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**Plant Biostimulant Industry Response to EPA Draft Guidance for Pesticide Registrants on Plant Regulator Label Claims, Including Plant Biostimulants**

On behalf of the U.S. Biostimulant Coalition (USBC) and the Biological Products Industry Alliance (BPIA) please accept our written comments on the “Draft Guidance for Pesticide Registrants on Plant Regulator Label Claims, Including Plant Biostimulants” (Guidance) [EPA–HQ–OPP–2018–0258; FRL–9986–27] RIN 2070–ZA21.

USBC is a joint initiative of companies that develop, sell or market biological, naturally derived products and/or similar products intended for use as beneficial plant biostimulants (PBS). The Coalition is a nonprofit affiliation of those interested parties.

BPIA promotes the responsible development of safe and effective biological products including biopesticides and PBS as beneficial tools for commercial agriculture, forestry, golf courses, home gardens, horticulture, ornamentals, and public health through education, outreach, and advocacy activities at the state, federal, and international levels. Collectively, our two groups represent over 160 member companies.

Members of both associations appreciate the Environmental Protection Agency’s (EPA) time, attention, and effort in drafting the Guidance.

The U.S. biostimulant industry (Industry) has also been working in coordination with the United States Department of Agriculture (USDA), EPA, National Association of State Departments of Agriculture (NASDA), Association of American Plant Food Control Officials (AAPFCO), American Association of Pesticide Control Official (AAPCO), and other stakeholders pursuant to the 2018 Farm Bill. The EPA’s Guidance and USDA-led initiative are developing in parallel and should support one another. To that end, our comments and recommendations will also be consistent with those provided to USDA.

Our comments and recommendations are structured as follows:

- I. General Comments
- II. Specific Line by Line Comments and Suggestions
- III. Specific Comments Relative to Table 4 in the Guidance.
- IV. Economic Impacts
- V. Additional Considerations
- VI. Concluding Thoughts

**EXECUTIVE SUMMARY:**

Members of both associations appreciate the EPA’s time, attention, and effort in preparing the Guidance. As an industry, we have been interested in EPA’s perspective on this emerging category of products and technologies. We, along with other stakeholders, have sought clarity with respect to the claims our products can make in relation to the existing laws and statutes under EPA’s purview.

We would like to focus our comments and recommendations on the following points.

- I. Primary points
  - a. To recognize PBS as products supporting natural plant nutrition processes and tolerance to abiotic stress
  - b. To recognize and accept that many PBS (substances and microbials) have multi-function properties and modes of action depending on formulation, rate and its application
  - c. To clarify EPA's definitions of product categories that are excluded from the definition of plant regulator under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- II. Specific Line by Line Comments and Suggestions to Table 1, 2 and 3
- III. Request to delete Table 4 as not consistent with the Guidance emphasizing claims/knowledge/intent-based approach while Table 4 is a list of substances registered as PR
- IV. Economic Impact of Guidance on manufacturers which could reach or exceed \$449 million annualized cost, totaling over \$2 billion over a five-year time period
- V. Additional Considerations and importance of parallel development of EPA's Guidance and USDA-led initiative on PBS under the 2018 Farm Bill in alignment with other agencies including National Association of State Departments of Agriculture (NASDA), Association of American Plant Food Control Officials (AAPFCO), American Association of Pesticide Control Official (AAPCO), and other stakeholders.
- VI. Concluding Thoughts summarizing importance of the Guidance and its positive impact on introduction of PBS to the sustainable agricultural practices through enhanced regulatory framework.

## **I. General Comments**

### **A. Plant biostimulants and optimal plant nutrition**

The commercial category of products known as PBS is comprised of products that enhance agricultural productivity and are valued for their contribution to sustainable agriculture production systems. Plant biostimulants are recognized as supporting natural plant nutrition processes independently of products' nutrient content, thereby improving nutrient availability, uptake, and/or use efficiency; tolerance to abiotic stress; and consequent growth, development, quality, and/or yield. The Industry considers this category to be distinct from pesticides, which include plant regulators (PR), as defined by FIFRA, and fertilizers.

Industry's position is consistent with legislation recently enacted by the EU Parliament on the marketing of fertilizing products (EU 2019/1009), which relies on a claims-based approach for its regulatory framework and explicitly recognizes that the functionality of any single material may be altered by its processing, formulation or use context. The new legislation specifically defines and includes PBS and clarifies their distinction from PR (considered pesticides under EU pesticide law). The EU's description of PBS is instructive as it recognizes that PBS have no direct action against pests, and therefore do not fall within the regulatory framework of biopesticides.<sup>1</sup>

Like many natural substances, PBS may positively impact nutritional processes by influencing physiological processes, such as photosynthesis, production of plant metabolites, enzymatic activity in plant tissues, up- or down- gene regulation, and plant membrane stability. Other PBS may act upon the microbial community in the rhizosphere resulting in effects on soil or plant

function. These effects may include enhanced beneficial microbial activity and soil respiration; increased number of microbes with positive attributes associated with plant growth promotion or stress tolerance (e.g., P-solubilization, ACC deaminase production); and production of enzymes or secondary metabolites by soil microbes, which in turn affect plant root physiology and/or soil properties.

