USDA

United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

DEC 20 2019

The Honorable Collin Peterson
Chairman
Committee on Agriculture
U.S. House of Representatives
1300 Longworth House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

Section 10111 of the Conference Report for the Agriculture Improvement Act of 2018 (2018 Farm Bill) directs the U.S. Department of Agriculture (USDA) to submit a report to Congress and the President on plant biostimulants identifying potential regulatory, non-regulatory, and legislative recommendations to ensure the efficient and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers.

The requested report and associated appendix are enclosed. To prepare it, USDA consulted with the Environmental Protection Agency 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.

Plant biostimulants have a variety of beneficial attributes, including maximizing yield when applied to plants, seeds, or soil. For decades, farmers have successfully used plant biostimulant products in agricultural production; some versions or categories have been in safe and effective use for centuries. Estimated to be at least a $2.2 billion global market, the plant biostimulant industry is growing quickly, and companies are innovating and expanding product development at a considerable rate. The attached report outlines current regulatory challenges and uncertainties and identifies six potential options, including two recommended by USDA. Also attached is a report appendix. The appendix provides supplemental information, including industry and State stakeholders' written input, and more detail about a law (the Virus-Serum-Toxin Act) that serves as a model for one potential legislative recommendation.

If you have any questions about this matter, please have a member of your staff contact USDA's Office of Congressional Relations at (202) 720–7095. We are sending a similar letter to Chairman Pat Roberts, Ranking Member Debbie Stabenow, and Ranking Member Michael Conaway.

Sincerely,

Sonny Perdue

Sonny Perdue
Secretary

Enclosures

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.

Appendix 1: Industry Report- Biostimulant Recommendations for USDA Report to Congress

Biostimulant Industry Stakeholder Recommendations to USDA Regarding Plant Biostimulants for Consideration in Its Report to Congress

Contents

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Executive Summary

Background:

Section 10111 of the Agriculture Improvement Act of 2018 (2018 Farm Bill) authorized the Secretary of Agriculture (Secretary) to submit a report (within one year of enactment) to the President and Congress that identifies any 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. The Secretary is to prepare the report in consultation with the Administrator of the U.S. Environmental Protection Agency (EPA), the several States, industry stakeholders, and such other stakeholders the Secretary determines necessary. For purposes of preparing the report, Congress described a "plant biostimulant" as:

> a substance or microorganism 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.

Finally, Congress authorized the Secretary to modify that description of a plant biostimulant, as appropriate.

Overview:

Secretary Perdue has stated that one of his goals is to encourage more young people to work in agriculture. He has argued that the STEM (Science, Technology, Engineering and Math) disciplines are in fact a perfect background and justification for someone with this educational background to start a career in agriculture.[1] The plant biostimulant industry creates the potential for additional job creation in these areas while promoting the sustainability and continued growth of agriculture in the United States and beyond. The Secretary also led development of a comprehensive report by an interagency task force on promoting agriculture and rural development. Plant biostimulant products address technology and economic development – two key indicators identified in that report for achieving a vision for a better rural America.

The commercial category of products known as "plant biostimulants" is comprised of products that enhance agricultural productivity and are valued for their contribution to sustainable agriculture production systems. Industry considers this category to be distinct from pesticides (which includes plant regulators as defined by the Federal Insecticide, Fungicide and Rodenticide Act, or FIFRA) and fertilizers.

Over many years, the plant biostimulant industry and associated stakeholders have been meeting to discuss options for mandatory and voluntary paths that would facilitate a more consistent framework for bringing plant biostimulant products to market, elements of which include the efficient and appropriate review, approval, and uniform national labeling, of these products.

To achieve these goals, a broad stakeholder workgroup was formed to evaluate the potential legislative, regulatory and non-regulatory recommendations to be included in this report. This group has included: the Association of American Plant Food Control Officials (AAPFCO), the Association of American Pesticide Control Officials (AAPCO), the American Seed Trade Association (ASTA), Biological Products Industry Alliance (BPIA), United States Biostimulant Coalition (USBC), Biotechnology Innovation Organization (BIO), Humic Products Trade Association (HPTA), National Association of State Departments of Agriculture (NASDA), the Fertilizer Institute (TFI), and the Phytobiomes Alliance. These stakeholders greatly appreciate the role USDA has played to date in facilitating greater dialogue between the various groups mentioned above. Without USDA's engagement, it is likely some of these discussions would not have occurred.

Challenges with Current Oversight Mechanisms:

Business analysts describe the plant biostimulant category as rapidly growing and global in its impact.[2] As a consequence of the many benefits plant biostimulant products provide to agriculture and society in general and their continued adoption by growers, many countries are evaluating the appropriate level of regulatory oversight for these products and clarifying their paths to market. Challenges in the United States that are appropriate for consideration in the report to Congress include the following:

- The terms "biostimulant" and "plant biostimulant" are in broad commercial use globally, but no U.S. state or federal level agency officially recognizes the term.
- As a result, product developers in the U.S. are prohibited from calling their products "biostimulants" in many States and limited in the benefit claims they can make by current State regulatory frameworks.
- Plant biostimulant products lack a clear, consistent and predictable regulatory path to market according to their intended use and benefits.
- Companies must either register their product as a pesticide with EPA or seek state-by-state approval under a variety of distinct product labels and categories, including as a soil amendment, plant amendment, plant inoculant, beneficial substance, or fertilizer, in every State in which they wish to market. Neither path is truly appropriate for these products and all can be unnecessarily burdensome, costly, 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 their Fertilizer Regulation (EU 2016/0084) that encompasses plant biostimulants. Other parts of the world are undertaking similar initiatives.

By addressing these challenges, agricultural producers, the plant biostimulant industry, other related stakeholders, and State regulators would all benefit from:

- The recognition of and ability to use a uniform, national legal definition for "plant biostimulant";
- The consequent ability for industry to make defined plant biostimulant claims;
- A responsible approach that builds credibility for the industry;

- A clear, consistent, and predictable process to market;
- A uniform and consistent environment for product labeling ("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
- Global regulatory consistency

Recommendations:

As described below, the group developed potential legislative, regulatory, and non-regulatory recommendations for Congress, USDA and EPA to consider as paths forward.

It is recommended that USDA's report to Congress propose the following shorter-term measures:

1. Enactment of legislation:
   a. To establish a uniform national definition of "plant biostimulant", and
   b. To direct the EPA Administrator to amend current pesticide regulations to (i) incorporate the same uniform national definition of "plant biostimulant" and (ii) clarify the exclusion of plant biostimulant products from regulation as plant regulators (or pesticides) under FIFRA.

2. USDA Facilitation:
   a. USDA to begin immediate facilitation of a work group of state regulatory officials, AAPFCO, and industry members to develop a more uniform approach to the state regulation of biostimulants. This includes the development of a common label format, consistent product and product claim definitions as required, safety criteria, a common approach to efficacy testing requirements, and the resolution of such other issues that are identified during the process as impediments to interstate commerce or conflicts among the states in adopting a uniform regulatory approach to biostimulants.
   b. USDA could also establish and facilitate a multi-stakeholder Plant Biostimulant Federal Advisory Committee or Task Force to include representatives from USDA, EPA, State regulators, NASDA, and industry stakeholders to identify regulatory and non-regulatory mechanisms for moving toward national uniformity in the oversight of plant biostimulant products.

3. In addition, it is recommended that the report to Congress propose legislation in the longer term that would authorize and direct the Secretary to develop a uniform national framework for plant biostimulant products in consultation with the several States, appropriate state organizations, industry stakeholders, and such other stakeholders the Secretary determines necessary.

These recommendations are discussed in greater detail in Chapter 3.

Chapter 1: History of Plant Biostimulant Industry and Regulation:

What Are Plant Biostimulants?

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. In fact, some versions or categories of plant biostimulants have been in safe and effective use for centuries. Despite this, many regulatory challenges and uncertainties exist for this growing suite of technologies.

