Biostimulants, Beneficial Substances & Plant Regulators: An EPA Perspective

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BIOSTIMULANT ISSUES

• No clear definition, statutory or otherwise

• Numerous products of uncertain composition

• Some product label claims may trigger State/Federal enforcement actions

• Uncertainty in the regulated community

• Uncertainty in the State/Federal regulating community

• FTE time devoted to enforcement issues

• Rapidly growing product category needing regulatory clarity
DEFINITIONS

What is a Biostimulant?

What is a Beneficial Substance?

What is a Plant Regulator?

What is a Vitamin-Hormone?

What is a Biochemical Pesticide?

Plant Regulator = Vitamin-Hormone = Biostimulant

Registration, Data Requirements, Label Claims
No Federal Statutory Definitions for Biostimulants or Beneficial Substances
BIOSTIMULANTS - US

“… biological or naturally-derived additives and/or similar products, including but not limited to bacterial or microbial inoculants, biochemical materials, amino acids, humic acids, fulvic acids, seaweed extract and other similar materials.”*

- In small quantities, enhance plant growth and development
- Improve nutrient uptake efficiency
- Soil amendment

* Biostimulant Coalition, 2015 (http://www.biostimulantcoalition.org/about/ )
“A ‘Plant Biostimulant’ is a material that contains substance(s) and/or microorganisms whose function, when applied to plants or the rhizosphere, is to stimulate natural processes to benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and/or crop quality, independent of its nutrient content.”

- No direct action against pests
- Enhance crop quality and yield
- Foster development of beneficial soil microorganisms

Beneficial Substances - AAPFCO

• “...any substance or compound other than primary, secondary and micro plant nutrients that can be demonstrated by scientific research to be beneficial to one or more species of plants, when applied to the plant or soil.”*

• does not include microbes

Plant Regulators

FIFRA Definition [Sec 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/nutritional chemicals
* trace elements,
* plant inoculants,
* soil amendments,
* vitamin-hormone horticultural products
Plant Regulators

• **Plant Hormones**
  - naturally-occurring growth substance

• **Non-Hormonal Substances**
  - not naturally-occurring
  - mimic or inhibit activity of plant hormones

• **Induced Resistance Promoters?**
  - stimulate natural defense mechanisms
  - no inherent fungicidal/bactericidal activity
**Plant Regulators**

- **Plant Hormones** – naturally-occurring
  
  - Auxins, Cytokinins, Gibberellins, ABA, Ethylene, etc.
  
  - Signaling molecules, extremely low concentrations
  
  - Each cell of plant capable of producing plant hormones
  
  - Growth & development, abscission, ripening, dormancy, fruit set, plant architecture, etc.
  
  - Secondary metabolites in fungi and bacteria
Plant Regulators

• Non-hormonal substances – do not occur naturally

- 1-MCP (ethylene inhibitor) (B)*

- Chlorocholine chloride (GA synthesis inhibitor) (CC)*

- Paclobutrozol, Flurprimidol (GA antagonists) (CC)

- Mefluidide (cell division inhibitor) (CC)

- NAA (herbicide) (CC)

*B = Biopesticide  *CC = Conventional Chemical
“A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a “plant regulator” under section 2(v) of FIFRA, provided it meets the following criteria:

(1) …meets the criteria …for Toxicity Category III or IV; and

(2) …is not intended for use on food crop sites, and is labeled accordingly.”
BIOCHEMICAL PESTICIDES*

STATUTORY DEFINITION:
CFR 158.2000(a)(1)(i), (ii), & (iii)

• Naturally-Occurring Substances
• Non-Toxic Mode of Action to Target Pest(s)
• History of Exposure to Humans and Environment with Minimal Toxicity

*Plant Hormones are Biochemical Pesticides
### Plant Regulators, Vitamin-Hormones & Biostimulants

<table>
<thead>
<tr>
<th></th>
<th>Plant Regulator</th>
<th>Vitamin-Hormone</th>
<th>Biostimulant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biochemical</td>
<td>Yes and No</td>
<td>Some components</td>
<td>Some components</td>
</tr>
<tr>
<td>Microbial</td>
<td>No</td>
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<tr>
<td>Hormonal</td>
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<td>Some components</td>
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<tr>
<td>Non-hormonal</td>
<td>Yes</td>
<td>No*</td>
<td>No*</td>
</tr>
<tr>
<td>Food Use</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-food Use</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Statutory Definition</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Exempt From Registration Under FIFRA</td>
<td>No</td>
<td>Yes</td>
<td>?</td>
</tr>
</tbody>
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* Does not contain synthetic non-hormonal plant regulators
To be registered as a biopesticide...

- Must contain a Biochemical, Microbial, or PIP active ingredient
- Must contain only approved inerts
- CANNOT contain a *Conventional Chemical a.i.*
DATA REQUIREMENTS

Biochemical pesticides: 40 CFR 158.2000

Tables under

40 CFR 158.2030  Product Chemistry
40 CFR 158.2050  Human Health
40 CFR 158.2060  Non-target Organism & Env. Fate

http://www.ecfr.gov/

OCSPP Harmonized Guideline study protocols

Series 830  Product Chemistry
Series 870  Human Health
Series 850  Non-target Organism & Env. Fate
DATA REQUIREMENTS

Product Chemistry, Product Analysis, Product Characterization

**Mammalian Tests Tier I:**
Acute, subchronic, in vitro mutagenicity, pre-natal developmental testing

**Mammalian Tests Tier II:**
In vivo mutagenicity, immunotoxicity, pre-natal developmental, applicator/user exposure

**Mammalian Tests Tier III:**
Chronic, repro/fertility, carcinogenicity, immune response, teratogenicity

**Non-Target Organisms Tier I:**
Short-term avian, aquatic organism, plant, insect testing

**Non-Target Organisms Tier II:**
Environmental fate: soil and water leaching & degradation studies

**Non-Target Organisms Tier III:**
Chronic aquatic/terrestrial, reproduction, field studies
Plant Regulators and Biostimulants

Microbes that produce plant hormones

- The microbe would be regulated, not the plant hormone
- Similar to “over-the-top” Bt products
  - endotoxin is not the regulated article
Label Claims for Plant Regulators

• Plant Regulator claims trigger regulation under FIFRA

• What is a Plant Regulator claim?
  - Gray area without a statutory definition
  - Viewed in context of intended use of product and other claims on label
  - Vitamin-hormones/biostimulant claims reviewed “case-by-case” (product specific)
  - Talk to us first!
Label Claims for Plant Regulators

- What does EPA Evaluate?
  - Food use?
  - Proposed use rate vs. intended result
  - Actual fertilizer benefit?
  - Known Biochemical/Microbial a.i present?
  - Overt/implied plant regulator claims?
  - Valid, significant alternative use
Where Do We Go From Here?

EBIC Proposal (2015)*

- Safety data requirements for biostimulant substances
  - a registered composition
  - product physical/chemical properties
  - human health & environment risk assessments (for EU and non-EU producers)

Where Do We Go From Here?

• Exempt/Exclude from Federal regulation?
  - Highly unlikely

• “Light-Touch” regulatory pathway?

• Align with proposed EU Fertilizer Law

• Business as usual – FIFRA Section 3 Registration?
Questions
For You
Thank You!

Questions?