



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Comments Received on the Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants (EPA Docket ID No. EPA-HQ-OPP-2018-0258)

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On March 27, 2019 (84 FR 11538, FRL-9986-27), the US EPA (the Agency) announced the availability of and sought public comment on the draft guidance document entitled “Guidance for Plant Regulator Label Claims, Including Plant Biostimulants” (the Draft Guidance). Comments, available in EPA Docket ID No. EPA-HQ-OPP-2018-0258 at <http://www.regulations.gov>, were accepted through July 27, 2019. The Agency extended the comment period twice and received 161 comments, of which 18 were requests for an extension of the comment period. The following is a breakdown of the comments received:

- 85 comments represented industry/trade groups/growers/law firms;
- 69 comments were from private citizens;
- 4 comments were from U.S. State governmental agencies [NV, CA (2 comments), and WA];
- 2 comments were from State associations of regulatory officials (AAPCO¹ and NASDA²);
- 1 comment was from a non-U.S. trade association (EBIC³); and
- A few commenters submitted two or more substantially similar comments as private individuals and as a member representing a stakeholder organization.

¹ Association of American Pest Control Officials

² National Association of State Departments of Agriculture

³ European Biostimulants Industry Council

This document consists of 23 comment essays, ordered by topic. Two topic areas were considered to be outside of the scope of the Draft Guidance: (1) changes to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and (2) changes to the Code of Federal Regulations (CFR).

I. Comment Response Approach and Scope

The following is the Agency's approach in responding to comments received to date on the Draft Guidance. The Agency received several comments and questions on the activities that are or are not covered within the Draft Guidance as well as suggestions to limit and revise activities covered under the Draft Guidance. Activities that are not covered by the Draft Guidance are divided into two main categories:

1. Legislative changes to FIFRA; and
2. Rulemaking to change regulations in Title 40 of the CFR.

Although a few comment documents were more extensive than others, all of the substantive comments covered overlapping topic areas. Instead of providing individual responses to each commenter, the Agency believes it is more efficient to address and discuss the major topic areas identified in the comments in an essay format.

II. The US EPA Responses to Comments

A. The following essays provide a discussion addressing activities identified in the public comments that are covered under the Draft Guidance.

1. *The US EPA response to comments that the Draft Guidance is a shift in the regulatory approach and/or that plant regulators are not pesticides and/or plant biostimulants are not plant regulators and should not be regulated under FIFRA.*

Several comments indicated that there is confusion as to why some plant biostimulants (PBS) are considered plant regulators and/or why plant regulators are considered to be pesticides by the US EPA. Several comments additionally indicated that the commenter believed the content of the draft guidance to be a change in the regulatory framework under FIFRA. The Draft Guidance is intended to give clarity to stakeholders and does not describe a change to the Agency's approach.

According to FIFRA Section 2(u): "The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer..." Part (2) of the definition specifically includes plant regulators amongst those substances that are considered to be pesticides. It is understood that plant regulators are not intended for use as pest control products.

Plant regulators are further defined in FIFRA Section 2(v): "The term "plant regulator" means 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, plant inoculants, and soil amendments. Also, the term "plant regulator" shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.”

The US EPA does not regulate products based on whether they are labeled as plant biostimulants. There are no Federal definitions for PBS, although one definition was used in the 2018 Farm Bill, and two additional alternative definitions were proposed in the 2019 USDA Report to Congress. The US EPA recognizes that the term “plant biostimulant” is used globally to include a diverse group of products that may or may not be considered plant regulators as defined in FIFRA Section 2(v). Many plant biostimulant products are excluded from the FIFRA plant regulator definition and, therefore, from FIFRA regulation as:

- a. 40 CFR 152.6(g)(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;
- b. 40 CFR 152.6(g)(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 through the root system;
- c. 40 CFR 152.6(g)(3): A soil amendment product containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth; and as
- d. 40 CFR 152.6(f): Vitamin hormone products. A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a “plant regulator” under FIFRA Section 2(v), provided it meets the following criteria:
 - (1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria of 40 CFR 156.62 ...for Toxicity Category III or IV; and
 - (2) The product is not intended for use on food crop sites, and is labeled accordingly.

