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Re: Request for Information re Section 8 of Executive Order 14081: Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology (87 Fed. Reg. 77900 (Dec. 20, 2022)), APHIS-2022-0076.

The Biological Products Industry Alliance (BPIA) is pleased to provide input to the Office of Science and Technology Policy's Request for Information (RFI) on Section 8 of Executive Order 14081 (EO), requesting input on how regulations can better facilitate the use of biotechnology to stimulate the economy, with the goal of accelerating biotechnology innovation and growing America's bioeconomy across multiple sectors, including health, agriculture, and energy.

BPIA is the premier organization dedicated to fostering the use of biological technology including biopesticides, biofertilizers, and biostimulants. Biological products are reduced-risk products based on biological or naturally derived chemistry. BPIA is a rapidly growing association with now over 160 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, and turf. Our members provide solutions that benefit growers, consumers, and the environment.

BPIA shares the intent and goals of the EO and agrees that US innovation and science are critical to meet the global challenges including climate change, food security and nutrition. Microbial products for agriculture are a rapidly growing sector due to increased

demand for biobased agricultural solutions. These products provide farmers and consumers with sustainable solutions that help address the impacts of climate change by increasing nutrient use efficiency, reducing synthetic fertilizer use, run-off and greenhouse gas emissions, increase crop resilience to abiotic stresses, improve carbon sequestration, and enhance soil health. To provide these solutions, developers of innovative microbial products need clear, science- and risk-based regulatory processes that allow safe products to reach the market.

In 2011, the White House published the memorandum *Principles for Regulation and Oversight of Emerging Technologies* for the heads of executive departments and agencies, describing guiding principles for regulation of emerging technologies. These rulemaking principles, which remain critical today, are aimed at ensuring that regulations are:

- Protective of health and the environment while promoting innovation
- Based on the best available scientific and technical information
- Cost-effective and commensurate with risk
- Flexible and adaptable to accommodate new evidence and learning
- Simple, clear, transparent, and minimize uncertainty
- Adopted through a public and transparent process
- Consistently applied and enforced
- Coordinated with other federal agencies, state authorities, a broad array of stakeholders, and the international community

We also reference the original Coordinated Framework and its recent 2017 modernization, together with the 2015 Memorandum *Modernizing the Regulatory System for Biotechnology Products*, and the 2019 EO *Modernizing the Regulatory Framework for Agricultural Biotechnology Products*. For products of biotechnology, clearly multiple administrations have reaffirmed the intent that regulation be applicable only where the use of the technology creates a new or different risk and focus on the characteristics of product and intended use, not on the technology used.

Within the last decade, genome editing technology, together with advances in bioinformatics and molecular biology, have revolutionized both basic biological research and applied biology. The tools of genome editing are broad; scientists can use genome editing precisely and rapidly to identify genes, edit or fine-tune genes, as well as swap or insert genes. It is critical to understand that genomes are not static – genetic changes occur naturally all the time. Genome editing tools currently used allow scientists to make these changes instead of relying on random events. Using genome editing, native microbes can be improved to precisely tailor performance to a specific target, or undesirable properties can be removed (e.g., to reduce production of a specific metabolite). BPIA also stresses that the use of microbes in agriculture is not new; they

have been in use for decades. Indeed, at the time the Coordinated Framework was announced in June 1986, OSTP noted "that microorganisms play many essential and varied roles in agriculture and the environment and that for decades agricultural scientists have endeavored to exploit their advantages through routine experimentation and introduction into the environment; and as a rule these agricultural and environmental introductions have taken place without harm to the environment." 51 Fed. Reg. 23302, 23303 (June 26, 1986). But advances in science can be used to improve these products.

