



October 16, 2023

Jan Matuszko  
Director, Environmental Fate and Effects Division  
Office of Pesticide Programs  
Environmental Protection Agency  
1200 Pennsylvania Ave NW  
Washington, DC 20460

*Submitted to Docket EPA-HQ-OPP-2023-0281*

**RE: Request for Comment: Draft Guidance to Registrants on Activities to Improve the Efficiency of ESA Considerations for New Outdoor Use Registrations of Conventional and Biopesticides Pesticides**

Dear Ms. Matuszko:

CropLife America (CLA) and Responsible Industry for Sound Environment (RISE) appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA or the Agency) Office of Pesticide Program's Draft Guidance to Registrants on Activities to Improve the Efficiency of ESA Considerations for New Outdoor Use Registrations of Conventional and Biopesticides Pesticides document. CLA and RISE also appreciate the Agency's comment deadline extension as there are concurrent open dockets on which our members are developing substantive technical comments.

Established in 1933, CropLife America represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell, and distribute virtually all the pesticide and biotechnology products used by American farmers.

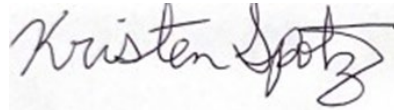
RISE is a national not-for-profit trade association representing more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the United States, including a wide range of products used on lawns, gardens, sport fields, golf courses, and to protect public health.

Our comments are divided into two categories, I. General Improvements to the Endangered Species Act (ESA) process, II. General Comments on the Draft New Outdoor Use Guidance document, and III. Specific Comments on the Draft New Outdoor Use Guidance document. We fully support the comments submitted by our member companies. Should you have any questions or comments, please feel free to contact us at [mbasu@croplifeamerica.org](mailto:mbasu@croplifeamerica.org) and [kspotz@croplifeamerica.org](mailto:kspotz@croplifeamerica.org) or (202) 296-1585.

Sincerely,



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Kristen R. Spatz  
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CC: Ed Messina Director, OPP  
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Lisa Marie Carruba, Acting Division Chief, NMFS Office of Protected Resources  
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## I. General Improvements to the ESA process

### Broad mitigation measures should not supplant appropriate risk assessments

CLA and RISE appreciate the significant updates the Agency has made in the ESA process over the past few years. The predictive Jeopardy/Adverse Modification (J/AM) analysis is a step toward the right direction. While the Agency has relied upon the use of early mitigation measures in the ESA process, they should not supplant product-specific risk assessments that could confirm the need for a particular measure or reveal that less stringent mitigations are sufficiently protective. As such, broad mitigation measures, such as those detailed in the Vulnerable Species Pilot Program (VSPP), should not automatically be incorporated into the ESA process. For a proper risk assessment, it is important to take toxicity, and exposure (usage) into account, otherwise proposed mitigations may be unnecessary for protecting species and detrimental for farming practices and can restrict access to pesticides that are vital to public health and infrastructure. Relatedly, it is imperative that EPA right-size mitigations early on in this process and remain open to adjusting the default mitigations as the Agency proceeds through the stages of the registration process.

Adopting an overly precautionary approach early on can hinder the eventual development of more appropriate and product-specific mitigations. For example, the Agency's recent VSPP follows the precautionary principle approach, as it assumes harm to all 27 species and does not consider that a particular pesticide product may not be likely to jeopardize a listed species based on its use pattern and physical/chemical properties of specific pesticide. Such an overly conservative and precautionary approach has most recently been rejected by the US Court of Appeals for the District of Columbia Circuit. *Maine Lobstermen's Association et al. v. National Marine Fisheries Association et al.*, Case No. 22-5238 (D.C. Cir. June 16, 2023).

We encourage the Agency, the United States Fish and Wildlife Service (FWS), and the National Marine Fisheries Service (NMFS) (hereafter, the Services) to greatly refine their exposure assessment to be more reflective of actual pesticide use and thus allow an accurate determination of potential population level effects.