2. *The US EPA response to comments supporting/opposing development of a US EPA definition of plant biostimulants.*

Plant biostimulants do not have a regulatory definition at the State and Federal level and are not recognized as an independent class of products. As part of the US EPA’s March 2019 Draft Guidance, EPA sought comment on whether it should develop an independent definition of PBS, noting that development of such a definition would require rulemaking.

Subsequent to the publication of the Draft Guidance for public comment in March 2019, the USDA developed and submitted a report to Congress in December 2019 that contained recommendations to address the appropriate review, approval, availability, and uniform labeling

of PBS products. The report also contains two proposed definitions of PBS for review and approval by Congress. EPA agrees with comments from several commenters that the development of another definition by EPA would only create confusion amongst regulators and the regulated community. Therefore, the US EPA does not intend to develop an independent regulatory definition of PBS at this time.

3. *The US EPA response to comments regarding development of a plant biostimulant definition by the Association of American Plant Food Control Officials (AAPFCO).*

Some commenters suggested that the AAPFCO may develop a definition of PBS for use by State regulatory officials. The Agency has no opinion on the development of a PBS definition by the AAPFCO or any other State regulatory body or association. It is noted that an AAPFCO definition for PBS would not be legally binding at the Federal level.

4. *The US EPA response to requests for the addition of a decision tree for FIFRA plant regulator determinations.*

In response to this request, the Agency will develop a Plant Regulator Decision Tree graphic that will be included in the appendix of the final version of the Guidance.

5. *The US EPA response to comments that the Draft Guidance departs from the historical (claims-based) approach to the regulation of plant regulators and that the presence of an ingredient that has a pesticidal effect does not in and of itself trigger regulation under FIFRA.*

Historically, the Agency has considered both the composition of a product and its claims, when making a regulatory determination. The Agency does not intend to depart from its historical approach. As per 40 CFR 152.15(b), “*The [pesticidal] substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide;* or per 40 CFR 152.15(c), “*The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.*” The Agency also notes that the preamble to 40 CFR 152.15 (49 FR 37917, September 26, 1984) states: “*the term "pesticide product" will be used to describe a particular pesticide in the form in which it is (or will be) registered and marketed, including the product's composition, packaging and labeling.*” However, as per 40 CFR 152.15 [(49 FR 37917, September 26, 1984)], the Agency will consider whether a substance “*has no significant commercially valuable use*” other than as a pesticide, when considering whether it is a pesticide.

6. *The US EPA response to comments that the phrase, “...alters the behavior of plants” is a key phrase of the FIFRA plant regulator definition, and that it is used to pull entire classes of products into regulation under FIFRA as plant regulators.*

The Agency acknowledges that the phrase “...alters the behavior of plants” in the FIFRA definition of a plant regulator is somewhat vague, however, the Agency does not consider it to be a key phrase of the definition. The phrase is but one part of the entire definition describing a plant regulator in FIFRA Section 2(v). “Behavior of plants” likely involves a general description of the manner in which plants grow and develop and can include but is not limited to:

accelerated or retarded growth; accelerated or retarded maturation; and/or changes in the quality (e.g., shape, color, odor, taste, nutritional traits, etc.) of the harvestable produce. The intended use of plant regulators would be to change, through physiological action, the behavior of plants in a manner that would not have occurred had the plant regulator not been applied to those plants.

7. *The US EPA response to comments on potential conflicts with the 2018 Farm Bill and the 2019 USDA Report to Congress on Plant Biostimulants.*

The 2018 Farm Bill directed USDA to submit a report to Congress in December 2019 (the 2019 USDA Report) containing different options to address future regulation of PBS products at the Federal and State level. The 2019 USDA Report contained six options, some of the of which would require legislative changes in FIFRA (Congressional action required) and in the Code of Federal Regulations (rulemaking required by the US EPA and/or other affected Agencies).

