

April 28, 2009

## **Issue 1: Scope of the Proposed Part 340 Regulations and Which GE Organisms Should Be Regulated.**

### *I. Objective of the Proposal*

The goal of APHIS' proposed revisions to the part 340 regulations with respect to the scope of its statutory authority to regulate certain GE organisms under the Plant Protection Act of 2000 (PPA) is to provide a clear description to the public of which GE organisms would be regulated by APHIS under 7 CFR 340 and which would not. Since the PPA only authorizes APHIS to regulate GE organisms that have the potential to be plant pests or noxious weeds, APHIS proposed a PPA regulatory scheme that would regulate those GE organisms which pose a plant pest or noxious weed risk.

To describe this regulatory scheme of regulating only those GE organisms that can pose a plant pest or noxious weed risk, the proposal listed "scope criteria" for determining whether a particular GE organism is likely to be a plant pest or noxious weed, and therefore should be regulated by APHIS. Moreover, applying the scope criteria listed in the proposal, those GE organisms which were unknown or uncharacterized would be also subject to the regulation until APHIS could make an initial evaluation whether APHIS did in fact have regulatory jurisdiction over those GE organisms since they were likely to pose plant pest or noxious weed risks. These plant pest or noxious weed scope criteria were intended to be sufficiently clear and definitive so that a developer of a particular GE organism would know whether their GE organism would fall within the scope of the regulations.

Recognizing that in a few cases, a person might be unsure if a particular GE organism might fall within the scope of the regulation, APHIS also proposed a way that a person could consult with APHIS in order to find out APHIS' initial evaluation of whether that specific GE organism did fall within the jurisdiction (scope) of APHIS' Part 340 regulations. Our objective was to make it clear that APHIS makes the final determination regarding which GE organisms fall within the scope of the regulation.

### *II. Description of Significant Comments Received To date.*

The description or characterization of the scope of the proposed regulations was one of the core topics raised by the comments. It was widely criticized by many stakeholders, including biotechnology developers as well as those generally opposed to the technology. Most commenters thought that there was a lack of clarity regarding the scope which was undesirable and undermined the effectiveness and goals of the regulatory scheme. Those groups that were generally opposed to allowing the use of genetically engineered plants or other host donors believed that it substantially weakened the agency's ability to regulate GE organisms and did not provide sufficient protections for adequate agency oversight. Many thought that the proposed scope made the regulatory scheme voluntary in the sense that it would be left to the developer of the GE organism to determine if it

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would be within the scope of the regulations. Even the regulated biotechnology industry believed that the lack of clarity and the presumed ability of the GE developer to independently evaluate the scope criteria to determine whether or not their GE organism would be regulated was not the appropriate regulatory scheme to have.

### *III. APHIS' Current Thinking*

APHIS believes that the scope of the regulations should be as unambiguous as possible. It must be made clear to the public that what falls under the jurisdiction and scope of the regulations is determined solely by APHIS. APHIS believes that the scope criteria which set out the perimeters of which GE organisms are likely to fall within the jurisdiction or the scope of the regulation may need to be refined and clarified. More lucid scope criteria will also reduce the number of GE organisms whose regulatory status may be ambiguous or unknown and also reinforce the essential fact that only the regulatory authority, namely APHIS, evaluates whether or not they should be or are subject to the Part 340 regulations. Most importantly, the scope of the regulation needs to accurately and definitively emphasize that APHIS' PPA authority currently only permits APHIS to regulate GE organisms in reference to their potential to pose plant pest and/or noxious weed risks.

### *IV. Issues for Further Discussion*

The comments on the scope of the regulations raised a number of issues that APHIS needs to carefully consider and needs the public's input on, including:

- What is the best way for APHIS to write clearer and less ambiguous scope criteria that define those GE organisms which will be subject to the Part 340 regulations?
- What is the best way to clearly explain and link the scope of the proposed regulatory scheme and APHIS' PPA authority which currently only permits APHIS to regulate GE organisms in reference to their potential to pose plant pest and/or noxious weed risks?
- How can the regulation better express and communicate that adherence to the regulation is not voluntary but mandatory since APHIS is the ultimate authority that evaluates whether a certain GE organism fall within the scope of its Part 340 regulations?
- Is there a better way to indicate or describe the regulatory status of GE organisms in cases where it is unclear whether they fall under the jurisdiction of the regulation and/or fit within the regulatory scope criteria?