BRS Factsheet

Biotechnology Regulatory Services

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

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APHIS Biotechnology: Permitting Progress Into Tomorrow

Under the authority of the Plant Protection Act, APHIS' Biotechnology Regulatory Services (BRS) regulates the introduction of GE organisms in the United States.

Genetically engineered (GE) organisms are big news—corn that resist attacks by insect pests, papayas that are resistant to viruses, and bananas that might one day carry vaccines to developing countries are all made possible by the science of biotechnology. Newspapers and magazines regularly announce the latest advancements in the great biotechnology race. While many products are already on the market, many more are being developed and tested every day. As this technology rapidly advances, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is right there to ensure that the GE organisms being created today do not pose a risk to plants and the environment tomorrow. APHIS works to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms.

GE Organisms

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. GE crops that can tolerate herbicides, resist insects or viruses, or produce modified fruit or flowers are just a few examples of crops currently being grown and tested. Many of these crops have been deregulated by APHIS and have also completed the required reviews from the Environmental Protection Agency and the Food and Drug Administration. Significant acreages of these crops are safely being grown by farmers today. In 2004, 40 percent of the corn, 81 percent of the soybeans, and 73 percent of the cotton grown in the United States were genetically engineered.

As technology advances, developers continue to introduce new types of traits. Some crops under development are not intended for food or feed. For example, crops are being engineered to produce compounds that will have pharmaceutical and industrial uses.

USDA Regulation of GE Organisms

APHIS is responsible for protecting U.S. agriculture from pests and diseases. Under the authority of the Plant Protection Act, APHIS' Biotechnology Regulatory Services (BRS) regulates the introduction of GE organisms in the United States. BRS refers to these organisms as regulated articles. Regulated articles are organisms that have been altered by or produced through genetic engineering and have the potential to be plant pests. Introduction includes any movement into (import) or through (interstate) the United States, or release into the environment that is outside an area of physical confinement. A plant pest is an organism that poses a direct or indirect risk to other plants or plant products. The term is generally applied to insects and diseases, but in the case of USDA biotechnology regulation, it is applied to GE organisms that have the potential to be plant pests. The resulting GE organisms are not necessarily plant pests; however, the review process that would demonstrate they are not plant pests has not been completed.

APHIS regulations provide a list of the organisms regarded as plant pests so applicants know if the organism they are developing is a plant pest. If the organism being engineered is on the list, then the engineered product will be considered to be a potential plant pest until determined otherwise. If DNA from any organism on the list was used to produce the GE organism,

the GE organism will be regarded as a potential plant pest even if the parental organism is not.

Two common examples of APHIS' regulations being invoked due to use of DNA in the engineering process are plants that contain small fragments of DNA from plant pests to control expression of new traits; and plants which contain DNA from specific plant viruses that cause the plant to be resistant to that same virus. Even if the original organism itself is not on the list and no DNA sequences from organisms on the list were used in the engineering, it still may be subject to APHIS regulations if it is an unclassified organism or if there is reason to believe that the resulting GE organism is or could be a plant pest.

APHIS exercises its regulatory authority through a system that includes both permits and notifications. A developer wishing to introduce a GE organism must obtain the necessary authorization before proceeding. Applicants must submit all plans for movement, importation, or field testing for thorough review by BRS' regulatory scientists. Depending on the nature of the GE crop, an applicant files either a notification or a permit application for APHIS review. With a notification, developers must adhere to specific criteria and established performance standards. For a permit application, BRS' scientists evaluate any potential plant pest risks posed by the organism and the procedures that the developer will use for introduction of the regulated article.

The Permit Process

APHIS–BRS conducts a more comprehensive review of permit applications if they are used for GE plants that could have an elevated risk, such as plants that produce pharmaceutical or industrial compounds, as well as for any GE organism other than plants. Applicants must obtain permits for field testing or movement of these GE organisms.

To apply for a permit, applicants must complete a detailed form (APHIS Form 2000) that can be found on the USDA–APHIS Web site at <http://www.aphis.usda.gov/brs/pdf/2000.pdf>. This application requires more-detailed information than a notification application, including a detailed description of how the developer will perform a field test or move the GE organism. BRS often works with applicants on field-test design protocols and may impose additional measures to ensure confinement as part of supplemental permit conditions. If portions of the application contain trade secrets or confidential business information (CBI), applicants submit two versions of the application: one with CBI marked and included and one with CBI marked and redacted. The CBI-redacted version is the edited version that is circulated for review by officials outside APHIS, such as State departments of agriculture.

