Draft Guidance Update:
Plant Regulators, Including Plant Biostimulants

Russell S. Jones, Ph.D.
Technical Contact
Biopesticides & Pollution Prevention Division
Office of Pesticide Programs

Argus Added Value Fertilizers US
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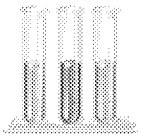
Plant Regulators: Background

- 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 and biotic stress
  - Induce or inhibit abscission, ripening, dormancy, flowering, fruit set
  - Influence plant architecture
  - Secondary metabolites in fungi and bacteria

Plant Biostimulants: Background

- 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

Plant Regulators/Plant Biostimulants:
Regulatory Issues – What is EPA Concern?

- 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 label claims may be considered plant regulator claims

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)

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.

European Parliamentary Research Service, March 2017*

Fertilizing Products

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

Other Products

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

*http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/582010/EPRS_BRI(2016)582010_EN.pdf

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 label 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

- The Guidance is not intended to be more restrictive or less restrictive
- It is intended to clarify regulatory activities already conducted by the Agency
- Claims-based, but not Claims Only
- Claims must be compliant with 40 CFR §152.15
- The Agency will consider "*significant commercially valuable uses*" that would not be regulated as pesticides

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

Comment Categories

- Plant Regulators are not pesticides and/or 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
- Coordinate draft guidance with USDA, other Agencies, States, USDA NOP

Comment Categories

- 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

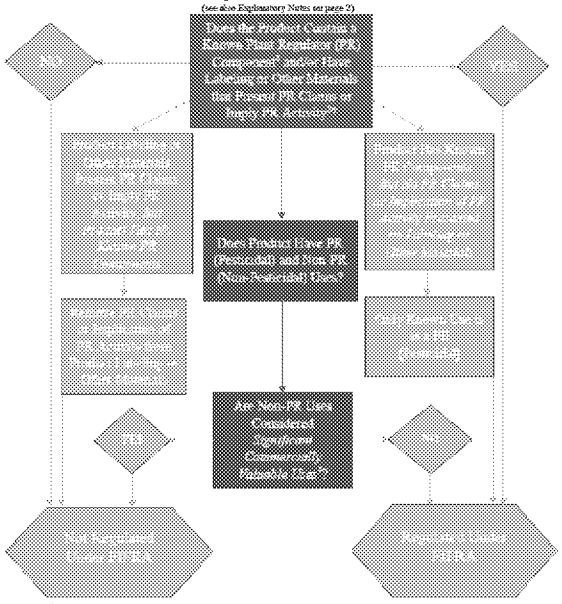
Comment Categories

Outside Scope of Guidance

- Revise FIFRA Sec §2 Plant Regulator Definition (Congressional Action)
- Revise exclusion definitions of plant nutrients, plant inoculants, soil and amendments in 40 CFR §152.6(g)(1), (2), & (3) to encompass all PBS products; or
- Add a definition for Nutritional Chemicals in the 40 CFR to encompass all PBS products, or
- Revise vitamin-hormone definition in 40 CFR §152.6(f)(1) & (2)

Plant Regulator Decision Tree

(see also Explanatory Notes on page 2)



[3] See Table 4 of the Draft Plant Regulator Guidance for list of known plant regulators.

[4] See Table 3 of the Draft Plant Regulator Guidance for examples of plant regulator claims.

[5] No criteria have been established for a "Significant Commercially Valuable Use" at this time.

Decision Tree Explanatory Notes

- Only applies to products that are plant regulators and does not other pesticidal (i. e. pest control) modes of action
- Product Labeling or Other Materials: refers to the product label affixed to any product as well as any other electronic or hardcopy media that are intended for use in advertising, educational, and/or other informational purposes related to the product.
- Table 3 (Examples of Plant Regulator Claims) and Table 4 (List of Known Plant Regulator Substances) in the EPA draft currently are being revised in response to public comments
- Significant Commercially Valuable Uses: Although no specific definition or criteria have been developed, the Agency will consider information to support this category under PRIA Code M009.
- Products excluded from FIFRA regulation include, but are not limited to plant nutrients, plant inoculants, soil amendments, and vitamin-hormone products
- Vitamin-hormone products are excluded from FIFRA regulation as plant regulators if they are Tox Category 3 or 4 and are not applied to food use sites; may contain plant hormones and make plant regulator claims.

Draft Guidance Timeline

- Guidance Development: 2014 – Present
- Public Comment (1st Round): March 2019 – June 27, 2019
- Response to Comments/Guidance Edits: Winter/Spring 2020
- Internal/Interagency/OMB Review: ?
- Public Comment (2nd round): ?
- Publish Final Guidance Document: ?

Thank You