BRS Factsheet

Biotechnology Regulatory Services

U.S. Department of Agriculture
Animal and Plant Health Inspection Service

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Biotechnology, Federal Regulation, and the U.S. Department of Agriculture

The Biotechnology Regulatory Services (BRS) program of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for regulating the introduction (importation, interstate movement, and field release) of genetically engineered (GE) organisms that may pose a plant pest risk. BRS exercises this authority through APHIS regulations in Title 7, Code of Federal Regulations, Part 340 under the Plant Protection Act of 2000.

Genetic engineering refers to the process in which one or more genes and other genetic elements from one or more organism(s) are inserted into the genetic material of a second organism using recombinant DNA techniques. Engineering a new gene or genes into the second organism in this way allows researchers and developers to introduce a particular new trait, or traits.

APHIS protects agriculture and the environment by ensuring that biotechnology is developed and used in a safe manner. Through a strong regulatory framework, BRS ensures the safe and confined introduction of new GE plants with significant safeguards to prevent the accidental release of any GE material.

APHIS has regulated the biotechnology industry since 1987 and has authorized more than 10,000 field tests of GE organisms. In order to emphasize the importance of the program, APHIS established BRS in August 2002 by combining units within the agency that dealt with the regulation of biotechnology.

Overview of the BRS Regulatory System

Developers of GE organisms that wish to import, move interstate, or field-test a GE organism must obtain USDA permission in advance. Applicants must submit all plans for movement, importation, or field testing for thorough review by regulatory scientists. Those scientists then evaluate the procedures that the company or organization will use and assess any potential risks. Depending on the nature of the GE organism, an applicant files either a notification or a permit application. With either application, the developer must adhere to certain measures that ensure adequate confinement of the organism. BRS also works closely with States to be sure that they are aware of field tests taking place within their jurisdiction and to allow them to request any additional conditions they may require. To ensure compliance with the permit and notification conditions, BRS inspects field-test sites and audits records.

The Notification Process

Most plants are field-tested under a notification. Notification is a streamlined process that may take up to 30 days for review and approval. Applicants may use the notification process only for engineered plants that meet specific safety-related eligibility. Often, plants field-tested under the notification process are altered to produce pest resistance or herbicide tolerance.

To qualify for the notification process, the GE plant must meet six requirements to ensure that it does not pose a significant plant pest risk. Applicants must also agree to carry out the test in such a way to meet the performance standards set forth by BRS to ensure that the GE plants remain confined. BRS requires that applicants provide detailed information about the plant, such as the source and identity of any genes introduced, the method of genetic engineering, and the size, duration, and location of the field test. If a plant does not meet the criteria for notification, or if the engineered organism is not a plant, the applicant must follow the full permitting process.

BRS approves a petition only when it reaches the conclusion that potential threats to the environment are no different than those posed by the nongenetically engineered version of the crop.

The Permit Process

The permit process is used for GE plants that could have an elevated risk (e.g., plants that produce pharmaceutical or industrial compounds) and for all other GE organisms besides plants. Field-testing permit applications are more extensive than notifications and may take up to 120 days to process. Applicants must also apply for permits for the movement or importation of a regulated article, which may take up to 60 days to process.

For field testing, permit applicants must provide BRS with details about the nature of the organism, its origin, its intended use, all new genes and gene products, and procedures for field production and isolation. For movement or importation permits, applicants must also submit a detailed description of the destination, the means of movement, and procedures to safeguard against the escape of the GE organism. Using this information, BRS scientists create a set of permit conditions that applicants must meet in order to receive approval to field test or transport their GE organism. Upon approval, permits are valid for 1 year from the date of issue and must be renewed if additional plant material is moved or planted after that time. When importing of a GE organism, an applicant must submit an application for each shipment.