The US EPA Draft Guidance is intended to provide guidance on identifying products and product claims that are considered to be plant regulator products and claims, which includes some PBS, but not all. It also is intended to clarify which products and claims are considered to be plant regulator claims that are subject to FIFRA regulation as a pesticide, and provides examples of such claims that are and are not plant regulator claims. The guidance does not propose any legislative or regulatory framework changes and is not in conflict with the 2019 USDA Report. The US EPA will continue to collaborate with USDA and will follow any directives made by Congress resulting from the 2019 USDA Report on Plant Biostimulants.

8. *The US EPA response on commenter requests that the US EPA work with the States so as not to unnecessarily bring products already registered as fertilizers or biostimulants in the States into the FIFRA registration process.*

The Agency will continue to consult with the States, as has been done in the past, regarding the FIFRA registration of products that may have pesticidal ingredients, claims and uses. The Agency is authorized by FIFRA to regulate the use of pesticide products, including those substances known as plant regulators. Only those products and label claims that fit within the FIFRA Section 2(v) definition of a plant regulator will be regulated as pesticides. The Agency is not authorized to, nor does it intend to, regulate fertilizer and PBS products that are not considered to be pest control products or plant regulators. The Agency acknowledges that some PBS products and label claims fit within the FIFRA definition of a plant regulator, whereas other products and label claims fit within the regulatory exclusions from the FIFRA plant regulator definition [i.e., as plant nutrients and trace elements (fertilizers), plant inoculants, soil amendments, or vitamin-hormone products as defined in 40 CFR 152.6(g)(1), (2), and (3); and 40 CFR 152.6(f)]. Registrations of products at the State level are typically handled by the individual States, with coordination amongst the States via the Association of American Plant Food Control Officials (AAPFCO).

9. *The US EPA response to commenter requests that the US EPA coordinate the Draft Guidance with USDA, other Federal agencies, the National Organic Program (NOP), and Association of American Plant Food Control Officials (AAPFCO) requirements.*

The US EPA will continue to coordinate with other Federal agencies and State regulators on the Federal registration of pesticides, as the Agency has done in the past. The Agency will only

regulate those products and label claims that fit within the FIFRA Section 2(v) definition of a plant regulator. Administration of the National Organic Program (NOP) is under the authority of USDA, and the Agency defers to USDA on all NOP issues. The AAPFCO requirements for product registrations within the States are handled by agreement amongst the States. The Agency and the States will continue to consult regularly, as they have done in the past, on those products that may require additional regulation as pesticides at the Federal level.

10. *The US EPA response to comments that the Draft Guidance will have economic and other market impacts on industry (small businesses) and farmers because it is interpreted to be a broadening of the regulatory authority under FIFRA. The annualized cost to manufacturers was estimated by US Biostimulants Coalition and the Biological Products Industry Alliance (USBC/BPIA) to be \geq \$449 million annually.*

Several commenters stated that they believed that the Draft Guidance was intended to regulate all PBS under FIFRA as pesticides, and that the additional regulatory burden would make PBS technologies less available and more costly to growers or other end users, restrict investment in research and development, increase the use of other fertilizers and crop protection products, and reduce farmers' ability to increase sustainability.

The Draft Guidance does not propose any new or additional regulatory framework changes. The Draft Guidance is intended to be a clarification of the current regulatory framework for plant regulators as defined in FIFRA Section 2(v). Costs related to Federal registration may be incurred by some manufacturers/distributors whose products should have been registered in the past, but were not, even in the absence of the Draft Guidance. The US EPA acknowledges that products may be more readily identifiable as plant growth regulators under FIFRA as a result of the Draft Guidance, including by enforcement agencies. However, it will also make products that are not subject to FIFRA more identifiable, including to enforcement agencies, and reduce costs associated with questions of compliance.

The Draft Guidance is not intended to influence State registrations of PBS products, nor to restrict investment in research and development of PBS products.