Developers using biotechnology, including genome editing techniques, to improve microbes for agricultural use must have clear, transparent regulations that enable a science-based, risk-proportionate, and predictable path for testing biotechnology-derived microorganisms in the field, and once tested, to bring them to the marketplace. Developers of such products are currently experiencing uncertainty-related delays in identifying, testing, and commercializing new products. Therefore, BPIA urges USDA and EPA to harmonize across agencies as to which organisms improved through biotechnology warrant pre-market regulatory oversight. The US government has a longstanding policy to regulate on a product and not process basis, analyzing the characteristics of the product and actual risks it may pose. BPIA strongly supports this policy and encourages OSTP and the regulatory agencies to do all they can to ensure it is implemented to the maximum extent.

1. ***Describe any ambiguities, gaps, inefficiencies, or uncertainties regarding statutory authorities and/or agency roles, responsibilities, or processes for different biotechnology product types, particularly for product types within the responsibility of multiple agencies.***

Utilizing biotechnology to develop microbial agricultural inputs for crop protection and fertility is a rapidly growing segment of research with the potential to develop transformational products that can replace or reduce the use of synthetic pesticides and fertilizers. These sustainable alternatives are critical tools needed to help American growers address the impacts of climate change. Developers of these technologies are struggling with ambiguities and inefficiencies in the current regulatory framework. Multiple uncertainties and redundancies need to be addressed. Importantly, these include regulatory uncertainties and inefficiencies for genetically engineered (GE) microorganisms under 7 C.F.R. part 340 and dual agency jurisdiction. Addressing these insufficiencies and establishing a clear, predictable regulatory path would enable developers to bring these much-needed sustainable tools to growers, positively impacting American agriculture as well as "maintain US technological leadership and economic competitiveness."

Regulatory Uncertainties and Inefficiencies for Genetically Engineered (GE) Microorganisms under 7 C.F.R. §340:

While regulations for genetically engineered plants have recently been revised under 7

C.F.R. §340, the revisions have created uncertainties regarding statutory authority and processes for the development and commercialization of genetically engineered microorganisms. The current regulations do not enable an appropriate, clear, and predictable regulatory path, hindering developers of genetically engineered microorganisms from efficiently testing and commercializing these effective and sustainable technologies.

To ensure developers of genetically engineered microorganisms can bring novel technologies to American agriculture, guidance on non-regulated categories of microorganisms that are not subject to permit under 7 C.F.R. § 340.2(b) or (d) is urgently needed.

7 C.F.R. § 340.2(b): Developers need clarity regarding what constitutes a "plant pest" and "plant pest potential." Ambiguity in the definitions make it nearly impossible for a developer to determine whether their product meets the definition of plant pest or has the potential to pose a plant pest risk. Developers must therefore bring every candidate product to the Agency for a jurisdiction determination. A list of microorganisms that would meet the definition of a plant pest under 7 C.F.R. § 340.3 is needed so the Agency can focus its resources on microorganisms the science affirmatively indicates would pose a plant pest risk. Reinstating the list of plant pest taxa from the prior version of 7 C.F.R. § 340.2 would help address the uncertainty and give developers, and the regulators, at least one definitive tool for determining regulatory oversight.

7 C.F.R. § 340.2 (d): The scope of the new regulation includes "a microorganism used to control plant pests." [7 C.F.R. § 340.2 (d)]. Industry needs additional guidance clarifying what microorganisms meet the criteria "...used to control plant pests". USDA APHIS BRS' current interpretation that any microorganism with public literature indicating the microbe has biocontrol activity meets the criteria "used to control plant pests" is overbroad and is stifling innovation. Microorganisms produce biological chemistry for their survival in the environment, some of which may exhibit biocontrol properties. However, a microorganism exhibiting biocontrol properties should not automatically be deemed "a microorganism used to control plant pests" without a scientific basis. Developing an effective biocontrol agent requires identifying the mechanism responsible for the biocontrol activity in a particular microbial strain and conducting extensive research to verify the activity under field conditions and increasing expression of the biocontrol mechanism in that particular strain. In addition, there is a great deal of variability between strains within a given species. Having a particular strain exhibit biocontrol properties does not mean that all strains within that species are efficacious in controlling plant pests. If developers are not enhancing biocontrol properties, and the strains are not being used to control plant pests, the strain does not warrant regulation under Part 340. If the host microorganism is not being used to control plant pests and it is not modified to enhance its biocontrol properties, the GE microorganism should not fall within the scope of 7 C.F.R. § 340 (d).

