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## **Issue 5: A Regulatory Policy for the Determination of Remediation in Low-Level Presence Instances**

### *I. Objective of the Proposal*

The goal of the Animal and Plant Health Inspection Service's (APHIS) proposed low-level presence (LLP) regulatory policy is to establish in the regulations an effective and transparent policy that describes the criteria APHIS will use when determining that a LLP event will or will not require remediation. LLP refers to the unintended mixing of small amounts of regulated genetically engineered (GE) materials which may occur in commercial seeds or grain.

APHIS made clear in the proposed rule that its LLP regulatory policy is safety-based, namely that APHIS will not allow commercial commodities or seeds with LLP GE material to be moved or distributed if they were likely to pose a plant pest or noxious weed risk pursuant to the Plant Protection Act. At the same time, the LLP regulatory policy does not necessarily require remediation, such as recalls, crop destruction, or movement restrictions, especially in cases where the LLP is unlikely to pose such risks. The LLP regulatory policy in the proposal was modeled on the agency's March 2007 LLP policy statement entitled "Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials," issued in a March 2007 *Federal Register* notice.

APHIS has found that during environmental releases of GE plants under permit, an inadvertent dispersal of GE plant materials may occasionally occur, resulting in the detection of such GE materials at low levels in commercial commodities and seeds. In making the decision on whether or not remedial action should be taken in response to such instances of LLP, APHIS has gained experience which it has used to devise a list of criteria. APHIS uses this criteria list when determining whether or not to take remedial action based upon the plant

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pest risk associated with the LLP incident. These criteria became the basis for the current policy.

In the proposal, that list of criteria has been augmented with new criteria to also take into account whether or not to take remedial action based both on plant pest risks and noxious weed risks. As with the March 2007 LLP policy statement, the LLP regulatory policy in the proposal gives the public an indication of when the agency is likely to take or not take remedial action in response to LLP incidents. Moreover, APHIS explained in the proposal that it retains the discretion to decide when to order or not to order corrective or remedial actions in all LLP situations, regardless of whether or not the LLP incident meets the actionable criteria listed in the regulations. Accordingly, APHIS is not predetermining a specific threshold level at which some remedial action may be required in any given LLP incident since it is APHIS' position that this remedial determination should always be made on a case-by-case basis.

Finally, any APHIS remedial decision for LLP instances is independent of and separate from any APHIS compliance or enforcement action that APHIS may take regarding that LLP incident. Some LLP situations may call for enforcement actions instead of or in addition to remedial actions. Therefore, for a given LLP incident, APHIS retains the discretion to take enforcement action measures and/or impose civil penalties for violations of the Part 340 regulations, even if remedial measures are not imposed for that LLP incident. As APHIS stated in its March 2007 LLP policy statement, in cases in which the agency determines that remedial action is not necessary to mitigate LLP of regulated GE plant material to protect plant health and the environment, APHIS is not precluded from taking enforcement action against a company or individual for violations of APHIS regulations.

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

Commenters responding to the LLP provision made several points.

Those who clearly opposed the policy made the following comments:

- There should be a zero tolerance for LLP of GE regulated material in commercial commodities and seeds.
- APHIS should consider the economic impacts of LLP to organic and/or conventional farmers who may not be able to market their non-GE crops containing LLP.
- APHIS should be aware of certain consumer market sensitivities to LLP and that many foreign countries impose restrictive market sanctions on commercial commodities with LLP.
- LLP incidents have resulted in significant market disruptions.
- Field trials should be designed to achieve strict containment of GE material.

Those not necessarily opposed to all aspects of the policy commented:

- There is no need to incorporate the LLP policy with its changes into the regulations. The agency only needs to update the 2007 LLP policy statement to reflect the addition of the noxious weed risk criteria.
- The LLP regulatory policy criteria in the proposal are focused on safety of the gene and protein and do not adequately take into account environmental effects or gene flow potentially resulting from the GE material mixing with the commercial commodity or seed.
- Agreed that the APHIS 2007 LLP policy should be incorporated into the rule and that violators would not be absolved from causing LLP incidents, but thought the

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agency should develop regulatory guidance that would prevent LLP from occurring.

- APHIS should establish tolerances for LLP.

### *III. APHIS Current Thinking*

APHIS believes that it is prudent to have its 2007 policy for LLP incorporated into the regulatory text of the Part 340 rule, with the modifications necessary to also incorporate APHIS' noxious weed authority. As explained in section I (Objective of the Proposal) above, APHIS has the discretion to decide when to order or not to order corrective or remedial actions in all LLP situations, regardless of whether or not the LLP incident meets the actionable criteria listed in the regulations. Moreover, APHIS is not predetermining a specific threshold level at which some remedial action may be required in any given LLP incident. Finally, any APHIS remedial decision for LLP instances is independent of and separate from any APHIS compliance or enforcement action that APHIS may take regarding that LLP incident.

### *IV. Issues for Further Discussion*

The comments on the LLP regulatory policy placed in the Part 340 regulations raised a number of issues that APHIS needs to carefully consider and likewise also needs the public's further input on, including:

- Currently APHIS provides LLP information to the public in the form of the policy statement and incident summary information on its Web site. In addition to including the proposed LLP provision in the regulation, are there other ways that APHIS might describe more clearly to the public about how it addresses LLP in the context of its regulations?

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- How can the criteria be revised to better accomplish APHIS' goal of deciding when to require remedial measures for LLP incidents?