



Draft Guidance Update: Plant Regulators, Including Plant Biostimulants

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AAPCO Meeting
Alexandria, VA | March 10, 2020

Plant Regulators: Background



► Naturally-occurring

- Plant Growth Substances (includes plant hormones and other hormone-like substances)
- Biochemicals
- Includes synthetic substances identical to those in Nature

► Artificial (Not naturally-occurring)

- Mimic or inhibit activity of plant hormones/other growth substances
- Conventional chemicals



Plant Regulators: Background

► Naturally-occurring Plant Growth Substances

- Signaling molecules in plants
- Operate at low concentrations
- Coordinate growth and development
- Coordinate cell division and differentiation
- Function in plant response to abiotic stress
- Induce or inhibit abscission, ripening, dormancy, flowering, fruit set
- Influence plant architecture
- Secondary metabolites in fungi and bacteria



Plant Regulator Definition

▶ FIFRA §2(v)

“...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...”

▶ Does not include:

- plant nutrients/trace elements*
- nutritional chemicals (not defined in FIFRA or CFR)
- plant inoculants*
- soil amendments*
- vitamin-hormone horticultural products**

*40 CFR 152.6(g)(1), (2), & (3)

**40 CFR 152.6(f)

Plant Biostimulants: Background

- ▶ No Federal Definition
- ▶ 2 alternative definitions proposed in 2019 USDA Report to Congress on Plant Biostimulants

It is understood by EPA that Plant Biostimulants generally are:

- ▶ Comprised of naturally-occurring substances and microbes
- ▶ Intended to stimulate plant growth via improved nutrition processes, nutrient/water use efficiency, protection from abiotic stress, and/or plant regulator activity
- ▶ Not considered to be fertilizers or to be used for pest control

European Union Plant Biostimulant Definition

▶ Regulation (EC) No 1107/2009, Article 3, 34

“plant biostimulant” means a product stimulating plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

(a) nutrient use

(b) tolerance to abiotic stress;

(c) quality traits;

(d) availability of confined nutrients in soil or rhizosphere.

Product Function Categories (PFCs) of EU Fertilizing Products*

Fertilizing Products

- ▶ Fertilizers
- ▶ Inorganic (mineral) fertilizers
- ▶ Organic Fertilizers
- ▶ Organo-mineral

Other Products

- ▶ Growing media
- ▶ Soil improvers
- ▶ Liming materials
- ▶ **Plant Biostimulants**
- ▶ Agronomic additives

*Official Journal of the European Union (Legislative Acts) Regulations, REGULATION (EU) 2019/1009 Annex 1, L 170/37

Plant Regulators/Plant Biostimulants: Regulatory Issues - What is EPA Role?

- ▶ FIFRA §2(u) defines plant regulators as pesticides
- ▶ FIFRA §2(v) defines plant regulators and substances excluded from definition of a plant regulator
- ▶ Some (not all) plant biostimulants may be considered plant regulators under FIFRA
- ▶ Some (not all) plant biostimulant product claims may be considered plant regulator claims

Purpose of Proposed Guidance

- ▶ It IS Plant Regulator Guidance

It IS NOT Plant Biostimulant Guidance

- ▶ Provide clarity to regulated community and to State/Federal regulators for products and product claims that trigger FIFRA oversight of plant regulators.
- ▶ Identify examples of product claims that are, and are not plant regulator claims
- ▶ Be legally non-binding

Note: The proposed guidance does not create any new statutory or regulatory definitions and was not intended to do so.

Purpose of Proposed Guidance

- ▶ It is intended to clarify regulatory activities already conducted by the Agency
- ▶ Claims-based, but not Claims Only (40 CFR §152.15)
 - Vol. 53, 1988, FR 15954: 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.
 - 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 it is a pesticide.

EPA and Stakeholder Involvement

- ▶ **2012:** EPA/BPPD Informal review of *The Science of Plant Biostimulants - A Bibliographic Analysis*
- ▶ **2014-2015:** Initial industry contact - European Biostimulants Industry Council (EBIC); US Biostimulants Coalition (USBC); and Biological Products Industry Alliance (BPIA)
- ▶ **2015 (summer):** EPA begins plant regulator guidance (including plant biostimulants) development
- ▶ **2015-2019:** Meetings/discussions with stakeholders including BPIA, EBIC, USBC, and plant biostimulant distributors/manufacturers
- ▶ **2017:** Plant Biostimulant Guidance development presentation to World Biostimulants Congress (700+ attendees)
- ▶ **2018:** Proposed guidance enters internal EPA review; USDA/EPA/FDA/Industry Workgroup formed to advise on Plant Biostimulant Verification Program
- ▶ **2019:** Draft guidance in OMB review and was posted for public comment on March 25, 2019

EPA and USDA Collaboration

- ▶ EPA and USDA consulted regularly during final development of the draft plant regulator guidance.
- ▶ 2018 Farm Bill mandated USDA to provide a report to Congress on legislative and regulatory options for PBS
- ▶ EPA and USDA consulted regularly on USDA Report
- ▶ USDA delivered the Report to Congress on Plant Biostimulants in December 2019
 - 6 legislative/regulatory options
 - 2 alternative definitions of Plant Biostimulants

Public Comment Overview

- ▶ 160 Substantive Comments
(18 additional requests for extension of comment period)
 - 70 from industry/trade groups/growers/law firms
 - 84 from private citizens
 - 4 from three US States
 - 2 from associations of State regulatory officials

General Comment Categories

- ▶ Plant Regulators are not pesticides
- ▶ Plant Biostimulants are Not Plant Regulators
- ▶ EPA should/should not develop a definition for Plant Biostimulants (PBS)
- ▶ EPA/State coordination on FIFRA registration of products already deemed fertilizers/PBS at State level
- ▶ Potential conflicts with 2018 Farm Bill and 2019 USDA Report to Congress on PBS

General Comment Categories

- ▶ Coordinate draft guidance with USDA, other Agencies, States, USDA NOP
- ▶ Draft guidance will have severe economic impact if implemented as written
- ▶ Remove Table 4 (List of known plant regulator active ingredients)
- ▶ Modify Table 4 (i.e. Remove one or more ingredients and/or more clearly qualify how certain uses may be excluded from FIFRA)
- ▶ Create a “Decision Tree” for the draft guidance document

General Comment Categories

- ▶ Revise FIFRA Sec §2 Plant Regulator Definition ([Congressional Action](#))
- ▶ Revise exclusion definitions of plant nutrients, plant inoculants, soil amendments in 40 CFR §152.6(g)(1), (2), & (3) to encompass all PBS products ([Rulemaking](#)); or
- ▶ Add a definition for Nutritional Chemicals in the 40 CFR to encompass all PBS products ([Rulemaking](#)), or
- ▶ Revise vitamin-hormone definition in 40 CFR §152.6(f) to include use on food crop sites ([Rulemaking](#))

Draft Guidance Timeline

- ▶ Guidance Development: 2014 - Present
- ▶ Released for Public Comment: March 2019
- ▶ Public Comment Period : March 2019 - June 2019
- ▶ Respond to Comments: Spring 2020
- ▶ Re-propose Guidance: Later in 2020

Thank You