Industry appreciates APHIS' recent publication of Questions & Answers – ***Working with Microorganisms Developed Using Genetic Engineering Under 7 C.F.R. § 340 – August 2022***. In this publication, APHIS encourages stakeholders to submit inquiries into the regulatory status of a GE microorganism using the email address biotechquery@usda.gov. Although this is a helpful tool, developers need a more structured process designed to efficiently address engineered microorganisms, such as providing categorical determinations, e.g., at the species level, or addressing multiple strains within a species. A process that enables developers to plan and execute research activities in a clear predictable manner while clarifying the regulatory status of microorganisms developed utilizing biotechnology and synthetic biology. A public-facing regulatory consultation process would allow for greater transparency into APHIS' decision making and enable technology developers to develop technologies that would systematically clear the regulatory process.

The revised regulations also create uncertainty and potential dual jurisdiction under 7 C.F.R. § 330 and 7 C.F.R. § 340 for microorganisms previously regulated under 7 C.F.R. § 330. If BRS determines that the genomic modifications made to an organism with potential biocontrol capabilities do not pose an increased plant pest risk and therefore should not require a permit under 7 C.F.R. § 340.2, BRS should then allow the microorganism to remain permitted under PPQ's jurisdiction.

Exemptions for certain genetic modifications in plants are included in revised 7 C.F.R. § 340. While this list is useful for developers of genetically engineered plant products, those exemptions are unavailable to developers of genetically engineered non-plant organisms. A set of appropriate exemptions must be established for genetically engineered microorganisms, enabling the Agency to focus efforts and resources on microorganisms which may pose an increased plant pest risk and warrant jurisdiction under Part 340.

Tagging mechanisms, such as DNA barcoding, are a tool utilized by microbial technology developers to differentiate genetically engineered microorganisms from their wildtype counterparts in the environment. DNA barcoding may require the insertion of short genome sequences into non-coding regions of the target microorganism's genome without increasing the target organism's plant pest potential, and no increased plant pest risks with small-scale field testing over their wild-type counterpart. Modifications for the purpose of DNA barcoding used solely for research purposes and identification in field studies, that have no other commercial purpose other than informing behavior in the environment, should be exempt from regulation and premarket regulatory review.

BRS should work with USDA-APHIS-PPQ to further delineate each agency's jurisdiction and ensure no regulatory duplication using the following categories of modifications in which neither the donor or host microorganism is a plant pest:

- Changes in genomic DNA to modulate expression or regulation of existing native genes

- Changes in genomic DNA to modulate existing native gene products
- Introduction of genes, associated regulatory sequences and/or gene products from donor organisms that come from the same genus and/or species
- Introduced genetic material consisting of only well-characterized, non-coding regulatory regions from another genus

An agile process enabling the addition of new exemptions from premarket regulatory review under 7 C.F.R § 340 needs to be implemented for GE microbes in the same way it has been implemented for GE plants. In addition, a formal confirmation process for microorganisms similar to the current 7 C.F.R. § 340.1(e) Confirmation Process for modified plants should be established.

Technology developers have an immediate need for a regulatory review process in which microorganisms developed through genetic engineering and subject, at least initially, to USDA BRS permit requirements can be evaluated by the agency and deemed not to pose a plant pest risk, enabling commercialization. See 7 C.F.R. § 340.4(b)(1), (2). It is critical to have a predictable regulatory framework with a clear endpoint that enables developers to make available much needed biological solutions for farmers, consumers, and the world, including genetically engineered microbial products.