Plant biostimulants represent a distinct category of products, which fit neither plant nutrients (fertilizers) nor pesticides (plant protectants or plant regulators) as classes of products. While there is currently no universally recognized definition, plant biostimulants can be derived from various sources[3] such as microbial inoculants, biochemical materials, nutritional chemicals, amino acids, humic acids, fulvic acids, seaweed extracts, plant extracts, and other similar materials, their synthetically derived equivalents or other synthetic substances. While a broad and diverse category, when applied to plants, seeds, or soil, plant biostimulants help the plant achieve its optimum genetic potential.[4] (See Appendix 1)

Size of the Plant Biostimulant Industry

The plant biostimulant industry is currently estimated to be at least a $2.2 billion global market.[2] The industry is active, growing quickly and expected to become a $5 billion global market by 2025. In fact, 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.

Benefits of Plant Biostimulants

Plant biostimulant products have a great variety of beneficial attributes. Some of the more notable independently researched benefits of plant biostimulants to agricultural production and environmental sustainability are as follows:

Plant biostimulants can:

- Generally 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 – among other benefits being discovered through ongoing research.
- 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.
- Help to enhance plant and soil health in the world's quest for more sustainable agricultural practices. There is an ongoing effort by federal, state and local governments, both domestic and international, to seek out and promote technologies that help reduce nutrient runoff into watersheds. Plant biostimulants can be valuable tools in this effort.

- Increase the uptake and utilization of existing and applied nutrients, thereby reducing the potential for off-farm nutrient runoff into rivers, lakes and streams; and the emission of carbon dioxide and other greenhouse gasses.
- 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.
- Be used in both conventional and organic crop production. They can be used to complement the use of conventional or organic agricultural products, enhancing the effectiveness of those inputs while creating demonstrable return on investments for the grower.
- Through all these contributions, help farmers improve overall environmental stewardship.

The Sustainability Consortium (TSC) a global organization transforming the consumer goods industry to deliver more sustainable consumer products recognizes the value of plant biostimulants as a means to improve agricultural sustainability[5]. TSC members and partners include manufacturers, retailers, suppliers, service providers, NGOs, civil society organizations, governmental agencies and academics. In 2017 they stated: "Research around the use of biostimulants points to clear opportunities for reducing key impacts related to agricultural production. Incorporating biostimulants into our improvement opportunities reflects The Sustainability Consortium (TSC) commitment to science as the foundation for our work. This effort ultimately strengthens the quality and impact of our toolkits by reflecting new scientific findings." [5])

Existing Regulatory Framework in the United States:

Plant biostimulants represent a unique segment of applied agricultural technology, in that they provide a specific type of benefit in agricultural crop production and work with other solutions. They do not replace, and are not effectively replaced by, other technologies.

Currently, plant biostimulants are regulated one of two ways.

1. Federally, (in primary part) under FIFRA. Products are regulated under FIFRA based upon the claims made about the product (namely, does the product confer pesticidal benefits, including functioning as a plant regulator) or if the mode of action necessarily has pesticidal properties. FIFRA does not establish clear jurisdictional boundaries for the myriad of products now developed for agricultural production, which is problematic for those developing products to bring to market. Industry has long argued, for example, that the definition of "plant regulator" in FIFRA did not anticipate the future development of plant biostimulant products (explained in greater detail below in the legislative recommendation section of this document). Further, FIFRA does not represent an appropriate oversight scheme for biostimulant products, in that FIFRA product registration requirements for pesticides far exceed what is reasonable and necessary for this category of products.

2. State Fertilizer Laws and regulations. Products outside the jurisdiction of FIFRA are most often regulated through a patchwork of laws and regulations in the States. Each State has its own unique laws and practices for managing these FIFRA Part 152 exclusions, but in general regulate

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) it is difficult to determine whether a product is regulated under FIFRA; (2) if it is not, the State schemes lack consistency and predictability in terms of requirements. For a more in-depth explanation of the various State requirements, please refer to APPENDIX 2.

Plant biostimulants are actually distinct from both of these general categories. They do not intentionally alter plant behavior in ways that are inconsistent with the plant's inherent genetic potential (as plant regulators would); nor do they provide sufficient nutrients to function primarily as fertilizers. As indicated above, plant biostimulants augment the soil-plant system to enable plants to achieve more of their full, inherent genetic potential. Therefore, a scheme that is distinct from these categories that confers appropriate oversight is needed.

For additional background and consideration in facilitating future conversations, the below describes the State-level stakeholders involved in the regulatory oversight of plant biostimulant products.

State Stakeholders: NASDA, AAPCO and AAPFCO

At the federal level, USDA and EPA work with the states on a wide range of co-regulatory programs including pesticide regulation, plant protection regulation, and economic development. Regarding plant biostimulants, the major state players are the National Association of State Departments of Agriculture, the Association of American Pesticide Control Officials, and the Association of American Plant Food Control Officials.

NASDA: The National Association of State Departments of Agriculture

NASDA represents the Commissioners, Secretaries, and Directors of the state departments of agriculture in all fifty states and four U.S. territories. State departments of agriculture are responsible for a wide range of programs including conservation and environmental protection, food safety, combating the spread of plant and animal diseases and fostering the economic vitality of our rural communities. In 43 states, NASDA members are the state lead agency for pesticide and fertilizer regulation.

In September 2018, the National Association of State Departments of Agriculture voted in support of identifying and supporting paths that efficiently move plant biostimulant products into the U.S. marketplace. NASDA members also voted to encourage state, federal, and industry partners to work together to explore existing and potential paths that allow plant biostimulants to be sold in the U.S., create any additional regulatory structures needed to cover materials not currently included under the existing framework, harmonize state and federal regulations, and support plant 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.

AAPCO: The Association of American Pesticide Control Officials

The Association of American Pesticide Control Officials (AAPCO) is the national organization for pesticide regulatory state lead agencies. AAPCO is the consolidated voice of the states that work with federal regulatory partners at EPA. AAPCO also collaborates with the pesticide industry, trade organizations, and other state and federal associations, as well as congressional delegations when necessary to solve regulatory issues.

AAPCO's mission is to represent State Pesticide Control Officials in the development, implementation, and communication of sound public policies and programs related to the sale, application, transport, and disposal of pesticides.

A primary goal of AAPCO is to encourage uniformity among the states in their pesticide regulatory programs. Other objectives are: to promote uniform and effective legislation, definitions, regulation, and enforcement; to encourage and sponsor the adoption of the best techniques for analysis of pesticides; to develop sound inspection procedures; to promote adequate labeling and safe use of pesticides; to provide opportunities for exchange of information and cooperative study of problems facing members of the Association; and to cooperate with industry to promote the usefulness and effectiveness of pesticide products. Given the fact that some biological products may confer pesticidal benefits, AAPCO has an important ongoing role in the biostimulant conversation.

AAPFCO: Association of American Plant Food Control Officials

AAPFCO was formed in 1946 with the first annual meeting and Official Publication following in 1947. AAPFCO was created to draft model laws and regulations and promote uniform regulation of fertilizers. Because laws and rules must be established through each states legislature and department of agriculture, there was not consistent adoption of the model in the states, which has caused many issues for industry and for the farmer.

Subsequent to its early focus on fertilizers, AAPFCO has added definitions and labeling recommendations for "beneficial substances" and "beneficial compounds". These categories were designed to capture all plant and media applied materials that do not meet existing model definitions – in other words, materials deemed to be helpful to growing desirable plants to their full genetic potential through means other than, but complementary to, good plant nutrition. These categories include many products that would appropriately be categorized as plant biostimulants.

The following definitions have been agreed to by state lead agencies, but are not necessarily uniform (in their legal adoption and use) across all fifty states:

1. **Fertilizer** - The term "fertilizer" means any substance containing one or more recognized plant nutrient(s) which is used for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth, except unmanipulated animal and vegetable manures, marl, lime, limestone, wood ashes and other products exempted by regulation by AAPFCO (Uniform State Fertilizer Bill)

2. **Plant Amendment** – Any substance applied to plants or seeds which are intended to improve growth, yield, product quality, reproduction, flavor, or other favorable characteristics of plants except fertilizer, soil amendments, agricultural liming materials, animal and vegetable manure, pesticides, plant regulators, and other materials which may be exempted by regulation. (Official 2013) T-92
3. **Soil Amendment** – (commonly referred to as Soil Additives or Soil Conditioners), means any substance or a mixture of substances which is intended to improve the physical, chemical, biochemical, biological or other characteristics of the soil, except fertilizers, agricultural liming materials, unmanipulated animal manures, unmanipulated vegetable manures, pesticides and other materials exempted by regulation. (Official 2013) T-90
4. **Beneficial Substances or Compounds** – Means 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 exogenously. (Official 2007) T-73

Under the existing AAPFCO structure, and also as ultimately regulated in the States, products that might be included in the plant biostimulant category must (sometimes uneasily) fit into one of the above definitions or default to being regulated as a pesticide. This is a fundamental issue that we believe warrants attention in the report to Congress.