The Agency does not intend to regulate these products under FIFRA if they are fertilizers nor any other product not already meeting the criteria for regulation under FIFRA. USBC/BPIA's estimates highlight the magnitude of potential lost revenue, losses that could occur if there are questions of compliance that temporarily remove a product from market. The Draft Guidance is intended to help avoid costly disruptions in the market by clarifying what products should be regulated under FIFRA and what products are not subject to FIFRA regulation. The clarifications provided by the Draft Guidance also are intended to provide regulatory certainty to manufacturers/distributors, small businesses, farmers, and other end-users.

The Draft Guidance is intended only to clarify which products and associated claims are considered to be plant regulator claims that are subject to FIFRA regulation as a pesticide, and provides examples of products and claims that are, and are not plant regulator claims. The Guidance does not obligate manufacturers to use certain terminology on labels or in advertising and manufacturers are not required to make changes to existing product labels. While the

Agency has historically followed a claims-based approach to pesticide regulation, claims made about the product are only one factor. The Agency has always considered the composition of a product, as well as its associated claims, when making a regulatory determination. Thus, terms used to describe a product will not, by themselves, subject a product to regulation.

11. The US EPA response to comments that the Draft Guidance does not recognize PBS products that may have more than one mode of action.

The Agency acknowledges that some PBS may have multiple modes of action (MOAs) and that some of these MOAs are not plant regulator action. When both plant regulator and non-plant regulator substances are present in a product, the Agency generally will consider these to be plant regulator products. However, on a case-by-case basis, if the applicant can demonstrate that there is a significant non-plant regulator use for a particular product, and that no plant regulator claims are made on the product label and any other informational media, the product may be excluded from regulation under FIFRA, even though it may contain a plant regulator substance. As per 40 CFR 152.15(b), the Agency will consider whether a substance “has no significant commercially valuable use” other than as a pesticide, when considering whether the substance (or product) is a pesticide. The Agency will consider product specific information for review under PRIA Code M009 prior to making such a determination.

12. The US EPA response to comments suggesting that PBS are solely intended to support optimal nutritional processes that enable the plant to alleviate abiotic stress and realize as much of its “innate genetic growth potential.”

The Agency does not agree that all PBS are intended only to support optimal nutritional processes that alleviate abiotic stress and enable plants to realize their “innate genetic growth potential.” Clearly, some PBS have no other purpose, whether or not stated in claims, than to alter plant growth, development, yield, and/or quality whether used by themselves or when combined in products with other non-pesticidal substances. Some PBS products may contain many plant regulator substances that act additively and/or synergistically to affect plant growth, development, yield and quality independent of nutritional processes. Other products may alleviate abiotic stress via non-nutritional processes that do not involve plant regulators. Still other products may have multiple modes of action that include non-nutritional, nutritional, and plant regulator activities.

The Agency acknowledges that some PBS are intended to support nutritional processes, alleviate abiotic stress, and/or change the characteristics of the soil such that the soil becomes an improved medium for plant growth and yield. Substances and products that fit within this category are excluded from the definition of plant regulators as plant nutrients, plant inoculants, and soil amendments (see The US EPA response A.1 above). When claims for increased or decreased growth, yield, germination, maturation, etc. are consequent to intended uses of products or substances as plant nutrients (fertilizers), plant inoculants, soil amendments, and/or as other non-pesticidal uses, such products and substances may be excluded from regulation under FIFRA, in the absence of any plant regulator claims. The claims listed in Tables 1a through 1c and 2 of the Draft Guidance are specifically tied to the exclusions from the FIFRA definition of a plant regulator and are worded as such. Examples of plant regulator claims are listed in Table 3 of the Draft Guidance. When claims for accelerating or retarding the rate of growth, or maturation, the behavior of plants, or the produce thereof are made without

qualification or reference to a specific exclusion (see examples in Tables 1a through 1c of the Draft Guidance), such claims will be considered plant regulator claims.

