

Office of Chemical Safety and Pollution Prevention

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Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants

DISCLAIMER

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1 **Executive Summary:** In recognition of the growing categories of products generally known as 2 plant biostimulants, this document is intended to provide guidance on identifying product label 3 claims that are considered to be plant regulator claims by the Agency, thereby subjecting the 4 products to regulation as pesticides under the Federal Insecticide, Fungicide, and Rodenticide 5 Act (FIFRA), 7 U.S.C. 136-136y. Examples are provided of both claims that are considered plant regulator claims and claims that are not considered plant regulator claims. EPA is taking 6 7 this step since there has been some confusion among industry and States as to how the emerging 8 product area, called plant biostimulants, does or does not trigger FIFRA's plant regulator 9 requirements. Although FIFRA does not define the term plant biostimulants, some products 10 being sold as plant biostimulants may trigger regulation under FIFRA as plant regulators. Other plant biostimulant products will not involve EPA oversight since they are excluded from the 11 12 plant regulator definition under FIFRA section 2(v), or do not fit within the specific FIFRA 13 definition of how a plant regulator functions. The background section of this document provides 14 examples of plant biostimulant definitions contained in the 2018 Farm Bill and proposed by the 15 European Commission. Neither definition affects this EPA guidance on plant regulator claims. 16 This draft guidance document is intended to clarify that products with label claims that are 17 considered to be plant regulator claims are subject to regulation as a pesticide. As guidance, this document is not binding on the Agency or any outside parties, and the Agency may depart from 18 19 it where circumstances warrant and without prior notice. The Agency is seeking comment on 20 this document through a Federal Register notice for a 60 day public comment period. The 21 Agency is also seeking comment on whether EPA should develop a definition for plant 22 biostimulants, noting that the development of such a definition would require rulemaking.

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24 Potentially Affected Entities or Persons: You could be affected by this action if you are a producer or registrant of pesticide products making labeling claims that are considered to be 25 26 plant regulator claims by the Agency, thereby subjecting the products to regulation under FIFRA 27 as pesticides. The North American Industrial Classification System (NAICS) codes are provided 28 to assist you and others in determining if this guidance might apply to certain entities. The 29 following listing of potentially affected entities is not intended to be exhaustive, but rather 30 provides a guide for readers regarding entities likely to be affected by this action. Other types of 31 entities not listed could also be affected. Potentially affected entities may include, but are not 32 limited to: 33

- Pesticide and Other Agricultural Chemical Manufacturing (NAICS 32532), *e.g.*, pesticide manufacturers or formulators of pesticide products, pesticide importers or any person or company who seeks to register a pesticide.
- Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing (NAICS 325300),
 e.g., establishments primarily engaged in manufacturing agricultural chemicals, including
 nitrogenous and phosphoric fertilizer materials, mixed fertilizers, and agricultural and
 household pest control chemicals.

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43 Applicable Statute or Regulations: Regulations, issued pursuant to FIFRA, regarding pesticide 44 registration and exemptions from registration are contained in 40 CFR parts 150 through 189. 45 This guidance provides information that is intended to help decision-making related to ensuring 46 compliance with these regulations, and is not binding on the Agency or any outside parties. 47 48 Background: Plant biostimulants (PBS) are a relatively new, but growing, category of products 49 containing naturally-occurring substances and microbes that are used to stimulate plant growth, 50 enhance resistance to plant pests, and reduce abiotic stress. The increasing popularity of PBS 51 arises from their ability to enhance agricultural productivity by stimulating natural processes in 52 the plant and in soil using substances and microbes already present in the environment. PBS can 53 promote greater water and nutrient use efficiency, but do not provide any nutritionally relevant 54 fertilizer benefit to the plant. PBS products are becoming increasingly attractive for use in 55 sustainable agriculture production systems and integrated pest management (IPM) programs, 56 which in turn can reduce the use of irrigation water, as well as agrochemical supplements and 57 fertilizers. 58 59 Statutory definitions for PBS currently exist in the 2018 Farm Bill and proposed in the European 60 Commission Fertilizers Regulation update: 61 62 2018 Farm Bill¹: For purposes of a report Congress directed USDA to prepare, "plant biostimulant" is considered a substance or micro-organism that, when applied to seeds, 63 64 plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient 65 uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield. 66 **Proposed European Commission Definition²:** "Plant biostimulant" means a product 67 68 stimulating plant nutrition processes independently of the product's nutrient content with 69 the sole aim of improving one or more of the following characteristics of the plant: (a) 70 nutrient use efficiency; (b) tolerance to abiotic stress; and (c) crop quality traits. 71 72 There currently is no applicable regulatory definition of PBS under FIFRA. Nonetheless, to help 73 provide guidance and clarity, EPA is providing the following description of a PBS, which 74 reflects EPA's current understanding and views of this particular product category. Generally 75 speaking, a "plant biostimulant" is a naturally-occurring substance or microbe that is used either 76 by itself or in combination with other naturally-occurring substances or microbes for the purpose 77 of stimulating natural processes in plants or in the soil in order to, among other things, improve 78 nutrient and/or water use efficiency by plants, help plants tolerate abiotic stress, or improve the 79 physical, chemical, and/or biological characteristics of the soil as a medium for plant growth. 80