Permit for Field Testing

On APHIS Form 2000, applicants must provide complete information about the plant, including all new genes and new gene products, their origin, the purpose of the test, the experimental design (how the test will be conducted), and precautions to be taken to prevent the escape of the regulated article from the field-test site.

These special precautions routinely include transporting the plants to the field-test site in enclosed containers and thoroughly cleaning test-plot equipment before and after use. Depending on the plant being field-tested, cross-pollination may be blocked by bagging the flowers, growing crops in cages that keep insects from carrying pollen out, removing the plants' reproductive structures, or physically isolating the plants from sexually compatible crops through mandatory separation distances. After harvest, any remaining vegetative material in a field-test site is allowed to dry down in the field, followed by cultivation to incorporate remaining plant parts into the soil. Test sites are monitored for a period of time that varies depending upon crop biology to prevent volunteer plants from germinating. Any unplanned and unwanted plants that sprout are destroyed.

When a permit application is submitted, APHIS–BRS personnel review the permit

application for completeness and assign it to a scientific reviewer who evaluates the proposed field test. APHIS–BRS also contacts State agricultural officials where the field test is proposed, to get their input. As part of the review process for some permits, BRS prepares an environmental assessment (EA), which is a document that analyzes any possible impacts the field test could have on the environment. The EA can be required by the National Environmental Policy Act, Council on Environmental Quality regulations, and USDA procedures. One permit application can cover field tests in more than one State. BRS personnel take into consideration the scope and size of a field test when they prepare an EA.

BRS has 120 days to send written approval or denial of a permit application to the applicant. All field tests are subject to inspection, and certain field tests are always inspected. The number and scope of inspections vary depending upon the type of product being tested. For example, there are up to seven inspections conducted before, during and after the growing season of GE plants that produce pharmaceutical compounds.

Permit for Movement or Importation

Applicants must also apply for permits for movement or importation of a regulated article. Permit applicants must provide APHIS with details about the nature of the organism, its origin, confinement measures, and intended use. As part of this process, APHIS requests concurrence of individual State departments of agriculture prior to granting permission for movement of any GE organism. APHIS and State officials also inspect the facility that will receive the organism to ensure that it will not be accidentally released into the environment. In addition, the inspectors will evaluate facilities, personnel, security, and operational procedures of laboratories, growth chambers, and greenhouses to ensure that National Institutes of Health guidelines for good laboratory practices are being followed.

BRS has 60 days to process movement permit applications. 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. In the case of the importation of a GE crop, an applicant must submit an application for each shipment of regulated articles.

The Notification Process: A Streamlined Alternative to the Permit, for Qualifying Plants

Most plants are field-tested under notification, a streamlined process that takes up to 30 days for a decision. Notifications are often used for GE plants that are altered to be pest resistant or herbicide tolerant. Applicants may use the notification process only for certain crops that meet all six 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.

Applicants must sign a statement indicating that they will conduct the test in a manner that meets the performance standards listed in the APHIS regulations. As part of the notification process, BRS requires that applicants provide 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 eligibility criteria for a notification, researchers must submit an application for

a permit for BRS to consider allowing a field test. CBI information for notifications is handled in the same manner as described above for permits.

Petition for Nonregulatory Status

After a GE crop has been field-tested extensively and the developer can show that the product does not pose a plant pest risk and can safely be removed from BRS oversight, the developer may file a petition for deregulation, or nonregulatory status. APHIS reviews the petition for completeness and often asks for additional data. Once sufficient data have been received, the petition is deemed complete. From this point, APHIS has up to 180 days to either approve or deny an application. After review of the complete data, BRS prepares an EA to analyze the potential impacts the crop may have on the environment and seeks public comment.

BRS makes a determination of nonregulatory status for a petition only when it can conclude that the organism does not pose a plant pest risk and reaches a finding of no significant impact (FONSI).

BRS publishes *Federal Register* notices to notify the public about a 60-day comment period for the EA and the petition itself. BRS then posts the EA and the petition on its Web site for public viewing.

BRS makes a determination of nonregulatory status for a petition only when it can conclude that the organism does not pose a plant pest risk and reaches a finding of no significant impact (FONSI). Once BRS has granted a product nonregulatory status, the product may be freely moved and planted without the requirement of permits or other regulatory oversight by BRS. Following USDA deregulation, these products are often commercialized after completing the reviews required by other Federal agencies. 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, and deregulated products have an established history of safe use in U.S. agriculture.

Additional Information

For more information about the permitting of GE organisms, contact
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or visit the BRS Web site at

http://www.aphis.usda.gov/brs.

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