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### **Issue 3: Elimination of Notification Procedure and Category-based Permitting System**

#### *I. Objective of the Proposal*

The goal of the Animal and Plant Health Inspection Service's (APHIS) proposed rule's changes to the notification and permitting procedures for authorizing importations, interstate movements, and releases into the environment of certain genetically engineered (GE) organisms is to provide more flexible, risk-appropriate oversight, better regulatory enforcement, and improved transparency. As a means to achieve this goal, APHIS proposed to authorize all importations, interstate movements, and environmental releases under the permitting procedure, thereby providing APHIS the flexibility to customize permit conditions (requirements) when needed. The current notification procedure does not provide such flexibility, because the required performance standards are built into the regulation itself. Additionally, performance standards can be difficult to interpret and enforce.

APHIS considers that the use of a permitting procedure will give the agency a way to address the recommendations of USDA's Office of Inspector General (OIG) and also certain provisions in the 2008 Farm Bill. OIG recommendations called on APHIS to require additional reports during the course of all environmental releases. The 2008 Farm Bill recommended additions to current recordkeeping and reporting requirements. Such recommendations can be implemented under the permitting procedure by imposing reports or recordkeeping requirements as permit conditions (current regulations do not allow APHIS to add conditions to notifications).

#### *II. Description of Significant Comments to Date*

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Some commenters supported the proposal, believing that eliminating notifications would increase APHIS oversight by requiring involvement by APHIS in tailoring specific conditions to individual field trials (environmental releases). Other commenters cited substantial shortcomings, including longer timeframes for APHIS action on applications, a lack of clarity about the information needed in applications, and vague descriptions of increased demands for reporting and recordkeeping.

Some commenters suggested that the increased regulatory burden of the proposal does not correspond to the low-risk nature of the majority of GE plants that APHIS has regulated under the notification procedure. Academic researchers commented that APHIS should make the existing notification procedure more streamlined, with fewer regulatory requirements in circumstances where APHIS has already seen that similar GE plants pose little or no risk as plant pests or noxious weeds. Some commenters were concerned that the categories for permits were not adequately based on risk and that the APHIS risk assessment procedure for permitting was not described adequately.

### *III. APHIS Current Thinking*

APHIS considers that the goal of more flexible, risk-appropriate oversight, better regulatory enforcement, and improved transparency can best be achieved by eliminating the notification procedure and by revising the permitting procedure in a way to provide regulatory oversight that is commensurate with the risk of introduction or dissemination of a plant pest or noxious weed. However, APHIS acknowledges the concern of many commenters that the proposed regulations need a clearer description regarding categories, permit conditions, and any other requirements associated with a category.

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APHIS also acknowledges the concern that the proposed regulations need to take into account how timely the system operates. Based on experience, APHIS considers that the timeframes needed for issuing a given permit will be based on the degree of APHIS familiarity with similar GE plants (i.e., familiar crops/traits will be reviewed in a similar timeframe as current notifications and other crops/traits will be reviewed in a similar timeframe as current permits). APHIS is still considering whether and to what extent such timeframes should be captured in the regulations.

APHIS considers that in certain cases, the proposed recordkeeping and reporting requirements could be a substantial increase for some permit holders, and APHIS is attempting to balance these burdens with the need for APHIS to have information available to verify compliance.

#### *IV. Issues for Further Discussion*

Comments related to the elimination of notifications and the proposed category-based permitting system raised a number of issues that APHIS will carefully consider and needs additional public input on, including:

- How can APHIS clarify in the regulations which GE organisms fall into each category? How can APHIS best revise the categories to make them more closely risk-based?
- How can APHIS better distinguish the regulatory consequences among the categories?

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- Other than the proposed category-based permitting approach, what other approaches might be considered to provide risk-appropriate oversight and better enforceability for environmental releases of GE plants under these regulations?
- What alternative approaches might be better suited to address and implement the recommendations in the OIG report and the 2008 Farm Bill for recordkeeping and reporting?