The evolution of plant nutritional science, bolstered by the increased understanding of plant/microbial and soil/plant/microbial interactions, mirrors a similar evolution in thinking about human nutrition. It is well established that a variety of substances, other than the so-called “essential nutrients”, are required for optimal human nutrition<sup>2</sup>. The USDA Food Composition database lists nearly 150 nutritional compounds that contribute to human nutrition.<sup>3</sup> These important, globally accepted and scientifically based tenets of human nutrition instruct us on the need for more holistic thinking about plant nutrition.

Industry maintains that the ultimate outcome of improved nutritional or physiological processes is improved plant health, tolerance to abiotic and other environmental stress, and as a result, improved growth, quality and yield.

In the Guidance (lines 166-183), EPA states that when “*determining what natural substances are considered plant regulators, and what may constitute a plant regulator claim on a product label, the mode of action of the substance(s) and associated label claim(s) must be congruent with the intent of the plant regulator definition. Based solely on the FIFRA section 2(v) “plant regulator” definition, a naturally occurring substance would be considered a “plant regulator,” and a product label claim would be considered a “plant regulator claim” if:*

*The substance or mixture of substances, through physiological action:*

- 1. Accelerates or retards the rate of plant growth;*
- 2. Accelerates or retards the rate of plant maturation;*
- 3. Or otherwise alters the behavior of plants or the produce thereof;*

*and if the substance or mixture of substances does not fall under one of the exclusion categories listed in 40 §CFR 152.6(f) & (g) as vitamin-hormone products, plant nutrients, plant inoculants or soil amendments; or under 40 CFR 152.8(a) as a fertilizer.”*

As outlined above, PR are intended to alter or modify the growth habit of a plant or its produce, through direct physiological action, in a way that it would not normally behave under optimal growing conditions. Substances that have no other purpose than to alter a plant's behavior, such as auxin, cytokinins, and gibberellins, are recognized PR requiring registration as pesticides, whether used by themselves or when added in known quantities to other substances.

Plant biostimulants are neither intended nor claimed to alter or modify the natural growth habit of the plant but rather to support optimal nutritional processes that enable the plant to realize as much of its innate genetic growth potential as possible. FIFRA Section 2(v) and EPA’s implementing regulations (40 CFR 152.6(f), 40 CFR 152.6(g), and 40 CFR 152.8(a)) expressly exclude substances from regulation as pesticides that are plant nutrients, inoculants, or soil amendments, as well as fertilizers and vitamin-hormone products not intended for use on food crop sites. These products are designed to aid the growth of desirable plants, and are not for use against pests. Consequently, it follows that nutritional-based products with one or more of these claims should be excluded from regulation as pesticides including PR.

The Guidance does not recognize that the products excluded from regulation under FIFRA enhance plant growth such as germination, seedling growth, root and shoot growth, yield quality, fruit size, etc. For product(s) that provide such benefits consistent with the excluded categories resulting in measurable improvements EPA should specifically state in the Guidance that those products would not be considered PR, provided they do not make PR claims.

### **B. Multi-function products**

The Guidance does not recognize that a PBS may have more than one function depending on timing of application, application rate or concentration, use pattern, formulation process and/or intent. The EPA, Food and Drug Administration (FDA), and State governments each have a long history of regulating the same product for its intended use and there are many examples of products registered and used as a pesticide/active ingredient but also being registered and/or sold for non-pesticidal purposes like food/feed additives, inerts, plant nutrients, cosmetics, etc.

Furthermore, the suggestion that a raw material is always processed with the goal of producing a pesticide or PR, and thus would always have a finite and limited mode of action (MOA) requiring FIFRA registration: (1) ignores consideration of any claims or intent (or lack thereof) on the part of the producer, as required under 40 CFR 152.15(a); (2) runs counter to the stated single-purpose provision, as stated in 40 CFR 152.15(b); (3) assumes that anyone selling such substances has actual or constructive knowledge that the substance, irrespective of label claims or use instructions, will be used as a pesticide per 40 CFR 152.15(c); and (4) overlooks the wide variety of processing variables that determine the nature and purpose of the intended product.

EPA's jurisdiction under FIFRA is based on claims, knowledge and intent and defines a pesticide as "any substance (or mixture of substances) intended for a pesticidal purpose..." (FIFRA Section 2(u), 40 CFR 152.15). The active ingredient's mode of action (MOA) and use pattern is pivotal in determining the intent, activity, and claims, as well as establishing essential context that drive the product claims. PRs accelerate or retard the rate of plant growth by directly altering the plant's baseline developmental potential, whereas, plant biostimulants act in positive ways to assist the plant in reaching its innate growth potential.

EPA considers a product to be intended for "pesticidal purpose" if the person distributing or selling the substance claims, states, implies or intends that the substance can or should be used as a pesticide, has knowledge that it will be used as a pesticide or that the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide (40 CFR 152.15). The description in lines 81-99 of the Guidance is not fully consistent with EPA, USDA, or the Industry's description or actual use of a PBS. Furthermore, and most pertinent to whether a product can have multiple functions or uses, 40 CFR 152.15(b) states that a substance is considered to have a pesticidal purpose if it consists of or contains at least one active ingredient and has no significant commercially valuable use as distributed or sold other than use for pesticidal purpose (by itself or in combination with any other substance). Therefore, it should follow that if a substance has non-pesticidal commercially valuable use (e.g. pesticidal inert, food additive, soil or plant inoculant, industrial, etc.), these uses should be permitted without FIFRA registration.

