Report to the President of the United States and United States Congress on Plant Biostimulants Submitted by the United States Department of Agriculture (USDA) in Consultation with the Environmental Protection Agency (EPA) on December XX, 2019

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I. Executive Summary

The "Agricultural Improvement Act of 2018" (the Act), also known as the 2018 Farm Bill, directed the Secretary of Agriculture to submit a report to Congress on the status and regulatory review of plant biostimulant products. This report was to include a definition of plant biostimulants and recommendations to address the appropriate review, approval, availability, and uniform labeling of plant biostimulant products to agricultural producers.

USDA consulted with the Environmental Protection Agency (EPA) and other stakeholders as directed in the Act, hosting and facilitating meetings that brought together participants from industry as well as State and Federal government agencies.

Three working groups were convened to address (1) regulatory issues, (2) State interactions, and (3) product certification. The working groups submitted their recommendations to USDA (see Appendix 1), and these comments and recommendations assisted in the preparation of this report. USDA used industry, State, and Federal cooperators' comments to draft this report.

Plant biostimulants and biostimulant products, when applied to plants, seeds, or soil, help the plant achieve its maximum yield or growth. They can be derived from various sources, such as microbial inoculants, biochemical materials, nutritional chemicals, amino acids, humic acids, fulvic acids, seaweed extracts, plant extracts, and their synthetically derived equivalents. The plant biostimulant industry is estimated to be at least a $2.2 billion global market.

Marketing and regulating plant biostimulants and plant biostimulant products is complicated due to overlapping Federal and State authorities, or conversely, due to gaps in those authorities. At the Federal level, EPA, the Food and Drug Administration (FDA), and USDA all have some regulatory authority in this arena.

Plant biostimulants do not have a regulatory definition at the State and Federal level and are not recognized as an independent class of products.

In this report, we provide alternatives to the plant biostimulant definition written in the Act, list six options to achieve the goals of the Act regarding plant biostimulants, and indicate what options we recommend.

II. Plant Biostimulant Definitions

Multiple definitions of "plant biostimulant" are in use in industry and research, but not at Federal and State government levels. As the Act directs for purposes of this report, USDA considers a "plant biostimulant" to be:

> "a substance or micro-organism that, when applied to seeds, plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield."

In considering that the Secretary may modify this definition of "plant biostimulant," we list two working alternatives, each with its own merits.

Alternative definition 1: A plant biostimulant is a naturally-occurring substance, its synthetically derived equivalent, or a microbe that is used for the purpose of stimulating natural processes in plants or in the soil in order to, among other things: improve nutrient and/or water use efficiency by plants, help plants tolerate abiotic stress, or improve characteristics of the soil as a medium for plant growth. The characteristics may be physical, chemical, and/or biological. The plant biostimulant may be used either by itself or in combination with other substances or microbes for this purpose.

Alternative definition 2: A plant biostimulant is a substance(s), microorganism(s), or mixtures thereof, that, when applied to seeds, plants, the rhizosphere, soil or other growth media, act to support a plant's natural nutrition processes independently of the biostimulant's nutrient content. The plant biostimulant thereby improves nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality or yield.

While plant biostimulants are a sub-category of biostimulants, all references to biostimulants in this report refer generally to plant biostimulants. This report does not address non-plant biostimulants.

III. Plant Biostimulants and their Benefits

For decades, farmers have been successfully using plant biostimulant products in agricultural production. Other users including golf course superintendents, landscape professionals, and even homeowners have experienced the benefits that such products can offer. Some versions or categories of plant biostimulants have been in safe and effective use for centuries.

Plant biostimulant products have a variety of beneficial attributes. Some of the more notable benefits to agricultural production and environmental sustainability are that plant biostimulants can:

- Help to increase crop yields; enhance crop or plant performance by improving tolerance to abiotic stress factors such as drought, heat or salinity; improve root structure and function; enhance seed germination and plant emergence; increase soil nutrient retention and availability; increase soil water holding capacity; improve nutrient use efficiency.
- Help increase yield and quality without increasing applied fertilizer, water or planted acres, by enhancing the efficient use of these natural resources and / or reducing food loss in the field.
- Increase the uptake and utilization of existing and applied nutrients, thereby reducing the potential for off-farm nutrient runoff into rivers, lakes, and streams.
- Be readily incorporated into existing agricultural practices—for example, as seed treatments, in fertilizer combinations, incorporated in growing media, in-furrow or as foliar sprays, and can be used in both conventional and organic crop production.

