

USDA's Biotechnology Deregulation 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 importation, movement, and field release of genetically engineered (GE) plants, insects, microorganisms, and any other organism that is known to, or could, be a plant pest.

APHIS' biotechnology regulations are designed to ensure that GE organisms, such as herbicide-tolerant cotton or virus-resistant papayas, do not pose a significant plant pest risk. BRS involvement begins when a person or organization wishes to import, move interstate, or field-test a GE plant, which is done under BRS' permitting and notification system.

After the permitting or notification process takes place and a company field tests a GE plant, they can choose to begin preparing for commercialization. To do this, a company must file a petition for the determination of nonregulated status with USDA, which means they feel the plant is not a plant pest and should no longer be regulated by USDA.

Petition for Determination of Nonregulated Status

The petition for deregulation must include:

- A description of the biology of the plant before it was genetically engineered and information necessary to identify it in the narrowest taxonomic grouping applicable.
- Relevant experimental data and publications.
- A detailed description of the differences in genotype between the GE plant and the original plant. This is to include all scientific, common or trade names, and all designations necessary to identify: the donor organism (where the new genetic material came from), the nature of the transformation system (how that genetic material was inserted), the inserted genetic material, and the GE plant. Information about the locations of the origin and processing of the plant, the donor organism, the original plant, vector organisms (if utilized), and any other regulated articles must be included.

- A detailed description of the phenotype of the GE plant. The known and potential differences from the original plant that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the original plant from which it was derived must be described. This description may include plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes or changes to plant metabolism, weediness of the GE plant, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on non-target organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information that APHIS requests. Any other information known to the petitioner that indicates that a GE plant may pose a greater plant pest risk than the original plant must also be included.
- Field test reports for all trials conducted under permit or notification procedures involving the GE plant. These reports must include the methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, and the environment.

APHIS BRS Receives a Petition

After receiving the petition for nonregulated status, BRS biotechnology experts review it to ensure that the petition is correct and contains all of the required information. If information is missing or BRS determines more information is needed, a letter will be sent to the petitioner. The requested information must be submitted before the petition can move forward.

A petitioner may supplement, amend, or withdraw a petition in writing without prior approval of BRS and without affecting resubmission at any time before BRS rules upon the petition.

After completing the review, BRS will publish in the *Federal Register* an environmental assessment along with a notice seeking comments from the public on the environmental assessment or the petition for a period of 60 days. All comments are welcome and will be considered in the final decision. Petitioners will be notified no later than 180 days after receipt of their completed petition that it has either been approved (whole or in part) or denied.

Post–Market Authority

After a petition for deregulated status has been approved, BRS no longer has authority over the item as it has been judged to pose no risk to plants. However, in the unlikely event that the item becomes a plant–pest risk in the future, BRS can re–regulate it and take any necessary action to protect America’s agricultural and natural resources.

Additional Information

For more information about the deregulation process contact:

USDA, APHIS, BRS
4700 River Road, Unit 98
Riverdale, MD 20737
or visit the APHIS Web site at
<http://www.aphis.usda.gov>

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