duty period under the certificate holder's operations specifications.

(f) A certificate holder may assign a flight attendant to a scheduled duty period of more than 16 hours, but no more than 18 hours, if the certificate holder has assigned to the flight or flights in that duty period at least two flight attendants in addition to the minimum flight attendant complement required for the flight or flights in that duty period under the certificate holder's operations specifications.

(g) A certificate holder may assign a flight attendant to a scheduled duty period of more than 18 hours, but no more than 20 hours, if the certificate holder has assigned to the flight or flights in that duty period at least three flight attendants in the addition to the minimum flight attendant complement required for the flight or flights in that duty period under the certificate holder's operations specifications.

(h) Except as provided in paragraph (i) of this section, a flight attendant scheduled to a duty period of more than 14 hours but no more than 20 hours, as provided in paragraphs (e), (f), and (g) of this section, must be given a scheduled rest period of at least 12 consecutive hours. This rest period must occur between the completion of the scheduled duty period and the commencement of the subsequent duty period.

(i) The rest period required under paragraph (h) of this section may be scheduled or reduced to 10 consecutive hours if the flight attendant is provided a subsequent rest period of at least 14 consecutive hours; this subsequent rest period must be scheduled to begin no later than 24 hours after the beginning of the reduced rest period and must occur between the completion of the scheduled duty period and the commencement of the subsequent duty period.

(j) Notwithstanding paragraphs (e), (f), and (g) of this section, if a certificate holder elects to reduce the rest period to 10 hours as authorized by paragraph (i) of this section, the certificate holder may not schedule, nor may any flight attendant accept a schedule, for a duty period of 14 or more hours during the 24-hour period commencing after the beginning of the reduced rest period.

(k) No certificate holder may assign, nor may any flight attendant accept, any duty period with the certificate holder unless the flight attendant has had at least the minimum rest required under this section.

(l) No certificate holder may assign, nor may any flight attendant accept, an assignment to perform any duty with any certificate holder during any required rest period.

(m) Time spent in transportation, not local in character, that a certificate holder requires of a flight attendant and provides to transport the flight attendant to an airport at which the flight attendant is to serve on a flight as a crewmember, or from an airport at which that flight attendant was relieved from duty to return to the flight attendant's home station, is not considered part of a rest period.

(n) Each certificate holder shall relieve each flight attendant engaged in scheduled air transportation from all further duty for at least 24 consecutive hours during any 7 consecutive calendar days.

(o) A flight attendant is not considered to be scheduled for duty in excess of duty time limitations if the flights to which the flight attendant is assigned are scheduled and normally terminate within the limitations, but due to circumstances beyond the control of the certificate holder (such as adverse weather conditions), are not at the time of departure expected to reach their destination within the scheduled time.

Issued in Washington, DC, on March 26, 1993.

David R. Harrington,

Acting Director, Flight Standards Service.

[FR Doc. 93–7433 Filed 3–29–93; 8:45 am]

BILLING CODE 4910–13–M

federal register

Wednesday
March 31, 1993

Part VIII

Environmental Protection Agency

40 CFR Parts 700 et al.

Premanufacture Notification; Revisions of Notification Regulations, Exemptions for Chemicals in Quantities of 1,000 Kilograms or Less, and for Polymers, and Amendment to Expedited Process for Issuing Significant New Use Rules; Proposed Rule; Extension of Comment Period

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 700, 720, 721 and 723

[OPPTS–50593A, 50594A, 50595A, 50596A; FRL–4579–7]

Premanufacture Notification; Revisions of Notification Regulations, Exemptions for Chemicals in Quantities of 1,000 Kilograms or Less, and for Polymers, and Amendment to Expedited Process for Issuing Significant New Use Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rules; notice of public hearing and extension of comment period.

SUMMARY: This document extends to May 24, 1993, the comment period for persons who want to submit comments on EPA's proposed revisions of the Toxic Substances Control Act (TSCA) section 5 premanufacture notification (PMN) regulations, exemptions for chemicals in quantities of 1,000 kilograms or less and for polymers, and an amendment to the expedited process for issuing significant new use rules (SNURs), which were published in the **Federal Register** on February 8, 1993 (58 FR 7646–7701). EPA will also hold a public hearing in Washington, DC on April 26 and 27, 1993.

DATES: Written comments must be received by May 24, 1993. A public hearing will be held from 9:30 a.m. to 5 p.m. on April 26 and 27, 1993, in Washington, DC. Requests to make an oral presentation at the public hearing must be received by April 21, 1993.

ADDRESSES: Further information on procedures for submitting comments, including "Confidential Business Information" (CBI), is provided in the proposed rules (see **Federal Register** of February 8, 1993 (58 FR 7646–7701)). Public hearing. The April 26 and 27, 1993 public hearing will be held at the Regional Office Building Auditorium, room 1041, first floor, National Capital Region, General Services Administration, 7th and D Streets, SW., Washington, DC 20407.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS–799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–543–B, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551.

SUPPLEMENTARY INFORMATION: **Electronic Availability:** This document is available as an electronic file on *The Federal Bulletin Board* at 9:00 a.m. on the date of publication in the **Federal Register**. EPA's proposed Premanufacture Notification; Revisions of Notification Regulations, Exemptions for Chemicals in Quantities of 1,000 Kilograms or Less, and for Polymers, and Amendment to Expedited Process for Issuing Significant New Use Rules published as a separate part III in the **Federal Register** of February 8, 1993 (58 FR 7646) is available on *The Federal Bulletin Board*. By modem dial (202) 512–1387 or call (202) 512–1530 for disks or paper copies. These files are available in Postscript, Wordperfect and ASCII.

EPA published its proposed amendments to the PMN regulations, exemptions for chemicals in quantities of 1,000 kilograms or less, exemption for polymers, and an amendment to expedited process for issuing SNURs on February 8, 1993 (58 FR 7646–7701). Subsequent to the publication of the proposed amendments, the Chemical Manufacturers Association (CMA) and the Synthetic Organic Chemical Manufacturers Association Inc. (SOCMA) requested an extension of the comment period and a public hearing on the proposed regulations. CMA and SOCMA's letters cited a long-standing interest in these proposed amendments and the considerable analysis of complicated technical and legal issues required before comments could be drafted. EPA is extending the comment period until May 24, 1993 and will hold a public hearing in Washington, DC on April 26 and 27, 1993.

Any person wishing to present an oral statement at the public hearing should contact the TSCA Assistance Information Service by phone (202) 554–1404 (Fax: 202–554–5603). Each request to present an oral statement at the public hearing must identify the speaker; organization represented, if any; daytime telephone number; and the anticipated length of the presentation, not to exceed 10 minutes per session, as discussed below. Written text of the oral statement should be presented to the hearing officer prior to the oral presentation.

The April 26, 1993 public hearing will address the following proposed amendments:

Session 1. The proposed revisions of exemptions for polymers (OPPTS–50594, 58 FR 7679–7701).

Session 2. The proposed revisions of premanufacture notification regulations (OPPTS–50593, 58 FR 7661–7676).

The April 27, 1993 public hearing will address the following proposed amendments:

Session 1. The proposed revision of exemption for chemical substances manufactured in quantities of 1,000 kilograms or less per year (OPPTS–50596, 58 FR 7646–7661).

Session 2. The proposed amendment to expedited process for issuing significant new use rules (OPPTS–50595, 58 FR 7676–7679).

The hearings may conclude before 5 p.m. on each day if all persons wishing to testify have been heard.

Dated: March 25, 1993.

