



Federal Regulatory Update: Plant Biostimulants

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Overview of Presentation

- Statutory and Regulatory Structure of U.S. Biostimulants Regulatory Scheme
- USDA Update
- EPA Update

Regulating Biostimulants

- Biostimulant Substances
 - Microbials
 - Plant Extracts
 - Organic Acids
 - Seaweed Extracts
- From a regulatory standpoint, there are several non-identical, but reasonably consistent, relevant definitions of “biostimulants”

Regulating Biostimulants (cont.)

Plant biostimulants contain substances(s) and/or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality.

Biostimulants have no direct action against pests, and therefore do not fall within the regulatory framework of pesticides.

The European Biostimulants Industry Council

<http://www.biostimulants.eu/>

Regulating Biostimulants (cont.)

A plant biostimulant is a substance or substances and/or micro-organisms whose function when applied to seeds, plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, crop quality and/or yield.

The Biological Products Industry Alliance

<https://www.epa.gov/sites/production/files/2018-11/documents/session-4-bpia-biological-products-k-jones-n-wilson.pdf>

Regulating Biostimulants (cont.)

“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 efficiency; (b) tolerance to abiotic stress; (c) quality traits; (d) availability of confined nutrients in soil or rhizosphere.”

Regulation (EU) 2019/1009, Art. 47 (05 June 2019), establishing Regulation (EC) No. 1107/2009, Art. 3, ¶ 34

Regulating Biostimulants (cont.)

“ . . . 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.”

U.S. Farm Bill (2018)

Regulating Biostimulants (cont.)

“ . . . a naturally-occurring substance or microbe that is used either by itself or in combination with other naturally-occurring substances or microbes for the purpose of stimulating natural processes in plants or in the soil in order to . . . improve nutrient and/or water use efficiency by plants, help plants tolerate abiotic stress, or improve the physical, chemical, and/or biological characteristics of the soil as a medium for plant growth.”

U.S. EPA Draft Guidance for Plant Regulator Label Claims

Regulating Biostimulants (cont.)

Pesticides

FIFRA § 2(u) defines “pesticides” as:

- Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest
- Any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant

Regulating Biostimulants (cont.)

Plant Regulators

FIFRA § 2(v) defines “plant regulators” as:

- “... 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 ...*”
- excluding:
 - plant nutrients/nutritional chemicals
 - trace elements
 - plant inoculants
 - soil amendments
 - vitamin-hormone horticultural products

Regulating Biostimulants (cont.)

Plant Regulators and Biostimulants

- The statutory definition of plant regulators directly implicates some biostimulants –
 - Any biostimulant that purports to act by “*accelerating or retarding the rate of growth or rate of maturation,*” or by “*altering the behavior of plants or their produce*” could be construed to be a plant regulator – and, therefore, subject to regulation as a pesticide

Regulating Biostimulants (cont.)

Plant Regulators and Biostimulants

- 2019 legislative and regulatory actions

2018 Farm Bill

The 2018 Farm Bill requires USDA to submit to the Congress and the President within one year a report on potential legislative and regulatory reforms “to ensure the expeditious and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers”

Regulating Biostimulants (cont.)

2018 Farm Bill:

Sec. 10111. Report on Plant Biostimulants.

(a) USDA to prepare a report to Congress and the President no later than December 22, 2019 “that identifies any potential regulatory, non-regulatory, and legislative recommendations, including the appropriateness of any definitions for plant biostimulant, to ensure the efficient and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers.”

(b) In developing this report, USDA is to consult with EPA, States, industry stakeholders, and other interested stakeholders at USDA’s discretion

(c) For the purposes of the report, the definition of “biostimulant” is “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;”

In the report, USDA may modify the definition of plant biostimulant, as appropriate

Regulating Biopesticides

Plant Regulators and Biostimulants

- *2019 legislative and regulatory actions*

EPA Draft Plant Regulator Biostimulant Guidance

- In March, EPA released for public comment its *Draft Guidance for Pesticide Registrants on Plant Regulator Label Claims, Including Plant Biostimulants*. The Draft Guidance addresses:
 - Which products are (and are not) subject to regulation under FIFRA as plant regulator pesticides
 - Label claims that can be made for products that will not subject them to regulation as pesticides

Regulating Biopesticides

Plant Regulators and Biostimulants

EPA Plant Biostimulant Guidance

EPA's Stated Purposes:

- 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

Regulating Biopesticides

Plant Regulators and Biostimulants

- Thoughts on EPA's Draft Guidance:
 - Interesting that EPA included the potentially restrictive description of biostimulants as “naturally-occurring.”
 - Table 3 indicates that EPA intends to regulate specific plant growth and development claims (e.g., plant and fruit growth, stem elongation, root/shoot stimulation, flowering and sprouting, yield and yield quality, etc.) as pesticidal plant regulator claims.
 - Table 4 lists ingredients that EPA says will categorically trigger plant regulator claims. Some of these ingredients are substances that have long use as recognized fertilizers and soil amendments (e.g., seaweed extracts). EPA's Draft Guidance implies that all products with those ingredients require registration under FIFRA.

Regulating Biopesticides

Plant Regulators and Biostimulants

- Thoughts on the Comments on EPA's "Draft Guidance:
 - Many of the comments fail to apprehend the distinction that EPA made in its draft guidance between label claims and substances.
 - Many of the anonymous public commenters appear not to fully understand the nuances of FIFRA Sections 2(u) and 2(v).
 - Among the substantive comments filed by knowledgeable entities, there is almost universal opposition to EPA's Table 4 listing of substances that will be considered categorically as plant growth regulators, notwithstanding the label claims that may accompany such products.

Regulating Biostimulants

What's next?

- USDA Report development process continues.
 - (USDA says **will** be submitted by 20 December)
- EPA's plan going forward is
- Stakeholders and interested parties must note that this is still the early stage of a long process. Ultimate resolution of the plant regulator/plant biostimulant conundrum will require either a legislative or regulatory solution (or both).

Biostimulants Update



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