The plant biostimulant industry is estimated to be at least a $2.2 billion global market. The industry is active, growing quickly and expected to become a $5 billion global market by 2025. Nearly all midsized to major agricultural products companies have investments in the plant biostimulant categories. Innovation and new product development is expanding at a considerable rate by large, medium, and small companies. Despite this, many regulatory challenges and uncertainties exist for this growing suite of technologies.

IV. Participants and Process

Federal and State regulatory agencies and industry representatives met to generate possible options to put forward to the Congress, defining biostimulants and generating regulatory and non-regulatory approaches to address labeling and product availability. As instructed by the Act, participants included:

- Federal Agencies: Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and United States Department of Agriculture (USDA) - Agricultural Marketing

Service (AMS) and Animal and Plant Health Inspection Service (APHIS).

- State Regulatory Officials: Association of American Pesticide Control Officials (AAPCO), Association of American Plant Food Control Officials (AAPFCO), and the National Association of State Departments of Agriculture (NASDA).

- Industry: American Seed Trade Association, Biological Products Industry Alliance, United States Biostimulant Coalition, Biotechnology Innovation Organization, Humic Products Trade Association, the Fertilizer Institute, and the Phytobiomes Alliance.

USDA-APHIS hosted and facilitated on-site meetings which brought participants representing industry trade associations and State and Federal agencies together to develop this report. As requested by Congress, the report includes "potential regulatory, non-regulatory, and legislative recommendations, including the appropriateness of any definitions for plant biostimulant, to ensure the efficient and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers." Key issues and goals addressed in these sessions included:

- The ability to use a uniform, national legal definition for "plant biostimulant;"
- The consequent ability to make defined plant biostimulant claims;
- A responsible approach that builds credibility for the industry;
- A clear, consistent, and predictable pathway to market;
- A uniform and consistent environment for labeling and regulation – "one label," for all States;
- Clear and reasoned criteria to assess product efficacy, safety and compositional claims;
- Clear rules and / or regulations for so-called "multi-function" active ingredients; and
- Global regulatory consistency.

The meeting participants created three working groups which were led by industry representatives and NASDA officials. These groups worked throughout the year and addressed the tasks to:

1. Identify regulatory issues, explore State and Federal interactions involving biostimulants, and product certification, standards and criteria.
2. Develop recommendations and options for the Congressional report.

The working groups submitted their recommendations to APHIS on June 14, 2019 (See Appendix 1). USDA-APHIS reached out to AMS, EPA, FDA, AAPCO, AAPFCO, and NASDA, for their comments on the draft recommendations for this report. APHIS provided working group reports to all participants for review. USDA-APHIS in conjunction with other federal partners then worked to develop this report. Drafts of the report were provided to Federal agencies (EPA and FDA) for comment and review to facilitate the development of a draft unified Federal approach.

V. The Regulatory Dilemma

Many of the ingredients of plant biostimulant products have multiple modes of biological activity. The mode of biological activity (e.g., acting as a pesticide, acting as a nitrogen fixer, etc.) informs whether and how plant biostimulants are regulated and by what entity. Hence regulating these products is very complicated. Federal and State regulatory agencies' authorities can overlap, or conversely, there can be gaps in those authorities. Plant biostimulants as defined in this report cover products that are in many categories, including pesticides, fertilizers, soil/plant amendments, and soil/plant inoculants.

Products outside the jurisdiction of EPA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are most often regulated through a variety of States' laws and regulations. Each State has its own unique laws and practices for managing these products, but in general States regulate these products as fertilizers (those that contain certain plant nutrients), and/or other categories including soil amendments, plant amendments, and other beneficial substances. The combination of Federal and State approaches presents a two-fold challenge: (1) industry indicates it is difficult to determine whether a product is regulated under FIFRA; (2) States' requirements are not consistent or predictable.

