United States Department of Agriculture
Animal and Plant Health Inspection Service
Program Aid No. 1862

Biotechnology Regulatory Services

Coordinated Framework for the Regulation of Biotechnology

Working together to ensure safety

Biotechnology Regulatory Services

HISTORY OF BIOTECHNOLOGY

For hundreds of years, people have used traditional methods such as selective breeding to improve plants and animals. The last century was marked by rapid advances in agriculture, including mechanization, improved breeding techniques, and a vastly expanded knowledge of plant sciences. Genetic engineering—a precise and predictable method for introducing new traits into organisms—is one of the most recent methods for improving plants. Scientists have safely been using genetic engineering and other tools of modern biotechnology since the 1980s to develop new plant varieties and to enhance agriculture. The technology has been readily adopted by U.S. farmers since becoming commercially available in the mid-1990s—so much so that a significant portion of the corn, soybeans, cotton, and canola grown in the United States is now genetically engineered (GE) varieties.

APHIS–BRS regulates the products of biotechnology that are undergoing confined field trials.

Biotechnology and the Need for Federal Regulation

While biotechnology has the potential to provide new varieties with a wide array of useful characteristics, government regulatory agencies have the responsibility to ensure that this science advances safely. In 1986, the Federal Government's Office of Science and Technology Policy (OSTP) published a policy document known as the Coordinated Framework for the Regulation of Biotechnology. This document specifies three Federal agencies that are responsible for regulating biotechnology in the United States: the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), the Environmental Protection Agency (EPA), and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA). Products are regulated according to their intended use, and some products are regulated by more than one agency.

Together, these agencies ensure that the products of modern biotechnology are safe to grow, safe to eat, and safe for the environment. USDA, EPA, and FDA apply regulations to biotechnology that are based on the specific nature of each GE organism. Assessments are based on the biological characteristics of the new organism.

USDA and EPA are the agencies responsible for ensuring the safety of the agriculture and environment. FDA has primary responsibility for ensuring the safety of food and any food ingredient derived from genetic engineering. EPA is responsible for ensuring that a type of pesticide engineered and used in living plants—termed Plant-Incorporated Protectants (PIPs)—can be safely consumed and safely used in the environment. People or companies that violate any of these agencies' laws or regulations are subject to high monetary fines and other punitive actions.

The Role of the Federal Agencies Within the Coordinated Framework

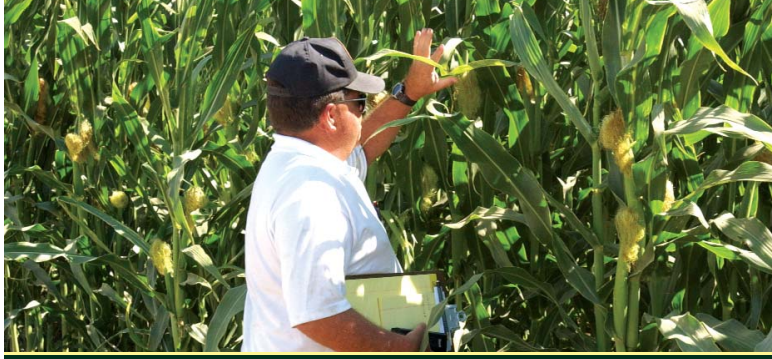
U.S. Department of Agriculture

Within USDA, APHIS is responsible for protecting U.S. agriculture and the environment from pests, diseases, and weeds. Under the authority of the Plant Protection Act, APHIS regulations require that a developer of a GE organism have authorization in the form of a permit or an acknowledged notification prior to introducing a regulated article into the United States. Regulated articles are organisms and products altered or produced through genetic engineering that may pose a risk as a plant pest. The act of introducing includes any movement into (import) or through (interstate) the United States, or release into the environment, as in a field test.

Biotechnology Regulatory Services (BRS) is the unit in APHIS responsible for ensuring the safety of these GE organisms through a comprehensive program of rigorous regulatory oversight. Applicants seeking permission to move, import, or field-test a GE organism must submit detailed information to BRS for thorough review by regulatory scientists before the introduction can be authorized. Depending on the nature of the GE crop, an applicant files a permit application or uses the more expedited notification process.

Both permits and notifications are subject to APHIS review by biotechnologists trained in relevant scientific disciplines. Developers must comply with the regulations and permit conditions throughout the duration of the authorized action. To ensure that developers do so, APHIS conducts inspections and audits.

Most of the field trials that BRS regulates are for crops genetically engineered for insect, herbicide, and drought resistance, such as this drought-tolerant cotton.



BRS Compliance Specialists use set criteria to thoroughly evaluate all GE field-test sites for adherence to rigorous safety standards.

The regulations also provide for a petition process for the determination of nonregulated status. Developers can file a petition request after a product has been adequately field-tested and enough data have been collected to ensure that it is as safe as its traditionally bred counterparts. Once a determination of nonregulated status has been made, the product and its progeny no longer require APHIS review for movement or release in the United States. Developers typically seek nonregulated status for their products after years of field testing as a practical step needed to commercialize their products.

