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# Regulation of Biochemical Substances, Microbes, and Genetically Engineered Organisms

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# Overview of Presentation

- Structure of U.S. Regulatory Scheme Applicable to the Phytobiome
  - EPA
  - USDA
  - FDA
- International Approaches (very briefly)



# U.S. Regulation of Pesticides - EPA

## Pesticides

In the United States, pesticides are regulated by the U.S. Environmental Agency under authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

7 U.S.C. § 136 et seq.



# U.S. Regulation of Pesticides - EPA

## Pesticides

FIFRA § 2(u) defines “pesticides” as:

- (1) Any substance or mixture of substances *intended* for preventing, destroying, repelling, or mitigating any pest  
and
- (2) Any substance or mixture of substances *intended* for use as a plant regulator, defoliant, or desiccant



# U.S. Regulation of Pesticides EPA

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# U.S. Regulation of Pesticides - EPA

## Pesticides

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- (2) Any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant



# U.S. Regulation of Pesticides - EPA

## Biopesticides:

Biochemical pesticides

Microbial Pesticides

Plant Growth Regulators

PIPs



# U.S. Regulation of Pesticides - EPA

## Examples of potentially pesticidal activities:

- *Protection of citrus from Huanglongbing by using the antibacterial peptide without threatening the inherent microbiome of leaves*
- *Plant and bacterial inositol exchange influences root colonization outcomes*
- *Manipulating the soil microbiome and root growth of grapevines with under-vine cover crops*





# U.S. Regulation of Pesticides - EPA

## Examples of potentially pesticidal activities:

- *Soil microbiome regulates trade-offs between productivity and disease pressure for circular growth media*
- *The impact of biostimulants on drought stress tolerance in barley*



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# U.S. Regulation of Pesticides - EPA

## ASTM – Biorational:

**biorational**, *n, adj*—the term used to characterize a broad range of low environmental impact substances or products that are typically biologically-derived or, if synthetic, structurally similar and functionally identical to a biologically occurring material with minor differences between the respective stereochemical isomer ratios derived from biological or synthetic origins.

**DISCUSSION**—Biorationals include biopesticides as well as nonpesticidal products, such as, but not limited to, those that are used for crop stress management, enhanced plant physiology benefits, root growth management, postharvest treatments or as an alternative to pesticides.

**ASTM Designation: E2880 – 16b**



# U.S. Regulation of Pesticides - EPA

## Plant Regulators

- “... 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

7 U.S.C. 136(v)



# U.S. Regulation of Pesticides - EPA

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# U.S. Regulation of Pesticides - EPA

## Plant Regulators

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# U.S. Regulation of Pesticides - EPA

## Plant Regulators

Legislative History:

(1) to define plant regulators as substances that alter a plant's behavior from how such plants would normally behave under ideal normal conditions,<sup>1/</sup>

and

(2) to include a broad exception for “substances intended to promote the growth of beneficial plants.”<sup>2/</sup>

<sup>1/</sup> Hearing Before the Committee on Agriculture House of Representatives, 86th Cong., 1st Sess. On H.R. 6436 (May 21, 1959).

<sup>2/</sup> Senate Committee on Agriculture and Forestry Report, S. Rep. No. 519, 86th Cong., 1st Sess. (1959).





# U.S. Regulation of Biostimulants

## Plant Regulators and Biostimulants

- The FIFRA 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



# U.S. Regulation of Biostimulants

## Biostimulant Substances

- Microbials
- Plant Extracts
- Organic Acids
- Seaweed Extracts



# Plant Biostimulants Definitions - EPA

“ . . . 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's Initial Draft Guidance for Plant Regulator Label Claims*



# **U.S. Regulation of Biopesticides - USDA**

## **USDA APHIS PPQ / BRS**

### **Microbial strains:**

### **Movement, Import, and Environmental Release Permits**



# **U.S. Regulation of Biopesticides - USDA**

- **USDA – United States Department of Agriculture**
  - **APHIS – Animal, Plant Health, and Inspection Service**
    - **PPQ – Plant Protection and Quarantine**
    - **BRS – Biotechnology Regulatory Service**



# U.S. Regulation of Biopesticides - USDA

## USDA APHIS

APHIS statutory responsibility is to safeguard U. S. agriculture and the environment

APHIS jurisdiction is plant pests and biocontrol organisms that can possibly impact plant health

Authority derives from the Plant Protection Act



# U.S. Regulation of Biopesticides - USDA

## USDA APHIS

A “plant pest” is any organism that “can directly or indirectly injure or cause disease or damage in any plants or parts thereof ...”

A biological control organism is “any enemy, antagonist, or competitor used to control a plant pest or noxious weed”



# U.S. Regulation of Biopesticides - USDA

## USDA APHIS

PPQ implements 7 C.F.R. Part 330:

*Federal Plant Pest Regulations; Plant Pests, Biological Control Organisms, and Associated Organisms*

BRS implements 7 C.F.R. Part 340:

*Movement of Organisms Modified or Produced Through Genetic Engineering*





# U.S. Regulation of Biopesticides - USDA

## USDA APHIS

PPQ and BRS regulate importation, movement in interstate commerce, and environmental releases of microbes (environmental releases of less than 10 acres of pesticidal microbes)

### Key considerations:

- Any information relevant to USDA PPA plant health risk assessment
- NEPA
- ESA



# U.S. Regulation of Biopesticides - USDA

## USDA APHIS

APHIS and EPA risk assessments are similar in key respects:

Each application is analyzed on an individual case-by-case basis

Application is expected to be as complete as possible (recognizing that some relevant information may not be available for each isolate or species that is proposed)

The regulators will conduct their own investigation of all sources where relevant information may be found (peer-reviewed literature, patents, public presentations and advertising)



# U.S. Regulation of Biopesticides - USDA

## USDA APHIS

APHIS issues **General Permits** for the importation of EPA-registered biopesticides manufactured overseas and imported by domestic pesticide producers.

Once imported under an APHIS General Permit, EPA-registered microbial pesticides move in U.S. interstate commerce under EPA regulation.



# U.S. Regulation of Biopesticides - USDA

## USDA APHIS BRS

[https://www.aphis.usda.gov/aphis/newsroom/stakeholder-info/sa\\_by\\_date/sa-2022/training-update](https://www.aphis.usda.gov/aphis/newsroom/stakeholder-info/sa_by_date/sa-2022/training-update)

2020 “SECURE” Rule:

[https://www.aphis.usda.gov/aphis/newsroom/stakeholder-info/sa\\_by\\_date/sa-2022/purple-tomato](https://www.aphis.usda.gov/aphis/newsroom/stakeholder-info/sa_by_date/sa-2022/purple-tomato)

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extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.aphis.usda.gov/biotechnology/downloads/faq-modified-microbes.pdf



# Regulation of Biopesticides - EU

## New regulations applicable to microorganisms in the EU:

- **Regulation 2022/1438** will amend Annex II to EU Agrochemical Regulation 1107/2009 regarding specific criteria for the approval of A.I.s that are micro-organisms.
- **Regulation 2022/1439** will amend Regulation 283/2013 regarding information and data requirements for micro-organisms.
- **Regulation 2022/1440** amends Regulation 284/2013 regarding required information and data requirements applicable to crop protection products containing micro-organisms.
- **Regulation 2022/1441** amends Regulation 546/2011 dealing with specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms. This regulation will replace Regulation 1107/2009 as it applies to microbial biopesticides.



# U.S. Regulation of Biocontrol and Biostimulants



# For questions contact:

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