In September 2018, the National Association of State Departments of Agriculture (NASDA) members passed a policy item stating:

> "NASDA supports identifying and supporting paths that efficiently move biostimulant products into the United States' marketplace. State, federal partners, and industry must continue to work together to explore existing and potential paths that allow biostimulants to be sold in the United States, create any additional regulatory structures needed to cover materials not currently included under the existing framework, harmonize state and federal regulations, and support biostimulants' market growth internationally. This process should also inform consumers about the products' efficacy and allow these technologies to grow and develop into the future."

VI. Current Federal Regulation

EPA regulates the distribution, sale, and use of pesticides by authority granted under FIFRA and through Title 40 of the Code of Federal Regulations (40 CFR). All pesticides or plant growth regulators distributed or sold in the United States must be registered (licensed) by EPA. Independent of this report, EPA published a draft document, "Guidance for Plant Regulator Claims, Including Plant Biostimulants" (Federal Register docket number EPA-HQ-OPP-2018-0258). This guidance clarifies for industry and States how EPA has implemented FIFRA's plant growth regulator statutory requirements in the past. EPA is providing this guidance to help the regulated community and State regulatory partners better understand what is and is not a pesticide/plant growth regulator. The draft guidance does not seek to establish any new policies. EPA is now reviewing the comments received on the draft guidance. In addition, the recently

amended Pesticide Registration Improvement Act - includes a specific category for a company to obtain a determination as to whether something is or is not a pesticide or plant growth regulator.

USDA-APHIS regulates the importation or interstate movement of plant pests and biological control agents under authority granted by the Plant Protection Act of 2000, and through 7 CFR Part 330. APHIS shares dual jurisdiction with EPA regulating bacteria and fungi that help the plant by actively discouraging plant pests and pathogens (*i.e.,* acting as biocontrol agents or microbial pesticides).

APHIS also reviews and issues permits for laboratory, greenhouse, and field research with plant pests and microbes that act as biological control agents. Typically, APHIS reviews and issues permits for small scale testing (less than 10 acres of land and less than one acre of water per year nationwide) as per a memo of understanding with EPA. EPA regulates testing on areas greater than 10 acres and/or commercialization of products determined to be a pesticide or plant growth regulator. However, when EPA has determined that it does not have jurisdiction, APHIS may regulate the use of plant pests and microbes in areas greater than 10 acres of land or one acre of water.

USDA-AMS enforces the interstate commerce provisions of the Federal Seed Act (FSA). The FSA regulates the interstate shipment of agricultural and vegetable seeds. Any agricultural or vegetable seed, for seeding purposes, that has been treated must be labeled to indicate that the seed has been treated, and show the name of any substance used in such treatment (ex. endophyte-enhanced). Seed that is inoculated with microbes must be labeled to show the month and year beyond which the inoculant on the seed is no longer claimed to be effective. Many plant biostimulants are applied as seed treatments, and in these cases, they fall under FSA regulation.

USDA-AMS also offers a non-regulatory, fee-for-service program through its Process Verified Program (PVP). This auditing program potentially works without additional Federal legislation; industry pays associated costs. The AMS PVP is a verification service that offers applicants an opportunity to market products to customers using clearly defined, implemented, and transparent process points. An applicant's program may include one or more agricultural processes, or portions of processes, where self-described process points are (1) supported by a documented management system, and (2) independently verified by a qualified AMS auditor. The AMS PVP process could be implemented as a non-regulatory option to address the uniform process and availability of plant biostimulants as directed in the Act. However, the PVP process would not address the uniform labeling of plant biostimulant products.

