



Regulation of Plant Biotechnology: An Overview

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BIOTECHNOLOGY REGULATORY SERVICES



Where Biotechnology Fits

Biotechnology Regulatory Services (Program)

Animal and Plant Health Inspection Service (Agency)

Marketing and Regulatory Programs (Mission Area)

U.S. Department of Agriculture

Capitalize on Experience Reviewing Products of Biotechnology

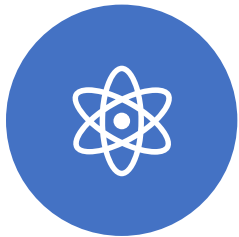
Product reviews beginning in 1987
(30+ years)

135 products designated as “not
regulated” following petition reviews

166 product responses to “Am I
Regulated?” inquiries

40,000 permit authorizations

Modernizing the Regulations



Based advances on science, technology, and experience



Clear, consistent, science-based and risk-based framework



Focus on areas of plausible risk to plant health and ease burden in well-understood areas




Nearly two years of experience with the revised regulations (since May 18, 2020)

Regulated Organisms

Plants
Unless exempt



Plant Pests



Biological Control



If they could pose a plant pest risk

Received Pest DNA

If it produces an infectious agent or compound that causes plant disease



PMPI Plants

Plant-made Pharmaceutical or Industrial Compounds



Three Key Components

1

EXEMPTIONS and CONFIRMING EXEMPT STATUS (only plants)

2

REGULATORY STATUS REVIEW (only plants)

3

PERMITTING

Scientific Rationale for Exemptions:

Treat Similar Products In A Similar Way

Genetic engineering, in and of itself, does not introduce plant pest risk

Conventional breeding has a history of safe use related to plant pest risk

Exempt plants with certain modifications achievable through conventional breeding

Ability to expand list of modifications achievable through conventional breeding

**Scientific
Rationale for
Exemptions:**

**Focus
Resources on
Novel Products**

Plant pest risk assessment 1) plant biology; 2) trait and mechanism of action; and 3) effect of trait and mechanism of action on plant and agricultural health

When a modified plant is found unlikely to pose an increased plant pest risk, it is not subject to the regulations

Exempt plants with the same plant-trait-mechanism of action combination as one previously reviewed and found not subject to the regulations

Developers may voluntarily request a letter confirming exempt status

Request and response posted on USDA website

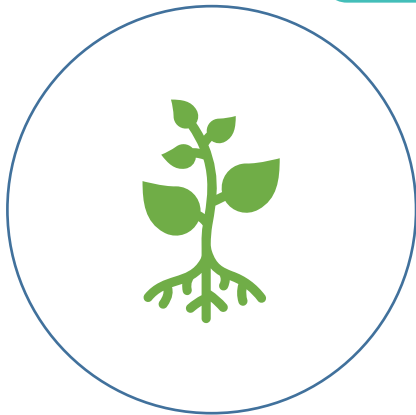


Regulatory Status Review

Biological properties of the plant;

trait (or new characteristic); and

the mechanism of action (or how the modification caused the new trait to occur).



Two-Step Process

1

Initial Review

Problem formulation to identify whether there are plausible pathways to increased plant pest risk.

2

Plant Pest Risk Assessment

Determines likelihood and consequence of the plausible increased plant pest risk.

Permitting



Any plant or organism subject to the regulations that is imported, moved interstate or released into the environment



Application requirements and permitting conditions are in the regulations



Supplemental permit conditions to protect plant health, as appropriate



Compliance Inspections and reporting requirements

Protect Plant Health and Enable Innovation



**Early submissions signal
innovation beyond
standard row crops**



**Confirmation requests
include apples, wild
tobacco, and camelina**

Thank You!

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- For more information on USDA's Regulations:

[USDA APHIS | About the SECURE Rule](#)