### Early Coordination with Registrants

CLA and RISE believe that registrant-submitted data and information will play an essential role in supporting this effort to develop robust risk assessments, as well as manageable and meaningful mitigations. From the outset of the registration and consultation processes, pesticide registrants have a significant role to play in completing a pragmatic ESA process. To achieve efficiency in the process, registrants, growers, and applicators should be included early in the discussion based on their knowledge of the product, its use patterns, and field practices. It is important for EPA and the Services to consider that, as ESA applicants, registrants must be involved at every step of the way. EPA, in its recent workplan update<sup>1</sup> document, highlighted the additional work created by the ESA process which affects the Agency, pesticide registrants, and state agencies. That is precisely why it is so important that EPA include registrants early and at every step of the registration process, and the Services should also be included in those aspects impacting consultation.

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<sup>1</sup> Workplan Update – <https://www.epa.gov/pesticides/epa-advances-early-pesticides-protections-endangered-species-increases-regulatory>

## Stakeholder Engagement

The rapidly changing ESA regulatory environment requires an increased focus on communication, transparency, the use of best available data, and collaboration with applicants. CLA and RISE recognize the importance, and legal obligation as codified by the 2018 Farm Bill<sup>2</sup>, of collaboration among EPA, the US Department of Agriculture (USDA), and the Services on ESA and other issues. In addition, we strongly encourage greater collaboration with individual registrants as ESA applicants, growers, and applicators, as part of this process in the future. This is particularly important when EPA is making predictive J/AM determinations for individual species/critical habitats as discussed further below. CLA and RISE, along with its members are well positioned to provide scientific expertise, novel tools (e.g., models), information on use patterns for agricultural and non-agricultural use sites, farmer/applicator interaction information, and other relevant information to assist EPA in establishing the scientific foundation for Agency findings during the biological evaluation (BE) process and to assist the Services with developing the biological opinion (BiOp) and associated potential mitigations. As described in EPA's own Stakeholder Input Enhancement Plan<sup>3</sup> for Pesticide Registration Review and ESA consultation, relevant stakeholders must have meaningful opportunities to participate in a manageable, efficient, defensible, and transparent process to share information to protect vulnerable species, provide regulatory certainty, and support agriculture and pest control.

## Identifying process efficiency

EPA has made tremendous progress in the past few years in improving the ESA consultation process, including the publication of ESA Workplan document in April 2022. The ESA Workplan Update document was published in November 2022, and this draft guidance is a continuation of the work initiated by the Agency to improve its ESA process. As the Agency focuses on streamlining the ESA process, we request that the Agency consider publishing an ESA predictive J/AM guidance document like the 2020 publication of the draft Revised Methods for national level BE.<sup>4</sup> This document could be used by registrants to take on more of the work of preparing documentation, analyses, and draft risk assessments for submission and review by EPA. This would shift the burden of preparation of the underlying materials away from the Agency, allowing it greater time and resources to review these risk assessments and take appropriate regulatory action. This would tremendously help the Agency streamline its resources and would be like the approach taken for ecological risk assessments prepared under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).

## II. General Comments on the Draft Guidance to Registrants on Activities to Improve the Efficiency of ESA Considerations for New Outdoor Use Registrations of Conventional and Biopesticides Pesticides

EPA's initiative to expedite ESA consultations and improve the ESA review process is greatly appreciated. We also appreciate the effort EPA has been making to communicate its decisions more clearly, by providing more detailed explanations around effects determinations, what they mean, and where a particular action by EPA (for example, a draft BE) might fall in the overall consultation process. Below we offer general comments on EPA's Draft New Outdoor Use Guidance.

