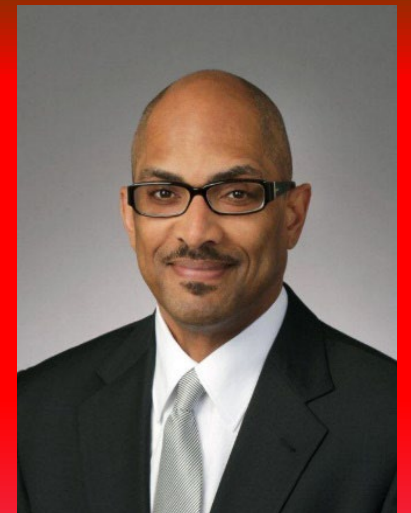


Navigating the Regulatory Complexity of Microbial Interventions for Climate Change Mitigation

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Overview of Presentation

Structure of the U.S. Regulatory Scheme Applicable to Microbial Interventions

- EPA
- USDA

Words Matter . . .

“Defining what is in your product may be easy, but the label in terms of what it does may be more difficult to define; for example it may be a biopesticide, bioadjuvant, biofertilizer, or biostimulant. It may be easier to register under a different term in different regions of the world just to enable its release.”

U.S. - Biopesticides

“Biopesticide”

- Regulated by EPA under FIFRA
- 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

U.S. - 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. – Plant Regulators

Plant inoculants

Products intended to aid the growth of desirable plants. A product of any of the following types, intended only to aid the growth of desirable plants, is not a “plant regulator” under section 2(v) of FIFRA, and therefore is not a pesticide:

(2) A plant inoculant product consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system.

U.S. - TSCA

Under the Toxics Substances Control Act EPA imposes regulatory requirements on new “chemical substances”*

“Chemical substance” is defined as “any combination of substances occurring in whole or in part as a result of a chemical reaction or occurring in nature.”

Microorganisms are subject to regulation as chemical substances.

*or “new uses” of chemical substances.

U.S. - TSCA

- ❑ EPA imposes regulatory requirements under TSCA on intergeneric genetically engineered organisms
- ❑ Naturally occurring microorganisms are not regulated by EPA under TSCA
- ❑ EPA regulates intergeneric genetically engineered microbes intended to be released into the environment for research purposes or that are intended for commercial use
- ❑ Microorganisms intended for pesticidal use are not regulated under TSCA

U.S. – Plant Protection Act

- ❑ The Plant Protection Act authorizes USDA to control or prevent the movement or environmental release of “plant pests” and “biological control organisms”.
- ❑ 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. - Plant Protection Act

- APHIS – Animal Plant Health Inspection Service

- PPQ – Plant Protection and Quarantine

- BRS – Biotechnology Regulatory Service

- 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. - Plant Protection Act

APHIS – SECURE Rule

- In 2020, APHIS promulgated a regulation that, in part, clarified explicitly that GE organisms are regulated by BRS under Part 340.
- The primary purpose of the SECURE Rule was to revise the APHIS regulations applicable to GE organisms to make them more fit for purpose given technological advances.
- The SECURE Rule was vacated by a Court order in 2024.

U.S. – Plant Protection Act

USDA Request for Information (15 May 2026)

Request for Information on Modified Organisms Subject to the Plant Protection Act

APHIS's regulations do not take clear notice of substantial advances in biotechnology since the late 1980s. APHIS, therefore, wishes to explore alternative frameworks for regulation of GE organisms under the plant pest provisions of the PPA, to ensure that regulation and oversight are proportionate to risk, that biotechnology developers in the United States have a predictable regulatory pathway to commercialization and, importantly, to ensure APHIS operates within its statutory authority.

U.S. – Plant Protection Act

USDA RfI

1. Are there material differences in plant pest risk between conventional and genetically engineered organisms? . . . If not, should APHIS continue to distinguish between conventional and genetically engineered organisms in its PPA regulations?
2. Describe regulation under the SECURE rule. Could it have been improved? Field trials/Commercialization? What areas worked well?
3. Describe regulation under current 7 CFR part 340. Can it be improved? Field trials/commercialization? What are the costs incurred complying with and/or navigating the regulatory requirements of 7 CFR part 340?
4. Could APHIS effectively address plant pest risks of modified organisms by regulating them under 7 CFR part 330 instead of 7 CFR part 340?

U.S. – Plant Protection Act

USDA RfI

5. What would the benefits and challenges of regulating modified organisms under 7 CFR part 330?
6. Describe key elements of a regulatory framework, including oversight of field trials, that would enable a scientifically sound assessment of a modified organism's plant pest risk.
7. Did the SECURE rule and does the current 7 CFR part 340—impose disproportionate burdens on smaller entities developing regulated plants or microorganisms?
8. Are there any other specific issues or topics APHIS should consider in developing a regulatory framework for assessing the plant pest risk of modified organisms, or possible pathways to commercialization for modified organisms?

U.S. Regulation of Microbes

Much work is ongoing . . .

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