¹ Agriculture Improvement Act of 2018, Section 10111 (<u>https://www.congress.gov/bill/115th-congress/house-bill/2</u>).

² European Commission Fertilizers Regulation update amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009, document 1, p. 16 (<u>https://eur-lex.europa.eu/legal-content/EN/TXT/DOC/?uri=CELEX:52016PC0157&from=EN</u>

81	In developing this guidance, EPA considered whether a PBS product, as understood by EPA,
82	physiologically influences the growth and development of plants in such a way as to be
83	considered plant regulators under FIFRA thereby triggering regulation as a pesticide. FIFRA
84	section 2(u) includes plant regulators, defoliants, desiccants, and nitrogen stabilizers in its
85	definition of a pesticide, so they are subject to federal registration as pesticides under FIFRA. In
86	addition, FIFRA section 2(v) both defines plant regulator and explains which substances are
87	excluded from the definition (See Appendix A). Based on the plant regulator definition contained
88	in FIFRA section 2(v), many PBS products and substances may be excluded or exempt from
89	regulation under FIFRA depending upon their intended uses as plant nutrients (<i>e.g.</i> , fertilizers),
90	plant inoculants, soil amendments, and vitamin-hormone products (see Tables 1a-1c and Table
91	2). A key consideration is what claims are being made on product labels.
92	
93	Pesticide products required to be registered. Pesticide products that must be registered are
94	described in 40 CFR 152.15. Under FIFRA, a person may not distribute or sell a pesticide
95	product that is not registered under FIFRA, except as provided in 40 CFR 152.20, 152.25, and
96	152.30. A pesticide is any substance (or mixture of substances) intended for a pesticidal purpose,
97	i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a
98	plant regulator, defoliant, or desiccant. A substance is considered to be intended for a pesticidal
99	purpose, and thus to be a pesticide requiring registration, if:
100	
101	(a) The person who distributes or sells the substance claims, states, or implies (by
102	labeling or otherwise):
103	(1) That the substance (either by itself or in combination with any other
104	substance) can or should be used as a pesticide; or
105	(2) That the substance consists of or contains an active ingredient and that it can
106	be used to manufacture a pesticide; or
107	-
108	(b) The substance consists of or contains one or more active ingredients and has no
109	significant commercially valuable use as distributed or sold other than (1) use for
110	pesticidal purpose (by itself or in combination with any other substance), (2) use for
111	manufacture of a pesticide; or
112	-
113	(c) The person who distributes or sells the substance has actual or constructive
114	knowledge that the substance will be used, or is intended to be used, for a pesticidal
115	purpose.
116	
117	Products That Are Not Pesticides Because They Are Excluded by Regulation from the
118	Definition of a Plant Regulator:
119	
120	• Plant nutrients and trace elements: Plant nutrients and trace elements, which can be
121	considered as falling under the umbrella term "fertilizers," are described in EPA's FIFRA
122	regulations as "plant nutrient product[s] consisting of one or more macronutrients, or