Mark Greenwood,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 93–7421 Filed 3–30–93; 8:45 am]

BILLING CODE 6560–50–F

federal register

Wednesday
March 31, 1993

Part IX

Department of the Interior

Bureau of Indian Affairs

List of Rejected Statute of Limitations Claims; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

List of Rejected Statute of Limitations Claims

AGENCY: Bureau of Indian Affairs.

ACTION: Correction.

SUMMARY: This document corrects notice document 92–31410 beginning on page 62112 in the issue of Tuesday, December 29, 1992.

FOR FURTHER INFORMATION CONTACT:

Muskogee Area Director, Bureau of Indian Affairs, 5th & West Okmulgee, Muskogee, OK 74401–4898, Telephone (918) 687–2296.

SUPPLEMENTARY INFORMATION:

Background

On December 29, a notice was published in the **Federal Register** listing certain potential pre-1966 damage claims which had been rejected for litigation by the Secretary of the Interior pursuant to the Indian Claims Limitation Act of 1982, Public Law 97–394 (96 Stat. 1966, 1976).

Need for Correction

Nine claims, which have not been rejected by the Secretary of the Interior, were erroneously included in the published list.

Correction of Notice

On page 62113, delete "MUSKOGEE AREA REJECTED CLAIMS:" and the nine claims prefixed "G09–" listed thereunder.

Dated: March 25, 1993.

Eddie F. Brown,

Assistant Secretary—Indian Affairs.

[FR Doc. 93–7480 Filed 3–30–93; 8:45 am]

BILLING CODE 4310–02–M

federal register

Wednesday
March 31, 1993

Part X

Department of Agriculture

Animal and Plant Health Inspection Service

7 CFR Part 340

Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status; Final Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. 92-156-02]

Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends the regulations pertaining to the introduction of certain genetically engineered organisms and products to provide for a notification process for the introduction of certain plants with which APHIS has had experience. The introduction of certain regulated articles under notification may be allowed provided that the introduction is in accordance with the provisions of this rule.

This document also amends the regulations to provide for a petition process allowing for a determination that certain plants are no longer regulated articles. The amendments provide a procedure for the release from regulation of such plants which do not present a plant pest risk and therefore should no longer be regulated

These actions supplement the existing permitting requirements for the introduction of certain genetically engineered plants by adding two alternatives. The effect of these actions is to provide standardized procedures for notification of the introduction of regulated articles in accordance with eligibility criteria and performance standards and a petition for the determination of nonregulated status.

EFFECTIVE DATE: April 30, 1993.

FOR FURTHER INFORMATION CONTACT: Terry L. Medley, Director, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-7602.

SUPPLEMENTARY INFORMATION:

Background

On November 6, 1992, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** a proposed rule on Genetically-Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status (See 57 FR 53036-53053 Docket No. 92-156-1). This rule proposed amendments to 7 CFR part 340. APHIS solicited comments for 60 days with the comment period ending January 5, 1993.

Summary and Analysis of Comments

APHIS received 84 comments on the proposed amendments from State, Territorial, and Commonwealth officials, universities, industry, environmental and consumer organizations, business and professional associations, members of Congress, Federal agencies, individuals, and unions. In general, the comments were well-researched and constructive. After a careful analysis of the information and views presented by the commenters, APHIS has made a number of modifications in the amendments as proposed on November 6, 1992. The most significant changes were made in proposed § 340.3(b), in which the second alternative in proposed § 340.3(b)(2) allowing a researcher to determine eligibility after consultation was eliminated, and in proposed § 340.3(d), in which a 10-day interval prior to interstate movement and a 30-day interval prior to importation and release have been added to provide for notification and review by State officials. Minor changes have been made in the eligibility requirements and performance standards in response to commenters' requests for clarification and definition of terms. In the proposed petition requirements in § 340.6, certain wording changes have been made, and the total response time has been extended to 180 days to accommodate a now specified, initial 60-day period for public comments. A general discussion of the comments appears below, followed by a section-by-section response to comments and explanation of modifications.

Comments on Reduced Regulation

A majority of the commenters expressed either general support for the proposed amendments, or qualified support based on suggested changes. The commenters favoring a measure of reduced regulation represented industry, the university research community, and State governments. A small number of commenters opposed the amendments for a variety of reasons, ranging from concerns that their scope was too broad, to conclusions that they were premature. The two proposed provisions that elicited the largest number of comments were the proposal to allow a researcher to determine eligibility through consultation with an "appropriate Institutional Biosafety Committee," and the proposal that notification could be made on the day of introduction. In each case, a majority of the commenters expressed opposition to these proposals. There was general agreement among these commenters, who represented State governments, industry, universities, Federal agencies, and environmental and consumer groups, that these two provisions represented an abrupt or premature move toward deregulation and/or self-regulation by researchers. APHIS has accordingly maintained the overall intent of the proposed notification and petition amendments, while adding additional procedural constraints to ensure uniformity and accountability.

Comments on Eligibility Criteria for Notification (§ 340.3(b))

Eligibility Criterion 1 (§ 340.3(b)(1))

Several comments explicitly expressed approval of the list of six crops in § 340.3(b)(1)(i) that were proposed as eligible for notification. Approximately sixteen commenters proposed a variety of additions to the list. Some of the suggested list additions were to pertain to interstate movement or importation only, while others were to pertain specifically to release into the environment. Several commenters suggested that all common crop species be eligible for notification for interstate movement or importation.

APHIS wishes to clarify that the provisions of § 340.3(b)(1)(ii) in the proposed rule also allowed for notifications for "any additional plant species that BBEP determines may be safely introduced in accordance with the eligibility criteria set forth in paragraphs (b)(2) through (b)(6) and the performance standards set forth in paragraph (c) of this section." For an organism to be approved according to this clause, all of the other eligibility criteria in § 340.3(b) must be met, and evidence would need to be presented that the organism would be introduced in accordance with the performance criteria set out in § 340.3(c). This clause provides for additional flexibility in broadening the set of organisms eligible for notification. Such a determination would be based on consultation with the responsible individual and designated State regulatory officials. APHIS will make determinations upon request as to whether any additional plant in a particular proposed introduction is eligible for notification.

With regard to other suggested modifications to the list of plants eligible for notification for release, it should be noted that in many instances,

commenters suggested including on the list those organisms with which they had particular familiarity. A sample of crops suggested by commenters for addition to the list included walnuts, carrots, endive, artichokes, sunflowers, lettuce, sugarbeets, wheat, beans, canola, apples, and oats. No single crop was identified by more than a few commenters as appropriate for inclusion on the list, and there was no scientific consensus on any additional species that are appropriate for the notification provision. Accordingly, no additional species have been added to the list in the final rule. This is not to imply that these six species will remain the only species eligible for introduction by the notification alternative or that these are the only six species that can meet the eligibility criteria and the performance standards for notification; these six crops have been the most actively field tested and have been individually considered by APHIS and found to be appropriate for notification. APHIS is receptive to receiving information which will support the addition of other species to the list in § 340.3(b)(1)(i). These additions would be made through notice and comment rulemaking.

