June 16, 2023

Via Federal eRulemaking Portal: http://www.regulations.gov

Mr. Brian Anderson, Associate Director
Environmental Fate and Effects Division (7101M)
Office of Pesticide Programs
US Environmental Protection Agency
William Jefferson Clinton East Building (WJC East)
1201 Constitution Avenue NW
Washington, DC 20004

SUBJECT: **"Draft Guidance to Registrants on Activities to Improve the Efficiency of Endangered Species Act Considerations for New Active Ingredient Registrations and Registration Review"**
Docket ID EPA-HQ-OPP-2023-0281
Submission of Comments

Dear Mr. Anderson:

Thank you for the opportunity to comment on the subject **Draft Guidance to Registrants on Activities to Improve the Efficiency of Endangered Species Act Considerations for New Active Ingredient Registrations and Registration Review** concerning EPA-OPP's draft guidance to improve the efficiency of EPA's Endangered Species Act (ESA) analyses for new pesticide active ingredient applications and active ingredients undergoing registration review as required under PRIA 5. The Biological Products Industry Alliance (BPIA) submits herewith these comments regarding EPA's proposals outlined in the draft guidance.

By way of introduction, BPIA promotes the responsible development of safe and effective biological products including biopesticides, biofertilizers, and biostimulants. These beneficial tools are used in a variety of settings, including commercial agriculture, forestry, golf courses, home gardens, horticulture, and ornamentals. BPIA also supports public health through education, outreach, and advocacy activities at the state, federal, and international levels. BPIA's membership includes both large and small producers of biological pest control products, biofertilizers, and biostimulants used extensively by US farmers, including organic growers, as well as producers of pesticide inert ingredients.

DISCUSSION

BPIA appreciates the opportunity to comment on the draft guidance. BPIA requests that the Agency collaborate with BPIA to outline specific considerations related to biopesticides in the guidance and include an alternate or amended process explicitly for biological active ingredients whose data indicate that they present minimal risk to threatened and endangered species.

The current EPA draft guidance document does not distinguish between conventional pesticides and biopesticides in its requirements or approach. Listed below are several important distinctions between conventional pesticides and biopesticides that should be considered when increasing efficiency of an ESA analysis for biopesticides. BPIA would appreciate a continued dialogue with the Agency to discuss these items in more detail.

ACTION AREAS

The methodology for defining the "action area" for conventional pesticides is not appropriate for biopesticides. The approach utilized for conventional active ingredients does not account for the unique application types of some products (*e.g.*, traps, pastes, etc.) or give proper consideration that many biological products are naturally occurring and ubiquitous in the environment. Use of EPA models currently calibrated for conventional applications will highly exaggerate the action area. EPA should qualitatively or quantitatively account for the unique attributes of biological products that may limit exposure to organisms feeding on treated items (*e.g.*, bait) or that prevent exposure to broader stressors, such as repellent products, in a refined approach to the current methodology described.

In addition, biological products are often registered in niche markets for use on specific fruit, vegetable, and specialty crops. EPA should work with growers and organizations like IR-4 to better refine the Use Data Layers (UDLs), so the footprint of individual crops is better defined and the use footprint for biological products is not overly inflated.

MODE OF ACTION (MoA)

Based on the unique and generally non-systemic MoA on target pests coupled with lower environmental toxicity, the data package required for a biopesticide is less complex than that required for a typical conventional pesticide chemical. Biopesticide data requirements use a tiered approach and higher-tiered ecotoxicology, mammalian toxicology, and environmental fate data that drive endangered species assessments are rarely triggered. Looking at the overlap of range and critical habitat data for listed endangered species with the expected biopesticide usage area is a useful screening tool for potential exposure, but in and of itself is not a sufficient to make an effect or non-effect decision to endangered and threatened species. If there are no identified effects suggesting toxicity to a particular type of organism, then simply having an exposure scenario does not indicate that there is a risk to endangered and threatened species arising therefrom.

The diverse MoAs for biopesticides require a refined approach for uses that have the potential to affect endangered and threatened species. For example, the MoA for some products is to repel organisms, which may be a net benefit to species by avoiding potential exposure to other products. In other cases (*e.g.*, arthropod pheromones), active ingredients are species-specific, which also can greatly limit their potential impact on endangered and threatened species. EPA should collaborate with registrants, BPIA, and growers to identify additional options to assess the effects of biological products, with consideration to their unique application patterns and MoAs, which can be implemented where EPA identifies the need for further measures to avoid or mitigate exposure.

RISK ASSESSMENTS

While BPIA understands the importance of ESA risk determinations, a full ESA risk assessment is a complex, data-heavy, expensive, and time-consuming undertaking for both registrants and EPA. Biopesticides have not traditionally needed full risk assessments. Rather, EPA often takes a weight of evidence approach to evaluate the risks of biopesticide uses. BPIA strongly supports the use of a qualitative, weight-of-evidence approach for biological products to meet the Agency's obligations under ESA. Through a qualitative approach, EPA is able to appropriately consider the unique application methods and mode of action characteristics of biological products that avoid and minimize potential impacts on endangered and threatened species that cannot be adequately characterized with current quantitative approaches. Qualitative approaches for biological products are aligned with precedent for conventional product evaluations where EPA and the Services use qualitative factors to make expert judgment calls, considering aspects such as species behavior and biology that impact effect and jeopardy determinations.

The Agency has communicated its intent to develop approaches for similar technologies (*e.g.*, herbicide strategy). BPIA agrees with this approach to streamline the process by which the Agency considers the unique profile of individual technologies but conducts reviews for sufficiently similar technologies (*e.g.*, different strains of the same organism with comparable toxicological profiles, arthropod pheromones) in parallel and leverages past assessments with comparable technologies when a new product is introduced (*e.g.*, bridges from past assessments) to avoid the need for an entire review.

CONCLUSIONS

In summary, BPIA has highlighted a few key considerations for developing a streamlined ESA approach for biopesticides as compared to conventional pesticides. BPIA is concerned that the lack of specific considerations of and an alternate process for biopesticides in the current draft guidance will subject biopesticide products to a very complex risk assessment process that is not designed to account for the unique characteristics and activity of these materials. Such a conventional chemical-based, expensive, data-heavy process is not germane to biopesticides, and the costs associated with such a process will almost certainly inhibit innovation in this space, where many registrants are small businesses and startup companies. Evaluating biopesticides using the same metrics as for conventional chemicals will also certainly complicate and increase the time required for EPA to complete these ESA assessments, creating additional work for the Agency, and increasing backlogs and delays. BPIA respectfully requests that the

Agency collaborate with BPIA in a continued dialogue to develop a separate process explicitly for biological active ingredients whose data indicate that they present low risk to threatened and endangered species. Creating a system that takes into account the characteristics of biopesticides while balancing the need to identify and protect any potentially impacted endangered and threatened species will provide the most benefit, while also allowing the Agency to make the best use of its resources.

We appreciate the opportunity to comment and offer support to EPA concerning ESA and we look forward to working together to craft a solution that meets the needs of the statute while recognizing the unique nature of biopesticide products. Should you have any questions about this response, please feel free to contact me.

Sincerely,

BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE

Keith J. Jones
Executive Director

cc: Ed Messina, Director, OPP
Madison Le, Director, BPPD