### **C. Clarify definition of plant regulator:**

The Industry would like the Guidance to clarify the definition of PR so there is a clear distinction between PR and the products excluded from regulation by FIFRA. This will avoid the ambiguity in product classification and inconsistency in regulated status between the various types of products

existing today. It is also important to the Industry that the Guidance be applied to current and future products. In present form, the Guidance does not remove the ambiguity nor include the flexibility for application to future products. Product claims are placed in various categories and are highly specific. This specificity could 1) limit new technology and 2) cause non-Federal regulators to potentially interpret the claims as binding. Additionally, if a claim is not listed in one of the categories, it may be unclear how the product is regulated. Finally, the categories are not exhaustive or fully aligned to those found in states with additional categories, which leaves significant room for confusion. Stakeholders need consistent parameters to determine whether a product is regulated under FIFRA. A decision tree could aid in this regard and support implementation of the final Guidance.

**D. Comments on Guidance Tables 1, 2 and 3:**

As we reviewed the Guidance, we realized that a number of areas require further clarification. Without modification, we are concerned that state regulatory agencies, industry and related stakeholders will continue to have questions regarding how particular PBS products should be regulated and brought to market.

We appreciate EPA’s efforts in developing several tables (Guidance Tables 1-3) that provide claim examples. We believe that a list of example claims is helpful for both regulators and the Industry, with certain caveats. On line 149 of the Guidance, EPA acknowledges, “The examples contained in the following tables are not comprehensive lists and may include other synonymous terms.” We appreciate this recognition, but think this sentence should be reiterated again above each table included in the Guidance. Furthermore, the claims in each Table need to be fully representative of all the types of claims for the respective categories of product, otherwise claims that are not synonymous with those listed, but are valid, may be disallowed by regulators.

**II. Specific Line-By-Line Comments and Suggestions:**

<b>General Comments on Text</b>			
<b>Text Line Number</b>	<b>Text from Guidance</b>	<b>Comments</b>	<b>Proposed Change to Text from Guidance</b>
48	Plant biostimulants (PBS) are a relatively new, but growing, category of products...	Farmers, golf course superintendents, landscape professionals, and homeowners have successfully used PBS for decades or millennia.	Plant biostimulants (PBS) is a new term for a growing category of products. Some of them have been used successfully by farmers, golf course superintendents, landscape professionals, and homeowners for decades or millennia.

<b>General Comments on Text</b>			
<b>Text Line Number</b>	<b>Text from Guidance</b>	<b>Comments</b>	<b>Proposed Change to Text from Guidance</b>
49	Containing naturally-occurring substances and microbes that are used to stimulate plant growth	Not all PBS substances are naturally occurring. Substances may also be synthetic, which were developed to simulate natural substances or have a novel benefit. We recommend EPA clarify the meaning of “natural” or “naturally occurring”, and consider whether “natural” should be interpreted to include both naturally-occurring substances and/or their synthetic equivalents.? This would be consistent with EPA’s definition of biochemical pesticides.	These products may contain microbes or naturally-occurring substances and their synthetic equivalents that are used to...
53-54	PBS can promote greater water and nutrient use efficiency, but do not provide any nutritionally relevant fertilizer benefit to the plant.	PBS frequently contain nutrients like amino acids, which contain nitrogen, and seaweed extracts, which contain potassium and micronutrients. Many PBSs (amino acids, seaweed extracts, humic acids, etc.) also contain chelating/complexing ligands, which are known to improve nutrient uptake and utilization.	Replace “any” with “any substantial”
67-70	“Proposed European Commission Definition: “Plant biostimulant” means a product stimulating plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant: (a) nutrient use efficiency; (b) tolerance to abiotic stress; and (c) crop quality traits.”	The European Union (EU) passed a new Fertilizing Products [Regulation (EU) 2019/1009], in March 2019 that specifically defines and includes PBS and clarifies their distinction from PR (considered plant protectants under their pesticide law, Regulation (EC) No 1107/2009).	“[Regulation (EU) 2019/1009] Definition: “Plant biostimulant” means a product stimulating plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere: (a) nutrient use efficiency; (b) tolerance to abiotic stress; (c) quality traits; (d) availability of confined nutrients in soil or rhizosphere”

<b>General Comments on Text</b>			
<b>Text Line Number</b>	<b>Text from Guidance</b>	<b>Comments</b>	<b>Proposed Change to Text from Guidance</b>
73-79	EPA's description of a PBS	Consistent with the collaborative effort and report to the President and Congress required under the 2018 Farm Bill Sec. 9201, "Report on Regulation of Plant Biostimulants", we recommend that any proposed description or definition of a PBS be included in that report.	We further suggest the following definition of a PBS for consideration by stakeholders pursuant to the 2018 Farm Bill process: <i>"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 independent 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."</i>
117-141	Products That Are Not Pesticides Because They Are Excluded by Regulation from the Definition of a Plant Regulator	The Guidance references the relevant existing definitions for both PR and their exclusions as found in FIFRA and EPA's implementing regulations. However, the Guidance does not attempt to address actions to define the term "nutritional chemicals", which is included as an exclusion from regulation as a pesticide under FIFRA Section 2(v) but is singularly excluded from treatment under the Guidance.	We further suggest the following definition of a nutritional chemical:  <i>"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."</i>
134-141	Vitamin-hormone products	Expand exclusion to allow use on food crop sites.	Delete "and is not intended for use on food crop sites"