Chapter 2: Challenges Facing Plant Biostimulant Industry:

The plant biostimulant industry faces many challenges. They can generally be placed into three categories: acceptance and education, appropriate oversight, and global regulatory activity.

Acceptance and Education:

Growers and other end users of plant biostimulants, including golf course superintendents, landscape professionals, and homeowners, have been using plant biostimulant products for several decades. The level of acceptance (user adoption rate) has been built from the ground up, through experience based on on-farm application, as well as company, university, and third-party field trial demonstrations to prove the value of the technologies – crop-by-crop, geographic market by geographic market, customer by customer. While acceptance has advanced significantly (to a global, multi-billion dollar industry with attractive prospects for future growth), companies must fit their products into one or more of the available categories for product registration state-by-state, and thus, are limited to claims consistent with those categories or they may be subject to regulation – we believe often inappropriately - as a pesticide. The inability of product manufacturers in the U.S. to make the full range of potential claims for their technologies on a nationwide basis is a powerful governor on that growth in market acceptance and utilization

The lack of clarity concerning acceptable claims also hampers the ability of manufacturers to educate customers on the unique and substantial benefits of their technologies. While products are supported by research and development investments in the hundreds of millions of dollars,

growers are being denied reasonable access to the full range of value that these innovative technologies could potentially contribute – in better yields (and, therefore, greater economic returns); improved sustainability of farmed acres; and more efficient utilization of all crop inputs in which they invest. The limitations on stakeholder education in turn create yet another barrier to broader adoption.

Oversight:

In the U.S., oversight of the plant biostimulant product category lacks clarity for a variety of reasons, some of which are mentioned above. First, there is no clearly defined, legally recognized path to obtain the ability to sell a plant biostimulant product and make the associated labeling claims for product benefits, nor is there a legal definition of the term "plant biostimulant" in federal or state law. While FIFRA defines plant regulators (as a unique subset of pesticides), many of the "plant biostimulant" products in the market today qualify for one or more of the statutory exclusions from regulation as pesticides. Confirming the applicability of those exclusions, however, can often be a confusing and time-consuming process, draining valuable public and private resources. Examples include the fact that the definitions of key terms in EPA's regulations have either never been established (e.g., "nutritional chemicals") or have not been modified for decades and have not kept up with product innovations (e.g., "plant nutrients", "plant inoculants", and "soil amendments"). These definitions need to be updated in a manner that reflects both current and future technological advancements, as well as Congressional intent.

Products have been registered at the state level utilizing the FIFRA exclusions. In some cases, however, this has required adapting product strategies (e.g., intentionally adding plant nutrient content (fertilizers), with the plant biostimulant additives positioned to make the products more efficient for nutrient utilization or quality); and tailoring claims to fit within the limits of those excluded categories (See APPENDIX 2 for further details on the State Regulatory Landscape). Industry has been in nearly constant contact with state associations (AAPFCO, NASDA), regulatory agencies (EPA, USDA) and congressional agricultural committees since 2012 on the need to clarify the "grey areas" or overlap in oversight mechanisms, as well as the gaps created by the evolution of plant biostimulant technologies.

EPA is currently working on a guidance document in an attempt to address these overlaps and gaps, a draft of which was released for public comment in March 2019.[6] The guidance document in its current form will not address the many regulatory issues industry faces in bringing products to market, in part because there is no federal definition of "plant biostimulant".

The States (led by AAPFCO initiatives) have expressed openness and willingness to work on definitions of biostimulant product categories, preferably under the AAPFCO defined term of "Beneficial Substances and Compounds". The state initiatives are, like EPA, hindered by the lack of an official definition of the term "plant biostimulant". Even if such definition were adopted at the federal level, the fact that each State department of agriculture and potentially legislature would have to address the term in its own oversight schemes would not lead to consistent outcomes, thus perpetuating the confusion for industry and customers alike.

The passage of the 2018 Farm Bill, and its call to the Secretary of Agriculture – in consultation with the EPA Administrator –represents an important opportunity for development of a cohesive, comprehensive, and efficient vehicle to address the major issues and barriers to creating a harmonized, national regulatory environment for plant biostimulant products.

Global Regulatory Activity:

US has a history of leading innovation and regulations that are science and risk-based. The European Union (EU) passed a new Fertilizer Regulation (EU 2016/0084), in March 2019 that specifically defines and includes plant biostimulants and clarifies their distinction from plant regulators (considered plant protectants under their pesticide law, Regulation (EC) No 1107/2009). The EU's description of plant biostimulants is instructive as it recognizes that plant biostimulants have no direct action against pests, and therefore do not fall within the regulatory framework of biopesticides.

"Certain substances, mixtures and microorganisms, referred to as plant biostimulants, are not as such inputs of nutrients, but nevertheless stimulate plants' natural nutrition processes. Where such products aim solely at improving the plants' nutrient use efficiency, tolerance to abiotic stress, quality traits or increasing the availability of confined nutrients in the soil or rhizosphere, they are by nature more similar to fertilising products than to most categories of plant protection products. They act in addition to fertilisers, with the aim of optimising the efficiency of those fertilisers and reducing the nutrient application rates. Such products should therefore be eligible for CE marking under this Regulation and excluded from the scope of Regulation (EC) No 1107/2009 of the European Parliament and of the Council. Regulation (EC) No 1107/2009 should therefore be amended accordingly."

Implementation of these regulations requires the establishment of standards to ensure companies conform to the data and information requirements. Certification of conformance is required before companies can affix the European CE mark to their product and sell in the 28 member states of the European Union.

The category of products includes (but is not limited to) bacterial or microbial inoculants; biochemical materials; amino acids; humic, fulvic and other organic acids; seaweed and botanical extracts; nutritional chemicals; and other similar materials and complex mixtures or their synthetically derived equivalents.

Europe's experience in navigating this regulatory uncertainty provides valuable lessons for the U.S. initiative. As European industries and regulators worked together to develop standards, it became clear that the definition of fertilizer needed to be updated. The traditional way of thinking has evolved to include plant biostimulants in a much broader, more holistic definition of fertility (or plant nutrition) that includes materials that aid in *nutrient uptake, nutrient efficiency, tolerance of abiotic stress and enhanced crop quality* as benefits of their use.

Brazil, China, India, Mexico, South Africa, and many other countries are also developing regulations for these products – with an eye towards actions in the U.S. and Europe that may favor consistent international approaches.

A consistent thought process in the U.S. would be helpful to create an environment that supports the innovation and growth of new generations of sustainable agricultural inputs to meet future demands for our crops. Further, the opportunity to coordinate U.S. criteria, practices, and processes for implementation of a plant biostimulant path to market with broader global initiatives could help facilitate trade, spur innovation, and ensure a commonality of standards regarding product composition, safety and efficacy. The industry strongly recommends that policy and technical leaders within the U.S. government maintain regular engagement with other countries to better ensure consistency among the current and evolving myriad of international governmental frameworks being debated internationally, particularly with key agricultural trading partners.

Looking to the Future:

A clear, credible, and consistent regulatory process for bringing plant biostimulant products to market is needed to ensure that agricultural producers, consumers, and the environment receive maximum benefit from these products, to maintain the competitive position of our Nation with respect to innovative agricultural technologies, and to facilitate interstate commerce and global trade. Looking to the future, facilitating the adoption of safe and effective new agricultural products and the availability of these products to our growers will be critical to our ability to continue to provide for the production of an adequate, wholesome, and economical food supply. National uniformity, including in nomenclature, labeling, standards, and jurisdiction, are key elements that need to be addressed in order to meet these goals.

