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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.

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. 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. Persons that wish to move or release a modified organism that may be a plant pest, must obtain authorization through a permit or notification. Permits provide details about the nature of the organism and the conditions that will be used to prevent the organism's spread and establishment in the environment. A notification is a streamlined alternative to a permit for modified plants that meet specific eligibility criteria and pre-defined performance standards. When a developer has gathered enough evidence to demonstrate that a modified organism does not pose a pest risk, they may petition APHIS for nonregulated status. Nonregulated status allows a modified organism to be moved and planted freely without the regulatory requirements of notifications or permits.

- View Biotechnology Regulations 7 CFR part 340

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