FDA has primary legal responsibility for determining the safe use of food additives. Section 201(s) of the Federal Food, Drug, and Cosmetic Act (FFDCA) [21 U.S. Code § 321(s)] defines "food additive" as any substance whereby the intended use results in its becoming a component of any food, unless the substance is Generally Recognized As Safe (GRAS) among qualified experts under the conditions of its intended use, or unless the substance meets a listed exception. Before a food additive that will have technical effect in food is marketed, FDA must first issue a regulation that authorizes such use. One of the listed exceptions is for pesticide chemical residues in or on

food. Pesticide chemical residues are deemed unsafe in food unless they conform to a tolerance or an exemption from a tolerance established by EPA [21 U.S. Code § 346 (a)]. Anyone that seeks a regulation for a new use of a food additive must submit a petition to FDA with evidence that the substance is safe for the intended use. FDA's Produce Safety Rule provisions in 21 CFR Part 112, Subpart F set baseline Federal requirements for the safe production, conveyance and use of Biological Soil Amendments of Animal Origin (BSAAO), which could include plant biostimulants, when used to amend fields for growing covered commodities. In such cases, plant biostimulants would be handled no differently than any other BSAAO. Under the FFDCA, FDA is responsible for enforcing pesticide tolerances as established by EPA for foods in interstate commerce.

VII. Current State Regulation

At the State level, plant biostimulants do not have a regulatory definition and are not a recognized independent class of products. Depending on the types of claims made in product labeling, plant biostimulants can be registered in one of two ways. 1) Plant biostimulants may be regulated as pesticides under FIFRA and regulated by EPA, or as delegated to State authority by EPA. 2) Plant biostimulants may be considered fertilizers or inoculants, and regulated by States either through the State Departments of Agriculture or other State lead agency. Additionally, some fertilizers may be regulated by the FDA as BSAAO under the Produce Safety Rule.

States vary significantly in the level of resources (budgetary funding and staff) available to manage this broad scheme of product registrations. Department structures and registration requirements can also be quite dissimilar. Some States have well-structured requirements for a fertilizer product registration – for example, requiring guaranteed analysis data, efficacy, or product performance data, heavy metal analysis, or microbial analyses for various products. Other States have minimal requirements, and may simply require a license to sell, while still others have no defined registration or licensing requirements at all. Some States require tonnage reporting, along with required fees based on those reports.

Product labeling requirements reflect the variable regulatory environment, and lead to the need for an average of three to five labels per product for soil/plant amendments. Quite often, States have different laws on what the required elements of a label are; what materials may or may not be claimed; how the concentration of those materials is measured or quantified; and even the order for presenting those components (*e.g.*, mineral ingredients) on a proposed label. The variability of these requirements can become highly complex and problematic for registrants to manage or for product users to understand, impacting interstate product movement, warehousing, storage, internet sales, etc. This exemplifies the current difficulty of creating a single label that satisfies all the State requirements.

In its guidance document for fertilizer regulatory officials on label standards, the Association of American Plant Food Control Officials (AAPFCO), describes "beneficial substances" as: "any substance or compound other than primary, secondary, and micro plant nutrients that can be demonstrated by scientific research to be beneficial to one or more species of plants, when applied

to the plant or soil." Among the 50 States, only 13 States either reference "beneficial substance" in their regulations or have their own definition of "beneficial substances."

VIII. Challenges with Current Oversight Mechanisms

Industry suggests that business analysts describe the plant biostimulant category as rapidly growing and global in its impact. Many countries are evaluating the appropriate level of regulatory oversight for these products and clarifying their paths to market.

- The terms "biostimulant" and "plant biostimulant" are in broad commercial use globally, but no U.S. State or Federal level agency officially recognizes either term.
- Product developers in the U.S. are prohibited from calling their products "biostimulants" in many States, and current State regulatory frameworks limit the benefit claims product developers can make.
- Companies must either register their product as a pesticide with EPA if it meets the definition of a pesticide under FIFRA, or seek State-by-State approval under a variety of distinct product labels and categories, including soil amendment, plant amendment, plant inoculant, beneficial substance, or fertilizer. This can be complex and confusing for developers, regulators, and users.
- The European Union (EU) also sees the need for regulatory clarity, a topic addressed directly in the recent revision of its Fertilizer Regulation (EU 2016/0084) that encompasses plant biostimulants. Other parts of the world are undertaking similar initiatives.

IX. Recommendations

The working group members recognized the need to develop a framework to move forward, and to develop clear guidance in order to evaluate efficacy and safety concerns consistent with risk management. We report six options to achieve the goals of the Act regarding plant biostimulants. Following the descriptions of the options is a table identifying what options we recommend. We provide more detail about recommendations at the end of this section of the report and in the report Conclusions.

