APHIS Factsheet

Biotechnology Regulatory Services October 2008

Questions and Answers: Proposed Revisions to Biotechnology Regulations

Biotechnology Regulatory Services (BRS), a program within the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), regulates the importation, interstate movement, and environmental release of certain genetically engineered (GE) organisms. APHIS has prepared a proposed rule that outlines potential revisions to its existing regulations for certain GE organisms and is seeking comments from the public, including U.S. and international stakeholders.

Q. Why is APHIS considering revisions to its regulations?

A. APHIS is considering the regulatory changes in order to stay ahead of current and future advances in technology. While APHIS' current regulations are effective in ensuring the safe introduction of certain GE organisms, the complexity and scope of biotechnology in the United States is increasing and new GE organisms are being rapidly developed. New regulations will allow APHIS to keep pace with the changes in technology and ensure that new GE products are safely developed and field tested in the years to come.

Q. What types of changes is APHIS considering in the proposed rule?

A. Proposed revisions include aligning the regulations with plant pest and noxious weed provisions of the Plant Protection Act (PPA) of 2000. Under the PPA, plant pests include certain organisms that may damage plants or plant products; noxious weeds include plants that may pose a broader array of harm to plants, animals, agriculture, the environment, and public health.

Under the proposed rule, APHIS would regulate certain GE plants as well as certain GE nonplant, nonvertebrate organisms if they could pose a plant pest or noxious weed risk, or if the APHIS Administrator determines they pose a plant pest or noxious weed risk. Revising the regulations will ensure appropriate oversight of GE organisms that could pose a plant pest or noxious weed risk as technology advances.

APHIS is also proposing additional changes, including a multiple-category permitting system based potential plant pest or noxious weed risks. With the proposed permitting system, APHIS would assign the environmental releases of certain GE organisms into administrative categories based upon the most important risk-related factors. The categories would contain the general type of releases of GE organisms grouped by broadly similar plant pest or noxious weed risks and management issues.

Q. Will this be the first time APHIS has revised its biotechnology regulations?

A. APHIS' biotechnology regulations have been revised several times to increase efficiency and to accommodate new technological trends. This is, however, the most comprehensive review and revision of the regulations since they were established in 1987.

Past changes to APHIS' biotechnology regulations include:

- In 1988 and 1990, APHIS established conditional exemptions from the requirement for interstate movement permits for certain GE microorganisms and one GE plant species used in plant genetics research
- In 1993, APHIS wrote regulations to establish a petition procedure for the agency to grant nonregulated status for GE organisms. When granted nonregulated status, a GE organism is removed from all obligations under APHIS' biotechnology regulations
- Also in 1993, APHIS introduced the notification procedure as a streamlined process for the introduction of familiar crops and traits considered to be low risk. In 1997, APHIS updated the eligibility requirements for field testing under notifications.
- In 1997, APHIS amended the regulations to provide for an "extension" of a nonregulated status—a streamlined procedure that allows the agency to extend nonregulated status to a new GE organism if it is very similar to a previously deregulated GE variety.
- In 2005, APHIS issued an interim rule to require permits, rather than notifications, for the field test ing of plants engineered to produce industrial compounds.

APHIS also made other changes to its policies and administrative practices that did not involve regulatory revisions. For example, APHIS has imposed more stringent permit conditions for field tests of plants engineered to produce pharmaceutical or industrial compounds, as well as increasing the inspection frequency

of such tests. Over the past 5 years, the adoption and subsequent expansion of the program's electronic permitting system has enabled applicants and APHIS to achieve greater efficiencies.

Q. Is this the first opportunity to comment on the rulemaking process?

A. No. The public is a key partner in the decision-making process, and APHIS has worked hard to ensure that this rulemaking process is transparent and that it offers ample opportunities for public input. In 2004, APHIS issued a notice of intent (NOI) to publish an environmental impact statement (EIS). The NOI asked for specific feedback from the public, and APHIS held 23 meetings with stakeholders to gain input.

APHIS again sought public input in July 2007 following the publication of the draft environmental impact statement (EIS). APHIS received more than 23,000 comments on the draft EIS and held public meetings at three locations in the United States during the comment period. The comments were an important part of the rulemaking process and were used to inform APHIS about issues that the public believed needed to be addressed by the rulemaking. APHIS evaluated these comments and used them to help refine and reorganize some of the regulatory aspects of the proposed rule.

