BRS Factsheet

Biotechnology Regulatory Services

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

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USDA's Biotechnology Notification Process

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), through its Biotechnology Regulatory Services (BRS) program, is responsible for regulating the introduction (importation, interstate movement, and field release) of genetically engineered (GE) organisms such as plants, insects, micro-organisms, and any other organism that is known to, or could be, a plant pest. Through a strong regulatory framework, APHIS, under the authority of the Plant Protection Act, thoroughly evaluates GE organisms to verify that they are just as safe for agriculture and the environment as traditionally bred crop varieties, which have been the cornerstone of American agriculture.

Notification is an expedited permitting process for GE plants that BRS considers to be lower risk and has extensive experience regulating in the past.

In regulating biotechnology, APHIS' BRS works in concert with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), which play important roles in protecting food safety and the environment. BRS is committed to the continual development of a regulatory framework that reflects the latest science and research, while continuing to protect America's agriculture.

BRS regulates the introduction of GE organisms through two processes: permitting and notification. Notification is an expedited permitting process for GE plants that BRS considers to be lower risk and has extensive experience regulating in the past. Examples of these GE plants include those altered for pest resistance, herbicide tolerance, and agronomic properties, such as male sterility, and product quality, such as delayed fruit ripening.

To qualify for the notification process, the GE plant must meet six eligibility requirements that are related to safety and primarily centered on the new variety's potential to pose a plant pest risk. The GE plant must also be introduced in accordance with BRS' specified performance standards to ensure confinement of the regulated material. These eligibility requirements and performance standards are detailed below.

In order to process the notification, BRS requires 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. BRS must receive notification from an applicant wishing to introduce a GE plant at least 10 days before the interstate movement of the organism to allow for review and processing. The program requires 30 days to review and process notifications for field testing or importation of GE plants. This timeframe is necessary to allow BRS employees time to review the notification and to obtain concurrence from State counterparts. Detailed follow–up reports are also required for field testing under notification, just as they are under the permitting process.

First introduced in 1993, the notification process covers only those GE plants that meet BRS eligibility criteria and performance standards. Introductions of GE plants engineered to express pharmaceuticals or new industrial compounds not intended for food or feed are not eligible for notification. If a GE plant does not meet notification eligibility criteria, the permit process must be followed for movement, importation, or field testing.

Eligibility Requirements for Notification

Any GE organism introduced under the notification process must meet all six eligibility criteria. BRS designed these criteria to ensure that the GE material being introduced is low risk. The criteria are as follows:

- The plant must not be listed on the Federal Noxious Weed list or be

considered a weed in the area of proposed release.

- The introduced genetic material must be stably integrated, which means the introduced DNA must remain inside the cell and replicate only with the plant DNA.
- The function of the introduced genetic material is known, and its presence in the regulated article does not result in a plant disease.
- The introduced genetic material does not cause the production of an infectious entity, produce substances that are known to be, or are likely to be, toxic to nontarget organisms, or produce products intended for pharmaceutical or industrial use.
- The introduced genetic sequences derived from plant viruses do not pose a significant risk of creating a new plant virus. For information on eligible plant virus–derived sequences, please contact BRS.
- The plant has not been modified to contain certain genetic material derived from an animal or human pathogens. In addition, plants containing coding sequences whose products are known agents of diseases in humans or nontarget animals are not eligible.

BRS requires companies or institutions utilizing the notification process to adhere to six performance standards that ensure complete confinement of the GE material.

Performance Standards for Notification

BRS requires companies or institutions utilizing the notification process to adhere to six performance standards that ensure complete confinement of the GE material. The goal of these standards is to manage the regulated article so that neither it nor its offspring is released into, or persists in, the environment.

The six performance standards are as follows:

- The introduced regulated article must be shipped to and maintained at the destination facility in a manner so that there is no release into the environment. There must be no inadvertent mixing of regulated articles and nonregulated articles.
- The regulated plant material should be maintained in such a way that the identity of all material is known. When the tests are complete, the plant material must be contained or killed.
- When the transformation process uses a live microorganism as a vector to introduce the genetic construct, the transformed plant should be free of the micro-organism before movement or introduction into the environment.
- The regulated article or its offspring cannot persist in the environment.
- No viable plant material (e.g. seeds or propagules) shall remain that is likely to germinate and create new plants known as volunteers. Any volunteers that do appear must be destroyed to prevent persistence in the environment.

Additional Information

For more information about the notification process for the introduction of genetically engineered organisms, contact:

USDA, APHIS, BRS
4700 River Road, Unit 147
Riverdale, MD 20737
Telephone (301) 734–7324
or visit the APHIS
Web site at

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

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