Other comments suggested that plant regulators act to influence plant growth, development, and produce quality in a manner that is “*beyond the innate genetic potential of a plant*” whereas PBS products influence plant growth, development, and produce quality in a manner that is “within the innate genetic potential of a plant.” It is the opinion of the Agency that the phrase “*innate genetic growth potential*” is not well defined (by commenters or otherwise) and is not a determinant factor in plant growth that may be readily evaluated or quantified. It is just as likely that “*innate genetic growth potential*” may be enabled by substances with plant regulator activity as well as by substances with non-plant regulator activity. Although plant regulators may alter phenotypic expressions of plant genes, it is not clear how this activity would be considered “*beyond the genetic potential*” of a plant.

B. The following essays provide a discussion addressing comments related to activities covered under the Draft Guidance and are specific to the examples of product claims listed in Tables 1a-c, 2, and 3.

Numerous comments were received, primarily from industry/trade groups/growers/law firms, regarding the revision of the lists of examples of product claims that are and are not considered to be plant regulator claims (Tables 1a-c, 2, and 3) listed in the Draft Guidance. Other comments suggested the addition of new claim examples. The Agency carefully considered these requests and some new claims were incorporated into the tables and others were edited or removed to improve clarity and reduce confusion. In other instances, the Agency declined to add new claims suggested by some commenters due to close similarity to example claims already listed in the tables. The Agency notes that the examples listed in Tables 1a-c, 2, and 3 were never intended to be comprehensive lists of claims that may be used for non-plant regulator and plant regulator products and substances, and that other synonymous terms and phrases may be used.

The Agency responses to comments on Tables 1a-c, 2, and 3 are listed in essay format below and are grouped according to the major topics identified in the comments.

- 1. The US EPA response to comments suggesting that examples of non-plant regulator claims and plant regulator claims are too broad or unclear; that examples of plant regulator claims also apply to plant responses that may be expected following applications of PBS that are not subject to FIFRA registration; and/or that example claims may be in conflict with certain State regulations and regulatory definitions.*

Examples of non-plant regulator claims listed in Tables 1a-c and 2 are for substances and products whose intended uses are not considered to be pesticidal (i.e., non-plant regulator) by the Agency. Examples of plant regulator claims in Table 3 are for those products and substances whose intended uses are for plant regulator purposes and are not directly tied to the specific exclusions from the plant regulator definition (see The US EPA response A.1. above). When product claims are directly tied to substances and uses that are not pesticidal, they will not be regulated under FIFRA.

2. *The US EPA response to comments that Table 1a addresses only soil nutrient conditions and does not specifically mention foliar or seed nutrient applications.*

The Agency agrees that the Draft Guidance did not specifically address foliar or seed applications of plant nutrient products in Table 1a, however, the absence of such specific examples did not exclude such claims. Example claims in Table 1a will be edited to encompass foliar and seed applications.

3. *The US EPA response to comments requesting that the phrase: "The examples contained in the following tables are not comprehensive lists and claims may include other synonymous terms" should be re-iterated with each claims example table.*

This phrase will be added to each claims example table as a footnote.

4. *The US EPA response to comments that the phrases "plant health" and "innate genetic potential" be added to certain claims in Table 3 of the Draft Guidance.*

The Agency considers any claims regarding "plant health" to be claims that imply that the product may mitigate plant pathogens and/or enhance resistance to plant pathogens. Therefore, plant health claims are considered to be pesticidal and subject to regulation under FIFRA.

In addition, some commenters suggested that plant regulators enable growth, development, yield, and product quality in a manner that is "*beyond the innate genetic growth potential of a plant/crop,*" whereas PBS products enable growth, development, yield, and produce quality in a manner that is "*within the innate genetic growth potential of a plant/crop.*" In the opinion of the Agency, the phrase "*innate genetic growth potential of a plant/crop*" is not well defined and is not a determinant factor of plant growth that may be readily evaluated or quantified. It is just as likely that "*innate genetic growth potential*" may be enabled by non-plant regulators (e.g., plant nutrients/fertilizers, plant inoculants, soil amendments) as well as plant regulators. Although plant regulators may alter the phenotypic expressions of plant genes, it is not clear how this activity would be considered "*beyond the genetic potential*" of a plant.

Therefore, the phrases "plant health" and "innate genetic potential" will not be added to any example claims listed in the Draft Guidance.