Additionally, APHIS is now seeking public comment on its proposed rule to update its regulations and plans to hold three public meetings in order to provide the public the opportunity to comment on the proposed rule.

Q. Will USDA notify the World Trade Organization (WTO) Sanitary and Phytosanitary Measures (SPS) Committee about the proposed rule?

A. Yes. Under the WTO Agreement on the Application of SPS, the WTO SPS Committee is to be notified—for the purpose of providing comment—concerning those measures that may directly or indirectly affect international trade.

Q. What is an EIS?

A. An EIS is a detailed and comprehensive analysis that identifies and evaluates the potential environmental impacts of a proposed government action. An EIS that addresses the impacts of an entire agency program rather than of a specific project is referred to as a programmatic EIS.

APHIS' draft programmatic EIS for the proposed rule outlined suggestions for revisions to APHIS' biotechnology regulations and addressed environmental issues associated with the current regulations and the suggested regulatory changes. APHIS used the information and alternatives contained in the draft EIS to form the basis of the new proposed regulations.

APHIS will also prepare a final EIS that includes summaries of public comments on the draft EIS and that considers the environmental impacts associated with the final rule. The draft EIS published by APHIS is a part of the normal rulemaking process for the programmatic approach to the regulatory revisions APHIS is considering.

Q. Was this the first EIS that APHIS prepared related to biotechnology?

A. This is the first EIS that APHIS has prepared for potential revisions to its biotechnology regulations. APHIS is also conducting two additional EISs. Those EISs, however, are not for regulatory revisions but are for petitions to deregulate Roundup Ready (RR) creeping bentgrass and RR alfalfa.

Q. How does this proposed rule build on the existing APHIS low-level presence policy?

A. APHIS' current regulations have no explicit provisions for the low-level presence (LLP) of regulated GE plants and materials when mixed into commercial grain or seed.

In 2007, APHIS outlined its policy for responding to LLP incidents. The agency policy is to respond with actions appropriate to the level of risk, determined by a scientific evaluation and warranted by the facts in each case when LLP occurs. In cases where LLP poses no risk to plant health and the environment, APHIS may decide not to take any remedial action for an unauthorized release into the environment of a regulated GE organism.

The proposed rule builds on this existing policy and places the new provision directly within the regulations. As described in the proposed rule, APHIS is proposing to evaluate specific factors associated with the occurrence of low levels of GE plant materials in grain or seeds that would support its decision not to order LLP remedial action. APHIS also lists criteria and outlines possible enforcement actions in the proposed regulations to improve transparency regarding how the program would respond to LLP in most instances.

Q. How do revisions in this proposed draft address imports of GE organisms and food and feed derived from GE crops?

A. Conditional exemptions could be used, for example, for the importation of certain GE commodities. A person could petition for an exemption from importation and interstate movement permits for shipments of a particular GE commodity grain under the condition that the grain is not grown, but will only be moved for direct use as food, feed, or for processing.

The proposed rule's procedure for approving new exemptions would be sufficiently adaptable to allow the approval of exemptions for the shipment of

certain GE commodities that would take into account any conditions necessary to make it unlikely to result in the introduction and dissemination of plant pests or noxious weeds.

Q. When could new regulations be in place? What are the next steps?

A. Prior to finalizing any new biotechnology regulations, APHIS will carefully review all comments received concerning the proposed changes. Additionally, APHIS will prepare a final EIS that includes a consideration of the environmental impacts associated with the final rule and a summary of public comments received in response to the draft EIS.

Q. How is the new rule going to be more transparent?

A. The proposed regulations offer added transparency by providing greater detail about how the permitting procedure works. This includes more detailed descriptions of the information needed when applying for a permit and a more detailed description of the nature of permit conditions that permit holders can expect.

In the case of permit conditions for environmental release of GE plants, the regulations provide greater detail about the administrative practices APHIS uses prior to its scientific evaluations as well as the way that APHIS can customize permit conditions to suit the particular activity to be conducted under the permit.