A more efficient permitting process is needed. The current process and eFile system was developed for genetically modified plants and needs to be adapted to meet the specific needs of microbial technologies. APHIS BRS needs to establish an abbreviated fast-track permitting process to enable interstate movement of genetically engineered microorganisms between APHIS approved containment facilities for laboratory contained research activities. Developers need to move numerous genetic variants of the same target product quickly between sites and need a permitting process that enables the timely movement of materials so research activities are not stalled.

Dual Agency Jurisdiction:

Developers need a single point of entry to determine agency jurisdiction and registration path. Agencies should have a harmonized approach for determining which engineered microorganisms pose an increased risk from their wild-type counterpart and warrant further oversight. USDA should have similar exemptions or exclusions as EPA. For example, under the Toxic Substances Control Act (TSCA), EPA only regulates the use of intergeneric microorganisms (those formed using DNA from organisms in different genera), excluded from TSCA section 5 reporting requirements are microorganisms developed by making edits within a single genome or using DNA from the same genus. In addition, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) microbial pesticides resulting from deletions or rearrangements within a single genome that are brought about by the introduction of genetic material that has been deliberately modified are exempt from the requirements of a Biotech Notification for small-scale field testing (40 C.F.R. § 172.45).

Genetically engineered microbial fertilizer replacement products require both EPA (TSCA TERA/MCAN) and USDA USDA BRS permits) oversight and for small-scale field testing of early product concepts. There is a lack of alignment across the agencies on requirements for small-scale field testing, requiring developers to comply with varying conditions and navigate different application requirements and review timelines. Developers need a clear and predictable process that provides consistency in reviews and unified small-scale field-testing requirements across agencies.

Industry works assiduously to be good stewards of our products and ensure our research and development activities are conducted in compliance with the regulations. We therefore need an efficient risk appropriate framework that aptly addresses potential concerns. A framework should be based on harmonized oversight and alignment across agencies on the types of genetically engineered microorganisms that pose an increased risk from their wild-type counterpart and warrant jurisdiction. If not adequately addressed, development of these emerging and beneficial technologies will be severely hampered and developers will be forced to pursue offshoring development and commercialization of these sustainable technologies to countries with clear and predictable regulatory frameworks.

a. Describe the impact, including economic impact, of these ambiguities, gaps, inefficiencies or uncertainties.

The current regulatory framework has numerous ambiguities and inefficiencies that if adequately addressed could enable development and commercialization of sustainable solutions for American agriculture.

Technology developers and regulators of new microbial technologies are both challenged with uncertainties, inefficiencies, and increased costs due to the ambiguity of the revised 7 C.F.R. § 340. These regulations do not enable risk-based evaluations, resulting in precautionary principles and onerous permit requirements that are not always commensurate with the potential risk. This creates significant inefficiencies and redundancies and is unnecessarily burdensome and resource consumptive for both regulators and developers, resulting in considerable (>1 year) delays in testing (field) and commercialization of new genome edited technologies and significant revenue losses for developers of new environmentally friendly and sustainable technologies. Technology developers request that APHIS clarify the regulatory framework through guidance or rulemaking to address the ambiguities and uncertainties in the current regulations for genetically engineered microorganisms that would enable a predictable path for field research and commercialization of said products as it relates to plant pest risk or the lack thereof.

The current permitting process for interstate movement of engineered microorganisms is inefficient resulting in significant delays in development timelines. The requirements to simply move a microbe from one APHIS approved containment facility to another is too onerous for the potential risk and does not warrant the level of oversight and lengthy

review times currently required. Developers must spend valuable time and resources filing detailed permit applications for every genetic variant for the same target product to simply move the microbial candidates through a screening pipeline. This causes significant delays in the research pipeline. Moreover, BRS is utilizing its limited resources to review highly detailed permits applications for every microorganism that simply needs to be moved from one APHIS approved containment facility to another for laboratory contained research. Interstate movement permits should be a streamlined process. APHIS BRS needs to establish an abbreviated permitting process that enables categorical permitting for interstate movement between APHIS approved containment facilities for laboratory contained research, similar to APHIS PPQ's high taxon permits. Once research activities progress from the APHIS containment lab to the greenhouse or field, then more detailed strain specific permits are appropriate. This would free up Agency resources to focus on research activities that warrant more oversight and allow developers to efficiently move material so research activities are not stalled.