<b>Comments on Table 1a, Table 1b, and Table 1c</b>			
<b>Text Line Number / Table Location</b>	<b>Text from Guidance</b>	<b>Comments</b>	<b>Proposed Change to Text from Guidance</b>
153-154	General comment	Table 1a addresses only soil nutrient conditions and does not mention foliar or seed nutrient applications, which are common in modern agriculture.	We recommend expanding the "soil/nutrient conditions" statement to "soil/nutrient conditions/seed nutrition/foliar nutrition/plant nutrition" when applicable

<b>Comments on Table 1a, Table 1b, and Table 1c</b>			
<b>Text Line Number / Table Location</b>	<b>Text from Guidance</b>	<b>Comments</b>	<b>Proposed Change to Text from Guidance</b>
Table 1a title	Examples of Plant Nutrition-based Claims (necessary for normal growth of plants and in a form readily useable by plants)		We recommend the following addition to the title for Table 1a:  Table 1a: Examples of Plant Nutrition-based Claims (necessary for normal growth of plants and in a form readily useable by plants <i>when applied to seeds, plants, the rhizosphere, soil or other growth media</i> )
Table 1a bullet 2	Improves soil/nutrient conditions for better overall plant mass		Improves soil/nutrient conditions/seed nutrition/foliar nutrition for better overall plant mass
Table 1a bullet 3	Improves soil/nutrient conditions for better plant/crop size/yield		Improves soil/nutrient conditions/seed nutrition/foliar nutrition for better plant/crop size/mass/yield/quality
Table 1a bullet 5	Improves soil/nutrient conditions for root growth		Improves soil/nutrient conditions/seed nutrition/foliar nutrition for root growth
Table 1a bullet 6	Optimizes soil/nutrient conditions for plant growth		Optimizes soil/nutrient conditions/seed nutrition/foliar nutrition for plant growth
Table 1a bullet 7	Optimizes soil/nutrient conditions for seed germination		Optimizes soil/nutrient conditions/seed nutrition for seed germination
Table 1a bullet 9 (new)	None	Insert new claim	Improves soil/nutrient conditions/seed nutrition/foliar nutrition to support plant/seed health/strength/vigor
Table 1a bullet 10 (new)	None	Insert new claim	Improves soil/nutrient conditions/seed nutrition/foliar nutrition to support root/shoot/foilage/fruit/nut growth/vigor
Table 1a bullet 11 (new)	None	Insert new claim	Improves soil/nutrient conditions/seed nutrition/foliar nutrition to increase plant strength
Table 1b bullet 2	Increases overall plant mass by improved nutrient uptake	Expand bullet to capture additional phenotype changes observed from improved nutrient uptake.	Increases/improves overall root mass/plant mass/early-season vigor by improved nutrient uptake

<b>Comments on Table 1a, Table 1b, and Table 1c</b>			
<b>Text Line Number / Table Location</b>	<b>Text from Guidance</b>	<b>Comments</b>	<b>Proposed Change to Text from Guidance</b>
Table 1b bullet 5	Improve/increase/support availability/release of bound nutrients from the soil	Add footnote 1 to the word “nutrients” to clarify that any nutrient(s) may be referenced in a claim	Improve/increase/support availability/release of bound nutrients <sup>1</sup> from the soil
Table 1b bullet 6	Improve nutrient/water transport/uptake/efficiency by plants/roots	Add footnote 1 to the word “nutrients” to clarify that any nutrient(s) may be referenced in a claim	Improve nutrient <sup>1</sup> /water transport/uptake/efficiency by plants/roots
Table 1b bullet 9	Improves Phosphorous solubilization/availability for improved uptake <sup>1</sup>	Allow flexibility in listing any applicable nutrient	Improves nutrient <sup>1</sup> solubilization/availability for improved uptake
Table 1b bullet 10	Reduces Phosphorous loss to the environment	Allow flexibility in listing any applicable nutrient	Reduces nutrient <sup>1</sup> loss to the environment
Table 1b bullet 12 (new)	None	Insert new claim	Increases/improves plant tolerance to weather stress/unfavorable soil conditions though improved nutrient <sup>1</sup> uptake
Table 1b footnote 1	May include other plant nutrients and trace elements	Expand the meaning of plant nutrients with the list of nutrient categories	<sup>1</sup> May include any plant nutrient(s) comprising macro-, secondary-, micronutrient(s) or trace element(s), or combination thereof.
Table 1c bullet 4	Increases/improves/optimizes soil conditions for increased plant vigor	Expand to capture additional phenotype changes observed from improved soil conditions.	Increases/improves/optimizes soil conditions for increased plant vigor/root mass/plant mass/seed germination

<b>Comments on Table 2</b>			
<b>Table Location</b>	<b>Text from Guidance</b>	<b>Comments</b>	<b>Proposed change</b>
Bullet 7	Improves/ aids/ supports/ helps/ enhances conditions for better plant establishment	Expand to capture additional phenotype changes observed from improved conditions.	Improves/aids/supports/helps/enhances nutritional conditions for better plant establishment, growth and production
Bullet 10	Aids/supports/ helps/enhances/ optimizes soil conditions for greater root mass	Add or other growth media as there may be various types of growing media.	Aids/supports/helps/enhances/optimizes soil or other growth media conditions for greater root mass

