

## Proposed Biotechnology Regulatory Revisions

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 importation, interstate movement, and environmental release of certain genetically engineered (GE) organisms. In light of advances in science and technology, APHIS is proposing revisions to its existing biotechnology regulations. The proposed changes are based on prior public input and BRS' extensive experience implementing the current regulations.

### Proposed Revisions

#### Scope of Regulation

APHIS currently regulates certain GE organisms—GE plants, GE arthropods (such as GE insects) and other GE invertebrates—to ensure that they are not a plant pest and do not cause damage, injury, or disease to plants. APHIS' authority comes from the Plant Protection Act (PPA) of 2000, which combined the authorities of several previous acts, including the Noxious Weed Act, the Federal Plant Pest Act, and the Plant Quarantine Act. APHIS is revising its regulations to make them more transparent and clearer concerning which GE organisms are subject to the agency's regulations. The revised regulations will also better utilize the agency's broad regulatory authority under the PPA.

To better align its biotechnology regulations with its authority under the PPA, APHIS is proposing to utilize and broaden its regulatory oversight of certain GE organisms that may damage crops and other plants (i.e., plant pests) to also include GE plants that may pose a broader array of risks to agriculture and the environment (i.e., noxious weeds).

Under the proposed regulations, APHIS would regulate the importation, interstate movement, and environmental release of certain GE plants as well as certain GE nonplant, nonvertebrate organisms if they could pose a plant pest or noxious weed risk, or if their risk as a plant pest or noxious weed is unknown.

APHIS is also proposing to expand its regulatory oversight to include the regulation of GE biological control macroorganisms, such as insects genetically engineered to control plant pests or noxious weeds. APHIS is not proposing, however, to regulate biological control *micro*organisms, such as bacteria and fungi,

which are already regulated by the Environmental Protection Agency.

In addition, APHIS is proposing to include non-viable GE plant material originating from field tests to the agency's oversight. Currently, nonviable materials, like plant stems and leaves that cannot propagate, are not regulated by APHIS.

### Revisions to Permit and Notification Procedures

Currently, APHIS regulates GE organisms within its authority using a two-tiered system that includes a notification and a permit procedure. APHIS is now proposing to remove the notification procedure and instead rely exclusively on a permit procedure for the importation, interstate movement, and environmental release of GE organisms subject to APHIS regulations.

APHIS had originally developed the current notification procedure as an expedited permitting process for GE plants that it considered to be lower risk and that the agency had had extensive experience regulating in the past. Under the current two-tiered system, APHIS requires permits for regulated activities that are not eligible for notification. As currently used, 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.

For environmental releases, APHIS is proposing to establish an expanded, multiple category permitting system (described below). For all permit applications, APHIS is providing greater detail in the proposed rule about the basic information requirements that would need to be addressed.

Also under the proposed rule, permit conditions—specific practices or requirements that an applicant must follow upon issuance of a permit—would be listed in a new, separate section of the regulations. Additionally, the proposed regulations clarify the procedure APHIS would use to amend permit conditions, transfer a permit to a different responsible person, and revoke an existing permit. In addition, APHIS is proposing to require that applicants agree, prior to permit issuance, to comply with all permit conditions.

### Proposed Permit Procedures for Environmental Releases

Under the proposed multiple category permitting system, GE organisms that share broadly similar plant pest or noxious weed risks and management issues would be sorted into the same category. APHIS is

providing details in the proposed rule regarding information requirements for these categories.

Under the proposed system, APHIS would do an initial sorting to assign environmental release requests into administrative categories based upon the most important risk-related factors. After the initial administrative sorting of proposed releases into a general category, a complete risk assessment would follow. This evaluation would be used as the basis for determining the specific category for a particular GE organism and the appropriate permit conditions prior to authorizing the release. The permit conditions and degree of oversight would be risk-proportionate and vary by category. APHIS would require additional oversight measures for less familiar organisms or those with the potential to pose elevated risks in more restrictive categories.

The new system would increase transparency with respect to how the agency intends to handle various types of GE organisms. It would also allow for greater flexibility by enabling the agency to re-categorize GE organisms as new information becomes available. These proposed changes would provide APHIS with more flexibility in setting risk-appropriate conditions for the environmental release of GE organisms that fall under the agency's regulations.