123	micronutrient trace elements necessary to normal growth of plants and in a form readily
124	useable by plants" [40 CFR $152.6(g)(1)$].
125	
126	• Plant inoculants: Plant inoculants are "product[s] consisting of microorganisms to be
127	applied to the plant or soil for the purpose of enhancing the availability or uptake of plant
128	nutrients through the root system" [40 CFR $152.6(g)(2)$].
129	
130	• Soil amendments: Soil amendments (which include soil additives and soil conditioners)
131	are "product[s] containing a substance or substances intended for the purpose of
132	improving soil characteristics favorable for plant growth" [40 CFR 152.6(g)(3)].
133	
134	• Vitamin-hormone products: A vitamin-hormone product is defined as: "A product
135	consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments
136	is not a "plant regulator" under section 2(v) of FIFRA, provided it meets the following
137	criteria:
138	(1) The product, in the undiluted package concentration at which it is distributed or sold,
139	meets the criteria for Toxicity Category III or IV; and
140	(2) The product is not intended for use on food crop sites, and is labeled accordingly."
141	[40 CFR 152.6(f))]
142	
143	Claim Examples: Tables 1a through 1c list examples of product label claims generally
144	considered "non-pesticidal" (i.e. non-plant regulator claims) by the Agency that are specifically
145	associated with the exclusions described in 40 CFR 152.6(f) & (g). Examples of non-pesticidal
146	claims were developed from (1) claims found on commercially-available products used as
147	fertilizers, plant inoculants, and soil amendments; (2) discussions with stakeholders in industry
148	and State regulatory bodies, and (3) discussions across EPA program offices and regional
149	offices. The examples contained in the following tables are not comprehensive lists and may
150	include other synonymous terms. Claims are listed for each currently defined exclusion from the
151	plant regulator definition, except for vitamin-hormone products. Plant regulator claims may be
152	made for vitamin-hormone products when they meet both criteria for exclusion from the plant
153	regulator definition, as specified under 40 CFR 152.6(f)(1) & (2).
	Table 1a: Examples of Plant Nutrition-based Claims (necessary for normal growth of
	plants and in a form readily useable by plants)

- Avoids/corrects/prevents nutrition-based/nutrient deficiency-based plant disorders (*e.g.* including, but not limited to: blossom end rot, chlorosis, necrosis, discoloration, stunting, etc.)
- Improves soil/nutrient conditions for better overall plant mass
- Improves soil/nutrient conditions for better plant/crop size/yield
- Improves/supports asymbiotic/symbiotic microbial associations with plant roots and rhizosphere
- Improves soil/nutrient conditions for root growth
- Optimizes soil/nutrient conditions for plant growth
- Optimizes soil/nutrient conditions for seed germination
- Optimizes conditions for tolerance of/resistance to abiotic stress

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 Table 1b: Examples of Plant Inoculant-based Claims (enhance availability/uptake of plant nutrients through root system)

- Enhance/improve/support/beneficial microbes in rhizosphere/soil microbiome
- Increases overall plant mass by improved nutrient uptake
- Increases/improves/optimizes conditions for tolerance of/resistance to abiotic stress by improved nutrition
- Improve/increase/support biodegradation of organic matter
- Improve/increase/support availability/release of bound nutrients from the soil
- Improve nutrient/water transport/uptake/efficiency by plants/roots
- Improve/support mycorrhizal/rhizobial association/symbiosis with plant roots
- Improve/support nodulation
- Improves Phosphorous solubilization/availability for improved uptake ¹
- Reduces Phosphorous loss to the environment ¹
- Reduces/protects against abiotic stress by improved nutrient/water uptake/availability

¹ May include other plant nutrients and trace elements.

 Table 1c: Examples of Soil Amendment-based Claims (intended for the purpose of improving soil characteristics favorable for plant growth)¹

- Buffers/changes soil pH
- Changes cation exchange capacity (CEC)
- Helps condition the soil for improved plant performance
- Increases/improves/optimizes soil conditions for increased plant vigor
- Increases/improves/optimizes conditions for tolerance of/resistance to abiotic stress
- Improves/increases water/nutrient availability/use efficiency/processing/retention
- Improves/increases soil/water nutrient retention/holding capacity/permeability
- Provides/supplies organic matter

- Reduces leaching
- Reduces soil compaction
- Supports beneficial microbes/augments activity and function of beneficial microbes