Bullet 19 (new)	None	Insert new claim	Helps promote plant growth and production through optimization of nutrient and water uptake
Bullet 20 (new)	None	Insert new claim	Helps enhance plant growth and development by reducing negative effects of abiotic stress.
Table 2 Footnote 1	Product claims may not state or imply...	All the claims listed in Tables 1 and 2 result in enhanced growth, production and improved yield quality of a plant as compared to the untreated control. These effects are obtained through physiological action on the plant. Thus, the footnote is contradictory and adds confusion to the interpretation of the document and the claims.	(...) accelerates or retards the rate of growth <u>beyond</u> the innate genetic potential of the plant, accelerates or retards the rate of maturation <u>beyond</u> the innate genetic potential of the plant, or otherwise alters the behavior of the plant or the quality of the produce <u>beyond</u> the innate genetic potential of the plant. A product/substance/microbe (PBS) should not be recognized/classified as a plant regulator if it accelerates or retards plant growth, maturation and other plant behavior within genetic potential of a plant/crop and its effects are a consequence of enhanced nutrition or enhanced tolerance to abiotic stress.

<b>Comments on Table 3</b>			
<b>Table Location</b>	<b>Text</b>	<b>Comments</b>	<b>Proposed change</b>
	Generic comment	Many of the claims listed in Table 3 are broad and apply also to plant nutrients, plant inoculants, soil amendments and PBS products so they may confuse regulators and the regulated community. The word “promote” means to support, to further the progress, or to encourage and can be applied to plant nutrients, plant inoculants, soil amendments and PBS.	
Bullet 1	Enhances/promotes /stimulates fruit growth & development	This is a broad claim that also applies to plant nutrients, plant inoculants, soil amendments, and PBS products.	Use wording: Regulates fruit growth and development beyond the innate genetic potential of the plant
Bullet 2	Enhances/promotes /stimulates plant growth and development	This is a broad claim that could also be applied to plant nutrients, plant inoculants, soil amendments, and PBS products.	Use wording: Regulates plant growth and development beyond the innate genetic potential of the plant
Bullet 3	Enhance/inhibit development	above	As above

Bullet 4	Promote stem elongation	The word “promote” is not appropriate since it means to support, to further the progress, to encourage and can be applied to plant nutrients, plant inoculants, soil amendments and PBS	Regulates stem elongation
Bullet 8	Induce/promote/retard/suppress flowering	The word “promote” means to support, to further the progress, or to encourage and can be applied to plant nutrients, plant inoculants, soil amendments and PBS	Regulate/induce/retard/suppress flowering
Bullet 9	Induce/promote/retard/suppress bud break	above	Regulate/induce/retard/suppress bud break
Bullet 10	Induce/promote/retard/suppress seed germination	above	Regulate/induce/retard/suppress seed germination
Bullet 13	Inhibits/promotes sprouting	above	Regulate/induce/retard/suppress sprouting
Bullet 14	Enhances/promotes crop/fruit/produce color/development/quality/shape	is a broad claim that could also be applied to plant nutrients, plant inoculants, soil amendments, and PBS products.	Use wording:  Regulates crop/fruit/produce color/development/quality/shape beyond the innate genetic potential of the plant
Bullet 15	Enhances/promotes fruit growth & development	above	As above

<b>Comments on Table 4</b>			
<b>Line number (e.g. 17)</b>	<b>Text from Guidance</b>	<b>Comments</b>	<b>Proposed change</b>
Table 4			Remove Table 4 from the Guidance.

### **III. Specific Comments Relative to Table 4:**

The Industry requests that all elements of the Guidance reflect the claims, knowledge and intent-based approach of FIFRA, and not contain a positive list of substances. Therefore, we request that Table 4 be deleted. The following is justification of our recommendations.

EPA’s jurisdiction under FIFRA has, from its inception, been based on claims, knowledge and intent. Section 2(u) of the statute defines a pesticide in relevant part as “any substance (or mixture of substances) intended for a pesticidal purpose [or] any substance or mixture of substances intended for use as a plant regulator...”. The active ingredient’s mode of action (MOA) and use

pattern are pivotal in determining the intent, activity, and claims, as well as establishing essential context that drive the product claims. PRs accelerate or retard the rate of plant growth by directly altering the plant's baseline developmental potential, whereas, plant biostimulants act in positive ways to assist the plant in reaching its innate growth potential. EPA considers a product to be intended for "pesticidal purpose" if the person distributing or selling the substance claims, states, implies or intends that the substance can or should be used as a pesticide, has knowledge that it will be used as a pesticide or that the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide (40 CFR 152.15).

The suggestion that a substance is inherently included as a class under the PR definition and requires registration solely based on a prior history of applicant submissions for registration, runs counter to the stated intent of the law under FIFRA and as stated in 40 CFR 152.15:

- a) Fails to provide for consideration of any claims or intent existing or not on the part of the applicant, as required under 40 CFR 152.15(a);
- b) Assumes that any substance, however broadly or narrowly defined, consists of or contains one or more active ingredients with no significant commercially valuable use other than as a pesticide under 40 CFR 152.15(b); a conflicting assumption when dealing with complex extracts of widely varying content, composition, and/or formulation and;
- c) Otherwise assumes the person selling such substance has actual or constructive knowledge that the substance will be used as a pesticide per 40 CFR 152.15(c).

The introduction of Table 4 is confusing (as to the responsibilities of the company) and contradicts or undercuts the prerequisites for registration in 40 CFR 152.15. Industry stakeholders (i.e., producers of the named ingredients, manufacturers who formulate with such ingredients, state regulators, growers and others) might assume EPA's intent in incorporating Table 4 is to provide historical examples of substances with PR claims in an attempt to aid their understanding of the regulatory requirements for new products.

