

Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants

DISCLAIMER

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This is a living document and may be revised periodically. EPA welcomes public input on this document at any time.

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
6 plant regulator claims and claims that *are not* considered plant regulator claims. EPA is taking
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
11 plant biostimulant products will not involve EPA oversight since they are excluded from the
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16 This draft guidance document is intended to clarify that products with label claims that are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
18 document is not binding on the Agency or any outside parties, and the Agency may depart from
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.

23
24 **Potentially Affected Entities or Persons:** You could be affected by this action if you are a
25 producer or registrant of pesticide products making labeling claims that are considered to be
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:

- 34 • Pesticide and Other Agricultural Chemical Manufacturing (NAICS 32532), *e.g.*, pesticide
35 manufacturers or formulators of pesticide products, pesticide importers or any person or
36 company who seeks to register a pesticide.
- 37
38 • Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing (NAICS 325300),
39 *e.g.*, establishments primarily engaged in manufacturing agricultural chemicals, including
40 nitrogenous and phosphoric fertilizer materials, mixed fertilizers, and agricultural and
41 household pest control chemicals.

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:
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62 **2018 Farm Bill¹:** For purposes of a report Congress directed USDA to prepare, “plant
63 biostimulant” is considered a substance or micro-organism that, when applied to seeds,
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

67 **Proposed European Commission Definition²:** “Plant biostimulant” means a product
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.
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¹ Agriculture Improvement Act of 2018, Section 10111 (<https://www.congress.gov/bill/115th-congress/house-bill/2>).

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

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 (*e.g.*, 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

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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Generic Product Label Claims for Products Not Covered by the Exclusions in the FIFRA 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 or proposed product applications or use sites for plant biostimulants. Table 2 provides examples of generic product label claims generally considered “non-pesticidal” (*i.e.* non-plant regulator claims) by the Agency. These claims are not associated with any particular regulatory exclusion or product application/use site. These claims must be fully compliant with the criteria of 40 CFR 152.15.

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:

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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.
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Table 3. Examples of Label Claims that are Considered by the Agency to be Plant Growth Regulator Claims that Trigger Regulation Under FIFRA as a Pesticide¹

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)
- Choline
- 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 silicate⁴
- 1-Octanol
- Seaweed Extracts⁶
- 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)

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195 Conventional chemical plant regulators are not listed in Table 4. If a conventional chemical
196 plant regulator is contained within a PBS product, the product likely would be considered a
197 Conventional Chemical pesticide by the Agency and would be subject to registration under
198 FIFRA.

199 **Paperwork Burden:** This guidance does not create paperwork burdens that require additional
200 approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* The information collection activities
201 associated with pesticide registration are already approved by OMB under OMB Control No.
202 2070-0060. The corresponding information collection request (ICR) document is entitled
203 “Application for New and Amended Pesticide Registration” (EPA ICR No. 0277.16).

204

205 **Potential Costs and Cost Savings:** The Agency anticipates that this guidance may reduce
206 confusion, in both the regulated community, EPA, and other State or Federal regulatory
207 agencies, as to whether specific products are or are not subject to registration as a pesticide under
208 FIFRA. Reducing uncertainty may reduce costs in the time and effort to bring a product to
209 market; in some situations, uncertainty could deter firms from developing products. Regulatory
210 clarity provided by this guidance could also increase costs for those producing PBS, when EPA
211 considers a plant regulator under FIFRA. To the extent this guidance improves the understanding

212 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
215 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
217 EPA and other State or Federal regulatory agencies spend to determine whether a product needs
218 to have an EPA registration number.

219
220 The clarity provided by this guidance may, in some situations, provide more tangible benefits.
221 Firms may be able to bring products to market more quickly if they do not have to spend time
222 and effort to determine and confirm the appropriate regulatory path. Firms may also avoid
223 product label redesign and reprinting costs because they will have examples of the appropriate
224 terms used to describe plant growth regulators and terms used to describe plant biostimulants
225 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
232 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

244 **References**

245

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256 a commercial seaweed extract made from *Ecklonia maxima*. *Journal of Applied Phycology* 26:
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260 **APPENDIX A: Federal Plant Regulator Definition and Exclusions**

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262 Plant regulators 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 the growth of desirable plants” including: (1) plant nutrients, trace elements, nutritional
268 chemicals, (2) plant inoculants, (3) soil amendments; and vitamin-hormones [40 CFR 152.6(g)].

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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)];

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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)];

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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

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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

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291 (2) The product is not intended for use on food crop sites, and is labeled accordingly.”

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293 [40 CFR 152.6(f)(1)(2)]

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