

Monsanto Comments to APHIS
March 13, 2009 Scoping Meeting for Additional 340 Public Comment Period
March 20, 2009

Monsanto is providing these comments in response to the March 11, 2009 Federal Register notice (Vol. 74, No. 46, page 10501) requesting input on format and content for the April 2009 public meetings on the proposed 7 CFR 340 regulation revisions.

A. Scope of the Regulations

The proposed rule lays out a set of criteria (in §340.0 (b)) to delimit those GE organisms that are within the scope of the regulation based on their potential to be a plant pest or noxious weed. This set of criteria is accompanied by a section (§340.0 (b)(3)) encouraging developers of new GE organisms to consult with APHIS “to discuss how the criteria ...apply in the case of a particular GE organism.” Monsanto believes that this text, along with language in the preamble¹ (section III.A.1) improperly indicates that the developer has discretion in determining if a particular GE organism is subject to the regulations in this part.

APHIS should clarify if their intent is to regulate all genetically engineered organisms for importation, interstate movement, and release or allow the developer to self-determine if their product is regulated.

B. Tiered Permitting System

Elimination of the Notification System. In the preamble to the proposed rule (pg. 60016) APHIS cites various administrative reasons, such as ease of inspection and lack of specificity in compliance conditions, for eliminating the notification process. However, APHIS has also proposed to eliminate other elements of the notification process that were not identified as shortcomings, but instead were deemed to be integral to an effective regulatory permitting system.

APHIS should discuss why the agency proposed to eliminate the entire notification process (whether it continues to be called notifications or permits), instead of only modifying it to strengthen some of the administrative requirements.

Data Requirements for Permits. APHIS has proposed five categories for permits. Although the categories are based on risks, the data requirements for the applications are the same. Therefore, the data requirements for low risk or Category A permit are inappropriately burdensome and not commensurate with the risks or presumably, the conditions placed on the permit.

¹ “under the proposed regulation, the responsible person for a GE organism could correctly apply the criteria in 340.0 to determine whether the GE organism is subject to the regulations” 73FR 60011

APHIS should explain the rationale for having the same application data requirements for all permit categories.

Permit Conditions. In the preamble (pg. 60020) APHIS states that “The Administrator will assign the permit conditions in a manner that is commensurate with the risk of the individual proposed movement or release.” How the permit conditions differ between categories is unclear.

APHIS should discuss examples of permit conditions and how they differ between categories.

Transition Period for any Changes to the Regulations. A key element that was not discussed in the proposed rule was a reasonable and rational timetable for implementation of key provisions of the proposal, especially those related to the conduct of field trials.

APHIS should discuss how any changes to the permitting system would be transitioned to allow for changes in the e-permitting system by APHIS and the applicants.

C. Format for the Public Meeting

APHIS should use a format that allows for an open dialogue between APHIS and the public. At previous public meetings, APHIS used posters to display sections of the rule. This format, although useful to display the proposed rule, does not allow for APHIS to clarify their intent of specific sections in the proposed regulation or explain how the regulations would be implemented. One means for more open dialogue may be for a panel of APHIS personnel to field written comments from the audience and respond publicly during the open comment period. Any additional information, such as “white papers”, prepared by the agency should be made available to the public before the April public meetings. Such documents could serve as the foundation for further questions to APHIS.