Justification for the Six Crops

Several commenters expressed the opinion that APHIS has not adequately justified the choice of the six plant species eligible for introduction by the notification alternative on either a biological or experience basis. We will therefore take this opportunity to address these concerns. Under the current regulations in 7 CFR part 340, a permit is required to introduce a regulated article. Between 1987 and March 2, 1993, we have granted 365 environmental release permits and 1,301 movement permits of transgenic organisms developed with genetic material from known plant pests. We have had the most experience with evaluating field tests for these six plant species, with percentages of total permits issued as follows: Corn (19%), cotton (10%), potato (20%), soybean (18%), tobacco (5%), or tomato (13%). This evaluation includes review of the application for field testing and other relevant information from the scientific literature and the field data reports. The data reports should verify that genetically engineered crops present the same types of ecological concerns (i.e., weediness, competitiveness, toxicity) associated with other plants. The permitted field tests have been safe and have not presented plant pest or environmental risks because these tests have been performed under appropriate confinement conditions imposed in the introduction permit. These confinement conditions form the basis for the performance standards stipulated in the notification process. In addition, the information provided by permittees in data reports from their respective field tests have confirmed our assessment that the confined field tests do not pose a risk of introduction or dissemination of a plant pest and do not present a significant impact on the quality of the human environment. The majority of the organisms that are the subject of these reports are transgenic plants that would meet the eligibility requirements in the notification amendment. Additionally, these field tests have been performed using agricultural practices that are encompassed by the proposed performance standards. That is to say, the tests have not resulted in viable progeny persisting in the environment or the introduction and dissemination of a plant pest. To date, APHIS has received 71 percent of the data reports that are due. These reports are available from APHIS upon request. The data reports will be available for public review in the Reading Room, suite 7, 6505 Belcrest Rd., Hyattsville, Maryland. APHIS will periodically publish a notice of their availability in the **Federal Register**.

The six plant species listed in § 340.3(b) have been carefully considered by APHIS. APHIS has already specifically considered any potential plant pest risks posed by the cultivation of certain tomatoes. APHIS made an assessment of the potential for gene transfer from a transgenic tomato when a petition for determination of regulatory status of a particular type of genetically engineered tomato was requested (57 FR 47608–47616, October 19, 1992). APHIS has also brought panels of world experts together in workshops to address issues of gene transfer and safeguards for planned introductions of corn (Conference Report: Workshop on Safeguards for Planned Introduction of Transgenic Corn and Wheat, December 6–8, 1990, Keystone, Colorado), potatoes (Meeting Report: Workshop on Safeguards for Planned Introduction of Transgenic Potatoes, August 16–17, 1991, St. Andrews, Scotland), and tomatoes ((report in preparation) Workshop on the Safeguards for Planned Introductions of Transgenic Tomatoes, August 19–20, 1992, Davis, California). The outcrossing frequency is known to be negligible for soybeans (Wilcox, J. (ed.), Soybeans: Improvement, Production, and Uses, 1987, American Society of Agronomy, Madison, Wisconsin) and tobacco (Durbin, R. (ed.), *Nicotiana*. Procedures for Experimental Use, 1979, USDA, Technical Bulletin Number 1586). Given the performance standards required under notification, there should be no gene transfer from these six plant species to other cultivated crops of the same species that results in the generation of progeny that can persist in the environment. Performance standard § 340.3(c)(5) specifically addresses gene transfer. When one considers both the biology and plant breeding practices of these six crops, any introgression by unique genes from genetically engineered plants to other nontransgenic breeding stock of the crop would be negligible. Breeders are very concerned about the maintenance of genetically pure lines. Hybrid off-types involving transgenic plants and breeders plants may be evident in some crops whenever the next generation of seed was grown and would be removed. With the exception of cotton, these crops lack volunteers that persist in the environment.

What follows is scientific evidence to demonstrate that the risk of gene transfer from these six plant species to a sexually compatible plant that results in the generation of progeny that can persist in the environment is negligible. APHIS has analyzed which of these six species has wild relatives (defined as species that are both sexually compatible with the six crop species without human intervention and whose hybrid progeny can persist in the environment), or has wild populations (defined as members of the same species that are both sexually compatible with a crop species and present in populations that can persist in the environment) in the United States. While potato and cotton have such wild relatives, wild populations only exist in the United States for cotton relatives. APHIS has also identified which of these six plant species has weedy relatives (defined as different species that are capable of receiving, incorporating, and maintaining genetic material via sexual reproduction from a crop species, that form populations that can persist in the environment, and that are so identified as weeds by expert organizations such as the Weed Society of America) in the United States. According to these definitions, we have devised the following table:

Crop	Wild relatives	Wild populations	Weedy relatives
Corn	None	None[1]	None.
Cotton	Hawaii[2]	Florida[3, 4]	None.[2]
Potato	AZ, NM, TX[5]	None[1]	None.
Soybean	None	None[6]	None.[6]
Tobacco	None[7]	None	None.[7]
Tomato	None	None[1 8]	None.[8]

Notes:

[1] Corn (Conference Report: Workshop on Safeguards for Planned Introduction of Transgenic Corn and Wheat, December 6–8, 1990, Keystone, Colorado), potato (D.S. Correll, The Potato and its Wild Relatives, 1962, Texas Research Foundation, Renner, Texas), and tomato (Atherton, J., Rudick, G. (eds.), The Tomato Crop: A Scientific Basis for Improvement, 1986, Chapman and Hall, New York) occasionally volunteer with a frequency depending on weather, location, and agronomic practices.

[2] *G. tomentosum* occurs in Hawaii. There is evidence for the possible historic introgression into *G. tomentosum* by other cultivated non-genetically engineered cottons as observed by Dr. Jonathan Wendel (personal communication, Iowa State University) and indicated by Dr. Paul Fryxell (The Natural History of the Cotton Tribe, 1979, Texas A&M University Press, College Station, Texas). Thus, cultivated cotton (*G. hirsutum* and *G. barbadense* are cultivated in the United States) in general, regardless of whether it is genetically engineered, presents a gene transfer risk. *G. tomentosum* is not an agricultural weed. Indeed, it is just the opposite; from loss of habitat due to human activities, it is in a precarious position for survival. We have no scientific evidence to demonstrate that field tests of genetically engineered cotton in Hawaii will present any further gene transfer risk. However, field tests of cotton in Hawaii will not qualify for notification unless all the eligibility criteria and performance standards are met. Our performance standards would preclude gene movement via pollen which could result in viable progeny persisting in the environment.

[3] Because *Gossypium tomentosum* is a different species, it is not included here. *G. tomentosum* occurs in Hawaii; *G. thurberi* occurs in Arizona. *G. thurberi* and cultivated cotton (*G. hirsutum* and *G. barbadense*) do not naturally form viable hybrids as the chromosomal types are incompatible. Although *G. tomentosum* is sexually compatible with cultivated cotton, cross pollination seems unlikely as published reports suggest they do not have common pollinators or common time periods during which their flowers are receptive (P. Fryxell, The Natural History of the Cotton Tribe, 1979, Texas A&M University Press, College Station, Texas).

[4] R. Long, O. Lakela, A Flora of Tropical Florida, 1976, Banyan Books, Miami, Florida.

[5] *Solanum tuberosum* can produce fertile hybrids with some wild *Solanum* species that grow in Arizona, New Mexico, and Texas (D.S. Correll, The Potato and its Wild Relatives, 1962, Texas Research Foundation, Renner, Texas; Meeting Report: Workshop on Safeguards for Planned Introduction of Transgenic Potatoes, August 16–17, 1991, St. Andrews, Scotland). However, field tests of potato in these States will not qualify for notification unless all the eligibility criteria and performance standards are met. Our performance standards would preclude gene movement via pollen which could result in viable progeny persisting in the environment.

[6] Polhill, R., Raven, P. (eds.) Advances in Legume Systematics, Part 1, 1981, Royal Botanic Gardens, England.