Industry requests that APHIS utilize all available data sources, to inform risk assessments and, including published literature, applicant lab, greenhouse, and/or ex-US field data. Developers need a process where the magnitude of the permit requirements regarding containment and tracking are adjusted in accordance with the knowledge available. In addition, permit conditions must be aligned with current agricultural practices and should not consist of requirements that are damaging to fields and growers are unwilling to implement, such as fumigation. If data show several log reductions of an engineered microbe in the environment, but a very small number of spores remain at completion of the trial, that should not be considered an unauthorized release and warrant devitalization. Rather, the Agency should focus its efforts on preventing proliferation in the environment.

2. ***Provide any relevant data or information, including case studies, that could inform improvement in the clarity or efficiency (including the predictability, transparency, and coordination) of the regulatory system and processes for biotechnology products.***

American agriculture urgently needs reliable, sustainable alternatives to conventional chemical inputs and nitrogen fertilizer is a prime example. Negative environmental impacts, supply shortages, and rising costs are limiting the use of this vital tool before there is a viable alternative. Developers are working to develop sustainable alternatives to nitrogen and other chemical fertilizers but are facing challenges due to the ambiguities and inefficiencies of the revised 7 C.F.R. § 340 regulations for genetically engineered microorganisms, hindering development. Addressing the uncertainty and developing a clear predictable path would enable developers to bring these much-needed tools to growers and positively impact American agriculture.

3. ***Describe any specific topics the agencies should address in plain language on the regulatory roles, responsibilities, and processes of the agencies.***

It is crucial that there be alignment across agencies on the types of genetically engineered microorganisms that pose an increased risk from their wild-type counterparts and warrant jurisdiction. In addition, the agencies need to harmonize on definitions as well as requirements for small-scale field research with microorganisms subject to jurisdiction.

4. ***Describe any specific issues the agencies should consider in developing a plan to implement regulatory reform, including any updated or new regulations or guidance documents.***

As technology advances and an increasing number of microorganisms are shown to have tremendous potential for complementing or even replacing some conventional agricultural inputs, it is critical that USDA, EPA and FDA advance clear, risk-based, transparent and efficient regulations and grow the bioeconomy in the U.S.A. The development of highly effective and sustainable solutions with genetically engineered microbes is providing solutions that can boost the U.S. economy, provide solutions to many factors that contribute to climate change and enhance the health of agricultural soils.

The lack of clear regulations for these promising biological technologies is driving industry to go to other countries to advance commercial products and threatens the U.S. as a leader in bringing sustainable technology to growers. Brazil is a prime example where the regulatory system is clear and efficient for biological products and leads the world in expansion of these products.

It is with a true sense of urgency that industry requests USDA, EPA and FDA to work together to develop clear, science and risk-based regulations for the advancement and commercialization of biological products.

Technology developers must navigate the regulations across the three agencies that act under the Coordinated Framework for Regulation of Biotechnology (USDA, EPA, and FDA). We strongly encourage the agencies of the Coordinated Framework to establish a single point of entry for developers to use to determine if/how genetically engineered microorganisms will be regulated. We further encourage improved harmonization of existing regulations across USDA-FDA-EPA to clarify the path for developers of such technologies.

There is considerable breadth of the types of genetic changes that are used to modify microorganisms ranging from fine-tuning endogenous genes or pathways to the insertion of genes from another organism. It is important the agencies use common language, definitions and clarity of those changes that are regulated and those that are exempt from regulation. USDA/APHIS/BRS' most recent 7 C.F.R. part 340 includes some exemptions for certain genetic modifications in plants. It is important that USDA, EPA, and FDA develop exemptions specifically for genetically engineered microorganisms.