Chapter 3: Recommendations:

In a process that began in 2015 and continues to the present day, the plant biostimulant industry and related stakeholders have aligned upon the following primary goals:

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

To realize these goals industry stakeholders have identified several specific non-regulatory, regulatory, and legislative recommendations. These measures would recognize the need for national uniformity in the oversight of plant biostimulant products and the need to facilitate removal of impediments to the development and commercialization of these products. Given their complexity, or time required to implement, these recommendations will likely be realized over a period of time but will provide much needed clarity to bring new products to market and

enable continued innovation. Accordingly, industry stakeholders propose the following actions for inclusion in the Secretary's report to Congress in both shorter and longer time frames.

Next 12 to 24 Months. The following measures would be initiated in the near term with a goal of realizing several key objectives and laying the groundwork for longer-term regulatory clarity:

1. Congress should enact legislation to address current issues impeding the development and commercialization of plant biostimulant products. The legislation would not amend any existing statutes nor would it attempt to duplicate any existing regulatory programs.
2.

    a. Rather, the legislation would first establish a uniform national definition of "plant biostimulant" as follows:

    "Substance(s), microorganism(s), or mixtures thereof, 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, thereby, improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress; and consequent growth, development, quality or yield."

    b. The proposed legislation should also direct the EPA Administrator to incorporate the same uniform national definition of "plant biostimulant" in the pesticide regulations codified in Section 152.3 of title 40, Code of Federal Regulations, Definitions. In addition, in order to eliminate a major source of regulatory confusion and delay and any potential duplicative and unnecessary regulatory oversight, the legislation would further direct the Administrator to adopt the following key regulatory amendments (shown in bold font) clarifying the exclusion of plant biostimulant products from regulation as plant regulators (or pesticides) under FIFRA:

    Section 152.6(g) of title 40, Code of Federal Regulations, Substances excluded from regulation by FIFRA, is amended to read as follows:

    (g) Products intended to aid the growth of desirable plants. A product of any of the following types, intended only to aid the growth of desirable plants, is not a "plant regulator" under section 2(v) of FIFRA, and therefore is not a pesticide:

    (1) A plant nutrient product, consisting of one or more macronutrients or micronutrient trace elements necessary to normal growth of plants and in a form readily usable by plants.

    (2) A plant inoculant product consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients, ***including a microorganism product meeting the definition of a plant biostimulant product.***

(3) A soil amendment product containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth, ***including a product meeting the definition of a plant biostimulant product.***

(4) A nutritional chemical product consisting of a substance or substances that act to improve a plant's natural nutrition processes independently of the substance's nutrient content, thereby improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and subsequent growth, development, quality or yield; including a chemical / biochemical product meeting the definition of a plant biostimulant product.

2. The Secretary and other USDA officials are in a unique position to facilitate dialogue between the various States (specifically including Agriculture Commissioners and fertilizer control officials) and industry to discuss paths forward at the state level that can be pursued in the short term to create a more efficient pathway to market for plant biostimulant products. USDA's leadership would be invaluable in allowing the relevant stakeholders to move forward to address some of the key issues affecting plant biostimulant products. Specifically these issues would include the creation of consistent labeling requirements, harmonized efficacy testing criteria, common definitions, and correction of such other impediments to interstate commerce as may be determined through this process.

    a. We request USDA immediately begin to facilitate with States to promote the adoption of new legislation to achieve industry goals of a harmonized regulatory framework and unified label.

    b. USDA could use existing authority to establish and facilitate a multi-stakeholder Plant Biostimulant Federal Advisory Committee or Task Force to include representatives from USDA, EPA, State regulators, NASDA, and industry stakeholders. Utilizing the proposed plant biostimulant definition, this group would be tasked to identify regulatory and non-regulatory mechanisms for moving toward national uniformity in the oversight of plant biostimulant products.

The Appendices of this document are offered, as illustrative exhibits only, to provide examples of supporting definitions and science-based criteria (e.g., for verifying the efficacy, composition, and safety of plant biostimulant products). The criteria take into account such factors as product characteristics and history of safe use. The full development of such criteria and standards, under the guidance of the facilitated initiative could form the basis of a USDA AMS PVP or other certification program(s) recognized by the States and provide for defined plant biostimulant claims and uniform product labeling.

AMS representatives have been extremely helpful in explaining the basics of the PVP process that they administer and have expressed their willingness to work with the plant biostimulant industry in establishing a PVP specifically tailored for plant biostimulants or designated categories of these products. We recommend that the advisory committee or task force consider establishment of a PVP or other third-party certification programs for

plant biostimulants, including harmonization to the greatest extent practicable. We recognize there are a number of considerations when engaging with other trading partners and encourage USDA to develop an ongoing dialogue with international governmental counterparts to better understand the evolution of thinking and creation of a regulatory framework for plant biostimulant products.

Next 24 to 36 Months. The following measure would be initiated with a goal of realizing several key objectives in order to provide uniform, nationwide regulatory clarity in the longer term.

3. Congress should enact legislation authorizing and directing the Secretary to develop a uniform national framework for plant biostimulant products. This initiative would be undertaken in consultation with the several States, appropriate state organizations, industry stakeholders, and such other stakeholders the Secretary determines necessary, and enable the uninterrupted ability to bring products to market during the transition to the framework. Such a framework would ensure yet to be developed plant biostimulant technologies were encompassed and would take into account the findings, conclusions, recommendations, and actions reached under the auspices of the aforementioned Plant Biostimulant Federal Advisory Committee or Task Force.

Finally, it is recommended that any legislation enacted in either the near or longer term provide that, to the greatest extent possible, the development and implementation of plant biostimulant initiatives at Federal and State levels be timed and coordinated to avoid dislocations and disruptions in the marketplace.

Industry stakeholders believe the implementation of these recommendations will establish a roadmap to success and opportunity to advance the plant biostimulant industry over time.

Conclusions: To Whom and how will these recommendations provide benefits?

Who benefits?

Federal and State Regulators: It has been our experience that significant time and resources go into the premarket review of plant biostimulant products. This has only increased in recent years as the plant biostimulant industry has grown. State regulators who have questions about specific products submit them to EPA for clarification. If a more efficient framework is established, time and resources at the state and federal level will be saved – significantly easing the burden on already strained resources. In two recent examples, California and Oregon have already asked questions of and/or issued notifications to plant biostimulant and fertilizer companies in their states referencing the EPA's March 2019 draft guidance.

Growers: These recommendations will provide increased and timelier access to this rapidly expanding category of products and the benefits they bring to agricultural production. Growers will also be in a better position to remain competitive with their counterparts in other countries.

Consumers: The ability to continue to provide for the production of an adequate, wholesome, and economical food supply will be of direct benefit to consumers. Consumers and other end

users of plant biostimulant products will also have the confidence that these products support sustainable agricultural practices and are well understood, reviewed for safety and efficacy, and vetted for use.

Industry: Industry stakeholders will benefit from a more efficient, predictable and uniform regulatory process and greater recognition by state and federal regulators of these valuable products. Plant biostimulant companies will be able to continue to invest in research and development and be able to continue to create innovative solutions, with a reasonable expectation of recapturing that value from the effective marketing of superior product technologies in which they have invested. While industry would be expected or required to bear the cost of obtaining product approvals (especially for certifications done by independent third parties), it would be expected that the efficiency, speed to market, and elimination of redundancy in the validation process would represent attractive tradeoffs.

How do these stakeholders benefit?

We believe the foregoing recommendations will bring significant benefits:

- Reduce the costs that exceed benefits imposed by current regulations.
- Reduce/eliminate animal testing – decision based on ingredients recognized as safe or already tested (this approach is already implemented by GHS (Globally Harmonized System) for the preparation of Safety Data Sheets).
- Eliminate the cost of data generation and preparation of safety / environmental dossiers that are inconsistent with the risk being managed including costs associated with the pesticide registration process.
- Reduce EPA's workload by reducing the number of dossiers requiring review and action.
- Invigorate small and medium sized companies and create new jobs in the U.S.
- Support global trade.

Many of the companies in the field of sustainable agriculture are small manufacturers. A simplified regulatory process modeled on the recommendations listed above would allow faster and easier access to the U.S. market, therefore increasing manufacturing demand and creating new jobs in the United States.