#### ***Nonregulated Status and Exemptions from Permit Requirements***

Other changes proposed by APHIS include a clarification of the deregulation process and the addition of a new process for determining "conditional exemptions." Under such exemptions, APHIS removes some but not all of the regulatory requirements for certain GE organisms. Conditional exemptions provide regulatory relief but retain APHIS' regulatory oversight over the specific GE organisms to which they apply

Current APHIS regulations include exemptions from the requirement for interstate movement permits for certain organisms, so long as they meet specific shipping requirements; however, such exemptions require the agency to amend the regulations every time a new conditional exemption is approved.

APHIS is proposing to retain the existing conditional exemptions for interstate movements, but is also proposing a new regulatory procedure that would enable APHIS to approve new conditional exemptions for interstate movements and importations more efficiently. This procedure would provide for a scientific review by APHIS as well as the opportunity for public review and comment on the proposed exemption.

In addition to these changes, APHIS is also proposing regulatory revisions concerning the granting of "nonregulated status" to GE organisms. Nonregulated status is granted to GE organisms that are no longer subject to APHIS' biotechnology regulations; GE organisms that receive this status do not require permits or any other APHIS oversight specifically related to genetic engineering.

The current regulations include a procedure for petitioning APHIS to grant nonregulated status to a GE organism. APHIS is proposing revisions that will clarify the petition procedure, the information requirements for petitions, and the standard used by APHIS' Administrator to determine whether a GE organism is approved for nonregulated status. APHIS is also proposing a regulatory procedure whereby the Administrator may revoke a previous approval of nonregulated status.

Under the proposed rule, prior determinations of nonregulated status would not be affected by the revision of the regulations; GE organisms that have been granted nonregulated status under the current regulations would continue to have nonregulated status under any new regulations without additional review.

#### ***Compliance, Enforcement, and Remedial Actions***

In recent years, APHIS has strengthened its biotechnology program in order to improve compliance with the regulations, to augment the approaches used to prevent or remediate potential risks to plant health, and to use appropriate enforcement strategies. The proposed rule clarifies the obligation for compliance with regulatory requirements, as well as the approaches available to APHIS to verify compliance.

The proposed rule includes requiring permit holders to establish and maintain records related to their permit, as well as requiring them to allow APHIS to review those records. This would improve APHIS' ability to conduct inspections and audit records related to regulated activities, and would also address specific biotechnology provisions in Section 10204 of Title X of the 2008 Farm Bill.

The proposed regulations also outline the possible consequences for not complying with the regulations. These include: denial of future permits; revocation of current permits; destruction, treatment, and removal of GE organisms; and issuance of penalties. Additionally, the proposed regulatory changes outline a means to settle alleged civil violations prior to the issuance of an administrative complaint.

#### ***Low-Level Presence (LLP) of Regulated GE Plants in Seed or Grain***

APHIS' current regulations have no explicit provisions for the low-level presence (LLP) of regulated materials when mixed into commercial crops, food, feed, or seed. In 2007, APHIS outlined its current LLP policy. The agency 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. In cases in which the occurrence of GE plant material poses no risk to plant health and the environment, APHIS can decide not to take any remedial action in reference to the unauthorized release.

APHIS is proposing to evaluate specific factors associated with the occurrence of low levels of

regulated GE plant materials in grain or seeds that would support its decision not to require remedial action. APHIS also outlines possible enforcement actions in the proposed regulations to improve transparency regarding how the program would respond to LLP in most instances.

### **Opportunity for Public Involvement**

APHIS is seeking public comment on the proposed rule, and will consider all comments received concerning the proposal before finalizing any regulatory changes. To provide interested individuals with the opportunity to submit comments in person, APHIS is scheduling three public meetings. The first will take place in California on October 28, 2008, followed by meetings in Missouri on October 30, 2008, and in the Washington, D.C., area on November 13, 2008. Specific meeting information is available in the *Federal Register* notice announcing the availability of the proposed rule at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0023>.

APHIS is committed to an open and transparent regulatory process that takes all comments into consideration and reflects the latest science, while continuing to protect America's agricultural and natural resources. APHIS publicly announced it was beginning a review of its regulations in January 2004, with the publication of a notice of intent to prepare an environmental impact statement (EIS). APHIS published a draft EIS for public comment in July 2007. The proposed rule was formulated based on information in the draft EIS, the latest scientific information and public comments.

### **Next Steps**

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.

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