C. The following essays provide a discussion addressing public comments to the Draft Guidance that are specific to Table 4 or to the plant regulator active ingredients listed in Table 4.

Numerous comments were received, primarily from industry/trade groups/growers/law firms regarding the inclusion, deletion, and/or revision of the list of plant growth regulator active ingredients listed in Table 4 of the Draft Guidance. The Agency responses are listed in essay format below and are grouped according to the major topics identified in the comments.

1. *The US EPA response on inclusion/deletion of Table 4 from the Draft Guidance.*

Several comments opposed the inclusion of Table 4 in the Draft Guidance for the following reasons:

- Ingredients listed in Table 4 would be automatically subject to regulation under FIFRA;

- The inclusion of Table 4 in the Draft Guidance runs counter to the historic pesticide regulatory practices in the United States;
- Some or all of the ingredients listed in Table 4 are not pesticides;
- The inclusion of Table 4 in the Draft Guidance runs counter to the direction in the European Union (EU) and other markets of global significance for trade.

In response to public comments, Table 4 has been removed from the Draft Guidance. The Agency agrees that certain substances formerly listed in Table 4 are likely not plant regulators [as defined in FIFRA Section 2(v)] and can be removed from consideration as plant regulator active ingredients. The ingredients that are not likely to be considered plant regulators are: chitosan, harpin proteins, laminarin, and potassium silicate. These substances were originally included in Table 4 due to their known ability to alter the physiology of plants. Although not now considered plant regulators, the aforementioned substances are still subject to regulation under FIFRA as pesticides due to their known activity as induced-resistance promoters that result in physiological changes in plants enabling them to resist pathogens. At this time humic acids and seaweed extracts are still considered to be plant regulators by the Agency, but qualifications regarding claims and/or intended uses may exclude these substances from FIFRA regulation under certain circumstances (see discussions in C3 and C4 below).

2. *The US EPA response to comments on the incorrect characterization of Complex Polymeric Polyhydroxy Acids (CPPAs) in the Draft Guidance.*

The Agency acknowledges that it incorrectly characterized the active ingredient, complex polymeric polyhydroxy acids (CPPAs) on Table 4 of the Draft Guidance. Generally speaking, CPPAs are a complex mixture of organic substances of varying molecular weight that are derived from decomposed plant materials, otherwise known as humic substances. Table 4 has been removed from the Draft Guidance. The narrative that replaces Table 4 has been revised to show that current EPA-registered CPPA-containing products are derived from two different sources: (1) CPPAs derived from leonardite; and (2) CPPAs derived from aqueous sources (i.e., concentrated organic substances obtained from water leached through forest soil using a proprietary manufacturing process). Leonardite is a naturally-occurring mineral that is thought to be an oxidation product of lignite (Broughton, 1972). Lignite is formed from compressed, partially decomposed plant materials (LEC, 2020) and is essentially a form of coal. Leonardite is a rich source of humic substances (Olivella, 2002). Both CPPA active ingredients, regardless of source, are considered plant regulators by the Agency. We note here that two components of CPPAs, Humic Acids and Fulvic Acids, are now addressed separately in the Draft Guidance and are discussed below in paragraph 3.

3. *The US EPA response to inclusion/removal of Humic Acids and Fulvic Acids from consideration as plant regulator active ingredients subject to FIFRA.*

Humic acids and fulvic acids *per se*, may not exist as discrete substances in nature, but are likely formed as a result of the process of extraction from naturally-occurring humic substances in the soil (review by Lehmann and Kleber, 2015). Humic acids and fulvic acids are highly variable mixtures of weak aliphatic and aromatic organic acids, ranging in molecular weight from approximately 10,000 to 100,000 for humic acids; and from approximately 1000 to 10,000 for fulvic acids (Pettit, 2008). Humic acids are defined here as alkaline extracts of humic substances

that precipitate when reacidified to \leq pH 2, whereas fulvic acids are soluble at all pH conditions (Pettit, 2008).