Technology developers recognize regulators' desire to distinguish genetically engineered microorganisms from their wildtype counterparts in the environment and agree the technology exists to make such distinctions. Tagging mechanisms, such as DNA barcoding, could provide regulators and developers a tool for in-field differentiation. DNA barcoding, as described above and defined below, may require the insertion of short genome sequences into non-coding regions of the target microorganism's genome without increasing the target organism's plant pest potential. Technology developers therefore request that modifications for the purpose of such tagging be exempt from regulation and premarket regulatory review by BRS.

BRS should work with USDA-APHIS-PPQ to further delineate each agency's jurisdiction and ensure no regulatory duplication using the following categories of modifications in which neither the donor or host microorganism is a plant pest:

- Changes in genomic DNA to modulate expression or regulation of existing native genes
- Changes in genomic DNA to modulate existing native gene products
- Introduction of genes, associated regulatory sequences and/or gene products from donor organisms that come from the same genus and/or species
- Introduced genetic material consisting of only well-characterized, non-coding regulatory regions from another genus

The above-mentioned exemptions should not be considered exhaustive of modifications that could be exempt from premarket regulatory review. Therefore, the agencies should enable a process that allows for the addition of new exemptions in the future, similar to what the USDA has provided for plants in 7 C.F.R. § 340.1(b)(4)(ii).

Developers also need a predictable permitting process with clear guidance on requirements with consistency of review and determinations across the agencies. The permit system should address specific considerations of microbial engineering and synthetic biology.

Industry requests that the agencies utilize all available data sources, to inform risk assessments and development of risk-appropriate permit conditions, including published literature, applicant lab, greenhouse, and/or ex-US field data. Developers need a process where the magnitude of the permit requirements regarding containment and tracking are adjusted in accordance with the knowledge available. In addition, permit conditions must be aligned with current agricultural practices and should not consist of requirements that are damaging to fields and growers are unwilling to implement, such as fumigation.

Technology developers request that the Agencies clarify the regulatory framework through guidance or rulemaking to address the lack of clarity in the current regulations for genetically engineered microorganisms that would enable a predictable path for field research and commercialization of said products.

5. ***Describe any new or emerging biotechnology products (e.g., microbial amendments to promote plant growth; food plants expressing non-food substances or allergens from non-plant sources) that, based on lessons learned from past experiences or other information, the agencies should pay particular attention to in their evaluation of ambiguities, gaps, or uncertainties regarding statutory authorities and/or agency roles or processes.***

Biotechnology products are an emerging and quickly growing segment. Microorganisms, including genetically engineered microorganisms, are one of the current leading technologies, however new technologies are emerging and will continue to expand. These biotechnology techniques produce products which are varied in their use. For example, technology developers are researching high-performing agricultural inputs which could replace more traditional crop protection products. These products could significantly reduce the amount of synthetic fertilizer and pesticide applied to crop land. Additionally, biotechnology products may also be used to improve soil health. Therefore, they are considered to be sustainable solutions to help cope with and address the ever-expanding impacts of climate change. The ambiguities in the current regulations, agency roles and process are limiting the development and commercialization of these beneficial, sustainable products.

When focusing on microorganisms, there is significant investment in these new technologies which could bring sustainable solutions to the market. However, with the ambiguity and lack of clear processes at the US agencies, these products find a lack of clarity in the US regulatory system as they are moving from the lab to the field, and then eventually into the market. At this time, there is uncertainty about if these products should go through the regulatory processes, including which agency to turn to, as well as what is required. Because the requirements for testing and commercializing these types of products is not clearly defined, it takes more time for developer and agency personnel to discuss back and forth before reaching a conclusion.

