

Breadcrumb

1. [Home](#)
2. Print
3. Pdf
4. Node
5. Entity Print

# Biotechnology Regulations

Last Modified:



Biotechnology Regulatory Services (BRS) implements APHIS regulations for plants and plant pests developed using genetic engineering that may pose a risk to plant health.

APHIS coordinates responsibility for regulating organisms developed using genetic engineering with other designated federal agencies as part of the Federal

Coordinated Framework for the Regulation of Biotechnology.

On May 18, 2020, APHIS published the first comprehensive revision of APHIS' biotechnology regulations since they were established in 1987. The revisions enable APHIS to regulate organisms developed using genetic engineering for plant pest risk with greater precision and reduce regulatory burden for developers of organisms that are unlikely to pose plant pest risks.

## **Biotechnology Coordinated Framework**

Established as a formal policy in 1986, the Coordinated Framework for Regulation of Biotechnology describes the Federal system for evaluating products developed using modern biotechnology. The three main Federal agencies responsible for regulating the safe use of genetically engineered organisms are APHIS, the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA).

FDA has primary responsibility for ensuring the safety of human food and animal feed. EPA regulates pesticides, including plants with plant-incorporated protectants (pesticides intended to be produced and used in a living plant), to ensure public safety. APHIS, through its Biotechnology Regulatory Services (BRS) program, regulates the introduction of certain organisms developed using genetic engineering that may pose a risk to plant health.

[Visit the Coordinated Framework Unified Website](#)

## **APHIS Regulatory Authority**

APHIS derives its authority to promulgate its biotechnology regulations from provisions of the *Plant Protection Act*, which is a part of the larger *Agriculture Risk Protection Act of 2000*. Congress authorizes various parts of USDA to regulate specified areas of U.S. Agriculture under these federal statutes.

- [Plant Protection Act](#) (233.84 KB)
- [Agriculture Risk Protection Act of 2000](#) (346.88 KB)

# APHIS Biotechnology Regulations

Agencies write regulations in accordance with their governing authority. All federal regulations are published in the Federal Register and the Code of Federal Regulations (CFR).

APHIS oversees the importation, interstate movement, and environmental release of genetically modified plants and plant pests through regulations found in Volume 7, part 340 of the CFR. The regulations have three key elements. First, individuals can determine whether their modified plant meets the criteria for an exemption from regulation or can request APHIS' confirmation of the plant's exempt status. Second, applicants can request a regulatory status (RSR) review to determine if their modified plant is subject to the regulations. Third, applicants must apply for a permit to move or release a modified organism that is not exempt or found through the RSR process to be not subject to APHIS's biotechnology regulations.

- [View Biotechnology Regulations 7 CFR part 340](#)
- [Learn More About the Revised Regulations](#)
- [Questions and Answers](#) (207.72 KB)

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