Q. How will the new rule provide regulatory relief?

A. The new regulations have several mechanisms to provide regulatory relief. One example is a new conditional exemption procedure, by which APHIS would keep certain GE organisms under the scope of the regulations (under APHIS regulatory oversight), but remove the need for a permit for certain types of actions. Conditional exemptions would include scientific reviews. Additionally, they would be approved only under conditions that ensure that the actions taken (such as transporting a GE organism interstate) are unlikely to result in the introduction or dissemination of a plant pest or noxious weed.

APHIS anticipates that the proposed exemption procedure would be more efficient than the current practice of amending the regulations every time a new conditional exemption is approved. To remain transparent, the proposed procedure would still provide opportunity for public comment.

Q. How will the new rule strengthen regulatory oversight?

A. The new rule will provide a detailed description of the regulatory requirements for permit holders that are not in the current regulations. This includes new reporting and recordkeeping requirements, requirements that field locations be identified with exact geographic coordinates, and the ability to impose binding conditions for all permits.

Currently, specific conditions are not attached to notifications. This is one reason why the notification procedure will not be part of the proposed regulations. Permits, however, will be required for the importation, interstate movement, and environmental release of GE organisms subject to the regulations.

Q. What do the proposed changes mean for GE organisms that have already been deregulated by APHIS?

A. The proposed regulation specifically states that prior determinations of nonregulated status would not be affected by the revision of the regulations. APHIS has determined that the previous deregulations are sufficiently consistent with the criteria that will be used to grant nonregulated status under the proposed regulations and therefore will continue to have deregulated status under the new regulations, without additional review.

Q. Is this proposed rule related to the recent request for information (RFI) on GE animals published in the *Federal Register* by APHIS on September 19, 2008?

A. No. The regulatory revisions that APHIS is considering under this proposed rule are separate from the RFI and would apply to GE plants, arthropods (such as insects), and other invertebrates that may pose a plant pest risk and GE plants that may pose a noxious weed risk. In the RFI, APHIS invited the public to comment on ongoing and future research, as well as the implications of importation and interstate movement, of GE animals.

Q. Is plant cloning considered genetic engineering?

A. No. Plant cloning, or vegetative reproduction, is not genetic engineering. This is an established, traditional technique for reproducing plants without the use of seed, such as when new plants are grown from cuttings taken from a parent plant. Genetic engineering occurs when recombinant-DNA techniques are used to introduce new traits into organisms.

Q. Where can I find a copy of the proposed regulations? How can I provide comments on the proposal?

A. A copy of the proposed rule is available at http://www.aphis.usda.gov. Comments can be submitted through the Internet or by postal or commercial delivery using the following instructions below. Consideration will be given to all comments received on or before November 24, 2008.

For postal mail or commercial delivery, please send two copies of written comments to:
Docket No. APHIS-2008-0023, Regulatory Analysis and Development, Policy and Program Development, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238. Please state in the body of your comment that it refers to Docket No. APHIS-2008-0023.

To submit comments using the Internet:
Go to the Federal eRulemaking portal at http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0023; then click on "Add Comments." This will also allow you to view public comments and related materials available electronically. Please do not use alternative means to send comments through the Internet. Using the Federal eRulemaking portal is the best way to ensure that your comments will be associated with the right docket and reviewed by the right people.

Q. Where will the public meetings be held?
A. The public meetings will be held in California, Missouri, and the Washington, D.C., area:

October. 28, 2008, from 4 p.m. to 7 p.m., local time
Walter A. Buehler Alumni & Visitors Center, Alpha Gamma Rho Hall, University of California, Davis, CA 95616. For directions or facilities information, call (530) 754-9195 or visit http://www.alumnicenter.ucdavis.edu/

October. 30, 2008, from 4 p.m. to 7 p.m., local time
Hilton Kansas City Airport, Shawnee Room A, 8801 NW 112th Street, Kansas City, MO 64153. For directions or facilities information, call (816) 891-8900 or visit http://www.hiltonkci.com/

November. 13, 2008, from 4 p.m. to 7 p.m., local time
USDA Riverside, Oklahoma City Memorial Conference Rooms B, C, and D, 4700 River Road, Riverdale, MD 20737. For directions or facilities information, call (301) 734-8010.