



Jan 24, 2025

Chad McIntosh, Associate Deputy Director
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20004

Dear Mr. McIntosh,

On behalf of the Biological Products Industry Alliance (BPIA), we welcome you to the United States Environment Protection Agency (EPA). As you may know, we are the voice for companies driving innovation in biological solutions for pest management, crop enhancement, and sustainable agriculture. Our diverse membership includes manufacturers, marketers, distributors, service providers, and users of biological products. Our members provide solutions that benefit growers, facilities managers, public health professionals, animal health experts, farmers, pest control operators, lawn care providers, and consumers.

BPIA appreciates the opportunity to provide recommendations to ensure the Office of Pesticide Programs (OPP) within the U.S. Environmental Protection Agency (EPA) is adequately resourced and functions predictably. Our focus is on strengthening OPP's ability to execute timely pesticide licensing activities, achieve robust regulatory outcomes, and uphold its vital mission of safeguarding human health and the environment while advancing sustainable pest management solutions.

The Role of Biopesticides and BPPD:

Biopesticides play a critical role in agriculture and public health by offering effective, sustainable solutions for crop protection, pest management, and community health. These products undergo rigorous registration and evaluation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) through OPP.

Within OPP, the Biopesticides and Pollution Prevention Division (BPPD) serves as the cornerstone for regulatory activities associated with biologically based pesticides. From product registration and amendments to experimental use permits and reviews, BPPD ensures these products meet the highest safety and efficacy standards for people, animals, and the environment. As the demand for biological products grows, a well-resourced BPPD is essential for timely and efficient regulatory processes that support innovation and sustainability.

However, BPPD is currently facing significant challenges. The division has historically been staffed to manage 20-30 new biopesticides per year, but in recent years, it has seen more than 80 new biopesticidal active ingredients submitted annually by registrants. Many of these new active ingredients involve novel RNAi and gene-edited (CRISPR) technologies, which require the development of new regulatory science and expertise at the agency. Most companies are

currently experiencing approval delays in excess of two years. To address these challenges, additional resources beyond PRIA funds are critical to support the increased workload and ensure timely approvals. We encourage EPA to work with industry and other stakeholders to secure adequate resources and implement necessary regulatory reforms.

Economic Impact and Growth:

The biologicals industry continues to be one of the fastest-growing sectors in the agricultural industry, contributing significantly to the U.S. economy. This sector supports thousands of jobs across the nation and provides critical tools for sustainable farming and pest management. It is essential to maintain the leadership role of the United States in the biologicals space to remain competitive globally.

BPIA's membership includes a broad spectrum of companies geographically distributed across all states. Metrics derived from both in-house data and DunhamTrimmer market research reports¹ estimate the US biopesticide market value in 2023 exceeded \$2 billion and projected it to double in size by 2030. These facts and figures underscore the critical economic and societal value of the biologicals industry.

Biostimulant Regulatory Path:

BPIA urges the EPA to continue collaborating with USDA, state regulators, and industry to develop and implement an efficient regulatory pathway to market for biostimulants. While progress has been made with EPA's support, significant challenges persist, including the need for clear definitions, streamlined processes, and harmonized state and federal regulations. To address these hurdles and unlock the full potential of biostimulants for sustainable agriculture, continued collaboration is essential. In addition, BPIA requests EPA's continued support for the bipartisan Plant Biostimulant Act [2](#), which would establish a federal definition for plant biostimulants and exempt them from regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Funding Challenges:

PRIA 5 increased user fees by 30% and established a statutory minimum appropriation of \$166 million to align with these fees. However, appropriations for OPP remain significantly below this threshold. Historical funding levels, once \$144 million in 2004 (\$237 million in today's dollars), have steadily declined, with fiscal years 2024 and 2025 funding levels falling short of statutory requirements.

This funding shortfall directly undermines OPP's ability to manage pesticide programs effectively, delaying critical registration actions and hindering access to innovative solutions. Meeting the \$166 million funding level, including \$147.1 million for the Environmental Programs and Management (EP&M) account, is imperative. Additionally, continued support for the State and Tribal Assistance Grants (STAG) and Science and Technology (S&T) accounts is vital to ensure a robust regulatory infrastructure.

Endangered Species Act (ESA) Implementation:

Another critical area of concern is the implementation of the Endangered Species Act (ESA). Regulatory challenges related to ESA implementation continue to create delays and uncertainties for the biological products industry. We encourage EPA to collaborate with

stakeholders to address these challenges and develop pragmatic solutions that balance environmental protection with the timely availability of innovative products.

Recommendations:

BPIA respectfully urges the Administration to:

1. Fully fund OPP to meet the \$166 million minimum appropriation, with targeted investments in BPPD to address the unique needs of biological products.
2. Provide additional resources beyond PRIA funds to support BPPD in managing the increased number of new and novel active ingredients.
3. Facilitate an independent third-party assessment to identify and resolve critical process and infrastructure deficiencies within OPP.
4. Endorse the bipartisan Plant Biostimulant Act
5. Enhance transparency by providing estimated completion dates for PRIA actions and leveraging registrant capabilities to streamline workflows.
6. Support continued modernization initiatives, such as the Salesforce-based IT system, to improve real-time tracking and communication for all regulatory submissions.
7. Continue collaborating with USDA, state regulators, and industry to develop an efficient regulatory path for biostimulants.
8. Address ESA implementation concerns to ensure timely regulatory approvals.

Conclusion:

A fully resourced and efficiently functioning OPP, with a strengthened BPPD, is essential for advancing sustainable pest management solutions that protect crops, communities, and the environment. These efforts will not only enable the timely introduction of innovative products but also bolster American agriculture and public health.

BPIA stands ready to collaborate with the Administration to achieve these shared goals, supported by a thriving biologicals industry that contributes significantly to the U.S. economy and maintains the nation's leadership in this vital sector. Once again, on behalf of our member companies, welcome to the EPA.

Sincerely,

John W.S. Dunmore
Director of Government and External Affairs