Option 1: Harmonize existing State and Federal programs that regulate fertilizers and soil inoculants. States would need to adapt existing guidance for beneficial substances and develop labeling options. This recommendation relies on industry to provide efficacy data, as well as certification of product ingredients.

AAPFCO would need to clarify label requirements in existing model bills for products such as fertilizers, soil/plant amendments, etc. (A model bill is essentially a template for a State-level bill that NASDA and AAPFCO develop to harmonize regulations across States.) This option addresses plant biostimulants not considered to be pesticides by EPA. Those plant biostimulant products with pesticidal plant growth regulator properties would continue to be regulated by EPA at the Federal level and by designated lead agencies at the State level. No Congressional legislation or Federal

rulemaking is required with this option. Rulemaking at the State level may be necessary. This option does not address the uniform labeling issue nor the issue of process verification of plant biostimulants. Industry would have to use the term "beneficial substance" rather than plant biostimulant. This option could be implemented fairly quickly, in as little as one to two years.

Option 2: NASDA facilitates a State by State approach and coordinates efforts with AAPFCO to create a model bill of State regulations for beneficial substances, including plant biostimulants.

Like Option 1, plant biostimulant products with pesticidal or plant regulator properties and claims continue to be regulated by EPA at the Federal level and designated lead agencies at the State level. Likewise, biostimulant products may be regulated by FDA as food additives or biological soil amendments under the Produce Safety Rule (21 CFR Part 112). This option requires neither Congressional legislation nor Federal rulemaking. Industry and the States would work together to develop and incorporate the criteria and standards for the plant biostimulant PVP in the model bills used to create harmonized regulations in the States. Industry provides the efficacy/safety data and ingredient certification. Product certification could be obtained through a PVP administered by USDA-AMS or by another entity recognized by the States. This would likely include a fee paid by industry. The model bills in this option would address labeling concerns, and industry would be able to use the term "plant biostimulant" in interstate commerce using a common definition established in the model bill. This option could take five to seven years to fully implement.

Option 3: This option is similar to Option 2, except that USDA would facilitate the process to bring about a model bill that States would use to enact legislation. Thus, neither Congressional legislation nor Federal rulemaking would be required, and the program addresses both product certification (via a plant biostimulant PVP) and label harmonization between the States. Plant biostimulant products with pesticidal or plant growth regulator properties and claims continue to be regulated by EPA at the Federal level and by designated lead agencies at the State level. Likewise, biostimulant products that meet the statutory definition of food additive or of a BSAAO and are utilized for covered commodities under the Produce Safety Rule are regulated by FDA.

Industry would be able to use the term "plant biostimulants" in interstate commerce using a common definition established in the model bill. USDA would facilitate a work group of State regulatory officials, AAPFCO, and industry members to develop a more uniform approach to the State regulation of plant biostimulants. This process could take four to six years to implement, depending on the level of USDA resources and involvement.

Option 4: Congress enacts legislation to establish a uniform national definition of "plant biostimulant" and directs the EPA Administrator to amend current pesticide regulations to (1) incorporate the same uniform national definition of "plant biostimulant," and (2) clarify the exclusion of plant biostimulant products from regulations as plant growth regulators (or pesticides) under FIFRA. However, such an exclusion may have implications for FDA, in particular for plant biostimulants that are no longer regulated as plant regulators or pesticides and are not otherwise exempt from regulation as food additives or by the Produce Safety Rule. USDA would need to create infrastructure to accommodate this change. States would also have to modify their

regulations as a result of this legislation. USDA would facilitate a working group of State regulatory officials, AAPFCO, and industry members to develop a more uniform approach to State regulation of plant biostimulants.

This option could include legislation similar to the Virus-Serum-Toxin Act (VSTA), by which Congress authorized USDA to regulate the safety and efficacy of animal vaccines and other biological products (see Appendix 2). Specifically, the VSTA, first enacted in 1913, makes it unlawful "to prepare, sell, barter or exchange… any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals." The VSTA gives USDA the authority to write regulations for the issuance, suspension, and revocation of licenses for these products and to require permits for their importation. An act like the VSTA could be used to fill gaps in regulation for plant biostimulants not already covered by EPA as pesticides or by FDA as BSAAO.

