APHIS Factsheet

Biotechnology Regulatory Services July 2007

Programmatic Environmental Impact Statement

Biotechnology Regulatory Services (BRS), a program within the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), is responsible for regulating the introduction—meaning the importation, interstate movement, and environmental release—of genetically engineered (GE) organisms. The program is considering potential revisions to update its existing regulations in light of advances in science and technology as well as the knowledge and experience BRS' experts have gained through their work.

As part of the evaluation of its regulatory program, BRS has published a draft Environmental Impact Statement (EIS). The draft EIS is a crucial step in the regulatory revision process. The purpose of this process is to provide a detailed analysis of the regulatory alternatives that BRS is considering and allow for public input and comment. The draft EIS evaluates the environmental impacts of the current regulations and the potential environmental effects of the revisions under consideration. The National Environmental Policy Act (NEPA) guides Federal agencies on the integration of environmental and public considerations into their decisionmaking processes. During this process, BRS officials are closely following NEPA requirements, which ensure that environmental impacts of proposed actions and reasonable alternatives to those actions are considered.

In January 2004, BRS publicly announced it was beginning a review of its regulations and published a notice of intent to prepare an EIS. The notice identified potential issues and alternatives to be studied in the EIS and requested public comment to further shape the scope of the issues and alternatives. The comments received contributed to the issues that BRS officials are now considering.

Changes Under Consideration Regulatory Authority

BRS currently regulates GE organisms to ensure that they are not a plant pest and do not cause damage, injury, or disease to plants. BRS' authority comes from the Plant Protection Act (PPA) of 2000, which combines the authorities of several previous acts, including the Noxious Weed Act, the Federal Plant Pest Act, and the Plant Quarantine Act. BRS is considering revising its regulations to better utilize the broad regulatory authority of the PPA.

BRS is considering expanding its regulatory oversight to include the oversight of GE organisms that have the potential to be noxious weeds. This would increase BRS oversight of GE organisms that may damage crops and other plants to also include GE plants that may pose a broader array of risks to agriculture, the environment, and public health.

In addition, BRS is considering expanding its regulatory oversight to include the use of biological control organisms (organisms genetically engineered to control insect pests) and nonviable GE plant material originating from field tests. Nonviable materials, like plant stems and leaves that cannot propagate successfully, are not currently regulated by BRS because they have been regarded as an insignificant risk to plant health. In some circumstances, however, they may pose other types of environmental risks.

BRS is also considering regulating nonviable GE material when there is reason to believe that such material might be harmful to the environment if it were allowed to remain, or when there is a violation of regulations or permit conditions that create the potential for the nonviable material to pose a risk.

Multi-Tiered Permitting System

BRS currently regulates GE organisms through a two-tiered system that includes notifications and permits. BRS uses notifications as an expedited permitting process for GE plants it considers to be lower risk and has extensive experience regulating in the past. BRS requires permits for any GE introductions that are not covered under notifications. Permits are generally more restrictive than notifications and are used for any GE organism that is not a plant, as well as for GE plants that could pose an elevated risk to plant health, such as plants engineered to produce pharmaceutical or industrial compounds.

BRS is considering establishing an expanded, tiered permitting system based on potential environmental risk and familiarity. The new tiered system would increase transparency with respect to how the agency intends to handle various types of GE organisms and would allow for the movement of GE organisms among the tiers as new information becomes available. The degree of confinement and oversight would be risk-proportionate and vary by tier. For instance, BRS would continue to use a system similar

to the current notification process for more familiar, low-risk GE organisms. These organisms would be introduced under the least restrictive tier "permit." BRS would require additional confinement and oversight measures for less familiar organisms or those with the potential to pose elevated risks. Additional tiers could be established to accommodate:

- Plants with higher plant pest or noxious weed potential;
- Plants engineered to express traits with which BRS is less familiar, such as plants that produce pharmaceutical or industrial compounds; and
- Plants engineered to express traits that are likely to pose a hazard to human health and the environment. For example, plants engineered to remove heavy metals from contaminated soil could pose a potential hazard if metals accumulate in the plant.

Nonregulated Status

Developers of GE organisms can petition BRS for a determination of nonregulated status. BRS does not currently place any restrictions or requirements on the use of GE organisms that have been granted nonregulated status. Organisms are granted nonregulated status, or deregulated, if BRS officials determine that they do not pose a risk to plant health.

As indicated in the draft EIS, BRS is considering developing an alternative process through which GE organisms could either be fully deregulated and removed from agency oversight, or could be granted conditional approval and be retained under some degree of oversight. This would accommodate commercialization while continuing, in some cases, to regulate the organisms based on minor unresolved risks to plant health.

GE Plants that Produce Pharmaceutical and Industrial Compounds

BRS is also considering proposing a more efficient but equally rigorous regulatory process for the commercial production of plants that produce pharmaceutical or industrial compounds. To date, no GE plants that produce pharmaceutical or industrial compounds have been deregulated. It is common for GE plants that produce pharmaceutical or industrial compounds for commercial purposes to be grown under permits, even though BRS' permit process was designed for the introduction—not commercial production—of GE plants. As a result, BRS repeatedly reviews full permit applications for these crops each year, even when the locations and protocols have not changed.