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<sup>2</sup> 2018 Farm Bill Sec. 10115. FIFRA interagency Working Group pp. 435-438

<sup>3</sup> Stakeholder Engagement - <https://www3.epa.gov/pesticides/endanger/2012/regreview-esa.pdf>

<sup>4</sup> Revised Methods – <https://www3.epa.gov/pesticides/nas/revised/revised-method-march2020.pdf>

### Action Area and Routes of Exposure

- Encouraging registrants to reduce action areas could inadvertently result in reduced availability of tools for crops and non-agricultural uses.
- Cooperation with IR-4 needs to be increased to address needed product registrations for minor crops.
- Making use areas more specific e.g., ‘Christmas trees’ vs ‘trees’ is understandable but may have unintended consequences for limiting use for specific or new crop types, or non-agricultural areas, and especially for Section 18 (emergency) or Section 24(c) (special local needs) registrations. EPA should provide flexibility and work closely with these stakeholder groups, including applicators, to refine risk assessments, using the best available data, and together develop practical ESA mitigations for pesticides needed in these areas.
- Due to the concern that non-agricultural uses could be disproportionately impacted due to the complexity of different use sites and potential overlap with listed species, more collaboration between EPA and the non-agricultural industry would allow establishment of more realistic use sites.
- EPA should also work closely with stakeholders to develop a better set of agreed upon definitions for use patterns and crop stages so that labels are consistent, and it is easier for end users to implement label requirements.

### Mitigation Measures

- Technologies that address off site movement need to be given more credit as ESA mitigations; newer precision application technologies and digital ag technologies need better inclusion as mitigation measures. EPA should consider both existing data and current research that supports these technologies in its assessments.
- EPA is suggesting it will consider “drift reduction or soil binding agents” in determining the need for and extent of mitigations if the registrant provides efficacy data. In addition, EPA should consider such efficacy data in reductions provided by equipment such as hooded sprayers and other targeted application technologies that reduce pesticide movement and field loads.
- Label mitigations need to be presented in a format that is both easily understood and implemented by the end-user.
- Revisions need to be made to Bulletins Live! Two (BLT) to ensure that it is a user-friendly interface; more emphasis on product- or crop-base queries could help.
- CLA and RISE appreciate the November 9, 2023, webinar EPA<sup>5</sup> is hosting to educate the public about BLT and anticipates meaningful dialogue on questions about the often-complex mitigations and language related to ESA protections. CLA and RISE encourage the Agency to partner with stakeholders, such as land grant universities, certified crop consultants, USDA’s Agriculture Research Service, and the relevant trade associations, to provide additional training and resources that will be critical to this initiative’s success. CLA and RISE are willing to collaborate with the agency and other stakeholders to build out and amplify these training materials at the appropriate time.

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<sup>5</sup> EPA Webinar – Understanding Bulletins Live! Two: and Overview of the System [Registration \(gotowebinar.com\)](https://www.gotowebinar.com)

### III. Specific Comments on the Draft Guidance to Registrants on Activities to Improve the Efficiency of ESA Considerations for New Outdoor Use Registrations of Conventional and Biopesticides Pesticides