[7] Native *Nicotiana* spp. occur in the United States, but successful introgression that results in populations that can persist in the environment is extremely unlikely. Most common wild species in the United States, such as *N. glauca*, have somatic chromosome counts of 24, as contrasted to the cultivated tobacco with counts of 48 (Kartesz, J., Kartesz, R., A Synonymized Checklist of the Vascular Flora of the United States, Canada, and Greenland, 1980, University of North Carolina Press, Chapel Hill; Durbin, R. (ed.), *Nicotiana*. Procedures for Experimental Use, 1979, USDA, Technical Bulletin Number 1586). Hybrids between wild and cultivated *Nicotiana* would exhibit abnormal chromosome behavior at meiosis, be sterile under normal conditions (Durbin, R. (ed.), *Nicotiana*. Procedures for Experimental Use, 1979, USDA, Technical Bulletin Number 1586), and would perish with the first generation of offspring. Such hybrids would also be unlikely to survive because of the genetic contribution of the cultivated parent, which is known to perish in almost all areas of the United States. There are no reports of such natural hybrids in the literature.

Holm et al. (Holm, L., Pancho, J., Herberger, J., Plucknett, D., A Geographical Atlas of World Weeds, 1979, John Wiley and Sons, New York) give an undocumented report of *N. tabacum* as a common weed in Hawaii. Although the plant grows wild to a limited extent in Hawaii, its weedy nature is not supported by the experience of botanists in Hawaii, and is not supported by other published works such as Neal (Neal, M., In Gardens of Hawaii, 1965, Bishop Museum Press, Honolulu) and Wagner et al. (Wagner, W., Herbst, D., Sohmer, S., Manual of the Flowering Plants of Hawaii, 1990, University of Hawaii Press et Bishop Museum Press, Honolulu).

[8] Cherry tomato, *Lycopersicon esculentum* var. *cerasiforme* occurs in Texas and Florida, but is not considered a weed pest. It can cross with the cultivated tomato, *L. esculentum* var. *esculentum*. However, introgression within the United States is not likely since the rate of outcrossing in var. *esculentum* is low (Rick, 1949, Proceedings of the American Society of Horticultural Science 54:237–284; C.M. Rick, personal communication) and var. *cerasiforme* is not present in areas of the United States that are devoted to large scale production of tomatoes (J. Scott, personal communication). There are no published reports that visible traits of cultivated tomato have introgressed into var. *cerasiforme* from cultivated tomatoes in areas where the wild cherry tomato commonly grows.

Environmental releases under notification will take place in a variety of environments. APHIS believes that the performance standards will provide for safe field testing regardless of the environment. The field trial environment needs to be carefully considered by the applicant in order to assure that the performance standards are being met and address any specific local concerns.

Comments on General Criteria for Eligibility

More than half of all commenters specifically addressed the provisions proposed in § 340.3(b)(2) for decentralizing determinations that particular organisms are eligible for introduction under notification. Approximately 12 commenters strongly endorsed the proposal to allow a researcher to determine eligibility for notification in consultation with an Institutional Biosafety Committee (IBC). The majority of the commenters favoring the use of IBCs represented the research communities of major universities, and included a university biosafety officer and the faculty chair of an IBC. However, the vast majority of the commenters opposed the general criteria of § 340.3(b)(2), and specifically, the proposal that IBCs be given the authority to make determinations about eligibility for notification. Most commenters were of the opinion that this authority should remain with APHIS. The commenters expressing these views represented State departments of agriculture, members of Congress, Federal agencies, unions, industry, environmental organizations, and IBCs. Several commenters expressed the opinion that IBCs and State authorities lack the expertise to make such determinations. Two commenters expressed concern that the proposed provisions would amount to self-regulation by researchers, while another expressed concern that IBCs would have no public accountability for their actions. A further comment identified three other potential shortfalls: "a. Lack of consistency in the reviews of different IBC's. b. Inadequate protection of confidential business information. c. Liability problems arising from IBC decisions." APHIS agrees with the general substance of these comments, and accordingly § 340.3(b)(2) of the proposed rule has been deleted. Since paragraph (b)(2) was removed from the proposed amendment, the remaining eligibility criteria are renumbered with Arabic

numerals 2–6, replacing the corresponding Roman numerals i–vi.

Eligibility Criterion 2 (§ 340.3(b)(2))

Several commenters expressed reservations regarding the use of the term "stably integrated." One commenter objected to the fact that researchers would, under certain circumstances, be able to make a determination regarding this eligibility criterion without oversight from APHIS. This objection has been addressed by the deletion of the proposed § 340.3(b)(2) which provided for decentralized determinations regarding eligibility for introduction. The other commenters on this section felt that "stably integrated" is imprecisely defined. These commenters felt that explanatory information contained in the preamble to the proposed rule, which provided examples of modifications that either fit or do not fit the definition of "stably integrated", should be provided in the final rule. APHIS agrees with the commenters. Although no change to the wording of the definition has been made, we are providing the following clarification. The intent of this criterion is to exclude from notification regulated articles that have been modified to contain genetic material: maintained in an extrachromosomal manner, whether on plasmids or on viral vectors; or maintained on transposable elements. Field tests utilizing regulated articles of these types would continue to require a permit. Genetic instability resulting from insertion of genetic material at a particular site in the recipient plant genome, or resulting from genetic mechanisms intrinsic to chromosomal maintenance in recipient plant cells, such as spontaneous deletion, rearrangement, and gene conversion, would not be grounds for exclusion from eligibility under this criterion. These types of genetic mechanisms occur in all plant cells regardless of whether they are genetically transformed.

Eligibility Criterion 3 (§ 340.3(b)(3))

Two commenters expressed the opinion that the phrase "well characterized" in the eligibility criterion in § 340.3(b)(3) is ill-defined; one of these commenters also felt that the phrase "results in plant disease" is also imprecise. In response, APHIS notes that the intent of the proposed eligibility criterion was to identify for notification those organisms that had new genetic material of which the function was understood, and that function was one not involved in pathogenesis. (APHIS believes that the concept of "plant disease" in the Federal Plant Pest Act (FPPA) and the Federal Plant Quarantine Act (PQA), and in the 7 CFR part 340 regulations, is both scientifically and legally clear.) The sense of "well characterized" is, therefore, characterized with respect to its cellular or organismal role. To clarify this intent, we have rephrased this criterion as follows:

"The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease." For example, if the nucleotide sequence encodes a protein, then the enzymatic reaction it carries out, or its structural or other intracellular role, should be known. On the other hand, a nucleotide sequence whose sole identification and/or characterization is the fact that it is expressed in response to a particular chemical or physical stimulus would not be considered to fit this eligibility criterion.

One commenter suggested that this criterion be modified to exclude genes that cause the regulated article to exhibit increased "weediness", but acknowledged that it would be difficult to define "weediness". APHIS agrees that the term "weediness" is a difficult term to define in a precise way. APHIS believes that the performance standards will preclude any risk associated with plants which may exhibit increased "weediness". However, if increased "weediness" is observed, it should be reported in accordance with the provisions for unusual occurrences in paragraph (d)(5) of this section.

Eligibility Criterion 4 (§ 340.3(b)(4))

One commenter suggested that we define "infectious entity" found in paragraph (b)(4)(i) of this criterion. APHIS believes that the meaning of this term is clear. Paragraph (b)(4)(i) will ensure that the plants introduced under notification have not been modified to produce a plant virus, an animal virus, a human virus, a viral satellite RNA, a defective interfering RNA molecule, or other entities which have not previously been introduced under permit.