Table 4 in the Guidance is being interpreted by state regulators of fertilizers, soil amendments, and other products, to require that any substance meeting the descriptions in the table is unarguably a PR subject to registration as a pesticide. This is inconsistent with a registration program based on claims, knowledge and intent and will result in confusion as well as potentially lead to an adverse economic impact on the Industry (including many small companies), growers, and states (lost revenue and cost of administering newly regulated articles).

For those reasons, no matter how well intentioned, the inclusion of Table 4 in the Guidance is inappropriate. The table is an oversimplification of the actual requirements under the law, creates a conflict between product registrations based on claims, knowledge, and intent as intended under FIFRA and substance-based standards, and has the potential to cause irreparable harm through the imposition of a significant economic burden on a large cross-section of stakeholders.

We also recommend a statement that seaweed extracts and humic acids can be recognized as fertilizers and allowed to be combined with fertilizers and registered as such according to the state regulations.

### **Historical perspective of how some of these substances became registered through FIFRA**

Based on past practice and historic interpretation of the definition of a PR under FIFRA and 40 CFR 152.6, it is reasonable to assume that certain substances included in Table 4 were registered as a PR by applicants wishing to make direct and specific claims that their product regulates plant

physiology or were formulated specifically for that purpose. Many of these registrations were sought and obtained 20 to 30 years ago when the lack of Federal and State regulatory clarity made such registration attractive solely for the purpose of seeking a uniform national label.

The inclusion of materials like seaweed extracts (SWE), humic and fulvic acids, and certain amino acids is especially problematic. Numerous market analyses suggest that products containing these three substances account for approximately 60% of the entire global PBS market.<sup>4</sup>

- Humic substances are a large grouping of organic acids and are well established as part of a normal plant living environment. The vast majority of organic acid products (humic acid, fulvic acid, and organic acids from Leonardite) in the US market have been safely sold and used as soil amendments and/or as components or complements for organic and conventional crop nutrition programs under state laws and registration processes for decades without choosing to make PR claims.
- A single applicant (FBS Sciences) made applications for five Complex Polymeric Polyhydroxy Acid (CCPA) products with specific claims (e.g., “to stimulate root and shoot growth”, “increase chlorophyll content”, or “increase yields”) based on specific concentrations of CCPA in proprietary formulations. The CCPA category in Table 4 of the Guidance appears to be a broader humic substance definition that does not follow any established testing standard for further identification.
- Corn gluten/corn gluten meal is a multi-use substance often used as the primary input for formulation of organic nutrient products (principally for nitrogen content), in addition to its ability to be formulated for use as a naturally derived herbicide and food/feed ingredient. The inclusion in Table 4 as a PR contradicts the plant nutrient exclusion from FIFRA as defined in 40 CFR 152.6(g).
- Seaweed products have been manufactured as liquid extracts since the 1950’s and sold as soil amendments and/or components or complements to organic and conventional plant nutrition programs as well as food/feed and cosmetic ingredients without active ingredient or PR claims under state fertilizer laws and registration processes.
- The first registration of SWE with EPA in 1978 was based on a “biologically equivalent activity” of 0.001%, and the actual presence of plant growth hormones, specifically four cytokinins, was only speculated. Research in peer-reviewed publications<sup>5</sup> now suggest that SWE do not contain agronomically significant levels of any of the four natural cytokinins mentioned in Table 4.<sup>6</sup>

In none of these examples is there a clear demonstration – or even a simple definition – of how these substances, *as entire classes*, meet the definition of a PR under FIFRA 2(v). The intention and meaning of the key phrase “**alters** the behavior of the plants or the produce thereof” when the law was passed or in any previous guidance efforts by the EPA is unclear. This fundamental definitional question is not addressed within the scope of the Guidance, and yet, assumptions as to its meaning are being used to pull entire classes of substances into the scope of interpretation of PR by the EPA, counter to decades of alternative interpretation.

The suggestion that a raw material is always processed with the goal of producing a PR, and thus would always have a finite and limited mode of action requiring registration, overlooks the wide variety of processing variables that determine the nature and purpose of the intended product. Simply assuming that a raw material will always be made into a pesticide is unreasonable as it completely ignores the idea of multi use or that a substance/material can have more than one

function, depending on the formulation, application, concentration, intended use and other aspects as described previously (i.e. as noted in Section B, “Multi-Function Products”).

The potential costs to the Industry, the growers using the products, and other stakeholders will be enormous in scale. Costs may include re-registration, removing or delaying products from access to the market and use by growers, or the potential loss of valuable inputs to specific growers (e.g., organic producers) if these substances are reclassified as pesticides. (See Appendix 1)

#### **Global regulation of biostimulants is moving towards a claims-based approach:**

The inclusion of Table 4 in the Guidance also runs counter to not only the historic practices in the US, but to the direction in the EU and other markets of global significance for trade. The regulatory framework of the recently enacted EU legislation on the marketing of fertilizing products (EU 2019/1009) relies on a claims-based approach, and explicitly recognizes that a single material may have more than one function when incorporated into a final formulation.

Furthermore, it treats all PBS materials beyond basic nutrients that aid in plant nutrition processes, as a subset of fertilizing products (and not as pesticides). This action follows the essential logic that such materials (including those cited above as problematic inclusions in Table 4) are materials that enhance the normal functioning of plants through contributions to improved plant nutrition. The proposed direction by EPA to include such technologies in an expanding definition of pesticides will create barriers to competitiveness for US companies in the global agricultural inputs market.