Humic acids have been well documented to have plant regulator activity with the capacity to have direct physiological effects on growth, yield, maturation, and produce quality (review by Canellas et al., 2015; Mora e.al., 2010; Piccolo et al., 1992). Growth responses to application of humic acids may differ according to the species treated and/or the source of the humic acids (review by Canellas and Olivares, 2014), but plant regulator activity has been linked to inherent phytohormone-like activity by humic acids (Piccolo et al., 1992; review by Zandonadi et al., 2013), particularly auxin-like activity (review by Canellas et al., 2012; review by Trevisan et al., 2011).

The Agency acknowledges that humic acids have multiple modes of action, in addition to plant regulator activity, including but not limited to: increasing nutrient availability and uptake, mitigation of abiotic stress, and positive effects on abiotic and biotic properties of soils (Erro et al., 2016; review by Mora et al., 2014; review by Zandonadi et al., 2013). The Agency also recognizes that not all uses of humic acids may be intended for plant regulator purposes. If it can be demonstrated that a *particular product* has the activity claimed on the product label (and any other informational media) and does not make any plant regulator or pest control claims on the product label (and any other informational media) it may be excluded from FIFRA regulation. As per 40 CFR 152.15(b), the Agency will consider whether a substance “has no significant commercially valuable use” other than as a pesticide, when considering whether the substance (or product) is considered a pesticide. The Agency will consider product specific information for review under PRIA Code M009 prior to making such a determination. An example of product specific information may include, but is not limited to: 1) the intended alternative use (e. g. increase nutrient availability or change in soil characteristics; 2) supporting information that the mode of action proposed for the intended use actually occurs (e.g., product specific data); and 3) evidence there is a commercially viable market for intended use to demonstrate commercial viability.

Fulvic acids do not have any known plant regulator activity and are no longer considered to be plant regulators by the Agency. Fulvic acids have been documented to improve the structure and fertility of soils, form complexes with inorganic plant nutrients that facilitate uptake by plant tissues (review by Canellas et al., 2015; Eshwar et al., 2017; Sootahar et al., 2020), and increase water and nutrient use efficiency (Xudan, 1986). Therefore, in the absence of any plant regulator or pest control claims on a product label (and any other informational media) or other plant regulator or pest control active ingredients, fulvic acid-containing products would not be regulated under FIFRA. Should new information become available suggesting that fulvic acids act as plant regulators, the Agency may then decide regulation under FIFRA is appropriate.

4. *The US EPA response to comments regarding inclusion/removal of Seaweed Extracts from consideration as plant regulator active ingredients subject to FIFRA.*

Seaweed extracts, derived from diverse species of seaweed, have been well documented to have plant regulator activity with the capacity to have direct physiological effects on growth, yield, maturation, and produce quality (Briceno-Dominguez et. al., 2014; Di Filippo-Herrera et al., 2018; review by Shukla et al., 2019) with the bioactivity of such extracts being dependent on the

method of extraction [e.g., water-based, acid hydrolysis, alkaline hydrolysis, microwave- and/or ultrasound-assisted, and super-critical fluid and/or pressurized-liquid extraction (review by Shukla et al., 2019)]. Most extracts are derived from the brown seaweed *Ascophyllum nodosum*, although bioactive extracts also are derived from many other seaweed species including, but not limited to: *Durvillaea potatorum* (Mattner et al., 2018), *Ecklonia maxima* (Stirk and Tarnkowski, 2014), *Ganoderma boninense* (Aziz et al., 2019), *Macrocystis pyrifera* (Briceno-Dominguez et al., 2014), and *Osmundea pinnatifida* (Silva et al., 2018). A comprehensive review of the literature by Shukla et al. (2019) agrees with previous technical reports cited in the March 2019 Draft Guidance (Battacharyya et al., 2015; Craigle, 2011; Stirk and Novak, 2003; Stirk et al., 2014) demonstrating that the presence of phytohormones and other phytohormone-like plant growth substances (i.e., naturally-occurring plant regulators) in seaweed extracts are responsible for the observed plant regulator activity and plant responses. Some commenters have argued that the levels of individual phytohormones and similar plant growth substances present in the extracts are not present in sufficient quantity to elicit plant regulator-like effects. However, it is the opinion of the Agency, based on the most recent technical literature available, that it is the combined bioactivity of all the plant regulator substances present in a particular extract, that act additively and/or synergistically to elicit the observed plant growth effects. The specific levels of individual plant growth regulating substances in a seaweed extract, or any other plant extract, are less relevant than the additive and/or synergistic activity of all the plant growth regulating substances that are present in an extract.

