Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. 03–031–2]

Environmental Impact Statement; Introduction of Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement and proposed scope of study.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service intends to prepare an environmental impact statement in connection with potential changes to the regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. This notice identifies potential issues and alternatives that will be studied in the environmental impact statement and requests public comment to further delineate the scope of the issues and alternatives.

DATES: We will consider all comments that we receive on or before March 23, 2004.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–031–2, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–031–2. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 03–031–2'' on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Ms. Stephanie Stephens, Environmental Services, PPD, APHIS, 4700 River Road Unit 149, Riverdale, MD 20737–1238; (301) 734–4836.

SUPPLEMENTARY INFORMATION: The Animal and Plant Health Inspection Service (APHIS) currently regulates the introduction (movement into the United States or interstate, or release into the environment) of genetically engineered organisms that may present a plant pest risk under 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests.'' The Agency is considering amending the regulations pertaining to introductions of genetically engineered plants and other genetically engineered organisms to, among other things, include genetically engineered organisms that may pose a noxious weed risk and genetically engineered biological control agents.

As used in this document, the term genetically engineered organisms means organisms that have been ''genetically engineered'' as defined in 7 CFR part 340 (*i.e.*, modified by recombinant DNA techniques).

Also, as used in this document, the following terms have the definitions given to them by the Plant Protection Act (7 U.S.C. 7701–7772):

Biological control organism: Any enemy, antagonist, or competitor used to control a plant pest or noxious weed.

Noxious weed: Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

Plant pest: Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

(A) A protozoan.
(B) A nonhuman animal.
(C) A parasitic plant.
(D) A bacterium.
(E) A fungus.
(F) A virus or viroid.
(G) An infectious agent or other pathogen.
(H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

APHIS recognizes that other Federal agencies also have authority to regulate genetically engineered organisms. For example, the Environmental Protection Agency (EPA) has authority over certain biological control agents. This notice only addresses changes to APHIS regulations. It is not intended to circumscribe, restrict, or otherwise preclude future actions taken under other Federal authorities.

Under the provisions of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), agencies must examine the potential environmental effects of proposed Federal actions and alternatives. We intend to prepare an environmental impact statement (EIS) in connection with the amendments being considered. This notice identifies potential issues and alternatives that we will study in the environmental impact statement and requests public comment to further delineate the issues and the scope of the alternatives.

We have identified two broad alternatives for study in the EIS.

- Take no action. This alternative contemplates no change in the existing regulations for genetically engineered organisms that pose a potential plant pest risk. It represents a baseline against which proposed revisions may be compared.
- Revise the regulations for introduction of genetically engineered organisms. This alternative contemplates revision of the current regulations to address issues related to scientific advances and new trends in

biotechnology (*e.g.*, increasing use of genetically engineered plants to produce pharmaceutical and industrial compounds) and changes in the scope of the Agency's authority under the Plant Protection Act (7 U.S.C. 7701 *et seq.*). The proposed revisions would be based in part upon environmental and pest risk criteria identified and analyzed in the EIS.

APHIS will reexamine the current regulations for the purpose of updating those regulations with due regard for the types of products being tested, and that may be tested in the future; the potential risks involved; and the quality of the human environment. Issues regarding possible regulatory changes with the potential to affect the quality of the human environment include the following:

1. APHIS is considering broadening its regulatory scope beyond genetically engineered organisms that may pose a plant pest risk to include genetically engineered plants that may pose a noxious weed risk and genetically engineered organisms that may be used as biological control agents. Do regulatory requirements for these organisms need to be established? What environmental considerations should influence this change in regulatory scope?

2. APHIS is considering revisions to the regulations that would define specific risk-based categories for field testing, including (a) product types shown to pose low pest and environmental risks; (b) product types considered to pose a noxious weed risk, of unknown plant pest or noxious weed risk, containing sequences of unknown phenotypic function, and involving new plant-incorporated protectants that have not completed applicable review at EPA; and (c) pharmaceutical or industrial crops not intended for food or feed. What environmental factors should be considered in further delineating such requirements? What criteria should be used to establish the risk-based categories? Should certain low-risk categories be considered for exemption from permitting requirements? If so, what criteria should apply?

3. APHIS is considering ways to provide regulatory flexibility for future decisions by allowing for commercialization of certain genetically engineered organisms while continuing, in some cases, to regulate the organisms based on minor unresolved risks. Other regulated articles could be treated as they have been under the current system, in which all regulatory restrictions are removed. What environmental factors should be considered in distinguishing between these kinds of decisions?

4. Are there changes that should be considered relative to environmental review of, and permit conditions for, genetically engineered plants that produce pharmaceutical and industrial compounds? Should the review process, permit conditions, and other requirements for non-food crops used for production of pharmaceutical and industrial compounds differ from those for food crops? How should results of a food safety evaluation affect the review, permit conditions, and other requirements for these types of plants? How should the lack of a completed food safety review affect the requirements for these types of plants?

5. *Noxious weed,* as defined in the Plant Protection Act, includes not only plants, but also plant products. Based on that authority, APHIS is considering the regulation of nonviable plant material. Is the regulation of nonviable material appropriate and, if so, in what cases should we regulate?

6. APHIS is considering establishing a new mechanism involving APHIS, the States, and the producer for commercial production of plants not intended for food or feed in cases where the producer would prefer to develop and extract pharmaceutical and industrial compounds under confinement conditions with governmental oversight, rather than use the approval process for unconfined releases. What should be the characteristics of this mechanism? To what extent should this mechanism be employed for commercial production of plants not intended for food or feed? What environmental considerations should influence the development of this mechanism?

7. The current regulations have no provision for adventitious presence—intermittent and low-level presence in commercial crops, food, feed, or seed of genetically engineered plant material that has not completed the required regulatory processes. Should APHIS establish a separate component within a revised regulatory system to address adventitious presence? Should the low-level occurrence be exempt from APHIS regulation? If so, what are the conditions under which the low level occurrence should be allowed? What environmental considerations would apply to establishment of such allowances?

8. Should APHIS provide for expedited review or exemption from review of certain low-risk genetically engineered commodities intended for importation that have received all necessary regulatory approvals in their country of origin and are not intended for propagation in the United States? What environmental considerations should be applied to determination of any such allowances?

9. Currently, genetically engineered *Arabidopsis* spp. are exempt from interstate movement restrictions under part 340 because they are well understood and extensively used in research. Should the regulation of other similar genetically engineered plants be consistent with the regulation of genetically engineered *Arabidopsis* spp.? Should the exemption from interstate movement restrictions apply only to those products that meet specific risk-based criteria? What should these criteria be? What species and/or traits should be considered for this exemption? What environmental factors should be considered?

10. What are other areas where APHIS might consider relieving regulatory requirements based on the low level of risk?

11. What environmental considerations should be evaluated if APHIS were to move from prescriptive container requirements for shipment of genetically engineered organisms to performance-based container requirements, supplemented with guidance on ways to meet the performance standards?

Comments that identify other issues or alternatives that should be examined in the EIS would be especially helpful. All comments will be considered fully in developing a final scope of study. When the draft EIS is completed, a notice announcing its availability and an invitation to comment on it will be published in the **Federal Register**.

Done in Washington, DC, this 16th day of January, 2004.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–1411 Filed 1–22–04; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 985

[Docket No. FV04–985–1 PR]

Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Salable Quantities and Allotment Percentages for the 2004–2005 Marketing Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.