A total of eight comments were received that specifically addressed paragraph (b)(4)(ii) of this eligibility criterion as it was stated in the proposal. In general, the commenters requested that the proposed terms "new to the plant" and "toxic to nontarget organisms" be better defined. Several of these commenters suggested that it would be very difficult to determine when a constituent is "new to the plant" and "toxic to nontarget organisms" and that such a determination may not be feasible. One commenter pointed out that the proposed wording would exclude plants from notification that express toxins that affect nontarget organisms that do not feed or live on that plant species. APHIS agrees with the commenters and has modified the criterion in paragraph (b)(4)(ii) to read the introduced genetic material does not encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species. This allows the notification alternative for plants expressing a toxin which may be toxic to nontarget organisms that are not likely to feed or live on that plant species. This would generally not allow the introduction of plants via notification that have been purposely modified to encode substances toxic to such nontarget organisms. APHIS considers the term "known" to mean "generally recognized", and the term "likely" to mean "supported by evidence strong enough to establish presumption if not proof."

There were a total of six commenters who questioned why pharmaceutical-producing plants would be eligible for introduction by the notification alternative. APHIS interpreted criterion (4) to be a trigger for pharmaceutical-producing plants, and did not intend that such plants would be introduced under notification. We have therefore modified this criterion to state specifically that in paragraph (b)(4)(iii) the introduced genetic material does not encode products intended for pharmaceutical use. If the applicant observes or finds that the introduced genetic material causes the production of an infectious entity or substances toxic to nontargets or having pharmaceutical activity, or the encoded substances are toxic to nontargets or have pharmaceutical activity, then such effects should be reported to APHIS in accordance with paragraphs (d) (4) and (5) of this section. If uncertain, an applicant can refer to the Federal Food Drug and Cosmetic Act (21 U.S.C. 321(g)) for clarification about substances with pharmaceutical use.

Eligibility Criterion 5 (§ 340.3(b)(5))

Two commenters on this eligibility criterion suggested that APHIS has had insufficient experience with the field testing of plants expressing plant virus genes to allow field testing of such genes under notification. In response APHIS has modified criterion (5) of the rule in paragraph (b)(5) to establish that to ensure the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, they must be: (1) Noncoding regulatory sequences of known function, or (2)

sense or antisense genetic constructs derived from viral coat protein genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and infect plants of the same species, or (3) antisense genetic constructs derived from noncapsid viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and infect plants of the same species. These changes clarify which sequences derived from plant viruses can be engineered into plants introduced by the notification alternative. The function of any noncoding regulatory sequences must be known; the DNA sequence must be known, for example, to be a promoter, enhancer, intron with enhancer activity, upstream activating sequence, polyadenylation site, or transcription terminator. The second and third elements of the criterion are intended to preclude the construction or reconstruction of viruses other than those that are prelavent and endemic in the area where the introduction will occur and infect plants of the same host species. These elements will also prevent the transmission of viruses by insect vectors that would not normally come in contact with a virus encapsidated by an exotic, nonendemic, or nonrevalent coat protein derived from a virus that does not normally infect the recipient plant. The third element of modified criterion (5) eliminates the release of transgenic plants expressing sense constructs to viral genes, other than the coat protein gene, under the notification alternative. Certain of these constructs, when introduced into plants, have been reported in the scientific literature to result in disease symptom expression. In addition, the precise function of many of the noncapsid genes and their encoded proteins is unknown. Plants expressing sense noncapsid plant viral proteins can still be introduced under permit. In the future, APHIS will seek input from the public on the inclusion under notification of plants expressing sense constructs from all other noncapsid viral genes from plant viruses. Of introductions under permit to date, nearly 100% of the plants have contained noncoding regulatory sequences derived from plant viruses. Of those plants introduced under permit that express plant virus genes, at least 95% have expressed sense viral coat protein genes, or antisense genes to coat protein and other viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and infect plants of the same species.

Eligibility Criterion 6 (§ 340.3(b)(6))

Six comments were received on eligibility criterion (6). Five of these commenters objected to the exclusion from notification of plants expressing nonpathogenic proteins from animal and human pathogens. One of the commenters suggested alternate language for this criterion, and the sixth commenter found the descriptor "functionally intact" to be confusing. APHIS agrees with these commenters, and has modified this criterion to establish that the plant has not been modified to contain the following genetic material from animal and human pathogens: (1) Any nucleic acid sequence derived from an animal or human virus, or (2) coding sequences whose products are known or likely causal agents of disease in animals or humans. The terms "known" and "likely" mean the same as they do in eligibility criterion (4). APHIS believes the exclusion from notification of plants containing any nucleic acid sequence derived from animal or human virus or sequences encoding products pathogenic to animals or humans is prudent because of our lack of experience with the introduction of plants expressing such sequences, and thereby, the possible need for additional containment measures to address potential new risk issues posed by such plants. Furthermore, we believe it is necessary to eliminate from notification all plants expressing any nucleic acid sequence from an animal or human virus because of the potential misperceptions by the public that animal and human "viruses" are being produced in plants and that these plants are subject to insufficient government oversight. Two commenters stated that APHIS may be "duplicating existing federal authority" by "regulating human pathogens" whose introduction into the environment is covered by the Public Health Service Act. APHIS disagrees with the commenters. APHIS is not "duplicating existing federal authority" or "regulating human pathogens", but rather overseeing the introduction of plants containing such genetic material that has never been expressed in a plant before.

Other Comments on Eligibility

APHIS specifically solicited comment on whether a regulated article that does not necessarily meet each of the eligibility criteria may nonetheless be safely introduced under the notification procedure based on the performance standards or additional confinement measures. While several commenters expressed the view that a regulated article could be safely introduced under the notification alternative even though it did not "technically" meet each of the eligibility criteria, APHIS believes it is prudent to be consistent in applying the criteria for introduction under notification. Therefore, to qualify for notification, a regulated article must meet all six of the eligibility requirements stipulated in paragraph (b) and the performance standards set forth in paragraph (c) of this section.

Several commenters suggested that the eligibility requirements for notification should be modified to include as one criterion for eligibility that an organism had been previously field tested under permit. APHIS disagrees. A major purpose of this rule is to establish safe conditions based on familiarity for field testing of a set or organisms that only have a restricted range of new introduced traits. If the eligibility criteria for notification and the performance standards for introductions are adequate to provide for safe field testing, then there should be no need for the imposition of an additional permitting requirement. APHIS believes that the specific revisions it has made to the eligibility criteria and performance standards, in response to comments, ensure this safe field testing.

Comments on Performance Standards (§ 340.3(c))

Procedure

Ten general comments were received on § 340.3(c) of the proposed notification amendment entitled "Performance standards for introductions under the notification procedure". Two commenters thought the performance standards were adequate; one thought they were too stringent, and the remaining seven thought they were too general and too vague. APHIS has sought to clarify some of the performance standards by considering issues raised for the individual performance standards by specific commenters. There were no comments directed toward performance standard 3 (§ 340.3(c)(3)).

Unique Ecology

Several commenters expressed the opinion that the proposed performance standards fail to take into account the potential effects of the introduction of regulated articles into unique environments. APHIS disagrees. The performance standards for introduction of regulated articles under notification are designed to prevent the persistence

of any organism which could have an effect on the surrounding environment, whether "unique" or otherwise. Moreover, the modifications to the proposed performance standards embodied in the final rule clarify what is required of the responsible persons to ensure safety. It should be emphasized, however, that the specific environment at the test site must be considered when the applicant determines how to comply with the performance standards.