The plant biostimulant industry acknowledges that U.S. regulators are constrained within the existing legal and regulatory frameworks on these topics. Nevertheless, we believe that USDA, EPA, and state regulators can work with stakeholders to create a regulatory framework that enables a more holistic approach to plant biostimulants. Current regulations do not allow for adequate development of new emerging technologies that aim to improve agricultural sustainability.

We believe the public is well served and protected by the existing FIFRA statute, which oversees pesticide products. Existing regulation of certain plant biostimulant products as plant regulators is an overly burdensome process that is inconsistent with congressional intent and calls out for clarity to a product category that is not intended to mitigate or kill pests or function as plant

regulators. Developers and manufacturers who choose to make use of the pesticide registration process can always do so by making one or more truthful and non-misleading pesticidal claims for their products.

We strongly urge USDA and EPA to make recommendations to Congress that will give direction on how to address and resolve many of the legislative, regulatory, and legal challenges facing the plant biostimulant industry. Only through a number of the above-described recommendations will the plant biostimulant industry be able to grow and provide innovative technological tools to growers and other end users who need them.

In summary, we believe USDA's report to Congress should recommend the following measures:

1. Enactment of legislation:

    a. To establish a uniform national definition of "plant biostimulant", and

    b. To direct the EPA Administrator to amend current pesticide regulations to (i) incorporate the same uniform national definition of "plant biostimulant" and (ii) clarify the exclusion of plant biostimulant products from regulation as plant regulators (or pesticides) under FIFRA.

2. USDA Facilitation:

    a. USDA facilitation of a work group of state regulatory officials, AAPFCO, and industry members to develop a more uniform approach to the state regulation of biostimulants.

    b. If an additional step of a multi-stakeholder Plant Biostimulant Federal Advisory Committee is deemed appropriate to achieve this result, USDA can establish it to create further dialogue between the impacted stakeholders to develop national uniformity in the oversight of plant biostimulant products.

3. In addition, it is recommended that the report to Congress propose legislation in the longer term that would authorize and direct the Secretary to develop a uniform national framework for plant biostimulant products in consultation with the several States, appropriate state organizations, industry stakeholders, and such other stakeholders the Secretary determines necessary.

Absent these important initiatives, the plant biostimulant industry will continue to struggle to bring products to market in an efficient manner. State regulators and other stakeholders will also continue to face uncertainty with respect to certain plant biostimulant products. Growers and other end users will not experience consistency in products they are choosing from and may have less access to these important technological tools. Additionally, if a more efficient regulatory framework is not established for this growing product category, the U.S. will fall behind Europe and other parts of the world that are beginning to recognize the value that these innovative

products bring to their farmers and economies, and our Nation's international trade could be hampered.

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Appendix 2: Virus-Serum-Toxin Act and Commentary

Order Code RS22014
January 3, 2005

The Virus-Serum-Toxin Act: A Brief History and Analysis

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Summary

The Viruses, Serums, Toxins, Antitoxins, and Analogous Products Act (21 U.S.C. 151-159), also known as the Virus-Serum-Toxin Act (VSTA), is intended to assure the safe and effective supply of animal vaccines and other biological products. The act and its applicable regulations are administered by the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA).

The VSTA was enacted in 1913, and revised once in 1985. A 2002 law affected the VSTA by transferring border and import inspection functions from USDA to the Department of Homeland Security.

Origins in 1913 (62nd Congress)

The Viruses, Serums, Toxins, Antitoxins, and Analogous Products Act (21 U.S.C. 151-159) was enacted in 1913 (the Act of March 4, 1913, ch. 145, sec. 1) and is known commonly as the Virus-Serum-Toxin Act (VSTA).[1] It was enacted primarily in response to substantial losses from the unregulated manufacture and distribution of anti-hog cholera serum. The authority to license and regulate the production and trade of affected products is granted to the Secretary of Agriculture. The act states that:

> It shall be unlawful for any person, firm or corporation to prepare sell, barter, or exchange [in the United States], or ship or deliver for shipment in or from the United States ... any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals.[2]

[1] This report draws upon CRS Report RL32414, *The Private Testing of Mad Cow Disease: Legal Issues*, by Stephen R. Viña, which discusses the VSTA in terms of regulating diagnostic tests.

[2] 21 U.S.C. 151.

In 1913, a USDA official testified that the bill was necessary "to protect the farmer and stock raiser from improperly made and prepared serums, toxins, and viruses."[3] The 1913 Senate report for the VSTA stated that the legislation would prevent:

> the introduction into the United States of dangerous and worthless viruses, serums and analogous products for use in the treatment of domestic animals, some of which products may be the means of introducing disease not now known in the United States, and also for the purpose of controlling the use, by preventing the interstate shipment, of similar dangerous and worthless products that may be manufactured within the United States.[4]

Revisions in 1985 (99th Congress)

After seven decades, the original provisions in the VSTA faced challenges from a modernized agricultural sector and a more complicated regulatory environment. Congress amended the VSTA in the Food Security Act of 1985 (P.L. 99-198, Title XVII, Sec.1768) to (1) authorize USDA regulate *intrastate*, as well as interstate, movement of biological products, (2) broaden the Secretary's authority to issue regulations, (3) enhance enforcement powers, and (4) recognize a congressional view that regulation is "necessary to prevent and eliminate burdens on commerce and to effectively regulate commerce."[5]

A Senate report cited the need for "national uniform standards" in the preparation and sale of biological products.[6] The same report refers to jurisdictional issues between USDA and the Food and Drug Administration (FDA) regarding the need to update the law and preserve USDA authorities:

> Two recent Federal court decisions have created confusion and concern among the producers of animal biological products and those who utilize them. The thrust of these decisions is that USDA has primary regulatory authority over finished products physically moving in interstate commerce, but all other products, such as those made and sold within a single State, are subject only to Food and Drug Administration jurisdiction. These "intrastate" products are not subject to USDA licensure, and FDA has, so far, not asserted its authority over them in a comprehensive manner. In the meantime, "interstate" products remain firmly under the jurisdiction of USDA.
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> The narrow "intrastate" versus "interstate" distinction found in the VSTA no longer exists for any class of comparable products. Federal laws make no such distinctions for human-use pharmaceuticals, animal drugs, food additives, color additives, medical devices, processed food, meat and poultry products, or pesticides; all are subject to uniform Federal regulatory standards, whether they cross state lines or not.[7]

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[3] Hearing before the Committee on Agriculture on the Estimates of Appropriations for the Fiscal Year Ending June 30, 1914 (H.R. 28283), 62nd Cong. 24 (1913) (statement of Dr. A. M. Farrington, Asst. Chief Bureau of Animal Industry, Dept. of Agriculture).

[4] S.Rept. 62-1288 (1913).

[5] 21 U.S.C. 151, 154, 159.

[6] S.Rept. 99-145, pp. 338-339.

[7] Ibid.

Transfer of Functions in 2002 (107th Congress)

The Homeland Security Act of 2002 (P.L. 107-296, Title IV, Sec. 421, 6 U.S.C. 231) transferred most major border inspection functions (immigration, customs, and agriculture) to the Department of Homeland Security (DHS). The VSTA was one of seven agricultural laws affected by this transfer. The law did not change provisions in VSTA, but only moved certain functions from one department to another. The purpose was to unify all major border inspection activities under the jurisdiction of one department after the terrorist attacks of September 11, 2001.

Although DHS now conducts the physical inspection of imports, USDA continues to have jurisdiction over VSTA regulations and policies, including setting such policies for imports. The Secretaries of USDA and DHS are to consult each other and coordinate their regulatory and inspection practices.

For more on border inspections, and the transfer of inspection functions to DHS, see CRS Report RL32399, *Border Security: Inspections Practices, Policies, and Issues*.

Analysis of Provisions and Regulatory Action[8]

Except as permitted in the act, the VSTA makes it unlawful for any person to prepare, sell, barter, or exchange anywhere in the United States, or to ship or deliver in or from the United States, any dangerous or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals.[9]

The VSTA further requires that a person who prepares, sells, barters, exchanges, or ships any virus, serum, toxin, or analogous product do so in compliance with USDA regulations through an establishment holding an unsuspended and unrevoked USDA license.[10] The VSTA authorizes the Secretary to issue, suspend, and revoke licenses for the maintenance of establishments that prepare viruses, serums, toxins, or analogous products for use in the treatment of domestic animals. In 21 U.S.C. 152, the VSTA also prohibits the importation of any virus, serum, toxin, or analogous product except under a permit from the Secretary of Agriculture.

