BRS Factsheet
Biotechnology Regulatory Services

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

February 2006

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, micro-organisms, and any other organism that is known to, or could, be a plant pest.

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In regulating biotechnology, BRS works in concert with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), which also play important roles in protecting agriculture, food safety, and the environment. BRS involvement begins when a person or organization wishes to import, move interstate, or field-test a GE plant, which is done under the program's permitting and notification system.

After several years of field testing and data collection, a company or researcher may choose to begin preparing for commercialization. At this point, an applicant typically files a petition for the determination of nonregulated status with USDA, which means they have gathered enough data to demonstrate the new crop variety is not a plant pest, poses no threat to agriculture or the environment, and should no longer be regulated by USDA. Depending on the product, reviews by FDA and EPA may also be required.

Petition for Determination of Nonregulated Status

The petition for deregulation must include:

- A description of the biology and taxonomy of the conventional plant variety that was used to produce the GE version.
- A detailed description of the differences in geno type between the GE plant and the original plant. The description must 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. 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 nontarget 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 BRS 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.

- Relevant experimental data and publications.
- 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, nontarget organisms, and the environment.

APHIS BRS Receives a Petition

After receiving the petition for nonregulated status, BRS scientists review it to ensure that the petition is correct and contains all of the required information. If any information is missing or BRS determines more information is needed, a letter will be sent to the petitioner. The requested information must be submitted, and the petition deemed complete, before the review of the petition can be finalized. Before BRS makes a determination on a petition for deregulation, an applicant may supplement, amend, or withdraw their application in writing at any time without prior approval of BRS and without affecting resubmission.

As part of the review process, BRS conducts an in-depth environmental assessment (EA), which fully evaluates the organism for deregulation and determines whether it can safely be released in the environment. The review is then published in the *Federal Register* along with a notice seeking public comments on the environmental assessment and the petition for a period of 60 days. All comments are welcome and will be considered in the final decision. Once the completed petition is received, BRS is required to process the petition for deregulation within 180 days. Based on the findings of the EA and the comments received from the public, BRS will either approve (in whole or in part) or deny the petition.

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 reregulate 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/brs/index.html

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