This option could include the additional step of USDA establishing a multi-stakeholder Plant Biostimulant Federal Advisory Committee to create further dialogue between impacted stakeholders. In addition, Congress would propose longer term legislation to authorize and direct the USDA Secretary to develop a uniform national framew

ork for plant biostimulant products in consultation with States, appropriate State organizations, industry stakeholders, and other stakeholders the Secretary determines necessary. This legislation could create harmonized labels, and would likely address product certification (such as what a plant biostimulant PVP could provide). The legislation could make product certification and States' acceptance of it mandatory. Since this process involves Congressional legislation and rulemaking at the State and Federal levels, it is likely to take many years.

Option 5: Congress passes a "Plant Biostimulant Act" and grants USDA, EPA, or another Federal agency authority to regulate those plant biostimulant products not currently regulated as pesticides or growth regulators by EPA, and not otherwise regulated as a food additive or as a BSAAO by FDA. Depending on how Congress defines plant biostimulants, EPA may or may not need to amend current pesticide regulations to exclude plant biostimulant products from regulation as plant growth regulators (or pesticides) under FIFRA. Likewise, FDA may or may not need to amend current food additive and Produce Safety Rule regulations to exclude plant biostimulant products from regulation as food additives or BSAAOs.

Through rulemaking, the agency authorized by Congress could work with other Federal agencies, NASDA, AAPFCO, and industry to develop suitable definitions. The "Plant Biostimulant Act" would provide the designated Federal agency with authority to create standards for efficacy and safety. Through rulemaking, the agency could set up a program by which industry, working with NASDA and AAPFCO, develops criteria and standards. The certification program could be administered through USDA-AMS as a fee-for-service PVP program.

As described in Option 4, this option could include something similar to the VSTA. As in Option 4, a Federal agency could use a VSTA-like law to regulate plant biostimulants that are not already covered by the EPA or FDA. Congress could give the agency the authority to create a single

national label to facilitate commerce. This would allow the Federal regulatory agency to delegate primary approval and review authority to State fertilizer programs, with the Federal agency running programs in States that do not adopt it. States would need to amend their fertilizer laws and develop State regulations that incorporate the Federal regulating agency's laws by reference. As in Option 4, since Option 5 involves Congressional legislation and Federal rulemaking, it will likely take many years to fully implement.

Option 6: This option is a voluntary, fee-for-service non-regulatory approach. It involves on-site verification that producers of plant biostimulants have their products and production processes audited annually by a third-party, confirming that products meet certain plant biostimulant standards and criteria. USDA-AMS would administer the PVP. Industry would set the criteria and standards, and provide efficacy/safety data and ingredient certification that would serve as the baseline criteria that qualified AMS auditors would verify. AMS auditors would conduct a rigorous review of a company's program, first with a desk audit to ensure all program requirements are accounted for and documented in their Quality Manual, followed by a comprehensive on-site audit of all facilities and phases of the operation. Neither Federal nor State legislation is required. The States themselves, either through NASDA or through AAPFCO, may also be able to administer such a program.

Applicants with an approved USDA PVP may use the USDA PVP shield in accordance with program requirements and market themselves as "USDA Process Verified." The USDA PVP does not relieve the company of meeting regulatory requirements. The standalone approach does not address labeling issues, nor does it allow producers to use the term "plant biostimulants."

Function	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
Non-regulatory option						✓
Regulatory option	✓	✓	✓	✓	✓	
Federal legislation required				✓	✓	
Federal rulemaking required				✓	✓	
State legislation required	✓[1]	✓	✓	✓[1]	✓	
State rulemaking required	✓	✓	✓	✓	✓	
Plant biostimulant defined		✓	✓	✓	✓	
Uniform national labeling		✓[1]	✓	✓	✓	
FIFRA amended (EPA)				✓	✓	
Plant Protection Act amended				✓[2]	✓[2]	
Implications for FFDCA (FDA)				✓	✓	
Based on model bill for States		✓	✓			
Federally facilitated			✓	✓		✓
Facilitated by others	✓	✓			✓	
Process Verified Product		✓	✓		✓	✓
Voluntary	✓[1]					✓
Preferred by		USDA/ EPA/ FDA	USDA/ EPA/ FDA /NASDA	Industry 1st	Industry 2nd	
Estimated time to completion (years)	1-2	5-7	4-6	8+	8+	2-3

Table 1. Options to improve oversight of plant biostimulants. FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act; FFDCA: Federal Food, Drug, and Cosmetic Act. [1] possible, depending on how States want to implement or make changes; [2] possible, depending on language used in legislation.

