United States Department of Agriculture
Animal and Plant Health Inspection Service
Program Aid No. 1841

Biotechnology Regulatory Services

Ensuring Safety in the Development of Genetically Engineered Organisms

Here, GE cotton is surrounded by other types of crops to ensure that confinement measures are achieved.

BIOTECHNOLOGY REGULATORY SERVICES

BRS MISSION

To protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered organisms

APHIS regularly inspects GE field tests to ensure that companies are complying with BRS' confinement conditions. Here, an APHIS employee inspects GE cotton.

Through its strong regulatory framework, **Biotechnology Regulatory Services (BRS)** protects America's agriculture and the environment by allowing for the safe development and introduction (importation, interstate movement, and field testing) of genetically engineered (GE) organisms. Under the authority of the Plant Protection Act, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) has regulated GE organisms since 1987. In 2002, APHIS established BRS to take over this role. The agency has authorized more than 10,000 permits and notifications for the introduction of GE organisms and deregulated more than 60 products for use, establishing itself as an international leader in the safe regulation of GE products.

One of BRS' permit conditions for GE plants that produce pharmaceutical and industrial compounds is the maintenance of a fallow zone of at least 50 feet.

BRS: Reaching Its Vision

It is the vision of BRS to work openly and cooperatively to provide a clear, timely, and strategic regulatory system that responds to the rapidly evolving field of biotechnology and fosters public confidence. Fulfilling this vision requires many things, among them the flexibility to respond. APHIS writes its biotechnology regulations with flexibility such that measures imposed on permits can vary based on case-by-case assessments. BRS regulations may also be revised and strengthened as needed, based on new trends in biotechnology, changes in the field, and experience gained.

Also as part of its vision, BRS makes it a priority to ensure that its processes, decisions, and activities are transparent to the public and to its stakeholders. As part of this initiative, BRS makes available on its Web site all environmental assessments for GE crops that produce pharmaceutical and industrial compounds; it announces the findings in the *Federal Register* and allows for a comment period. The BRS Web site also provides accessibility to permits and decisions and news and upcoming events. In addition, BRS has a stakeholder registry that allows interested parties to receive updates and other information relevant to selected topics of interest, such as regulation activities, communication and outreach, capacity building, and compliance issues.

Science Guiding BRS

BRS performs all aspects of its regulatory role with science as its basis. A diversified collection of scientific expertise enables BRS to make sound, science-based decisions that ensure the safe development of new GE organisms that are themselves as safe as their non-GE counterparts. BRS has experts in scientific fields (e.g., plant pathology, botany, animal science, entomology, virology, ecology, environmental science, molecular biology, and biochemistry) who conduct extensive scientific review of permit applications, petitions for deregulation, potential permit infractions, and proposed regulatory changes. To keep pace with the ever-evolving technology, BRS staff and scientists attend and host scientific meetings and workshops, read literature, and interact with outside scientists, stakeholders, and the public.

BRS' International Role

BRS also plays an active role in international standards setting and regulatory capacity building. In fulfilling these functions, along with other international activities, BRS supports other USDA agencies and Federal departments that are directly involved in trade activities by providing the technical and scientific expertise of its staff. BRS works with key international organizations to develop international biotechnology standards that are science based and consistent with U.S. regulatory policy and standards. BRS also works with developing countries to establish their own regulatory framework.

The BRS Permit System

APHIS regulations are mandatory, and developers must seek APHIS approval through its permit system before introducing a GE organism. Developers must also comply with the regulations and permit conditions throughout the duration of the approved permit. Applicants must submit all plans for movement, importation, or field testing for thorough review by regulatory scientists, who evaluate the risks and the procedures that the developer will use. Depending on the nature of the GE crop, an applicant files either a notification or a permit application for APHIS review. BRS also works closely with State departments of agriculture to ensure that they are aware of events taking place within their jurisdiction and to allow them to apply any additional safeguards they may require.

Here, an APHIS inspector is checking farm equipment for the presence of regulated material.

The Notification Process

Most plants are field-tested under notification, a streamlined approval process that is often used for plants that are altered with common agronomic traits, such as pest resistance or herbicide tolerance. Applicants may use the notification process only for plants that meet all six of the following eligibility criteria, based on their plant pest potential:

1. The GE plant is not listed as a Federal noxious weed and is not considered a weed in the area of introduction.
2. The genetic material must be "stably integrated" into the plant genome.
3. The newly introduced gene's function must be known and not result in plant disease.
4. The genetic material must not cause production of a plant pest; cause the plant to produce substances that are toxic to nontarget organisms; or be genetically engineered for the purpose of producing compounds intended for pharmaceutical or industrial use.
5. The newly introduced gene must not cause the creation of a new plant virus.
6. The plant must not have been modified to contain genes from animal or human pathogens.

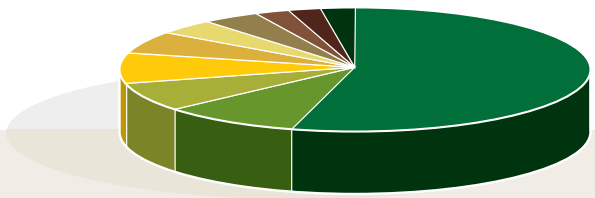
In 2003, roughly 81 percent of the soybeans grown in the United States were genetically engineered, nearly all for herbicide tolerance.

Applicants must also sign a statement indicating that they will conduct the test in a manner that meets the performance standards listed in APHIS biotechnology regulations. For example, one performance standard states that the field trial must be conducted in such a way that the regulated article will not persist in the environment and no offspring can be produced that could persist in the environment.