The new tiered system would provide continued rigorous oversight of GE plants that produce pharmaceutical and industrial compounds through multiyear permits, and would incorporate intensive reviews of standard operating procedures, audits, and inspections to protect the environment. The new system would result in BRS increasing the efficiency and transparency of its regulatory efforts.

Plants engineered to produce pharmaceutical and industrial compounds are presently grown under highly stringent conditions and with considerable oversight. In 2003, BRS published two *Federal Register* notices announcing more rigorous permit conditions for field testing of plants engineered to produce pharmaceutical or industrial compounds. These regulatory policy changes resulted in stricter confinement measures and greater oversight.

As noted in the EIS, BRS is considering maintaining its current strict oversight for the field testing of food or feed crops engineered to produce pharmaceutical or industrial compounds. BRS would consider the food safety of the new substance in determining appropriate confinement measures.

Low-Level Presence of Regulated GE Products

Plant breeding programs frequently work to develop and test several plant varieties simultaneously. As they develop new varieties, plant breeders go to great lengths to prevent them from mixing. Occasionally, however, with both conventionally bred plants as well as GE plants, low-level mixing may occur due to natural processes such as the movement of seeds or plant pollen, or human-mediated processes associated with field testing, plant breeding, or seed production. To prevent mixing and minimize low-level presence (LLP)—the occurrence of low levels of regulated GE products in commercial seeds and grain—developers of GE plants must comply with all BRS regulations and permit conditions.

In 2007, BRS clarified its existing approach for handling LLP. Should LLP occur, BRS' current policy is to respond with actions appropriate to the level of risk determined by a scientific assessment and warranted by the facts in each case. For cases in which LLP poses no risk to plant health and the environment, BRS may take no remedial action. Such cases could include those involving a minimal-risk plant that qualifies for APHIS' notification process or if the GE plant is similar to another GE plant that has already been deregulated or shown not to be a plant pest.

Current regulations do not address or expressly allow for LLP. BRS is considering establishing a system under which regulated GE products must meet pre-established safety criteria in order for APHIS not to take remedial action if LLP occurs. A product's ability to meet or not meet the safety criteria would determine the requirements under which it must be field tested.

Products not meeting the safety criteria would require more stringent confinement standards and be regulated in such a way that makes it highly unlikely that they would ever occur in commerce.

Importation and Movement of GE Organisms

BRS regulates the importation of new GE organisms. BRS currently handles requests involving the importation of low-risk GE organisms intended for nonpropagative use—that is, for food, feed, or processing—on a case-by-case basis. BRS anticipates that the number of importation requests will increase. The current system of permits and notifications does not have a separate process for reviewing (or exempting from review) low-risk products.

BRS is considering developing a new regulatory mechanism to allow for imports of commodities that are for nonpropagative use and that have not been deregulated by BRS in the United States. BRS would establish criteria to ensure safety and to allow for additional environmental review with the aim of protecting U.S. agriculture and human health without creating unnecessary trade barriers. Allowing such imports would not preclude the need for importers to comply with the requirements of other Federal agencies, such as the Food and Drug Administration and the Environmental Protection Agency.

BRS also oversees the interstate movement of regulated GE organisms by enforcing interstate movement requirements. Currently, only GE varieties of the species *Arabidopsis thaliana*, a small flowering plant related to cabbage and mustard, are exempt from interstate movement requirements because they are well understood, extensively used in research, and are not a plant pest.

As noted in the EIS, BRS is considering similarly exempting those GE organisms that are among the most well-studied and familiar GE organisms from the requirement of a permit for interstate movement. Exemptions would apply only to those organisms within a tier of organisms meeting specific safety-based criteria. Shippers would notify BRS that they plan to ship the organisms. No agency response would be required.

Whether being shipped interstate or arriving as import material, all GE material regulated under permits must be shipped in specified containers. BRS has a list of approved containers and issues variances for the use of other suitable containers when appropriate. BRS plans to continue regulating the types of containers used to ensure the safe shipping of GE organisms. However, as indicated in the EIS, BRS is considering proposing the use of performance-based standards for all shipping containers for regulated GE material. Numerous types of appropriate containers could meet given safety standards, namely that the containers prevent escape, dissemination, or environmental persistence of the GE material.

Next Steps

BRS is committed to ensuring that its regulations will be robust enough to meet the demands of biotechnology. BRS is seeking to create rigorous, consistent, and easily understood regulations that are based on science. These regulations must be effective, flexible, and impose a degree of oversight proportionate to the potential risks.

BRS' goals are to improve its regulatory system through new practices that will enhance environmental safety, increase public confidence, and make more efficient use of resources while maintaining scientific integrity, reducing the regulatory burden, and increasing transparency to the public.

A draft EIS is one step in the regulatory revision process, forming the basis of any new regulations which BRS will propose. The information and proposed changes under consideration in the draft EIS will assist BRS in making an informed decision regarding regulatory and policy changes and will help define the rationale for recommended changes. In addition to the draft EIS, BRS will use public comments and the latest scientific information to formulate new proposed regulations (a proposed rule). A final EIS will be prepared that addresses public comments responding to the draft EIS.

Any future proposed rule which results from these efforts will take into account deliberations recorded in the draft EIS, as well as the public responses to the draft EIS, and will be reviewed by other Federal agencies. Under the Federal rulemaking process, a notice of availability for a proposed rule would also be published in the *Federal Register* with a public comment period to follow.