Performance Standard 1 (§ 340.3(c)(1))

New § 340.3(c)(1) of the final rule establishes that the regulated article "* * * must be maintained at the destination facility such that there is no release into the environment." The proposed rule provided that "destination facilities shall provide for adequate containment of the regulated article(s)." Three commenters requested clarification and more detail as to what was meant by "adequate containment." APHIS does not believe that it is practical to define "adequate containment", since what is considered adequate will vary according to the subject organism. Adequate containment depends not only on the specific facilities on site and the physical containment measures employed, but also the biology of the plant and, if it is artificially infested or inoculated, the organism used in the challenge. Interested persons should consult the National Institutes of Health Guidelines at 51 FR 16958, "Appendix G—Physical Containment", for guidance on appropriate methods of physical containment. It remains the responsibility of the responsible person to ensure that appropriate measures are employed to prevent inadvertent release. APHIS believes that it is part of its responsibility to inspect these facilities, and it has been its practice to perform these inspections as provided in section § 340.4(d). The requirements for shipping in § 340.8(b)(1–3) must be adhered to when shipping regulated articles.

Performance Standard 2 (§ 340.3(c)(2))

New § 340.3(c)(2) establishes that "the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release." One commenter questioned whether mixing refers to mixture with a non-regulated article or with other plant species. APHIS has therefore added the words "of any species" to clarify that the regulated article not be mixed with plant materials of any species which are not part of the environmental release. This does not preclude the mixture of the regulated article with non-regulated plant species that are part of the environmental release.

Performance Standard 4 (§ 340.3(c)(4))

Two commenters suggested modifications to performance standard (4). One of the commenters suggested that the statement be clarified to read that the introduction not contain a viable vector agent. APHIS believes that it is clear from the context of the performance standards that we intend that no viable vector agent be introduced along with the regulated article. The other commenter suggested that the statement be clarified to read that no transgenic vector agent be associated with the regulated article. Again, we believe that our intent is clear that no transgenic vector agent be introduced along with the regulated article.

Performance Standard 5 (§ 340.3(c)(5))

New § 340.3(c)(5) establishes that the field trial must be conducted such that neither the regulated article nor any offspring derived from the regulated article can "persist in the environment." What APHIS means by "persisting in the environment" is producing feral or sustained populations of the regulated article or its offspring that can persist in agricultural or nonagricultural habitats without human intervention. This standard does not necessarily preclude the conduct of controlled genetic crosses or open pollination as part of a field test. In cases where open pollination is employed, any hybrid progeny produced outside the test site cannot be used for agricultural seed, and these progeny must not be capable of forming feral or sustained populations. When the regulated article is male fertile and allowed to flower, it must be separated from any foundation or breeder seed production of non-regulated plant material of the same species, by at least the isolation distances for foundation seed production given in 7 CFR 201.76. The change to this standard was in response to three commenters who either objected to the proposed standard terms "significant probability" and "minimized", the vagueness of the standard, or expressed the opinion that it was not based on experience and it was unclear how it would be implemented. APHIS does not believe that pollen movement can or need necessarily be prevented, but rather that progeny produced as a result of such pollen movement should not persist in the environment, as stated above. We also believe that we have had extensive experience with the imposition of these standards with the six crops eligible for introduction by the notification alternative, as 85% of environmental release permits have been with these six crops and there have been no reports of their persistence. We agree with another commenter that based on the biology of these six crops there is little opportunity for persistence in the environment without sustained human intervention.

Performance Standard 6 (§ 340.3(c)(6))

The content of performance standard six has not been changed; however, it has been punctuated for clarification. One commenter expressed the opinion that it is not based on experience and it is unclear how it would be implemented. Again, 85% of APHIS' environmental release permits have been with the six crops eligible for introduction under notification and agricultural practices have been developed to eliminate the potential for volunteers or remove them if they appear. As with performance standard (5), the regulated article or viable propagative material derived from it must not persist in the environment.

Comments on Procedural Requirements (§ 340.3(d))

Procedural Requirement 2 (§ 340.3(d)(2))

All or most of the information requested in the notification letter described in § 340.3(d)(2) may be used by APHIS for recordkeeping purposes. APHIS intends to provide the public with examples of such notification letters so that it is clear what information we require in order to verify that the regulated article is eligible for introduction by the notification alternative.

In response to a single comment on § 340.3(d)(2)(ii), the section was amended to specify the information APHIS believes is necessary to identify the regulated article. APHIS believes this clarifies section (2)(ii). Subsection (A) provides the name and phenotype of the organism; e.g., *Solanum tuberosum*, potato cultivar Russet Burbank, virus resistant. Subsection (B) provides the identify of the introduced genetic material, the encoded protein and/or function, and the donor organisms; e.g., promoter: enhanced *35S* 5′ from Cauliflower Mosaic Virus; coding sequence: antisense coat protein from Potato Virus Y, strain N; terminator: *nos* 3′ from the *Agrobacterium tumefaciens* T–DNA nopaline synthase gene; and promoter: *35S* 5′, coding sequence: *uidA;* encoding β-glucuronidase from *Escherichia coli*; terminator: *nos* 3′.

Other sequences that should be identified include all noncoding regulatory sequences associated with the coding DNA. Subsection (C) identifies the mode of transformation, e.g., via disarmed *A. tumefaciens* or microprojectile bombardment. The information provided for by these subsections will allow APHIS to determine that the regulated article meets the eligibility criteria set forth in § 340.3(b). Subsection (C) will also allow APHIS to ascertain when a modified plant is not a regulated article. APHIS has also modified § 340.3(d)(2)(iii) to include the size of the introduction. APHIS believes this information is necessary for inspection officials who may visit the introduction sites or facilities.

Procedural Requirement 3 (§ 340.3(d)(3))

Approximately 48 commenters commented specifically on the provision in proposed § 340.3(d)(3) that notification occur on the day of introduction. Virtually the only support for this provision was expressed for movement only, by a small number of commenters representing industry. Several of these same commenters suggested that same-day notification for movement be extended to other crop varieties, and/or all regulated articles. In contrast, approximately 37 commenters representing State governments, industry, environmental and consumer organizations, and members of Congress expressed strong opposition to same-day notification for introduction, based on concern about public perception and the need for State review. The intervals suggested ranged from 10–15 days for release to 60 days for all introductions, with suggested variations falling between these extremes. Approximately 17 commenters expressly requested advance notification for State review prior to introduction.

APHIS agrees that notification should precede introduction to accommodate both Federal and State review. Therefore proposed § 340.3(d)(3) has been changed to require that notification must be submitted to BBEP 10 days prior to the day of an interstate movement, and 30 days prior to an importation or environmental release. The rationale for these time intervals is discussed in detail in response to "Comments on Administrative Action § 340.3(e)."

Procedural Requirement 4 (§ 340.3(d)(4))

A sentence was added to § 340.3(d)(4) regarding the submission of data reports pursuant to field trials approved under notification. The added sentence, "Final reports for those field tests lasting more than 12 months are due 6 months after the termination of the field test," was added to clarify APHIS' intent that a final field test report is due after the completion of a field test with a duration of longer than 12 months. APHIS specifies that this report be submitted 6 months after the termination of such a test. APHIS believes the 6 month time period to be a reasonable length of time for the applicant to review relevant data and compose a field test report. APHIS views these data reports as critical to the substantiation of safety, and expects that these documents will also be essential components in petition submissions under § 340.6. APHIS agrees with the commenter who suggested that the reports be submitted 11 months after the start of the test, but have not changed the initial reporting time from 12 months. APHIS believes that it is prudent that it receive the data reports from an applicant prior to, whenever possible, their next notification for the environmental release of the same or similar material so that we can review the report and request additional information if necessary. The submission of data reports within the time specified is essential for compliance with the final rule. The data reports will be available for public review in the Reading Room, suite 7, 6506 Belcrest Rd., Hyattsville, Maryland. APHIS will periodically publish a notice of their availability in the Federal Register.