The Secretary of Agriculture is also authorized to make and promulgate rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment of a dangerous virus, serum, toxin, or analogous product for use in the treatment of domestic animals or otherwise to carry out the VSTA. Consequently, the Animal and Plant Health Protection Service has issued a comprehensive set of regulations governing the licensing of viruses, serums, toxins, or analogous products (9 C.F.R. 101-124).

Regulations for the VSTA broadly catagorize viruses, serums, toxins, or analogous products as "biological products" at any stage of production intended for use in the

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[8] Drawn primarily from CRS Report RL32414, *The Private Testing of Mad Cow Disease: Legal Issues*, by Stephen R. Viña.

[9] 21 U.S.C. 151.

[10] Ibid.

treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. A "biological product" includes but is not limited to:

> vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.[11]

"Treatment" under the regulations means the prevention, diagnosis, management, or cure of diseases of animals.[12] "Prepare" or "preparation" is generally referred to as the manufacture or production of a biological product and has been defined as the steps and procedures used in the processing, testing, packaging, labeling, and storing of a biological product. With respect to licensing, the regulations require every person who "prepares" biological products subject to the VSTA to have a valid U.S. Veterinary Biologics Establishment License and at least one valid U.S. Veterinary Biological Product License.[13] A USDA permit is also required for every person importing a biological product.[14]

The VSTA explicitly addresses preparation, sale, barter, exchange and shipment, but does not address use or distribution. However, USDA regulations authorize certain use and distribution restrictions. These include distribution of experimental products prior to licencing (9 C.F.R. 103.3), exemptions concerning USDA's use in emergencies and experimental programs (9 C.F.R. 106.1), packaging and labeling requirements (9 C.F.R. 112), and possession, use, and transfer of biological agents and toxins (9 C.F.R. 121).[15]

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[11] 9 C.F.R. 101.2.

[12] *Id.*

[13] *Id.* at 102.2.

[14] *Id.* at 104.1.

[15] Authority for 9 C.F.R. 121 concerning possession, use, and transfer of biological agents and toxins ("select agents") comes from the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188, sec. 211-213, June 12, 2002), but is directly applicable to the products covered by the VSTA.

Appendix 3: State Concerns and Priorities in a Framework for Biostimulants under the 2018 Farm Bill Report Language from National Association of State Departments of Agriculture (NASDA)

State Concerns and Priorities in a Framework for Biostimulants under the 2018 Farm Bill Report Language

Throughout the USDA stakeholder process on a biostimulant framework, NASDA has worked between federal agencies, industry and state regulators in our role as promoters of consensus driven agriculture policy. NASDA contributed heavily to the USDA report and has been working with the stakeholder effort since summer 2019. Through this process, we have hosted conference calls with the entire state workstream and with the American Association of Plant Food Control Officials (AAPFCO) and the American Association of Pesticide Control Officials (AAPCO) separately, including an in-person dialogue session with industry.

From these conversations, NASDA has compiled the below comments on state concerns. In addition, AAPCO submitted their own comment letter on May 29, 2019.

NASDA members and state regulators understand the need for a more efficient framework and path to market for plant biostimulant products. In September 2018, 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.

After working with state regulators at the AAPCO and AAPFCO, the states see many opportunities and challenges with creating a new biostimulant framework. Major concerns include how a new framework will interact with the existing regulatory framework, resources, and product categorization.

Existing Regulatory Framework

Currently, AAPFCO regulates plant fertilizer products as outlined in the previous state section. AAPFCO members have worked for years to hone this regulatory process and create uniform standards across states. While standards across states are not uniform, this is currently the nature of the state process and has been for decades. Making changes at the federal level that would fit biostimulants into existing state categories or create a new biostimulant category could result in all fifty states having to open their state fertilizer law in order to regulate biostimulants.

Additionally, many biostimulant products currently on the market fit into the existing state regulatory structure. State regulators have worked with industry through the registration process and often register biostimulant products as humic substances, soil amendments or other categories based on the action and ingredient of the plant. This regulatory structure does not however allow the products to be called biostimulants, because this is not a recognized definition within the AAPFCO framework.

NASDA members understand the time and resources it takes to open state fertilizer laws. Often, this step is avoided because it can lead to other input into the state fertilizer regulations that is costly to states or does not benefit agriculture. NASDA members are committed to working with industry and within the

state regulatory frameworks on regulating biostimulant products with the label "biostimulant" but in a way that is also transparent for consumers.

However, NASDA members are also cautious of ensuring the current regulatory framework is maintained. The proposed EPA guidance would classify certain claims as plant growth regulator claims, even though those claims are already used in state fertilizer laws. Many states have products like seaweed extracts, humic acid, corn gluten meals and potassium silicates as pesticides—even though hundreds of these products are regulated as fertilizers in the states. The states understand this in particular concerns the EPA guidance, but is a factor that also needs to be considered through the USDA process. How should states view other ingredients that have both fertilizing material properties and pesticidal properties (usually due to application rate or type) – some microbes, chitin, phosphites, silicate ingredients other than potassium silicate, etc. This is a major question states feel has not been adequately addressed and we look forward to working with federal agencies to understand.

Product Categorization

A major concern from state regulators in AAPFCO and AAPCO is that biostimulants present difficulties for states regarding assessing label claims, evaluating product safety and development and determining if there is a tolerance exemption for products used on food or feed crops. State regulators are concerned about the ability to implement a program that does not provide specific requirements about efficacy of products and safety standards. The industry process has sought to address this in regulatory and non-regulatory mechanisms. NASDA members and state regulators look forward to working with USDA, EPA and industry to find solutions to these questions.

State Resources

Finally, state budgets are constantly spread incredibly thin. State fertilizer and pesticide programs often work in tandem and with shared funding. The registration of biostimulant products has been confusing for state regulators, further stretching state resources. As such, we understand the need for further clarity. However, frameworks that would require even more work from states need to be clear on regulatory standards. Enforceability is a key tenet of state programs. The USDA report is also looking at non-regulatory options. Understanding how each of these options will impact state resources is a key concern for NASDA, AAPCO and AAPFCO.

Thank you for your consideration please let me know if you have any questions,

Britt Aasmundstad
Associate Director Policy, NASDA
NASDA AAPFCO Liaison

Appendix 4: Possible Regulatory Strategies at State Level from NASDA

Possible Regulatory Strategies at State level

1. Status Quo

"Biostimulant" does not have a regulatory definition in the USA. Biostimulants products have been registered as Fertilizer (regulated at state level by Department of Agriculture) or as Pesticides (regulated at federal level by EPA and additionally at State levels by department of Agriculture). Various challenges have resulted from the lack of regulatory definition and framework, including:

- Unclear, inconsistent and unpredictable process to market
- Different labels requirements making it almost impossible to have 1 label for all states
- Inability to use the word "biostimulant"
- Inability to make biostimulant claims
- Lack of credibility for the industry

The biostimulant industry agrees that the current situation impedes innovation and obstruct interstate commerce and is looking for an improved regulatory process for biostimulants products that will enable effective and efficient registration and a review process that will benefits all the stakeholders.

2. Regulate Biostimulants through the definition of "beneficial substance" and the existing framework of model bills

The proposed alternative below, relies on accepting the term "beneficial substance" as representative of biostimulants, defining additional beneficial substances ingredients, and then using the label formatting for beneficial substances already in place in the existing model bills (i.e. fertilizer products, soil and plant amendments, bulk compost or horticultural growing media).

1. Accept the term "Beneficial Substance or Compound".

"Beneficial substances have been in the Bill since 1994, although "beneficial substances" has only had its current definition since 2007: T-73 page 79 in the 2019 AAPFCO Official publication – "means 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 exogenously".