We request that new regulations, guidelines, and processes be developed which have the flexibility to grow effectively with emerging technologies, such as genetic engineering. These should not be based on previous regulations meant for other types of technologies, such as transgenic plants. Furthermore, the focus of the assessment should be based on the product which is made, not by the process in which it was produced.

We also request that the US regulatory agencies use the Coordinated Framework to address the concern of ambiguities in jurisdictional oversight, including how developers determine which agency has oversight for their product. For example, an intergeneric microbial fertilizer replacement product may require dual agency jurisdiction of both EPA under TSCA and USDA oversight under Part 340.

One particular focus of the agencies should be the permitting and commercialization process at USDA APHIS BRS for genetically engineered microorganisms. Currently, there is no viable commercialization path for genetically engineered microorganisms at BRS, which halts the progress of providing these products to growers. Aside from commercialization, the process for field testing genetically microorganisms at USDA BRS requires clarity. The permitting system is based on the regulations in place for modified plant products and does not directly fit with microorganisms.

Lastly, APHIS BRS previously used a tool to help developers, called "Am I Regulated". This process allowed developers to engage with the agency, resulting in clear documentation regarding whether a potential product falls under the jurisdiction of BRS. A similar process is needed for microorganisms.

6. ***Describe any new or emerging categories of biotechnology products on the horizon that the regulatory system and processes for biotechnology products should be preparing to address. Describe any specific recommendations for regulating these new or emerging categories of biotechnology products to guide agency preparations.***

As this category of biotechnology products will continue to grow, there are several different types of new innovations which should be monitored. Those include, but are not limited to the following: de novo engineered microbes created through biotechnology techniques, novel microorganisms which are newly discovered but don't yet have a complete reference literature set, RNAi technology for targeted pest and disease, or phage technology for targeted modification of microbiomes, pest control, etc.

As technology improves and changes, we believe it is important that agency personnel, including reviewers, are trained adequately and provided with continued training so they are able to utilize that knowledge consistently to review future products and that agencies are adequately staffed with appropriate scientific expertise to address microbial products.

We encourage the regulatory agencies to seek harmonization of regulatory processes, reviews and authorizations so that biotechnology products are evaluated consistently and predictably across and within agencies. Ultimately, US regulatory agencies should strive for consistency in regulations, but the regulations must also allow flexibility for new innovations that will inevitably come along. Therefore we encourage regulators to consider implementing regulations for products developed with new genomic techniques to accommodate even newer technology when it comes to light.

7. ***What is the highest priority issue for the agencies to address in the short term (i.e., within the next year) and in the long term?***

The highest priority issue is for USDA APHIS to address the lack of clarity in the current regulations for genetically engineered microorganisms for agricultural applications, and to clarify the regulatory framework through guidance or rulemaking that would enable a

predictable path for field trial permitting and commercialization of said products as it relates to plant pest risk or the lack thereof.

In the short term, the highest priority shall be USDA APHIS' development of a guidance document that would further clarify the regulation of genetically engineered microorganisms for agricultural applications.

As technology developers of genetically engineered microorganisms, we would appreciate the opportunity to provide comments on APHIS's draft of this guidance document, from the developers' perspective, in Q1' 2023 to support its ratification in Q2' 2023.

Currently, technology providers must navigate the regulations across the three agencies that act under the Coordinated Framework for Regulation of Biotechnology (USDA, EPA, and FDA). To create clarity and efficiencies, we strongly encourage the agencies of the Coordinated Framework to establish a single point of entry for developers to use to determine if/how genetically engineered microorganisms for agricultural applications will be regulated. We further encourage improved harmonization of existing regulations across USDA-FDA-EPA to clarify the path for developers of such technologies.

It is critical to have a time sensitive and predictable regulatory framework that enables efficient development and commercialization of agronomically effective sustainable biological technologies, including genetically engineered microbial products, with the objective to make these much-needed biological solutions available to American growers, consumers, and the world.

Sincerely,

BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE

Keith J. Jones
Executive Director