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Animal and Plant Health Inspection Service
U.S. Department of Agriculture
4700 River Road
Riverdale, MD 20737

Submitted Electronically via Federal eRulemaking Portal (<http://www.regulations.gov>)

Re: Document ID No. APHIS-2022-0035-0001 - APHIS Strategic Plan Framework

Dear Ms. Jennings:

The Biotechnology Innovation Organization (BIO) submits these comments in response to the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) request for public comment on APHIS' new strategic plan to guide the agency's work over the next 5 years.

BIO¹ represents 1,000 members in a biotech ecosystem with a central mission – to advance public policy that supports a wide range of companies and academic research centers that are working to apply biology and technology in the energy, agriculture, manufacturing, and health sectors to improve the lives of people and the health of the planet. BIO is committed to speaking up for the millions of families around the globe who depend upon our success. We will drive a revolution that aims to cure patients, protect our climate, and nourish humanity. BIO represents many of the agricultural and environmental biotechnology product developers in North America whose products are subject to APHIS regulations.

BIO applauds the Administration and the Department for prioritizing APHIS and its priorities moving forward, including by incorporating strategic foresight principles into APHIS's strategic plan. BIO supports 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.

¹ <https://www.bio.org/>



BIO urges APHIS to recognize that to meet the challenge of climate change, foster resiliency and sustainability throughout the agricultural value chain, and sustainably produce enough food to feed a growing world it is crucial to lead with science and U.S. innovation. This will require the government to incentivize the adoption of innovative, sustainable technologies and practices; and streamline and expedite regulatory pathways for breakthrough technology solutions. As such, BIO encourages APHIS to ensure that its updated strategic plan is consistent with broader Administration goals for climate change adaptation and mitigation, including support for climate smart agriculture, meeting net zero emissions by 2050, and environmental justice. Additionally, BIO supports Secretary Vilsack's new Comprehensive Framework for a Transformed Food System, with goals that include:

- Building a more resilient food supply chain that provides more and better market options for consumers and producers while reducing carbon pollution.
- Bolstering food security and mitigating food price inflation by making nutritious food more accessible and affordable for consumers.
- Emphasizing equity.

BIO responds as follows to APHIS' questions regarding the Strategic Plan Framework.

1. Are BIO's interests represented? Yes, broadly speaking, BIO's and BIO's members' interests are represented within the framework. We offer further comments on specific goals below:

Goal 1: Cultivate a talented, diverse, and public service-focused workforce where employees are supported, valued, and engaged. BIO member companies rely on the expertise and engagement of APHIS employees to bring innovative, safe, healthy, nutritious, and affordable food, fuel, and fiber to market, while adapting to a changing climate and ecosystem. BIO is very supportive of APHIS' goal to cultivate its workforce, recruiting new talent while ensuring important institutional knowledge is maintained. Given APHIS's role in the commercialization of new and innovative products, it is crucial to BIO's members that APHIS is fully staffed with well-qualified personnel who are subject to regular training opportunities to ensure that regulatory decision-making is consistent across reviewers. Please see our additional comments regarding opportunities to partner with universities to support this goal.



In addition, BIO commends APHIS on the inclusion of Objective 1.5, to “create sustainable and cost-effective IT solutions”. BIO members are extensive users of APHIS’ eFile for permit applications; the smooth functioning of eFile is critical to the efficiency of our high-throughput and seasonal product development processes. It is important that APHIS provide ample opportunities for stakeholder feedback regarding eFile and promptly implement system improvements based on such feedback, to ensure that agency and stakeholder resources are used efficiently and are implemented consistently.

Goal 2: Science-based solutions that reduce the impacts of zoonotic and emerging diseases and ecosystem changes. Biotechnology is a critical tool for the development of plants, animals, and microbes better able to adapt to emerging diseases and ecosystem changes resulting from climate change. The adoption of biotechnology in agriculture and the development of biobased technologies has already contributed to food security, sustainability, and climate change solutions. The acceptance of biotechnology has enabled large shifts in agronomic practices that have led to significant and widespread environmental benefits. These science-based solutions align with the Comprehensive Framework for a Transformed Food System goal to make nutritious food more accessible and affordable for consumers, leading to improved health outcomes for more people, in a more equitable fashion.

Importantly, however, there are numerous bio-based technologies under development in the United States capable of facilitating carbon capture and sequestration, fixing nitrogen in soils, and solving numerous other pressing ecosystem issues that are not able to reach their full potential through deployment and commercialization because of fundamental regulatory challenges facing them. As BIO outlined in its comments to USDA on the Executive Order on Tackling the Climate Crisis at Home and Abroad and in connection with USDA’s Climate-Smart Agriculture and Forestry Approach, APHIS should include as part of its strategic plan a critical look at the regulatory frameworks governing microbial technologies, innovative feed additives, veterinary products, and animal biotechnology to ensure that those processes are sufficiently streamlined, clear, transparent, and risk-based so that breakthrough technology solutions have a clear and efficient pathway to market.

Goal 3: Protect agriculture from plant and animal diseases and pests. To achieve APHIS’ Goal 3, BIO members develop production technology innovations, which are increasingly the most effective way to manage plant and animal diseases and pests



(e.g., citrus greening, invasive insect population control). However, these technologies have long lead times, regulatory uncertainty, and potentially narrow, APHIS-driven markets. APHIS' ability to enable future biotechnology products that fight plant and animal diseases, and pests can be achieved through strong support of research and development, regulatory, and commercialization assistance (including funding) processes.

