



Proposed Guidance: Plant Regulators, Including Plant Biostimulants

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Plant Biostimulants: Background

- ▶ New, growing category of agricultural products
- ▶ Comprised of naturally-occurring substances and microbes
- ▶ Stimulate plant growth via improved 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
- ▶ Reduce use of synthetic agricultural chemical fertilizers (DuJardin, 2015; Craggs, 2017)
- ▶ Attractive for sustainable agriculture and IPM programs (Russo & Berlyn, 1990; Velez & Kloepper, 2014)

Plant Biostimulants: Market

- ▶ Global market expected to reach over \$4.49 billion by 2025*
- ▶ Estimated compound growth rate of 13.2% over the next decade*
- ▶ North American market expected to reach \$766 million by 2022**
- ▶ North America is second largest global market**

*Global Plant Biostimulants Market (Business Wire-May 4, 2017)

**North America Biostimulants Market: Industry Growth, Trends, & Forecasts 2017-2022 (Mordor Intelligence, December, 2017)

Plant Regulators/Plant Biostimulants: Regulatory Issues

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

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)(1) & (2)

Purpose of Proposed Guidance

- ▶ Identify examples of plant regulator claims on product labels
- ▶ Identify examples of non-plant regulator claims on product labels
- ▶ Provide clarity to regulated community and to State/Federal regulators for product claims that trigger FIFRA regulation
- ▶ Be legally non-binding

Note: The proposed guidance does not create any new regulatory definitions.

Plant Biostimulants: Definition

- ▶ Not defined in FIFRA
- ▶ Defined in 2018 Farm Bill
- ▶ Proposed definition in European Commission Fertilizer Law update

Plant Biostimulants: 2018 Farm Bill Definition

“...a substance or micro-organism that, when applied to seeds, plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield.”

Agriculture and Nutrition Act of 2018, Section 9201(c)

(https://agriculture.house.gov/uploadedfiles/agriculture_and_nutrition_act_of_2018.pdf)

Plant Biostimulants: European Commission Fertilizer Law Update Proposed Definition

“... a product stimulating plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant: (a) nutrient use efficiency; (b) tolerance to abiotic stress; and (c) crop quality traits.”

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>)

Expected Benefits/Costs After Guidance is Finalized

- ▶ Eliminate ambiguity and provide regulatory clarity
- ▶ Specify products and label claims that may require registration
- ▶ Reduce regulatory burden
 - Cost savings not quantifiable; as industry grows, regulatory clarity increases in value
 - Savings mostly intangible (less effort to determine appropriate regulatory path)
 - Avoid delays in marketing, product recalls
 - Avoid label redesign/printing costs
- ▶ Savings for State and Other Federal Regulatory Agencies (USDA, FDA)
 - Clarity on products not needing registration under FIFRA

Perspectives: Industry

- ▶ Seeking clarification and guidance on products that may or may not be subject to regulation under FIFRA
- ▶ Some seek regulation under FIFRA
- ▶ Some seek third-party certification of products that are **not subject to regulation** under FIFRA
 - Proposal to create a U.S. Plant Biostimulant Verification Program (USDA AMS/APHIS oversight)
 - Certification process acceptable across all States
 - Standards and criteria
 - Registry of certified products
 - EPA in technical advisory role ONLY
- ▶ Some do not want any form of federal regulation or third-party certification

Perspectives: U.S. States

- ▶ State pesticide and fertilizer regulators frequently seek EPA guidance on plant biostimulant products:
 - Do they require registration under FIFRA?
 - Looking to EPA for regulatory clarity

USDA/EPA Collaboration

- ▶ 2018 Farm Bill Sec. 9201. Report on Regulation of Plant Biostimulants
 - Ag Secretary to submit report:
“...identifying potential regulatory and legislative reforms to ensure expeditious and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers.”
 - Consultation with EPA, States, industry, and other stakeholders
 - May include development of a Plant Biostimulant Product Verification Program
 - Proposed definition for plant biostimulants
 - Nearly identical to proposed European Union definition

Perspectives: International

- ▶ European Union drafted a definition and regulatory framework for plant biostimulants as part of their Fertilizer Regulation update
 - Undergoing technical modifications (completion 2019?)
 - Proposed implementation 2021
- ▶ Outside of U.S. and European Union, plant biostimulants are:
 - Unregulated
 - Regulated under existing fertilizer regulations, or
 - Regulated under existing plant protection/pesticide regulations

EPA & 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 biostimulant guidance development
- ▶ **2015-Present:** 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:** Final draft in OMB review and was posted for public comment on March 25, 2019

Next Steps

- ▶ Final Agency Review: Complete
- ▶ OMB Review: Complete
- ▶ Public Comment: March 2019 - June 27, 2019
- ▶ Develop Response to Comments: Summer 2019
- ▶ Publish Final Guidance: Winter/Spring 2020