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Issue 4: Environmental Release Permit Categories and Regulation of Genetically Engineered Crops that Produce Pharmaceutical and Industrial Compounds

I. Objective of the Proposal

The goal of the Animal and Plant Health Inspection Service's (APHIS) proposed regulations, with respect to plants genetically engineered (GE) to produce pharmaceutical or industrial substances, is to devise a permitting system under which the agency can determine and enforce confinement measures for environmental releases that would be sufficient to ensure that such GE plants are unlikely to result in the introduction or dissemination of plant pests or noxious weeds. Such regulatory restrictions must be consistent with APHIS' application of its Plant Protection Act (PPA) plant pest and noxious weed authorities. APHIS believes that it must therefore treat GE plants or crops that produce pharmaceutical or industrial substances just like any other GE plant it regulates under the Part 340 regulations rather than attempt to treat them separately as a distinct class based solely on their intended use.

The proposed permitting system features a new category-based sorting system, in which GE plants are placed in categories based on risk of the plant and the trait, not on their intended use. Though the proposed system differs somewhat from the current one administratively, the controls that would be placed on environmental releases of GE crops that produce pharmaceutical or industrial substances may not actually differ from those applied under the current regulations. In a 2003 policy statement, APHIS laid out certain very strict confinement measures and stated that the agency would provide intense oversight of the activities for all GE crops that produce pharmaceutical or industrial substances. APHIS has followed the policy under its current regulations.

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As with the current regulations, the proposed regulations would allow for the issuance of environmental release permits for GE plants that produce pharmaceutical or industrial substances if APHIS determined that the release is unlikely to result in the introduction or dissemination of a plant pest or noxious weed. Confinement measures would be determined case-by-case and based on the risk posed by the particular environmental release. Neither the current nor the proposed regulations prohibits the environmental release of GE plant or crop species that are ordinarily used for food or feed production.

II. Description of Significant Comments to Date

APHIS received more comments on this issue than any other aspect of the proposed rule. The same issue also drew the most comments in the draft programmatic Environmental Impact Statement that was published in July 2007 prior to the proposed rule for the purpose of assessing the environmental impacts of various regulatory options.

Overwhelmingly, commenters stated their opposition to the use of genetically engineering food or feed crop species for producing pharmaceutical or industrial compounds in outdoor settings; commenters raised concerns about the potential for serious public health, environmental consequences, or—absent any health or environmental consequences—that serious market disruptions could occur.

Some commenters opposed growing any plants that produce pharmaceutical or industrial substances outdoors, regardless of whether or not the GE plant species is ordinarily used for the production of food or feed. Some commenters did not believe that any plants should be genetically engineered for this purpose at all, no matter where they were to be grown. Some of the commenters were quite brief and did not elaborate on the

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rationale for their opposition. Other commenters expressed opposition for moral or religious reasons, believing that it was simply wrong to be manipulating the genes of plants that have been traditionally used for food.

III. APHIS Current Thinking About Issues

Under the current regulations, APHIS' approach has been to issue permits for environmental releases of crops that produce pharmaceutical or industrial substances for food or feed crop species, as well as plant species that are not ordinarily used for food or feed. These permits include conditions with very strict confinement protocols that are aimed at preventing plants that produce pharmaceutical or industrial substances from being disseminated or becoming mixed with the food supply throughout the duration of the permit. APHIS considers that science supports this approach, and that this approach fully meets our mandate under the PPA.

APHIS realizes that the public comments have expressed legitimate marketing and public perception concerns, and the commenters have strongly urged APHIS to act on these concerns. However, the PPA does not provide authority for regulating an organism based solely upon such issues or factors. Therefore, APHIS cannot implement a regulation that is not based upon its clear statutory authority to regulate plant pests or noxious weeds.

IV. Issues for Further Discussion

Comments related to GE food and feed crops producing pharmaceutical compounds raised a number of issues that APHIS must consider:

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- How can APHIS communicate more effectively to the public that its authority under the PPA for plant pests and noxious weeds is focused on the properties of the GE plant as a potential plant pest or noxious weed rather than on other factors or issues outside of APHIS' statutory authorities (e.g., on the intended use of the GE plant or its products for industrial or pharmaceutical purposes)?
- Considering the sole authorities APHIS has under the PPA for plant pests and noxious weeds, what types of additional risk-based permit conditions should APHIS consider for environmental release permits for GE crops that produce pharmaceutical or industrial substances?
- In addressing the public concerns about crops that produce pharmaceutical or industrial substances, are there other mechanisms or processes outside of the authorities outlined in the PPA that merit discussion, and in what appropriate venues should such discussions take place?