¹ Soil amendments may include microbes intended for improving soil characteristics favorable for plant growth

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156 Generic Product Label Claims for Products Not Covered by the Exclusions in the FIFRA 157 Section 2(v) Definition of a Plant Regulator. The Agency recognizes that the exclusions from the definition of a plant regulator, as listed under FIFRA section 2(v), may not cover all current 158 159 or proposed product applications or use sites for plant biostimulants. Table 2 provides examples 160 of generic product label claims generally considered "non-pesticidal" (i.e. non-plant regulator 161 claims) by the Agency. These claims are not associated with any particular regulatory exclusion 162 or product application/use site. These claims must be fully compliant with the criteria of 40 CFR 163 152.15.

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Table 2. Examples of generic product label claims generally considered by the Agency to be "non-pesticidal" ^{1,2}

- Alleviates/avoids/corrects/prevents nutrition-based/nutrient deficiency-based plant disorders
- Enhances/aids/supports/helps/improves abiotic stress tolerance
- Enhances/aids/supports/helps microbial populations
- Improves/aids/supports/helps/enhances conversion of applied nutrients to plant available forms
- Improves efficiency of applied fertilizers
- Improves nutrient uptake via natural chelating/complexing agents
- Improves/aids/supports/helps/enhances conditions for better plant establishment
- Improves overall plant nutrition
- Increases plant nutrient assimilation efficiency
- Aids/supports/helps/enhances/optimizes soil conditions for greater root mass
- Aids/supports/helps/enhances/improves tolerance of and/or resistance to abiotic stress
- Increased tolerance to sodium (Na)
- Optimizes nutrient use efficiency
- Protects plants/leaves from burning with over-application of foliar nutrients (and burning effects of salt)
- Recovers crops affected by stress due to inefficient management
- Reduces lodging
- Supports nutrient uptake
- Supports/aids/helps nutrient uptake to prevent, mitigate, or correct a specific plant nutrient disorder

Table 2. Examples of generic product label claims generally considered by the Agency to be "non-pesticidal" ^{1,2}

¹ Product claims may not state or imply that a plant biostimulant product, through physiological action, accelerates or retards the rate of growth, accelerates or retards the rate of maturation, or otherwise alters the behavior of plants or the quality of the produce thereof.

² Product claims must be compliant with 40 CFR 152.15.

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166	Plant Regulators and Product Label Claims: In determining what natural substances are
167	considered plant regulators, and what may constitute a plant regulator claim on a product label,
168	the mode of action of the substance(s) and associated label claim(s) must be congruent with the
169	intent of the plant regulator definition. Based solely on the FIFRA section 2(v) "plant regulator"
170	definition, a naturally occurring substance would be considered a "plant regulator," and a
171	product label claim would be considered a "plant regulator claim" if:
172	
173	The substance or mixture of substances, through physiological action:
174	
175	1. Accelerates or retards the rate of plant growth;
176	
177	2. Accelerates or retards the rate of plant maturation;
178	
179	3. Or otherwise alters the behavior of plants or the produce thereof;
180	
181	and if the substance or mixture of substances does not fall under one of the exclusion categories
182	listed in 40 §CFR 152.6(f) & (g) as vitamin-hormone products, plant nutrients, plant inoculants
183	or soil amendments; or under 40 CFR 152.8(a) as a fertilizer.
184	
185	Table 3 lists examples of plant regulator product label claims that are consistent with the FIFRA
186	Section 2(v) plant regulator definition. Thus, products making such claims must be registered
187	with the Agency.
188	
	Table 3. Examples of Label Claims that are Considered by the Agency to be Plant Growth
	Populator Claims that Trigger Population Under FIFDA as a Posticida 1

Regulator Claims that Trigger Regulation Under FIFRA as a Pesticide

Accelerates or retards rate of plant growth:

- Enhances/promotes/stimulates fruit growth & development
- Enhances/promotes/stimulates plant growth & development
- Enhance/inhibit development
- Promote stem elongation
- Root/shoot stimulator
- Stimulates cell division, cell differentiation & cell enlargement

Accelerates or retards rate of [plant] maturation: Accelerates/controls/delays abscission/development/ripening/senescence Induce/promote/retard/suppress flowering Induce/promote/retard/suppress bud break Induce/promote/retard/suppress seed germination Alters the behavior of plants: Alters/improves plant/tree shape/structure

- Controls suckering
- Inhibits/promotes sprouting

Alters the produce [of plants]:

- Enhances/promotes crop/fruit/produce color/development/quality/shape
- Enhances/promotes fruit growth & development
- Fruit and nut thinner/sizer

¹ Not a comprehensive list and may include other synonymous terms that influence growth development, maturation, and quality changes in plants.