#### Risk Assessment and the ESA Process

- When providing guidance to registrants on how to develop assessments, EPA should request refined data (e.g., refined exposure assessment) from registrants when available before initiating the ESA assessment. EPA should also engage with the registrant to share the use patterns considered, the toxicity values selected for risk assessment, the selected model inputs, or results of their analysis before issuing a BE to avoid multiple iterations. This step will allow registrants to offer appropriate mitigations and will result in more timely decisions.
- If registrants can elect to carry out their own assessment using EPA's methodology and tools, it would be helpful if there was a prior agreement between EPA and the registrants on the use patterns to be addressed, the toxicity values to use, and the model inputs.
- As EPA continues to predict the likelihood that a proposed action may result in J/AM, the Agency should learn from the Services rather than over-predict. The Agency needs to better align with the Services on when and where to apply mitigation. Currently in the ESA process, EPA is defaulting to applying mitigation to entire ranges of species. This leads to applying mitigation where it is not necessary. EPA should consider developing/using pesticide use limitation areas (PULAs) from completed consultations to identify where to apply early mitigation.
- As EPA conducts effects determinations and addresses potential J/AM more efficiently, the Agency should consider PULAs developed by academia and/or the industry to improve the efficiency of the process. EPA should establish a mechanism for collaboration between EPA, registrants, and Services to ensure a more efficient registration process for a new use.
- The use of refined models or endpoints needs to be investigated and discussed further. Guidance on how revisions could be accepted and what level of documentation would be required should be developed.
- Do "other tools" as listed with AgDRIFT, PWC, and T-REX mean that registrants can propose the use of higher-tier models of both exposure and effects?
- EPA should index existing overlap tools in the same manner as other exposure models and provide on their website the date the tool was released. Furthermore, EPA needs to provide registrants with early insight into which overlap tool is being used in the risk assessment process for a given active ingredient.
- Along with using the information on listed species ranges and any critical habitat as determined by the Services, registrants should be able to use publicly available FWS documents, such as Species Assessment Reports and 5-year status reports that identify the habitats important to a species as a basis for proposing mitigation. EPA should work with registrants and the Services to remove any perceived barriers to the use of these documents for proposing early mitigation prior to entering EPA consultation.

#### Action Area and Routes of Exposure

- EPA needs to approve the use of relevant models (such as VFSSMod) for estimating the efficacy of runoff mitigation measures.

- Proposing mitigations early in the registration process to protect the species within the action area can only occur if the exposure outputs are provided before the draft BE is published. It is not possible to provide relevant mitigations without this upfront information.
- For non-obligate species, and when the range of toxicity to potential prey varies widely, an effect on one sensitive species should not be a basis for concluding there is an indirect effect on the listed species that requires mitigation. Many products are designed to be selectively toxic to certain species (e.g., a fly species) and are relatively non-toxic to other species. This technology, which is meant to conserve non-target species, becomes irrelevant when EPA's risk assessment methods focus only on the most sensitive species, thus potentially disincentivizing the development of such products and addition of new uses. EPA should start to consider higher-tiered field studies in their decisions.
- FWS has a mechanism for stakeholders (non-government organizations, applicants, academia) to submit species range maps for consideration or incorporation into existing FWS maps. The EPA should enact a similar mechanism for Use Data Layers (UDLs) to expedite development of refined crop UDLs and non-Ag UDLs.

#### **Mitigation Measures**

- As requested in this guidance, registrants and CLA review all BEs published by the Agency. CLA is exploring the possibility of capturing proposed and final mitigations across multiple BEs and BiOps through the Mitigation Strategy Tool (MiST)<sup>6</sup>. We request that the Agency should also develop a process to capture feedback on the feasibility of mitigations received through the open docket.
- EPA needs to right size mitigation and should incorporate the body of existing and future research for these determinations.
- EPA mitigations required at the J/AM analysis stage should be informed using best available data and prior consultations. EPA should make it a priority to use information available in the FWS Species Assessment Reports and 5-Year Status reports to tailor mitigations to the species habitats that are important to species survival. PULAs developed during other consultations should also be used during the J/AM process.
- Any mitigation to address endangered species concerns under 50 CFR Part 402, Subpart D is only interim pending full consultation, and thus the early mitigations proposed here cannot be used to formally change an action to be considered during consultation without the consent of the registrants.

#### **IV. Conclusion**

CLA and RISE support our members' technical concerns about the use of the best available science, transparency, validated methodology, and data quality standards in making decisions regarding the protection of endangered species in the pesticide registration process.

CLA and RISE remain committed to supporting improvements to the ESA review process for pesticide registration decisions. In that spirit, we have offered the enclosed comments and recommendations above on overall improvements to the ESA process and specific comments on the Draft New Use Guidance. CLA and RISE recommend that the Agency resolve the outstanding questions, requests for

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<sup>6</sup> <https://mitigationstrategytool.org/>

clarity and refinement, inconsistencies between parallel ESA initiatives, and collect adequate stakeholder input on the resolutions.