#### **Not to make the same mistakes as others - case study from Spain:**

In Spain, regulators spent several years, establishing and then removing a regulation, after it was successfully demonstrated that this regulation had an undue effect on industry and agricultural producers. A brief timeline of their activities is below.

1. December 16, 2014 – Seaweed extracts and all products containing seaweed extracts including fertilizers were ordered to be removed from the market or required to be registered with Directorate General of Health of the Agricultural Production of the Ministry of Agriculture Food and Environment.
2. December 3, 2015 – Modifications to the fertilizer product regulations listed new categories allowing distribution of seaweed extracts alone or in combination with N, P, K fertilizers under Specialty Products (Group 4).
3. December 6, 2017 – Modifications to the fertilizer product regulations listed new categories of products allowing distribution of products containing seaweed extracts with secondary and micronutrients under Group 4 – Other fertilizers and Specialty Products.

#### **IV. Specific Comments related to Appendix A in the Guidance**

##### **Line number 267-268 Defining “Nutritional Chemicals” Exclusion:**

The Industry acknowledges that products such as seaweed extracts, organic acids, silicates, and other “beneficial substances” likely work by enhancing nutrient availability, uptake and utilization resulting in elicitation of physiological responses in plants. Those physiological effects are within the normal and expected range of plant behaviors, such as stimulating activities consistent with the positive growth, vigor, and productivity of desirable plants growing to their full genetic potential.

FIFRA Section 2(v) defines “plant regulator” in part as: any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not

include substances to the extent that they are intended as plant nutrients, trace elements, **nutritional chemicals**, inoculants, and soil amendments.

FIFRA section 2(v) clearly excludes from regulation as a plant regulator “nutritional chemicals”, but the EPA did not define “nutritional chemicals” in the implementing regulations contained in 40 CFR 152 that defines all the other excluded terms. EPA has acknowledged in their enabling regulations that plant nutrients, trace elements, inoculants and soil amendments all aid the growth of desirable plants and are not used against pests. Since nutritional chemicals were also included in the same list of exclusions under FIFRA, it follows that other nutritional-based chemical products that aid the growth of desirable plants should also be excluded from regulation as plant regulators.

Industry believes that many plant biostimulants such as amino acids, organic extracts, and other beneficial substances would fall within the category of nutritional chemicals based on their nutritional support function as evidenced by the testimony at hearings held in conjunction with the FIFRA legislation that created the plant regulator language. (See Appendix 2)

We strongly recommend EPA define **all** statutory exclusions under FIFRA including specifically “nutritional chemicals”. Also, as part of the above-described specific regulatory amendment to Section 152.3, and consistent with recommendations to USDA per the 2018 Farm Bill Directive, the Industry recommends the following definition for products that are nutritional chemicals and excluded from regulation as plant regulators (or pesticides) under FIFRA,

***(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.***

#### **Line number 284-291 Vitamin Hormone Exemption:**

In previous conversations with EPA, we have asked EPA to consider revisiting the current prohibition on using vitamin hormone products on food sites. Enabling FIFRA legislation did not exclude the use of these types of products on food sites, therefore we request that the regulatory language in 40 CFR (below) be amended.

40 CFR 158.6(f) describes “vitamin hormones” as: “A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a “plant regulator” under section 2(v) of FIFRA, provided it meets the following criteria: (1) ...meets the criteria ...for Toxicity Category III or IV; and (2) ...is not intended for use on food crop sites, and is labeled accordingly.” We recommend eliminating point 2 and amending the plant regulator definition to include language such as, “Or otherwise alters, beyond the innate genetic potential, of plants or the produce thereof.” This language captures the concept that PBS support optimal nutritional processes that enable the plant to realize as much of its innate genetic growth potential as possible.

#### **V. Economic Impacts of Guidance:**

The Industry has serious concerns regarding the economic implications of the Guidance as currently written. Some of the Industry’s partners have already encountered problems with State regulatory agencies due to the current Guidance Draft.

While intended to provide state regulatory agencies and the Industry with direction on determining what should trigger EPA registration or not, the table is being interpreted as essentially binding regulation by some state regulators. For example, on the base of the Table 4 list in the currently published Guidance Draft listing seaweed extracts as active ingredient of PRs, certain states have

refused to register products containing sea plant extract (irrespective of product claims) stating that these products have to be registered with EPA. Registering products containing these ingredients as pesticides that are currently on the market and/or new products, the Industry would realize a tremendous negative economic impact. If the Guidance is implemented as written, there would be a negative economic impact on numerous sectors, including manufacturers, companies producing end-use products, state regulatory agencies, and growers. For manufacturers, the annualized cost could reach or exceed \$449 million, totaling over \$2 billion over a five-year time period. Outlined in detail in Appendix 1 (attached) are some of the potential ramifications on the Industry (and state regulatory bodies) if the Guidance is finalized in its current form. As stated above, if the Guidance is implemented as written, there would likely be negative economic impacts on manufacturers, companies producing end-use products, state regulatory agencies, and growers.