The United States' science-based regulatory approach has enabled technology developers to generate and commercialize many highly beneficial products, while assuring consumers and markets that such products have received appropriate premarket regulatory scrutiny and are as safe and nutritious as their conventional counterparts. APHIS-BRS has over 30 years of experience in the oversight of GE organisms. Having reviewed and analyzed the results of thousands of field tests conducted under permit, APHIS has determined that the biotechnology derived products on the market do not present plant pest risks. APHIS' recently modernized Part 340 regulations continue to recognize that it is the characteristic of the product that determines the actual risk it may pose, not the process by which it is developed.

At the same time, it will be important to the success of APHIS's Goal 3 to ensure that developers of non-plant products of biotechnology, including but not limited to microbial technologies, have a clear understanding of APHIS's jurisdiction over their products, a clear and workable process for obtaining permits, where necessary, a method to confirm whether their products are within or outside the regulatory scope, and, for products meeting established risk-based criteria, a pathway to move outside the regulated space. Accordingly, BIO renews its request that APHIS promptly develop and issue guidance for non-plant GE organisms potentially subject to regulation under Part 340.

Goal 4: Maintain and expand the safe trade of agricultural products. BIO appreciates APHIS' leadership in international standard setting, collaboration, and regulatory capacity building. An example of supporting greater access to safe trade would be for APHIS BRS to be proactive in expanding the scope of edited plant exemptions to keep pace with the science- and risk-based regulatory approaches used in the rest of the world. It is important that APHIS BRS exemptions are consistent with science-based regulatory treatment in other countries, especially with those countries that are major trading partners, as inconsistencies may impact those markets' access to



U.S agricultural products when a product is regulated as genetically engineered in the U.S. yet exempt from GE regulations in another country.

BIO also urges BRS and USDA to work with our trading partners to create a more harmonized regulatory framework around the world to improve time to market, which promotes innovation and ultimately helps farmers and consumers. Mexico is a prime example of where such engagement is critical. Its treatment of innovative biotech products is undermining the development and deployment of technologies critical to sustainably feeding the world and addressing climate change.

In recent years the Government of Mexico's food and drug regulatory authority (Cofepris) has eschewed its responsibilities by failing to assess and approve new biotechnology products for human health and agricultural technologies – leaving Mexican citizens without a competent science-based regulatory authority to safeguard their interests.

This uncertainty also extends to its lack of a regulatory framework for gene edited products. Unlike most major agricultural production countries, Mexico has yet to develop a regulatory approach to gene edited agricultural products. As a result, life-science companies seeking to advance a pipeline of gene edited products must either move forward with product development without the benefit of regulatory clarity in Mexico, or cease developing gene edited products that may be produced in, or traded with, Mexico.

The Government of Mexico's failure to fulfill its most basic responsibilities has jeopardized the commercial launch of new agricultural biotechnology products here in the United States. These actions harm U.S. technology providers, farmers, and consumers by undermining efforts to use technology to address food price inflation and bolster food security, improve sustainability, and tackle climate change at home and abroad.

Inconsistent regulatory policies should not slow the access and deployment of tools important to APHIS's Goals 2 and 3.

Goal 6: Promote the welfare of animals. BIO appreciates APHIS's work on identifying opportunities to improve federal oversight of biotechnology in animals. As noted in BIO's comments on Docket No. APHIS-2020-0079, BIO is and remains committed to



continuing to work collaboratively with USDA, the Food and Drug Administration (FDA), and other Executive Branch offices on the urgent need to develop a regulatory system for products of animal biotechnology—including those poised to improve animal welfare—that continues to ensure the safety of animals, consumers, and the environment while fostering innovation and expediting commercialization of beneficial improvements to agricultural animals.

2. Are there opportunities for APHIS to partner with others to achieve the goals and objectives?

To meet Goal 1, APHIS needs to build and maintain a fully-staffed workforce from a well-prepared, educated pool. To that end, BIO encourages APHIS to strengthen its existing partnerships with, and funding opportunities for, land-grant universities, community colleges, and HBCUs to help educate the next generation of APHIS employees.

To meet goal 3 in protecting U.S. agriculture from plant and animal diseases and pests and Goal 6 in promoting animal welfare, it is critical that APHIS continue to emphasize and harmonize innovation policy with Coordinated Framework agency partners at the U.S. Environmental Protection Agency (EPA) and FDA. If the agency partnership within the Coordinated Framework is not harmonized, APHIS and U.S. agriculture may not have the tools it needs to mitigate the next disease or pest or to timely commercialize products of biotechnology capable of addressing animal welfare issues or other pressing problems of agriculture.

3. Are there other trends for which the agency should be preparing?

BIO agrees with APHIS' list of trends. BIO would emphasize that, under trend number 5 (Advances in Science and Technology), advances in biotechnology are key to developing products intended to improve sustainability in agriculture. Trend number 6 (Changes in Production Practices) appropriately calls out the changes and technological advancements in production practices, and the need for the agency to recognize diverse forms of agriculture without demonizing any of them. BIO notes that it is crucial to ensure that education accompanies changes in production practices and new innovations; BIO asks that APHIS consider partnering with USDA extension services to



expand technical assistance to underserved producers, potentially providing opportunities for rural development.

4. Are there additional items APHIS should consider for the plan?

BIO encourages APHIS to include as part of its strategic plan a commitment to ensure that its regulations and accompanying guidance documents and materials continue to be fit for purpose and comply with the “good governance” principles that have often been articulated by the Office of Management and Budget, including in “Principles for Regulation and Oversight of Emerging Technologies” from March 11, 2011², and the additional “good governance” guidance documents cited therein.

BIO appreciates the opportunity to provide feedback to APHIS on the Strategic Plan Framework and looks forward to continued work with USDA to ensure BIO members’ innovative solutions can be developed and deployed to give farmers and ranchers the tools they need to be self-sustaining and resilient to climate change.

² See <https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf>.