2. Create additional definitions for "Beneficial Substance or Compound" ingredients, as currently only the seven following ingredients are recognized: BSC-1 calcium silicate, BSC-2 potassium silicate, BSC-3 sodium silicate, BSC-4 available silicon (Si), BSC-5 aluminium sulfate, BSC-6 hydrophobic fulvic acids, BSC-7 calcium magnesium silicates.

   a. This would go through the Terms and Definitions (T&D) Committee at AAPFCO

   b. The "Beneficial Substance or Compound" ingredients that would be included in AAPFCO would be the non-pesticide ingredients.

   c. Efficacy data and mode of action would need to be demonstrated via peer reviewed research presented to the committee.

   d. States must be able to qualify and quantify the guaranteed ingredients for regulatory purposes.

3. Regulate Biostimulants through the existing framework of model bills

The proposed alternative below, relies on defining "biostimulant" and the biostimulants ingredients through AAPFCO, and then clarifying the label formatting for biostimulants in the existing model bills (i.e. fertilizer products, soil and plant amendments, bulk compost or horticultural growing media).

1. Create a definition for biostimulants within AAPFCO

   a. A biostimulant defintion would be created in the Terms and Definitions (T&D) Committee. States officials have issues with the definition that would have to be resolved. The proposed definition is viewed by the States official to be (too) extremely broad and would have to be limited in some way. This could be in the definition itself or in a Statement of Uniform Interpretive Policy (SUIP) that is proposed concurrently to the definition.

   b. The current proposed definition of a biostimulant is very close to the AAPFCO definition of a Beneficial Substance or Compound. Biostimulants would most likely fit into this category and would have to be distinguished from Beneficial Substances and Compounds in some way.

2. Create definitions for biostimulant ingredients.

   a. This would again go through the T&D committee.

   b. The biostimulant ingredients that would be included in AAPFCO would be the non-pesticide ingredients.

   c. Efficacy data and mode of action would need to be demonstrated via peer reviewed research presented to the committee.

   d. States must be able to qualify and quantify the guaranteed ingredients for regulatory purposes.

3. Clarify label formatting for biostimulants in the existing model bills (i.e. fertilizer products, soil and plant amendments, bulk compost or horticultural growing media). NB - This is already in process in the fertilizer model bill.

4. Biostimulant uniform Bill / or uniform bill for Beneficial substances/compounds (BSC) that includes Biostimulant

Create a model bill for Biostimulants / Beneficial substances/compounds that includes Biostimulant. All of the items in Option 3 would have to be done as well.

1. **Create a model bill for Biostimulants or BSC**

    a. This would be done by the Uniform Bills Committee.
    b. The model bill would contain definitions for anything related to the law/statute and rule/regulation. It would not contain definitions for the biostimulant ingredients. The term "biostimulant" may be defined in the model bill, and not in T&D committee. The limitations may be set on regulation, rather than on the term itself.
        i. For example: The definition of biostimulant may be similar to the current proposed definitions. Within the model bill, a statement such as: "The Department does not regulate Beneficial Substances or Compounds that are regulated by EPA as pesticides."
    c. The model bill would include the label formatting for Biostimulants or BSC.
    d. This method would allow industry to market Biostimulants without making misleading nutrient claims.

2. **Create definitions for biostimulant ingredients.**

    a. This would again go through the T&D committee.
    b. The biostimulant ingredients that would be included in AAPFCO would be the non-pesticide ingredients.
    c. Efficacy data and mode of action would need to be demonstrated via peer reviewed research presented to the committee.
    d. States must be able to qualify and quantify the guaranteed ingredients for regulatory purposes.
    e. There may be a need to clarify label formatting for biostimulants in the existing model bills (i.e. fertilizer products, soil and plant amendments, bulk compost or horticultural growing media).

5. "Model / Uniform bill" facilitated by USDA (option 4 accelerated by USDA involvement)

The proposed alternative is a voluntary process involving USDA as a facilitator with a group of states with the goal of harmonizing their approach to the regulation of biostimulants.

The process would consist of the following elements:

1. **USDA would convene a series of meetings with representatives of** various groups including:
   - state regulators that register biostimulants currently under one of their respective state's legislative mandates for fertilizers, soil amendments, etc. (Participation by the states is voluntary, but USDA would invite especially the states who have strong positions, but which are not consistent with each other, especially with regards to product labels and efficacy testing, thereby impeding interstate commerce)
   - representatives from AAPFCO
   - industry

2. The group, facilitated by the USDA, would identify differences among them and then work to draft a "model/uniform bill" that would include recommended label formats and efficacy testing.

   - The "bill" could also include the definitions and terms that the USDA workstream has developed for the states to use even if AAPFCO hasn't adopted them formally.
   - States could then
     - adopt this "model bill" legislatively as it stands or with modifications to fit into their regulatory framework
     - adopt pieces of it as amendments to their existing legislation,
     - adopt some or all of it into their regulations
     - use it as guidance.

6. National Framework Strategy

There are several options for creating a national biostimulant regulatory program to ensure a clear, consistent and predictable pathway for market approval, while eliminating interstate commerce barriers. The proposed alternative below, relies on USDA establishing the regulatory framework and labeling requirements for plant biostimulant products. The national framework will provide the minimum criteria for each State Control Official to adopt, while at the same time allowing each state sufficient flexibility to adopt more stringent requirements.

1. Congress will pass the "Biostimulant Act" to authorize USDA to develop regulations that:
    a. Establish broad biostimulant definitions;
    b. Designate efficacy, environmental, and safety criteria for products approval;
    c. Develop a single national label required to facilitate interstate commerce;
    d. Allow USDA to delegate primary approval/review authority to State Fertilizer Programs;
    e. The program would be implemented by USDA in states that do not adopt the program.

2. USDA would issue regulations for:
    a. Defining plant biostimulant categories;
    b. Minimum criteria for approving products including environmental, safety and efficacy;
    c. Minimum criteria for product label.

3. State Fertilizer Regulatory Programs (State Control Officials):
    a. Amend State Fertilizer Law to incorporate the national framework;
    b. Develop state regulations that incorporate the USDA regulatory program by reference;
    c. If necessary, develop additional requirements for product approval.

Appendix 5: Letter to USDA from the Association of American Plant Food Control Officials, Inc. (AAPFCO)

ASSOCIATION of AMERICAN PLANT FOOD CONTROL OFFICIALS, INC.

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July 3, 2019

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U.S. Department of Agriculture
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Dear Dr. Stewart,

Purpose

The purpose of this letter is to supply comments to USDA regarding the report on regulation of plant biostimulants required by Sec. 9201 of the Agricultural Improvement Act of 2018. The Act states that the Secretary of Agriculture will prepare the report in consultation with several States and other such stakeholders. The Association of American Plant Food Control Officials (AAPFCO) is an organization of fertilizer control officials from each state in the United States who are actively engaged in the administration of fertilizer laws and regulations. AAPFCO requests that the Secretary of Agriculture consider the comments provided in this letter when preparing his report on the regulation of plant biostimulants.

Main Points

- Currently, "biostimulant" is a broad and inconsistently utilized term that covers products in many different categories, including; pesticides, fertilizers, soil/plant amendments, and soil/plant inoculants.
- Any new regulatory structure for biostimulants would have to consider the current state and federal regulations for all categories of biostimulants.
- AAPFCO would be in support of continuing with the current regulatory structure for products marketed as biostimulants, with some improvements.
    - AAPFCO could work with industry to define biostimulants for products that would fit under the AAPFCO umbrella.
    - Additional guidance from AAPFCO plus State and Federal regulators will be extremely helpful in steering industry down the proper regulatory path for each individual product.
    - AAPFCO could develop model documents (including a Uniform Bill) providing a regulatory structure for Beneficial Substances or Compounds that would provide a place for biostimulants not otherwise covered under another regulatory structure. This regulatory structure could then be adopted by the states at the discretion of each individual state.

AAPFCO Background

The Association of American Plant Food Control Officials traces its roots to 1869 when Massachusetts enacted the first fertilizer control law in the U.S. By 1947, all but one of the 48 states had legislated laws to regulate the distribution and use of fertilizer products.

Many of these original fertilizer laws were narrow in scope and non-uniform, causing confusion and resulting in chaos for producers marketing products in more than one state. These laws also failed to provide regulatory authority over labeling or inspection of products to prevent misbranding and adulteration. Over the years, it became apparent that the need for uniformity in enforcement would be advantageous both to consumer and industry.