APHIS works in coordination with EPA and FDA, which also play important roles in ensuring the safe advancement of biotechnology.

Environmental Protection Agency

EPA regulates to ensure the safe use of pesticides, no matter how they are made or their mode of action. The BioPesticides and Pollution Prevention Division of the Office of Pesticide Programs uses the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to regulate the distribution, sale, use, and testing of pesticides, including PIPs produced and used in living plants. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA sets tolerance limits for substances used as pesticides on and in food and feed, or establishes an exemption from the requirement of a tolerance. EPA also establishes tolerances for residues of herbicides used on novel herbicide-tolerant crops, including those generated through genetic engineering.

FIFRA requires pesticide manufacturers to register pesticidal products prior to their sale and distribution and makes provisions for issuance of permits for field testing of pesticides. EPA sets conditions in the registration

Through a registration process, EPA regulates the sale, distribution, and use of pesticides in order to protect human health and the environment, regardless of how the pesticide was made or its mode of action.

All foods and feeds—whether imported or domestic and whether derived from crops modified by conventional breeding techniques or by GE techniques—must meet the same rigorous FDA safety standards.

process for use of the pesticide to minimize environmental impacts and establishes protective limits for pesticide residue in food, ensuring that both food and animal feed are safe for consumption.

EPA also regulates "new" micro-organisms—those formed by combining genetic material from organisms in different genera. These micro-organisms may express new traits or new combinations of traits with unknown effects on humans, wildlife, fish, and plants. EPA uses its authority under the Toxic Substances Control Act to regulate new micro-organisms used commercially in the production of industrial enzymes and other specialty chemicals.

U.S. Department of Health and Human Services' Food and Drug Administration

FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those developed through genetic engineering. All foods and feeds, whether imported or domestic and whether derived from crops modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. In addition, any food additive, including one introduced into food or feed by way of plant breeding, must receive FDA approval before marketing.

FDA ensures that food and feed manufacturers meet their obligations through its enforcement authority under the FFDCA. To help sponsors of foods and feeds derived from genetically engineered crops comply with their obligations, FDA encourages them to participate in its voluntary consultation process.

Who Regulates What

Biotech products are regulated according to their intended use, with some products regulated under more than one agency. The table below illustrates how the authority of the three agencies of the Coordinated Framework results in differing regulatory oversight according to the traits introduced through biotechnology.

New trait/organism	Regulatory review by	Reviewed to ensure
Insect resistance in a food crop, e.g., Bt corn	**APHIS**	Safety for agriculture and the environment
	EPA	Safety for the environment and food and feed safety of PIPs
	FDA	Safety for food and feed use
Modified oil content in a food crop, e.g., oleic acid in soybean seed	**APHIS**	Safety for agriculture and the environment
	FDA	Safety for food and feed use
Herbicide tolerance in a food crop, e.g., glyphosate-tolerant corn	**APHIS**	Safety for agriculture and the environment
	EPA	Safe use of companion herbicide
	FDA	Safety for food and feed use
Herbicide tolerance in an ornamental crop, e.g., glyphosate-tolerant marigold	**APHIS**	Safety for agriculture and the environment
	EPA	Safe use of companion herbicide
Modified flower color in an ornamental crop, e.g., blue carnation	**APHIS**	Safety for agriculture and the environment

Staying Connected, Assuring Coordination

The OSTP leads a biotech working group where senior representatives from each of the three agencies of the Coordinated Framework meet and review current and emerging issues. Additionally, interagency conference calls are held monthly with staff from the regulatory agencies. At these critical sessions, the group reviews pending decisions on new products, exchanges pertinent information, and identifies and addresses emerging issues.

The Coordinated Framework joins science with policy, creating an effective system that safeguards American agriculture, native ecosystems, and the food supply while allowing for the safe field testing of GE crops.

BIOTECHNOLOGY REGULATORY SERVICES

For More Information

For information on BRS, please visit the program's Web site at <http://www.aphis.usda.gov/brs>. If you have additional questions on permitting or regulatory activities, please call (301) 734–5715.

USDA–APHIS
http://www.aphis.usda.gov

U.S. Environmental Protection Agency
http://www.epa.gov/pesticides/biopesticides
http://www.epa.gov/oppt/biotech

U.S. Department of Health and Human Services' FDA
http://www.cfsan.fda.gov/~lrd/biotechm.html

Photo credits: On the cover, the streamside image was taken by APHIS photographer R. Anson Eaglin. The corn shot is a USDA file photo, and USDA–Agricultural Research Service photographer Peggy Greb took the picture of cotton. Inside the leaflet, Anson Eaglin furnished all the photographs except that of the pesticide equipment (taken by USDA photographer Bill Tarpenning) and the shopper buying grapefruit (taken by USDA photographer Ken Hammond).

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