May 27, 2025

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

Antitrust Division
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530

SUBJECT: Request for Public Comment on Anticompetitive Regulations
***Federal Register*, March 26, 2025**

Docket DOJ-ATR-2025–0001-0002
Submission of Comments

Dear Anticompetitive Regulations Task Force:

Thank you for the opportunity to respond to the Department of Justice Antitrust Division's request for public input on anticompetitive regulations. The Biological Products Industry Alliance (BPIA) submits herewith these comments.

BPIA champions the advancement of safe, effective, and environmentally responsible biological solutions—including biopesticides, biostimulants, and biofertilizers. These innovative tools play a vital role across diverse sectors such as commercial agriculture, forestry, horticulture, golf course management, home gardening, and ornamental plant care. Through education and outreach at the state, federal, and international levels, BPIA actively promotes public health and sustainable agricultural practices. Our diverse membership includes not only large and small manufacturers of biological pest control products, biostimulants, and biofertilizers—widely used by conventional and organic growers in the United States and globally—but also distributors, formulators, suppliers, consultants, research organizations, regulatory experts, and other service providers who support the development, commercialization, and responsible use of these technologies.

COMMENTS ON THE ANTICOMPETETIVE REGULATION

As highlighted in our recent correspondence related to the Make America Healthy Again (MAHA) initiative, the U.S. biological products industry is not only driving innovation, but also contributing new, naturally-derived products to farmers, significantly benefitting local economies and the broader agricultural sector. Companies of all sizes in our sector – including new start-ups – are creating jobs, attracting private investment, and expanding manufacturing capacity across rural America. Removing regulatory barriers would further incentivize investment and innovation in our industry, unlocking additional economic benefits.

However, inconsistent and outdated federal regulations threaten to stifle this progress. The lack of a clear federal definition for plant biostimulants, combined with regulatory fragmentation across EPA, USDA, and FDA, undermines business certainty and limits market access. This fragmented oversight delays product development and commercialization, deters much-needed private investment and raises barriers to market entry by new players in the industry – including smaller start-ups.

The consequences go beyond lost opportunity: they place the U.S. at a competitive disadvantage. While other countries modernize their frameworks to support biological innovation, the United States risks falling behind. Our regulatory environment must evolve to match the pace of scientific advancement and meet the growing global demand for safe, sustainable agricultural tools.

We urge the Anticompetitive Regulations Task Force to evaluate how duplicative or misaligned oversight may be limiting market entry and growth for biological product innovators. A more coordinated, risk-based approach will strengthen domestic competitiveness and support the national interest in food security, environmental health, and economic development.

CONCLUSIONS AND NEXT STEPS

As U.S. agriculture faces growing demands to increase productivity while also maintaining and improving practices to benefit public health and the environment, it is critical that our regulatory systems evolve to support the full range of science-based solutions available to growers.

Biological products—including biopesticides, biostimulants, and biofertilizers—are essential tools that complement existing agricultural practices. Together with other crop inputs and strategies, they form an integrated approach that supports diverse cropping systems, enhances soil health, and improves long-term productivity. However, regulatory uncertainty and misalignment continue to slow the development and adoption of these technologies, limiting the ability of American farmers to access the full range of innovative solutions needed to meet today's challenges.

To support a fair, modern, and competitive regulatory environment that advances U.S. agriculture, we respectfully recommend the Task Force:

1. **Launch a cross-agency regulatory review** to assess where duplicative or inconsistent oversight across EPA, USDA, and FDA may be limiting access to biological products and creating barriers to entry.
2. **Support statutory clarity** through bipartisan efforts such as the Plant Biostimulant Act, which would establish a federal definition and coordinated oversight framework for plant biostimulants.
3. **Ensure adequate resources and accountability** within EPA's Biopesticides and Pollution Prevention Division (BPPD) to address review backlogs and deliver timely, science-based regulatory decisions.
4. **Establish a fit-for-purpose regulatory pathway** at USDA APHIS for genetically engineered (GE) microbes, grounded in risk-based principles and developed in consultation with stakeholders.

5. **Advance international harmonization and trade facilitation** to support market access and regulatory alignment for U.S. biological products in key export markets.

BPIA and its members are committed to working across sectors and agencies to build a regulatory system that fosters innovation, strengthens rural economies, and supports the continued leadership of U.S. agriculture on the global stage. A more coordinated and modernized regulatory framework will provide American farmers with the tools they need to thrive—today and into the future.

Thank you for your leadership and attention to these important matters. We welcome the opportunity to continue engaging with the Task Force to promote fair competition, regulatory modernization, and sustainable innovation in U.S. agriculture.

Sincerely,

BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE

Keith J. Jones
Executive Director