The PBS market in the US is growing every year. It is projected that the global agricultural biologicals market will exceed \$4 billion by 2024. Biostimulants are projected to comprise half of the total market, with almost 60% of product lines containing SWE or humic and fulvic acid.<sup>7</sup> In the United States, PBS are not regulated as pesticides. Therefore, any change to the regulation has the potential to place an economic burden on manufacturers, companies producing end-use products, federal and state regulatory agencies, and growers. The entities directly affected by the Guidance would include manufacturers of PBS and end-use products, third party distributors, and growers, as well as federal and state regulatory agencies.

An economic analysis of the potential impact of the Guidance focused on the affected entities manufacturing, utilizing, and regulating active ingredients most commonly found in PBS products (potassium silicates, SWE, and complex polymeric polyhydroxy acids, including humic acid, fulvic acid, tannins, and organic acids from Leonardite) is included in Appendix 1.

Additionally, the estimate does not include the potential impact to growers due to delayed access to products during the registration process and/or lack of access to products no longer produced for marketing or use in a particular state. While reduced access to PBS would impact all growers currently using the products, it would have a greater impact on specialty crop growers, both conventional and organic.

State licensing agencies would experience reduced revenues or a redistribution of workload and revenue. State fertilizer registration programs would experience reduced revenue due to fewer fertilizer products being registered, and, depending on the number of products registered as pesticides and the number of manufacturers exiting the market, the licensing and fee departments could see an overall reduction in revenue.

## **VI. Additional Considerations**

### **Potential conflicts with ongoing federal efforts**

Other ongoing activities at the federal level should be well coordinated with the finalization of the Guidance. Section 10111 of the Agricultural Improvement Act of 2018 included an important provision regarding PBS. In the law, Congress authorized the Secretary of Agriculture 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 PBS, to ensure the efficient and appropriate review, approval, uniform national labeling, and availability of PBS products to agricultural producers. The Secretary is to prepare the report in consultation with the Administrator of EPA, the states, industry stakeholders, and such other stakeholders the Secretary determines necessary.

For purposes of preparing the report, in the Farm Bill Congress described a “plant biostimulant” as: “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.”

Finally, Congress authorized the Secretary to modify that description of a PBS, as appropriate. The Guidance asks the question as to whether EPA should attempt to define PBS at this time. We believe it would be premature for EPA to attempt to define PBS given the coordination that will be required with USDA to develop a definition as part of the Section 10111 process.

Given this important development, we strongly believe EPA and USDA should discuss these overlapping efforts and wait to finalize the Guidance until USDA has submitted the report and Congress has reviewed and addressed the report.

### **Impacts on innovation**

As the Guidance acknowledges, PBS “products are becoming increasingly attractive for use in sustainable agriculture production systems, which in turn can reduce the use of irrigation water, as well as agrochemical supplements and fertilizers.” We strongly agree with this statement and believe that the Industry has great potential to improve agricultural production systems through innovative product development. Many of the products on the market today and in development in the coming years will have the ability to help growers or end users improve their crop quality or yield while also reducing their environmental footprint. We believe if the economic implications of the Guidance become a reality much of the current and future innovative research and development will either be delayed or cease altogether.

### **Accessibility for end-users**

As stated above, the Industry, growers, and public all benefit from affordable, innovative agricultural technologies. With PBS, we are often impacting a subset of agricultural production. Additional regulation will likely make these technologies less available to growers or end users due to high costs or because the Industry may be unable to make the necessary investment in research and registration process to make them available.

Many of the industries that have positive experiences with PBS will not be able to have easy access to these technologies. These include conventional and organic growers, agricultural retailers, golf course superintendents, landscape professionals, and many other industries.

### **VII. Concluding Thoughts**

We appreciate EPA’s effort in the development of the Guidance, and consideration of these comments. As demonstrated in our comments, we see certain aspects of the Guidance as helpful and of assistance; however, the major concerns we have with Table 4 of the Guidance undermine the positive aspects of the Guidance.

We believe that if Table 4 is removed from the Guidance document and other modifications are made to the other three Tables as described above, the Guidance document will serve to clarify the existing regulations for both regulators and the regulated community and thus help the industry continue to grow. This in turn will ensure access by end-users to these important agricultural tools and improve the sustainability of agricultural production in the future.

We appreciate your attention in reviewing these comments and the consideration that you can give to them at such time as you turn to finalizing the Guidance. Please feel free to contact us if you have any questions or would like any additional information.

Sincerely,

David Beaudreau, Executive Director, U.S. Biostimulant Coalition (USBC)

Keith Jones, Executive Director, Biological Products Industry Alliance (BPIA)

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<sup>1</sup> “Certain substances, mixtures and micro-organisms, 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.”

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32019R1009>

<sup>2</sup> World Health Organization, Food and Agricultural Organization of the United Nations (2004). *Vitamin and mineral requirements in human nutrition* (2. ed.). Geneva [u.a.]: World Health Organization. ISBN 978-9241546126.

<sup>3</sup> USDA Food Composition database (<https://ndb.nal.usda.gov/ndb/nutrients/index>)

<sup>4</sup> Markets and Markets. 2019. Available at:

<https://www.marketsandmarkets.com/PressReleases/biostimulant.asp>

<sup>5</sup> <https://www.bpia.org/solutions-provided-by-biological-products-biostimulants/>

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<sup>6</sup> Wally O.S. et al; 2012; Regulation of phytohormone biosynthesis and accumulation in Arabidopsis following treatment with commercial extracts from the marine macroalga *Ascophyllum nodosum*. *Journal of Plant Growth Regulation* DOI 10.1007/s00344-012-9301-9

<sup>7</sup> Markets and Markets. 2019. Available at:

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