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- 190 Table 4 lists current EPA-registered, naturally-occurring, plant regulator active ingredients
- 191 having modes of action and associated product label claims that are consistent with the FIFRA
- 192 definition of a plant regulator.
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Table 4. Plant Regulator Active Ingredients Contained in EPA-Registered Products Having Modes of Action that Trigger Regulation Under FIFRA as a Pesticide ^{1, 2, 3}

- Abscisic Acid (ABA)
- gamma-Aminobutyric Acid (GABA)
- 6-Benzyladenine (6-aminopurine; a cytokinin)
- <u>Choline</u>
- Complex Polymeric Polyhydroxy Acids (including Humic acid, fulvic acid, tannins; & organic acids from Leonardite) ⁴
- Corn glutens/Corn gluten meal
- Cytokinins (as all isopentenyladenine and zeatin derivatives)⁵
- Cytokinin (as kinetin)
- Ethylene
- Gibberellic Acid A₃ (GA₃)
- Gibberellins A₄/ A₇ (GA₄+₇)
- L-Glutamic Acid
- Harpin proteins ⁴
- Homobrassinolide
- Indole-3 Acetic Acid (IAA)
- Indole-3-Butyric Acid (IBA)

	Table 4. Plant Regulator Active Ingredients Contained in EPA-Registered Products Having
	Modes of Action that Trigger Regulation Under FIFRA as a Pesticide ^{1, 2, 3}
	 Jasmonates (includes all derivatives of jasmonic acid)⁴
	• Lysophosphatidylethanolamine (LPE)
	Laminarin
	• Potassium silicate ⁴
	• 1-Octanol
	• Seaweed Extracts ⁶
	Sodium o-nitrophenolate
	Sodium p-nitrophenolate
	Sodium guaiacolate
	 ¹ Some EPA-registered microbial pesticides are registered as plant regulators or have plant regulator claims listed on their product labels ² Includes Biochemical and Microbial Induced Resistance Promoters ³ This list only includes naturally-occurring plant regulators contained in EPA-registered products; it
	does not include substances under review by the Agency or known plant regulators for which no
	products have been proposed, but that may have plant regulator activity
	⁴ Foliar applications only, soil applications may be excluded as a soil amendment in the absence of any
	pesticidal claims (including plant regulator claims)
	⁵ Isopentenyladenine derivatives are typically produced by microbes; zeatin derivatives are typically
	produced by plants
	⁶ Seaweed extracts (SWE) are heterogenous mixtures of naturally-occurring plant regulators
	(Battacharyya et. al., 2015; Craigle, 2011; Stirk and Novak, 2003; Stirk et. al., 2014)
94	
95	Conventional chemical plant regulators are not listed in Table 4. If a conventional chemical
6	plant regulator is contained within a PBS product, the product likely would be considered a
7	Conventional Chemical pesticide by the Agency and would be subject to registration under
8	FIFRA.
99	Paperwork Burden: This guidance does not create paperwork burdens that require additional
)0	approval by OMB under the PRA, 44 U.S.C. 3501 et seq. The information collection activities
1	associated with pesticide registration are already approved by OMB under OMB Control No.
2	2070-0060. The corresponding information collection request (ICR) document is entitled
3	"Application for New and Amended Pesticide Registration" (EPA ICR No. 0277.16).
4	
5	Potential Costs and Cost Savings: The Agency anticipates that this guidance may reduce
6	confusion, in both the regulated community, EPA, and other State or Federal regulatory
7	agencies, as to whether specific products are or are not subject to registration as a pesticide under
8	FIFRA. Reducing uncertainty may reduce costs in the time and effort to bring a product to
9	market; in some situations, uncertainty could deter firms from developing products. Regulatory
0	clarity provided by this guidance could also increase costs for those producing PBS, when EPA
1	considers a plant regulator under FIFRA. To the extent this guidance improves the understanding