As part of the notification process, BRS requires that applicants provide detailed data, such as information about the plant; descriptions of genetic modifications; the source and identity of any genes introduced; and the size, duration, and location of the field test. If a plant does not meet the criteria for notification, the applicant must follow the full permitting process.

The Permit Process

The permitting process involves a more comprehensive review and is used for GE plants that could pose an elevated risk, such as plants that produce pharmaceutical or industrial compounds, as well as for any GE organism other than plants. As part of the permit application process, applicants must provide the same data as required in the notification process and, in addition, must provide a detailed description of how the developer will perform the test. When applying for a permit, applicants must include specific measures to reduce the risk of harm to other organisms to ensure that the plants being tested do not pose a significant plant pest risk. BRS often works with applicants on design protocols and may impose additional measures and supplemental permit conditions.



2% Rice	6% Tomato
2% Rapeseed	8% Cotton
3% Tobacco	8% Potato
4% Alfalfa	9% Soybean
4% Wheat	54% Corn

Corn followed by soybeans, potatoes, cotton, and tomatoes are the most common crops for which developers request permits.

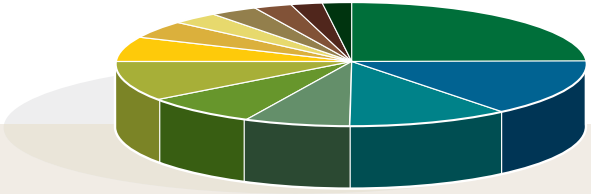
BRS requires that organizations conducting GE field tests keep detailed records on all GE seed. Here, the seeds are counted, weighed, and logged.

Workers are sprayed with compressed air to remove any regulated material from their clothing.

Plants engineered to produce pharmaceutical or industrial compounds for humans or animals fall into a distinct category, and APHIS policy makes clear that these GE plants are handled differently from those being developed for use as food or feed. APHIS issues permits for GE plants that produce pharmaceutical and industrial compounds on a case-by-case basis after BRS experts complete an extensive scientific review or an environmental assessment. In addition, APHIS imposes more stringent confinement measures, such as increased isolation distances and fallow zones and restrictions against using the same land to produce pharmaceutical and industrial crops for the production of food or feed crops. BRS also requires developers of pharmaceutical and industrial crops to have dedicated equipment and storage facilities for those crops. BRS inspects every field test site with GE crops that produce pharmaceutical and industrial compounds up to seven times before, during, and after production.

Petition for Deregulation

After a GE plant has been field-tested and the developers have demonstrated that the product is as safe as its non-GE counterpart and should be removed from BRS oversight, they may file a petition for deregulation, or nonregulatory status. As part of the deregulation process, petitioners must submit detailed data, such as a description of the biology of the plant before it was genetically engineered, extensive data from tests designed to detect differences between the GE plant and the original plant, characterization of genetic changes, plant pest-risk characteristics, disease and pest susceptibilities, expression of gene products, new enzymes, effects on nontarget organ-



2% Papaya
2% Rice
2% Tobacco
2% Flax
2% Chicory
3% Squash
3% Sugar Beet
8% Soybean
8% Potato
11% Rapeseed
14% Cotton
17% Tomato
26% Corn

Corn followed by tomatoes, cotton, rapeseed, potatoes, and soybeans are the most commonly deregulated products.

isms, changes in plant metabolism, weediness of the GE plant, impact on the weediness of relatives of the GE plant, and impacts on agricultural practices or on other agricultural products.

After review of the data, BRS prepares an environmental assessment to analyze the potential impacts the GE plant may have on the environment and then seeks public comment. BRS approves a petition only when it determines that the organism does not pose a plant pest risk.

Once BRS has granted a petition for nonregulatory status, the product may be freely moved and planted without the permits or other regulatory oversight by BRS. Developers will seek to obtain nonregulated status for their products, along with completion of applicable reviews at other agencies, as a practical step toward commercialization. BRS has the authority to bring any deregulated item back under regulation if new information becomes available that demonstrates unanticipated effects or plant health risks. This authority, however, has never been used because deregulated products have an established history of safe development.

Since 1987, APHIS has overseen the deregulation of more than 60 GE products. Of these approved products, 40 percent were engineered for herbicide tolerance and 25 percent for insect resistance.

BRS requires that researchers field-testing plant-made pharmaceuticals or industrials use farm equipment dedicated only to that use.

APHIS inspectors utilize global positioning systems to document the exact location of GE field tests.

Compliance With BRS Regulations

Failure to adhere to the regulations, permit conditions, and requirements can result in serious penalties, including fines up to $500,000 per adjudication. BRS' compliance unit is dedicated exclusively to ensuring that companies and organizations maintain compliance through defined procedures that include violation-prevention efforts, risk-based criteria for quality inspection, uniform enforcement, and thorough documentation of any compliance infractions.

Compliance specialists and APHIS inspectors perform targeted inspections and audits of field tests and use set criteria to thoroughly evaluate all potential compliance infractions. In the case of an infraction, BRS immediately implements procedures to bring the developer back into compliance with all necessary measures to protect U.S. agriculture, the food supply, and the environment. Depending on the seriousness of the infraction, BRS may refer the case to APHIS' Investigative and Enforcement Services for further investigation. BRS also works closely with State departments of agriculture and other Federal agencies, including the Food and Drug Administration and the U.S. Environmental Protection Agency, to ensure compliance with regulations.

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For More Information

To find out more about 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 contact (301) 734–5715.

Photo credits: The soybean shots on the front cover and inside the leaflet were taken by USDA–Agricultural Research Service photographer Scott Bauer. All the remaining images were taken by APHIS photographer R. Anson Eaglin.

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