism throughout the BEs and thus unrealistic exposure and effect characterizations.

5. 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.

Overall, the review of the Draft Neonic BEs led to the following conclusions:

1. EPA should foster collaboration and communication with stakeholders throughout the BE process.
2. The Revised Method process as implemented by the Agency is not a workable, legally defensible, or sustainable approach to risk assessments for listed species.
3. According to normal practice, both the MAGtool and PAT should be reviewed by the Scientific Advisory Panel 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.
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.

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