AAPFCO was created from the regulatory committee of the Association of Agricultural Chemists (AOAC), founded in 1884, when the scope of the work being addressed started to significantly diverge from the purpose of AOAC which was the development of new methods of analysis. The Association of American Fertilizer Control Officials was formed to address, definitions, sampling methods, and model bills for uniform administration of fertilizer laws throughout the country, later changing its name to the Association of American Plant Food Control Officials (AAPFCO).

The current AAPFCO Mission is:

> *The mission of the Association of American Plant Food Control Officials is to establish uniform standards that promote consumer protection, environmental stewardship, and provide a forum to achieve regulatory consensus.*

Most states that regulated fertilizers had a hand in creating the AAPFCO model documents, so they adopted them in whole, in part, or by reference in their laws and rules. In order to remain current with industry and regulatory needs, the model documents are revised continuously. Over time, AAPFCO has created model documents for regulation of the following:

- Fertilizers
- Liming Materials
- Soil Amendments
- Ammonia
- Chemigation
- Horticultural Growing Media

AAPFCO has added definitions and labeling requirements for Beneficial Substances or Compounds in fertilizers. These categories were designed to capture all plant and media applied materials that do not meet the definition of one of the above mentioned materials and are not pesticides. This category includes many products also known as biostimulants.

AAPFCO Definitions

Products currently marketed as biostimulants will fit into the Environmental Protection Agency (EPA) definition of a pesticide or one of the AAPFCO definitions below:

> **Fertilizer** - The term "fertilizer" means any substance containing one or more recognized plant nutrient(s) which is used for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth, except unmanipulated animal and vegetable manures, marl, lime, limestone, wood ashes and other products exempted by regulation... (Uniform State Fertilizer Bill)

> **Plant Amendment** – Any substance applied to plants or seeds which are intended to improve growth, yield, product quality, reproduction, flavor, or other favorable characteristics of plants except fertilizer, soil amendments, agricultural liming materials, animal and vegetable manure, pesticides, plant regulators, and other materials which may be exempted by regulation. (Official 2013) T-92

Soil Amendment – (commonly referred to as Soil Additives or Soil Conditioners), means any substance or a mixture of substances which is intended to Improve the physical, chemical, biochemical, biological or other characteristics of the soil, except fertilizers, agricultural liming materials, unmanipulated animal manures, unmanipulated vegetable manures, pesticides and other materials exempted by regulation. (Official 2013) T-90

Beneficial Substances or Compounds – Means 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 exogenously. (Official 2007) T-73

What is a Biostimulant?

There are many definitions/descriptions of what a biostimulant is. The 2018 Farm Bill describes a biostimulant as:

- *(c) Plant biostimulant.—For the purposes of the report under subsection (a), the Secretary—*
  - *(1) shall consider* ***"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****; and*
  - *(2) may modify the description of plant biostimulant, as appropriate.*

The EPA Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants includes this description:

> *Plant biostimulants (PBS) are a relatively new, but growing, category of products containing naturally-occurring substances and microbes that are used to stimulate plant growth, enhance resistance to plant pests, and reduce abiotic stress.*

The figure below shows what industry views as potential biostimulant products. This image was copied from the Biological Products Industry Alliance (BPIA) webpage (https://www.bpia.org/solutions-provided-by-biological-products-biostimulants/). Clearly, it is much broader than the description that EPA included in its draft guidance. The BPIA diagram includes products that are not from living things and in many cases, not even natural.

The Emerging Landscape of Products – Broad and (Potentially) Confusing

Biostimulant Background

Biostimulants have been around for many years, but the term has become popular recently. One category of biostimulants is plant extracts. With the plant extracts, industry is targeting specific compounds and only wanting to list the source. One such source is seaweed extract. The compounds that are being targeted are phyto-hormones. When a seaweed extract is applied to a plant, the phyto-hormones promote increased root and shoot growth. This action meets the definition of a plant regulator found in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This is the reason that the vitamin-hormone exemption was included in FIFRA and why these products were exempted from registration (when meeting certain conditions), but not from the definition of a pesticide.

For years, these products have been registered as fertilizers in many states because seaweed extract contains Soluble Potash, a primary nutrient. It was not taken into consideration that application rates are too low for the products to meet the definition of a fertilizer. The products may contain nutrients, but they are not being used for their plant nutrient content.

Most biostimulant functions are already included in other regulatory structures. For example:

"Biostimulant"	Claim(s)	Regulatory Category
Seaweed/Kelp Extract	Improve root growth; improve plant establishment	Pesticide (Plant Regulator)
Humic acid (soil applied)	Improved nutrient use efficiency	Soil amendment
Phosphate solubilizing bacteria	Makes mineral phosphate available to the plant (benefit nutrient uptake)	Soil amendment/soil inoculant
Soy protein hydrolysate	Increase germination and crop quality; supply nitrogen to the plant	Possible pesticide (plant regulator); Fertilizer

However, many biostimulant claims are secondary effects of the biostimulant. The primary effect, or mode of action, would frequently be considered a pesticide. For example, many seaweed extract products claim improved nutrient use efficiency. This sounds like a soil/plant amendment. What is not usually mentioned, though, is that the nutrient use efficiency is a result of the increased root growth that is a result of the plant regulator in seaweed extract.

The Future of Biostimulant Regulation

Regulatory structure is based on FUNCTION. Therefore, most of these products already have a regulatory path in place, though there is not a single one for all biostimulants. The term biostimulant is an overarching term that includes many functions, hence many regulatory structures.

Moving forward, the following decision scheme should be applied.

1. Does the product meet the definition of a pesticide (including plant regulators and induced resistance promoters)?
    a. Yes – Regulated as a pesticide with EPA and State Lead Agencies
    b. No – Go to question 2
2. Does the product contain a significant amount of a recognized plant nutrient in a form that is usable by the plants?
    a. Yes – Is the application rate high enough that a significant amount of these nutrients will be applied to the plant?
        i. Yes – Regulated as a fertilizer with the states
        ii. No – Question 3
    b. No – Question 3

3. Does the product meet the definition of a soil amendment?
    a. Yes – Regulated as a soil amendment
    b. No – Question 4
4. Does the product meet the definition of horticultural growing media?
    a. Yes – Regulated as horticultural growing media
    b. No – Question 5
5. Does the product meet the definition of a beneficial substance/compound?
    a. Yes – Regulated as a beneficial substance/compound
    b. No – What is the benefit of applying this product?

AAPFCO understands that there is not currently a uniform bill for beneficial substances/compounds, but it does have the flexibility and expertise to develop one that can be adopted by the states.

Conclusion

In conclusion, creating a single regulatory structure for all products marketed as biostimulants would create confusion with regulators, industry and consumers. Products should be regulated based on their intended function, not based on a broad marketing term.

A Process Verified Program (PVP) for biostimulants may have limited benefit for the biostimulant industry. It would not be a regulatory process to market and would not give them a uniform label, but it could be useful in meeting some of industry's stated goals. Reasons for a PVP rather than a single, overarching regulatory structure include:

- The term "biostimulant" is very broad and includes many different classes of products
- These classes of products are already regulated at the federal and/or state level, and include:
    - Pesticides (mostly plant regulators)
    - Fertilizers
    - Soil Amendments
    - Beneficial substances
- Some of industry's stated goals would be achieved through a similar process
    - Credibility – through a safety and efficacy review
    - Use of the term "Biostimulant" and biostimulant claims
    - Predictable process – registration of the product based on the intended use and function of the product.

AAPFCO's primary concerns are that "biostimulant" is an overarching term and that any federal regulation of biostimulants could be in conflict with the state laws currently applied to these types of products. Any new federal legislation would require every state to, at minimum, amend their current laws and rules to ensure alignment with federal law. However, if AAPFCO were to create a uniform bill for beneficial substances/compounds, only the states with an interest in regulating these products within their own distinct category would have to make new laws. For states without that interest, the products would be un-regulated and industry would be free to distribute.

Thank you for your time and for considering our comments.

Sincerely,

Lance Kunneman
AAPFCO President

William "Eddie" Simons
AAPFCO Biostimulant Task Force Chair

Appendix 6: Letter to NASDA from the Association of American Pesticide Control Officials Inc. (AAPCO)