



*AAPFCO Industry Regulatory Council Meeting
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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/>)



BIOSTIMULANTS - EUROPE

- *“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



***European Biostimulants Industry Council, 2015** (<http://www.biostimulants.eu/wp-content/uploads/2015/07/EBIC-PP-Optimal-Regulatory-Framework-Biostimulants-v4-270715.pdf>)



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



*AAPFCO Official Terms T-73, AAPFCO Product Label Guide, 2015
http://www.aapfco.org/pdf/label_guide.pdf



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



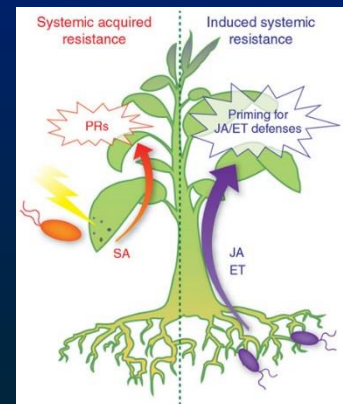
- **Non-Hormonal Substances**

- 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

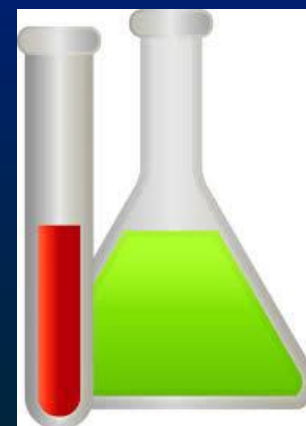


- Auxins, Cytokinins, Gibberellins, ABA, Ethylene, etc.
- Signaling molecules, extremely low concentrations
- Each cell of plant capable of producing plant hormones
- Growth & development, abscission, ripening, dormancy, fruit set, plant architecture, etc.
- Secondary metabolites in fungi and bacteria



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



VITAMIN-HORMONES

Statutory Definition: 40 CFR 158.6(f)

“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

	Plant Regulator	Vitamin-Hormone	Biostimulant
Biochemical	Yes and No	Some components	Some components
Microbial	No	Some components	Some components
Hormonal	Yes	Some components	Some components
Non-hormonal	Yes	No*	No*
Food Use	Yes	No	Yes
Non-food Use	Yes	Yes	Yes
Statutory Definition	Yes	Yes	No
Exempt From Registration Under FIFRA	No	Yes	?

** 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:

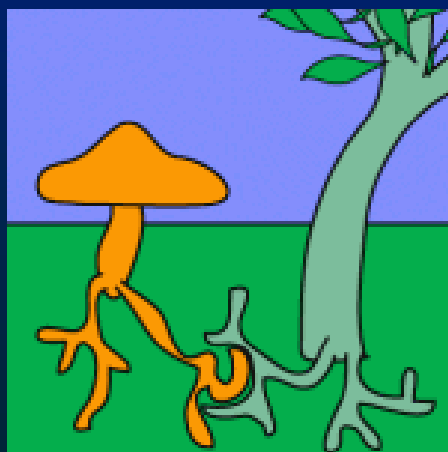
Chronic aquatic/terrestrial, reproduction, field studies



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)

*EBIC Position Paper, Towards an Optimal Regulatory Framework for Biostimulants (<http://www.biostimulants.eu/wp-content/uploads/2015/07/EBIC-PP-Optimal-Regulatory-Framework-Biostimulants-v4-270715.pdf>)



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



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Thank You!
Questions?