Petition for Deregulation

During field testing, the developer may gain data to show that the product is safe and does not pose a plant pest risk. When developers can show that the product is not a plant pest risk and should be removed from BRS oversight, they may petition BRS for deregulation, or nonregulated status. In order to have a GE organism deregulated, a developer must submit information such as a description of the biology of the plant before it was genetically engineered, differences between the GE plant and the original plant, and field-test reports for all trials the petitioner conducted involving the GE plant.

BRS conducts an environmental assessment in compliance with the National Environmental Policy Act to analyze the potential impacts the GE organism may have on agriculture and the environment. This assessment includes a wide variety of environmental parameters and specifically looks for possible damage to threatened and endangered species. When BRS completes the assessment, it is posted on the Web and made available for a 60-day public comment period through a *Federal Register* announcement.

BRS approves a petition only when it reaches the conclusion that potential threats to the environment are no different than those posed by the nongenetically engineered version of the crop. BRS will often ask for additional information before the petition can be deemed complete and the assessment can be finalized. BRS notifies petitioners within 180 days after the petition is complete that it has either been granted nonregulated status (in whole or in part) or been denied. Once APHIS has reached a determination of nonregulated status—and other Federal authorities with regulatory oversight, such as the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), have also completed their reviews—the product may be used commercially.

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. Corn, tomatoes, and cotton, in that order, are the most frequently deregulated products.

Compliance With BRS Regulations

It is the responsibility of BRS to establish and enforce regulations that protect American agriculture and the environment while allowing for the safe introduction of GE organisms. BRS determines the conditions under which GE organisms can be introduced into the United States and allows for the importation, interstate movement, and field release of these materials only after rigorous conditions and safeguards are put into place. Failure to adhere to the regulations, permit conditions, and requirements can result in serious penalties.

The BRS compliance unit is dedicated solely to ensuring that developers maintain compliance with permit and notification conditions. Compliance specialists and APHIS inspectors perform targeted, risk-based inspections and audits of field tests and use set criteria to thoroughly evaluate all potential compliance infractions. BRS addresses all compliance issues and takes appropriate actions to correct the compliance infraction.

Compliance Infractions

When a company does not adhere to APHIS regulations and permit conditions, BRS refers to these incidents as "compliance infractions." Compliance infractions can include a wide range of issues. For example, some infractions involve administrative issues such as the wrong name on a permit. Other types of infractions include failing to notify APHIS in the event of vandalism or destruction of a field test; failing to obtain a permit; and failing to follow performance standards, such as isolation distances. Planting at a field-test site before a permit becomes effective and planting after it expires also qualify as compliance infractions. In such cases, BRS immediately implements procedures to bring the company or institution 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 (IES) for further investigation. BRS refers to infractions as "violations" in cases where IES determines that a penalty for an infraction is warranted. BRS also works closely with other Federal agencies, including FDA and EPA, and the State departments of agriculture, to monitor compliance with regulations.

The developers conducting field tests are responsible for identifying and reporting potential compliance infractions. Many developers have compliance reporting programs as part of their operating procedures to comply with BRS regulations and ensure safe field testing. Between 1990 and 2001, developers self–reported more than 60 percent of the total number of compliance infractions examined by APHIS.

BRS ensures compliance with its permit conditions by performing frequent and thorough inspections and audits. Permitted field tests are inspected at least once, and plants engineered to produce pharmaceutical and industrial proteins are inspected up to seven times before, during, and after the field trial to verify that developers are carefully following the conditions set forth by BRS. These inspections are performed at critical times during field testing, including preplanting, flowering times, harvesting, postharvest, etc. Through rigorous inspection and enforcement activities, BRS is ensuring that products are safely developed in a way that protects agriculture and the environment.

Additional Information

To apply for a permit to introduce a GE organism, please contact BRS' regulatory division at (301) 734–5715.

For more information on BRS, please visit the program's Web site at <http://www.aphis.usda.gov/brs>. There you will find the latest information on BRS, its regulations, answers to frequently asked questions, and links to databases with every introduction of a GE plant in the United States.

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