- as to which products will likely need to be registered and which products may not need to be
- 213 registered, the effort firms expend to determine the appropriate regulatory path is reduced. If a
- 214 PBS is determined to be a plant growth regulator under FIFRA, the firm will bear the costs of
- registration, but if it is not considered a plant growth regulator, the firm does not need to seek
- 216 EPA approval. Similarly, clarifying the meaning of terms on products may reduce the effort
- EPA and other State or Federal regulatory agencies spend to determine whether a product needs
- to have an EPA registration number.
- 219
- 220 The clarity provided by this guidance may, in some situations, provide more tangible benefits.
- Firms may be able to bring products to market more quickly if they do not have to spend time and effort to determine and confirm the appropriate regulatory path. Firms may also avoid
- product label redesign and reprinting costs because they will have examples of the appropriate
- terms used to describe plant growth regulators and terms used to describe plant biostimulants
- before they reach the market. In the extreme, firms may avoid having to pull product from the
- 226 market due to confusion over the appropriate regulatory category.
- 227
- 228 Monetary cost savings are likely to be small. State and regional enforcement offices
- 229 occasionally seek guidance from the Agency as to whether a product on the market should be
- 230 registered, given the claims associated with the product. In general, these issues are resolved
- 231 quickly and without substantial resources. As the number and type of biostimulant products
- increases, however, the potential for regulatory uncertainty to hamper the market also increases.
- 233 This guidance should help to reduce confusion.
- 234
- 235 **Summary:** This document is intended to provide guidance on identifying product label claims,
- 236 including for plant biostimulants, that are considered to be pesticidal in nature (*i.e.* plant
- 237 regulator claims), thereby subjecting the products to regulation under FIFRA as pesticides. As
- 238 guidance, this document is not binding on the Agency or any outside parties, and the Agency
- 239 may depart from it where circumstances warrant and without prior notice. The Agency is
- 240 seeking public comment on this draft guidance. The Agency is also seeking comment on whether
- 241 EPA should develop a definition for plant biostimulants, noting that the development of such a
- 242 definition would require rulemaking.
- 243

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- a commercial seaweed extract made from Ecklonia maxima. Journal of Applied Phycology 26:561-567.
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- 258 259

260	APPENDIX A: Federal Plant Regulator Definition and Exclusions
261	
262	<u>Plant regulators</u> are defined in FIFRA section 2(v)], as "any substance or mixture of substances
263	intended, through physiological action, for accelerating or retarding the rate of growth or rate of
264	maturation, or for otherwise altering the behavior of plants or the produce thereof."
265	
266	Excluded from the plant regulator definition are those products that are "Products intended to aid
267 268	the growth of desirable plants" including: (1) plant nutrients, trace elements, nutritional chemicals, (2) plant inoculants, (3) soil amendments; and vitamin-hormones [40 CFR 152.6(g)].
269	······································
270	For purposes of this document:
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272	Plant nutrients are "products consisting of one or more macronutrients, or micronutrient trace
273	elements necessary to normal growth of plants and in a form readily useable by plants" [40
274	CFR156.6(g)(1)];
275	
276	Plant inoculants are "products consisting of microorganisms to be applied to the plant or soil for
277	the purpose of enhancing the availability or uptake of plant nutrients through the root system"
278	[40 CFR 152.6(g)(2)];
279	
280	Soil amendments (which would include soil additives and soil conditioners) are "products
281	containing a substance or substances intended for the purpose of improving soil characteristics
282	favorable for plant growth" [40 CFR 152.6(g)(3)]; and
283	
284	Vitamin-hormone products are: "A product consisting of a mixture of plant hormones, plant
285	nutrients, inoculants, or soil amendments is not a 'plant regulator' under section 2(v) of FIFRA,
286	provided it meets the following criteria:
287	
288	(1) The product, in the undiluted package concentration at which it is distributed or sold,
289	meets the criteria of §156.62 of this chapter for Toxicity Category III or IV; and
290	
291	(2) The product is not intended for use on food crop sites, and is labeled accordingly."
292	
293	[40 CFR 152.6(f)(1)(2)]
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