The Agency acknowledges that seaweed extracts have multiple modes of action, in addition to plant regulator activity, including but not limited to: increasing nutrient availability and uptake, mitigation of abiotic stress, and positive effects on abiotic and biotic properties of soils (reviews by Battacharyya et al., 2015; Sangha et al., 2014; and Shukla et al., 2019). Additionally, extracts from a number of different seaweeds have been shown to have antifungal activity, indicating that some of the observed growth effects of seaweed extracts may result from anti-pathogen activity, either from direct effects on pathogens or activity as induced-resistance promoters (Aziz et al., 2019; review by Battacharyya et al., 2015; review by Sangha et al., 2014; review by Shukla et al., 2019; Silva et al., 2018). Therefore, under certain circumstances and intended uses, some seaweed extracts may be considered pest control products.

The Agency recognizes that seaweed extracts have multiple modes of action that are occurring simultaneously when applied in PBS products. The Agency also recognizes that not all uses of seaweed extracts may be intended for plant regulator or other pest control purposes. If it can be demonstrated that *a particular product* has the activity claimed on the product label (and any other informational media) and does not make any plant regulator or pest control claims on the product label (and any other informational media) it may be excluded from FIFRA regulation. As per 40 CFR 152.15(b), the Agency will consider whether a substance “has no significant commercially valuable use” other than as a pesticide, when considering whether the substance (or product) is a pesticide. The Agency will consider product specific information for review under PRIA Code M009 prior to making such a determination.

5. *The US EPA response on Inclusion/Removal of Corn Glutens from consideration as plant regulator active ingredients subject to FIFRA.*

Corn glutens have long been known to be an effective weed control substance. When applied to soils prior to the emergence of weed, or as a pre-plant incorporated application, corn glutens have been shown to be effective in reducing seed germination and early seedling growth on all species tested (Bingaman and Christians, 1995; McDade and Christians, 2000) while not harming plants with mature root systems. In experiments with perennial ryegrass, five dipeptides (glutamyl-glutamine, alaninyl-asparagine, alaninylglutamine, glycyl-alanine, and alaninyl-alanine) were identified as substances responsible for the growth inhibitory activity of corn glutens (Liu and Christians, 1994). There is little information available on the specific use of corn glutens as a fertilizer and, if used as such, would likely need to be applied at rates far in excess of that applied in a typical PBS product.

D. The following essays provide a discussion of public comments addressing activities that are not covered under the Draft Guidance.

Several commenters suggested that the definitions of pesticides, plant regulators, and/or the definitions of the substances excluded from the plant regulator definition that are contained in FIFRA and in Title 40 of the CFR require changes so as to exclude or exempt the class of products known as plant biostimulants (PBS) from regulation under FIFRA. The Agency responses are listed in essay format below and are grouped according to the major topics identified in the comments.

1. *The US EPA Response to Rewriting the FIFRA Section 2(v) Definition of a Plant Regulator.*

The definition of a plant regulator as written in FIFRA Section 2(v) can only be changed by Congressional action and is outside of the scope of EPA's authority and of the Draft Guidance.

2. *The US EPA Response to (1) Rewriting Current Definitions for Substances Excluded from the FIFRA Plant Regulator Definition and (2); and Developing a Definition for Nutritional Chemicals.*

The definitions for plant nutrients, plant inoculants, soil amendments, and vitamin-hormone products listed at 40 CFR 152.6(g)(1), (2), (3) and 40 CFR 152.6(f) respectively, may be amended by the Agency, through rulemaking. The Draft Guidance does not initiate any new rulemaking activities in this regard.

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