July 24, 2023 *Submitted via Regulations.gov*

Curtis Hildebrandt
Registration Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001

RE: Comments by CropLife America on: Draft Biological Opinion on the Registration of Enlist One and Enlist Duo Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act. Docket EPA-HQ-OPP-2021-0957

Dear Mr. Hildebrandt:

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's member companies produce, sell, and distribute nearly all the pesticide and biotechnology products used by American farmers. CLA submits these comments to the U.S. Environmental Protection Agency's (EPA or the Agency) on the Fish and Wildlife Service (FWS) *Draft Biological Opinion on the Registration of Enlist One and Enlist Duo Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act* (Draft BiOp).

CLA recognizes and agrees with the need for EPA to develop and implement a workable, defensible approach for consistently complying with the Endangered Species Act (ESA). CLA also supports our members' technical concerns about the use of best available science, transparency, validated methodology, and data quality standards.

To date, EPA's process for evaluating the potential effects of pesticides on endangered species has been slow and laborious, and completion of consultation with FWS and/or National Marine Fisheries Service (NMFS) has taken significant additional time. This Draft BiOp represents a significant step forward, demonstrating progress in convergence of technical and policy approaches between EPA and FWS. In a fairly short time, considering historical ESA consultation timelines, FWS has developed the Draft BiOp, concurred with essentially all of EPA's conclusions regarding lack of jeopardy to the listed species and their habitats, and removed all county-wide prohibitions on product use. We hope the draft BiOp can be finalized quickly and lead to prompt updating of the Enlist registrations and improved access for growers. In addition, it is of critical importance both to our members and to growers and pesticide users that EPA build on what worked well in the Enlist case.

Reasonable and Prudent Measures

EPA's "Instructions for Commenters" on the Draft BiOp ask for:

> … public feedback on the proposed reasonable and prudent alternatives (RPAs) and/or the reasonable and prudent measures (RPMs). … EPA is particularly interested in feedback on the feasibility of the conservation measures that are intended to further reduce movement of Enlist One and Enlist Duo off treated fields after application.

The Draft BiOp (p. 120) identifies four RPMs (but no RPAs) involving:

1. Reporting to FWS on data collected.
2. Implementing label changes for the Enlist products. An 18-month timeline is set for EPA to accomplish the following:

   a. Notify registrants to submit amended labels according to the registrant commitment letters (it is not clear if more than the single commitment letter included in Appendix D will be required);
   b. Review and act on those amended labels;
   c. Implement Endangered Species Protection Bulletins; and
   d. Provide confirmation that label changes have been completed and Bulletins have been posted.

   This RPM is silent on the essential details of (i) review and approval of the label amendments by State lead agencies, which can take upwards of 18 months alone, but only after EPA's review and approval process is complete; and (ii) use of existing stocks labels in the marketplace. EPA and FWS must not place the registrant in a difficult position regarding label compliance in the marketplace.
3. Detecting changes in estimates of exposure to listed species.
4. Training and education to pesticide users and applicators.

In implementing the RPMs, EPA and FWS must consider the practicality and reasonableness of any burdens that might be imposed on growers and applicators. Some of the actions and activities described in the RPMs are applicable across many pesticides and future BiOps. Economies of scale and effort must be pursued in coordinating with future BiOps for other pesticides, and the burden must be equitably shared.

Concerns regarding the RPMs that are identified by growers and applicators in this comments process may signal the need for additional dialogue with those stakeholders before the Draft BiOp is finalized.

While incorporation of up-front ESA mitigations into EPA's registration decisions, based on Likely to Adversely Affect (LAA) determinations during EPA's biological evaluation (BE) process, rather than delaying such decisions until the BiOp is completed by the Services, may allow earlier access to new crop protection technology for some crop uses and geographies, it must be based on sound science. Further it limits availability to additional crops and geographies until refinement of the assessment. This process is not fair and equitable for growers in the specific regions for whom access to the new technology is denied, deferred, or delayed. Therefore, the process should include steps which could lead to earlier access overall. Hopefully, in the long run, practical experience with the processes can significantly reduce the denials, deferrals, and delays.

Early Coordination with Registrants

CLA believes 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 major role to play in completing a pragmatic ESA process. To achieve efficiency in the process, registrants should be included early in the discussion process based on their knowledge of the product, its use patterns, and field practices. It is important for EPA, and FWS and NMFS (collectively referred as the Services) to consider that, registrants must be involved every step of the way. EPA, in its recent workplan update document, highlighted that product registrations, label amendments, review, and approval creates additional work for the Agency, pesticide registrants, and state agencies. That is precisely why it is so important that the EPA, Services, and the registrants be included in discussions with the Agency at every step of the ESA process.

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 recognizes the importance of collaboration among EPA, the US Department of Agriculture (USDA), and the Services on ESA issues, and strongly encourages greater engagement with individual registrants, growers, and other pesticide users, as part of this process in the future. This is particularly important when EPA is making predictive Jeopardy/Adverse Modification (J/AM) determinations for individual species/critical habitats as

discussed further below. CLA and its members are well positioned to provide scientific expertise, novel tools (e.g., models), agricultural knowledge, farmer/applicator interaction information, and other relevant information to assist EPA in establishing the scientific foundation for Agency findings during the BE process and to assist the Services with developing the BiOp and associated potential mitigations. Relevant stakeholders should 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.

EPA and the Services must remain true to the plans and processes laid out over the last decade-plus for involving stakeholders in the process to expedite assessments and approvals. These agencies must consider all practical approaches, proposed by growers and registrants alike, for recognizing the true lack of jeopardy and/or eliminating jeopardy to listed species. Transparency on the part of the Agencies is essential to build and maintain trust among growers, pesticide users, registrants, and policy makers alike.

Conclusion

As a representative of developers, manufacturers, formulators, and distributors of pesticides for agriculture and pest management in the United States, CLA appreciates the opportunity to provide comments on the draft BiOp. We recognize the work that goes into such an effort and commend the EPA for the many improvements that have taken place in recent years regarding the ESA process. We also encourage EPA to establish a learning process towards becoming more realistic with their upfront mitigations; engage more with the Services; and continue engagement with registrants, growers, and the agricultural research community on mitigations and credit for existing practices. We intend the comments provided here to assist the EPA in moving towards an efficient and scientifically defensible process that is protective of species and is based on an appropriate risk assessment. We believe that there is a significant opportunity in front of us to collaboratively work towards achieving an efficient ESA process. We would request the Agency to consider the general improvements to the ESA process, and the draft BiOp.

Sincerely,

Manojit Basu
Vice President, Science Policy
CropLife America