In response to one commenter's inquiry concerning the content of the field test reports, we have modified the paragraph to require that the APHIS reference number given in the acknowledgement of receipt of the notification, as well as "methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment", be included. By these modifications APHIS intends that applicants provide APHIS with information about how its observations were made, and provide their analysis of the significance of them. We encourage the inclusion of other types of data, such as new information acquired regarding the phenotype of the regulated article as given in § 340.6(c)(4), if the applicant anticipates submission of a petition for determination of regulatory status for their regulated article. One commenter was interested in what the information in the data reports will be used for. In addition to ensuring that APHIS is informed of the progress of the field trial, this information will be utilized to fulfill our commitment to adjust regulations based on experience gained.

Procedural Requirement 5 (§ 340.3(d)(5))

Several State officials favored changed language to require a specified reporting time to the Federal Government of any unusual occurrence. APHIS agrees with these comments. The reporting periods for such occurrences for introductions under permit are also appropriate for notification. New § 340.3(d)(5) provides that the Director, BBEP, shall be notified "of any unusual occurrence within the time periods and in the manner specified in § 340.4(f)(10)."

Comments on Administrative Action (§ 340.3(e))

To provide for State notification and review, § 340.3(e)(1) has been changed to include a provision that the Director, BBEP, will notify State regulatory officials within 5 business days of receipt of notification. Section 340.3(e)(2), (3), and (4) were modified to establish that the Director, BBEP, will provide acknowledgement within 10 days of receipt for interstate movement, or 30 days of receipt for importation and environmental release that the introduction is appropriate under notification. These intervals were selected based on the estimated average time required to process a typical permit application for the introduction of a regulated article that meets the eligibility requirements for notification. In the case of importation, the 30 day interval will allow adequate time for the administrative requirements associated with importation of regulated articles, including consulting with State and other APHIS officials, printing special importation labels, contacting port inspectors, and inspecting the imported material for plant pests. When APHIS determines the introduction can not be made under notification, the applicant will be notified of denial of notification and the need to obtain a permit. The applicant can then request a permit for introduction of that regulated article without prejudice, as provides by § 340.3(e)(5).

APHIS will maintain an updated list of all notifications submitted. In the interest of providing the public access to information regarding the field trials that have been judged by APHIS to be eligible for notification, APHIS will periodically publish a notice in the Federal Register announcing the availability of such a list. Several commenters requested that a list of the

notifications be published in the Federal Register. APHIS will instead, on request, directly provide the list of interested parties in a timely manner, either by mail or through the use of electronic equipment. APHIS has made arrangements with the National Biological Impact Assessment Program (a free biotechnology data base) which is administered by USDA's Cooperative State Research Service, to make available current lists of notifications for release, that are pending and those which have been acknowledged by APHIS. The public may also review such lists in the Reading Room, suite 7, 6505 Belcrest Rd., Hyattsville, Maryland.

Petition for Determination of Nonregulated Status

Apart from the eleven comments that expressed general approval for the entire proposed rule as written, another twenty-one comments addressed the proposed petition process in § 340.6 directly. Of the twenty-one comments, eleven were in favor of the petition rule as proposed. Ten comments requested amendments to, or deletion of, the proposed petition rule.

Two comments requested that the proposed petition process be withdrawn. One of these comments gave no clear rationale for the request. The second comment expressed the opinion that the proposed petition process would provide inadequate oversight of the commercialization of transgenic plants and that the indicated data requirements were inadequate to address the known risks of commercialization. The commenters also stated that petitions were currently being reviewed by APHIS on an "ad hoc" basis and the new process would be one without scope or standards. The commenter specifically requested that proposed § 340.6(b)(A) be amended to specify that a petitioner shall include all data and not just one type of data that is relevant to a petition.

APHIS wishes to clarify that the FPPA and PQA are intended to protect American agriculture and the environment against the introduction and dissemination of plant pests. They are not statutes for the commercialization or marketing of plants. Therefore, the petition process allows APHIS to determine, based upon the review of data, whether certain transgenic plants which are regulated articles should continue to be regulated. Currently prior to commercialization new plant varieties, including those varieties produced through biotechnology, must comply with State and Federal marketing statutes such as State seed certification laws, the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In this regard, the Food and Drug Administration and the Environmental Protection Agency which administers these statutes have published policy or proposed policy statements in the Federal Register (57 FR 22984–23005; May 29, 1992) and 57 FR 55531–2; November 25, 1992). The petition process, which addresses the initial field testing of transgenic plants, supplements these commercialization requirements. To the extent the petition process is viewed as addressing commercialization, it should be viewed as an interim measure pending adoption of the Administration's policy for reviewing and approving applications to commercialize genetically engineered plants and other products.

With regard to the petition process acting in a supplementary capacity to the above marketing statutes as a means of addressing plant pest issues, APHIS believes that the data elements in the proposed petition process specifically relating to the new phenotype of the transgenic plant, outlined in § 340.6(c)(4) including, but not limited to:

> plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organism, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Director believes to be relevant to a determination.

specifically address any substantive pest issues that might conceivably be raised in consideration of a new plant variety.

APHIS has recently reviewed a petition that a determination be made that an organism which had been a regulated article, the FLAVR SAVR™ tomato from Calgene, Inc., be given nonregulated status under 7 CFR part 340 based on evidence that it posed no plant pest risk, and published an interpretive ruling on that petition in the Federal Register on October 19, 1992. This ruling was based on analysis of the same types of issues presented in § 340.6(c)(4) based on scientific literature, laboratory data, field test data derived during three years of field testing, and public comments. APHIS is currently in the process of reviewing another such petition, received from Upjohn, Inc., regarding certain varieties of virus-resistant squash. The proposed rule formalizes a process analogous to that which has been operating for the first two petitions received by the agency. In response to the comment that review of petitions was being conducted on an "ad hoc" basis, APHIS notes that prior to the finalization of this rule, APHIS published notices of intent to issue interpretive rulings in the Federal Register in response to two petitions, and solicited public comment on these proposed actions. Once this proposed rule is finalized, its procedures for review of petitions will become codified in the regulations.

APHIS also disagrees with the comment that the proposed petition process for transgenic plants has no scope and no standards. APHIS believes that the issues that petitioners need to consider to fulfill the data requirements of § 340.6(c)(4) illuminate the full range of substantive risks that might conceivably be presented by a transgenic plant. With respect to standards, APHIS has followed the procedural requirements under the National Environmental Policy Act (NEPA) and existing USDA authorities to identify any plant pest risk posed by a transgenic plant under the FPPA. Based on these facts, and on its experience in having completed one determination of nonregulated status, APHIS does not believe that its review under the petition process provides inadequate oversight; nor that the data requirements are inadequate. No changes to the regulations are made in specific response to any of these comments. However, several small changes to wording describing information requirements for submission have been made, and these will be discussed below.