Option 1 as described maintains status quo, which no participants wish to continue. USDA, EPA, and FDA prefer either Option 2 or Option 3. Option 2 and Option 3 address industry's request for a harmonized product label and provide a mechanism by which their products may be marketed as safe and effective. Options 2 and Option 3 work within existing Federal structures. These options do not shift the regulatory oversight of plant biostimulants that are plant growth regulators from EPA to USDA. These options require neither Congressional legislation nor Federal rulemaking, and will address industry's needs in a timely manner. NASDA prefers Option 3, depending on the level of USDA resources and facilitation, both of which would affect the timeliness of the model bill process.

Industry prefers Option 4 and secondarily, Option 5. Options 4 and 5 would require USDA to develop a process similar to EPA's existing structure in order to provide proper oversight. While the timeline to implementation could take several years, Federal authority to regulate biostimulants

would present industry with several benefits, such as a unified label and a federally recognized class of biostimulant products.

X. Conclusions

The definition of plant biostimulants as it appears in the Farm Bill, if adopted, with the appropriate changes to FIFRA and 40 CFR Part 152 would lead to many bio-pesticides and other conventional plant growth regulators being unregulated. Any changes to FIFRA would need to be addressed through Congressional legislation, including rulemaking to amend 40 CFR. Currently, plant biostimulants that fall under EPA's FIFRA authority have a clear regulatory pathway to market. However, not all plant biostimulants need to be regulated by EPA, nor are all plant biostimulants minimal risk products. Decoupling plant biostimulants from EPA's oversight under FIFRA could trigger a review of the FFDCA as well as FDA involvement with these products for any residues in/on food crops and animal feed.

Transferring authority to USDA-APHIS to regulate plant biostimulants would require Congressional action to amend the Plant Protection Act or develop legislation similar to the Virus-Serum-Toxin Act (see Appendix 2), along with the rulemaking that would be required to implement any such change. USDA-APHIS' current authorities under the Plant Protection Act are limited to regulating organisms, not substances. USDA would need to develop and duplicate EPA's existing infrastructure to evaluate these products properly in order to ensure environmental safety and address labeling issues.

A PVP program for plant biostimulants, carried out by USDA-AMS or other third-party certification programs for plant biostimulants, if approved, could provide States with efficacy/safety data and ingredient certification standards. A standalone program, like PVP might be of interest in some instances, but USDA determinations do not supersede State pesticide and fertilizer laws. A PVP could be a valuable component that complements some of the other options mentioned, but alone it does not address uniform national labeling.

Fertilizers are not regulated at the Federal level, with the exception of BSAAO covered under the FDA's Produce Safety Rule. Should Federal legislation be enacted, States and territories may have to amend their current laws and rules to ensure alignment with Federal legislation in order to regulate this new class of biostimulant products. States have expressed concerns about amending fertilizer laws as a means to regulate biostimulants. The majority of options are not achievable at the State regulatory level without additional resources and legislative changes.

AAPFCO could develop model bills outlining a regulatory structure that would provide a place for biostimulants that are not otherwise covered. This regulatory structure could then be adopted by States at their discretion. For States without interest, the products would be un-regulated and industry would be free to distribute their products.

Industry stakeholders will benefit from a more efficient, predictable and uniform regulatory process and greater recognition by State and Federal regulators of plant biostimulants. Plant biostimulant

companies will be able to invest in research and development, and continue to create innovative solutions with an expectation of recapturing value from the effective marketing of superior product technologies. Industry would be expected or required to bear the cost of obtaining product approvals. However, the efficiency, speed to market, and elimination of redundancy in the validation process likely represent attractive tradeoffs.