



July 29, 2022

**SUBMITTED VIA REGULATIONS.GOV**

Mr. Kevin Shea  
Administrator  
United States Department of Agriculture  
Animal and Plant Health Inspection Agency  
4700 River Road  
Riverdale, MD 20737

Re: Comments on APHIS Strategic Plan Framework

Dear Administrator Shea:

The Biological Products Industry Alliance (BPIA) appreciates the opportunity to provide comments regarding the United States Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) request for public comment on APHIS' new Strategic Plan Framework, Document ID No. APHIS-2022 0035-0001, [Docket \(APHIS-2022-0035\)](#).

BPIA is the premier organization dedicated to fostering the use of biological technology including biopesticides, biostimulants, and biofertilizers. Biological products are reduced-risk products based on biological or naturally derived chemistry. By combining performance and safety, biological products offer value and benefits generally not realized by conventional chemistry. BPIA is a vibrant association with 150 member companies ranging from small, innovative sole proprietors to large, international companies. Our member companies have developed dependable, pioneering products for commercial agriculture, forestry, home gardens, horticulture, ornamentals, public health, turf – and more. Our members provide solutions that benefit growers, consumers, and the environment.

BPIA is very supportive of APHIS's new mission and vision statements and core values, and looks forward to the benefits APHIS's focus will bring to incentivizing innovations in agriculture and the environment.

**Comments on Goal 1**

**Cultivate a talented, diverse, and public service-focused workforce where employees are supported, valued, and engaged.**

APHIS staff play a critical role in the development and commercialization of BPIA member products. Consequently, it is important that APHIS staff are well qualified and have regular training opportunities. APHIS needs to ensure staffing numbers and expertise are in place to adequately support the needs of the growing biological products industry and other stakeholders.

BPIA strongly supports Objective 1.5 to “create sustainable and cost-effective IT solutions.” Microbes regulated under Part 340 will likely use eFile for permitting. This is one example of an APHIS IT solutions that should be sustainable and cost-effective. It is important for APHIS to have IT solutions in place and maintain them to support the growing need for microbial products in the market.

### **Comments on Goal 2 and Goal 3**

- 1. Science-based solutions that reduce the impacts of zoonotic and emerging diseases and ecosystem changes.**
- 2. Protect agriculture from plant and animal diseases and pests.**

The biological products industry is utilizing microorganisms, biotechnology, and synthetic biology to develop high-performing agricultural inputs for crop protection and fertility that can be used alone or in conjunction with conventional products to create more sustainable solutions to satisfy grower needs. These sustainable solutions are being developed to address the impacts of climate change on American agriculture, including:

- Reduce use of synthetic fertilizers and pesticides, and therefore reduce run-off
- Increase nutrient use efficiency
- Foster the development of microbial solutions to help agriculture adapt to emerging diseases as a result of climate change
- Increase crop resilience to abiotic stress
- Increase carbon sequestration
- Enhance soil health

In order to bring these much-needed sustainable solutions to the market and into growers’ fields, developers need a predictable, risk-based regulatory path under the SECURE rule. The goal of revising the regulations was to be more risk focused, enabling development of new technology. The SECURE rule has outlined the path for genetically modified plants but has no equivalent path for products of microbial technology, which has impeded testing and commercialization of these innovative, sustainable solutions.

- Jurisdiction should be based on the potential for the organism itself to pose a plant pest risk and not on the fact that it is used to control plant pests
- There is no path or process to move microbial products under APHIS’s jurisdiction from research to commercialization
- BPIA is seeking consistent guidelines on the requirements needed for interstate movement and field release permits
- There is no way for developers to self-determine if a microbial engineered organism falls under BRS’ jurisdiction, therefore BPIA is seeking a way to understand how to determine what is regulated
- BPIA is looking for guidance from APHIS on what is regulated, and why, and the risks being weighed in making that determination.
- Developers need practical risk-based containment and confinement conditions that are aligned with agricultural practices

**Comments on Goal 4**  
**Maintain and expand the safe trade of agricultural products.**

BPIA commends APHIS's stewardship, collaboration, regulatory capacity building, and international standard setting. BPIA encourages APHIS to use these skills in influencing other regulatory agencies to provide consistent regulations and a pathway to market for future microbial products around the world. Biological products are sustainable and are one of many options for APHIS in regard to the goals of their strategic plan.

BPIA wishes to partner with APHIS to create an environment where microbial products are part of the solution for farmers, consumers, and the world. APHIS has the ability to influence and to help other countries see microbials as a solution going forward.

Should you have questions about or wish to have further discussion regarding these comments, please contact me. Thank you for your consideration of these comments, and for the opportunity for stakeholder engagement.

Respectfully submitted,

**BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE**



Keith J. Jones  
Executive Director