Four commenters expressed the desire that the public be allowed to comment on any proposed petitions under this section. Several of these commenters stated that 60 days, or a minimum of 60 days, should be afforded the public for their input. APHIS utilized a 45 day comment period in its interpretive rulemaking process for Calgene's petition concerning the FLAVR SAVR™ tomato, and in its ongoing review of another petition concerning virus-resistant squash from Upjohn, Inc. APHIS published notices of proposed interpretive rulemaking in the Federal Register (57 FR 31170, July 14, 1992; 57 FR 40632, September 4, 1992) with a request for public comment regarding determination of the regulatory status of the organisms that were the subject of these petitions. Many of the comments received on these two petitions have proven extremely useful in APHIS'

analyses. APHIS recognizes the valuable role that can be played by public input in this process. Accordingly, we have added a provision for a 60-day public comment period. The amended section, § 340.6(d)(2), reads as follows:

> After the filing of a petition, APHIS shall publish a notice in the **Federal Register**. This notice shall specify that comments will be accepted from the public on the filed petition during a 60 day period commencing with the date of the notice. During the comment period, any interested person may submit to the Director, BBEP, written comments, regarding the filed petition, which shall become part of the petition file.

APHIS has also modified the proposed regulations to lengthen the review period for petitions from 120 days to 180 days. This change has been made to allow for adequate review of public comments after the new 60 day public comment period.

APHIS disagrees with one commenter's contention that an exemption from regulated status deprives the public of access to information regarding releases of transgenic plants. This statement does not accurately represent the history of organisms determined to have nonregulated status. This determination of safety for a transgenic plant is based upon scientific evidence, which may include successful field tests that have been approved after Agency environmental assessments and findings of no significant impact, and other scientific data and public comment indicating that the constructs pose no significant plant pest risk. There is a history of public access and involvement throughout the regulatory processes utilized by APHIS. Notices are published in the **Federal Register** when a permit application for a field trial is received, and when an environmental assessment has been prepared for than field trial. In addition, in an effort to be responsive to public interest in field tests performed under the notification process, APHIS will make a list of notification for release available on request. APHIS has now also modified the proposed regulation to include a specified public comment period in the petition process; if significant issues are identified that cannot be satisfactorily addressed in that process, a petition for determination of nonregulated status will not be successful and the transgenic plant will remain under regulated status.

One commenter offered the opinion that a public participation in APHIS' decision making process is also inadequate because the public has inadequate access to information protected as Confidential Business Information (CBI) by a petitioner, particularly during the appeals process for CBI determinations. APHIS disagrees. Its requirements for substantiation of CBI claims by petitioners and public access to non-confidential materials comply fully with the Freedom of Information Act (FOIA) (5 U.S.C. 552). APHIS balances the need for confidentiality against the publics right to know. All non-confidential data submitted in support of a petition is available for public inspection in a reading room provided by APHIS. Thus, APHIS, believes that adequate opportunity is provided for public participation in the determination. No change to the rule has been made in response to these comments.

Three comments expressed the opinion that establishment of the petition process for determination of nonregulated status is premature and is not founded on adequate information or data. APHIS disagrees. APHIS believes that valid procedures have been proposed to ensure that adequate data and justification be provided before APHIS makes a determination that an organism should be exempted from the regulations. The new procedures include an opportunity for public comment and public review of the data that has been submitted to APHIS in support of a petition for determination of nonregulated status. State regulatory agencies, academic institutions, and individual research scientists will have the opportunity to present all relevant information to the agency pertaining to a specific organism prior to a determination of nonregulated status by APHIS. Thus, no changes are made to the regulations in response to these comments.

One commenter expressed the opinion that data reviewed in the petition process must necessarily include "peer reviewed scientific studies". APHIS disagrees with this contention. Data related to the safety of the regulated article must be submitted with the petition and be reviewed by APHIS' scientific staff and the data made available to the public. Public comment and the review process utilized by APHIS provide for adequate peer review of submitted data. Although the precise meaning of the phrase "peer reviewed scientific studies" is not entirely clear, one interpretation is that the commenter is suggesting that these data need to be published in the scientific literature. APHIS believes it would place unreasonable temporal and monetary burdens on applicants to require that their studies be published in this way, particularly all of those studies that indicate no new or scientifically interesting characteristics for the regulated article. Moreover, such a provision would deny applicants the ability to protect CBI as provided under FOIA.

Another comment relating to data requirements suggested that APHIS should generally require that petitions be substantiated by data, rather than descriptive information. APHIS disagrees with this comment at least in part. APHIS believes that descriptive information is, in fact, data. Much of the useful agronomic information that has been collected over the years on crop plants has been collected through "description." Nonetheless, while not all useful observations are easily presented in the form of tables and statistics, it is important to point out to petitioners that accurate recording of when, how, and how often particular observations are made can be critical to the validity of their observations. It should also be pointed out, however, that for particular transgenic plants, experiments may sometimes need to be designed expressly to address particular issues that may be raised by use of those plants. These experiments might conceivably be of a type that will require field testing under permit rather than notification, even for crops listed as eligible for notification.

In response to a specific request that proposed § 340.6(b)(A) be amended to include all data relevant to a petition, APHIS notes that the proposed regulations in § 340.6(b)(A) stated:

> The petitioner shall include copies of scientific literature, copies of unpublished studies, or data from tests performed upon which to base a determination.

It was the intent of APHIS, by using the disjunctive "or", to require all available data. In order to clarify this requirement, APHIS is amending the regulations to indicate explicitly that all three types of data shall be required with a petition if they are available. The regulations are amended accordingly in the final rule in response to this comment.

Another commenter argued that the scope of the petition section of the proposed rule is ambiguous. The comment argued that the scope of the rule might not be limited to plants because some "regulated articles" which might be the subject of petitions are microorganisms. If the rule is to apply to organisms other than plants, the commenter continued, the appropriate data requirements must be specified. The commenter is correct in noting that the data elements listed in § 340.6(c) apply specifically to characteristics of plants, rather than

microorganisms. APHIS notes that it is stated in the summary to the proposed rule that the petition process is designed to apply to "a petition process allowing for a determination that certain transgenic plants are no longer considered regulated articles." To further clarify the intent of the proposed rule, we have also amended the petition data element proposed in § 340.6(c)(1) by substituting the word "plant" for "organism". The section redesignated as § 340.5 in the proposed rule, "Petition to amend the list of organisms," would still apply if an applicant wishes that the regulatory status of a particular microorganism be considered by APHIS.

Several minor changes have been made to § 340.6(c) for clarification or in response to comments. We have further amended § 340.6(c)(1) by adding the words, "and information necessary to identify the recipient plant in the narrowest taxonomic grouping applicable," in order to indicate to petitioners the requirement that they specify exactly those species, varieties, cultivars, or transformat lines to which the petition applies.

Another commenter noted that the language setting out data requirements for specifying the genotype of a regulated article in § 340.6(c)(3) seemed open-ended. It would often be difficult and irrelevant, the commenter contended, to provide a detailed genotype of the parental organism, and it would make more sense to focus on that subset of genotype information that could be relevant to the determination. APHIS concurs, and accordingly, the first sentence of this section has been modified to read, "A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism."

One commenter noted that it would be helpful for investigators if there were some comment in the rule regarding the significance of the traits imparted to plants as a criterion for risk. Accordingly, the following sentence has been added to § 340.6(c)(4):

> Any information known to the petitioner that indicates that a regulated article may pose a greater plant pest risk than the unmodified recipient organism shall also be included.

Executive Order 12778

Twenty-five comments were received related to the statement made under Executive Order 12778, Civil Justice Reform, that appeared on page 57 FR 53040 of the proposed rule. Twenty-two of these comments objected to the statement that the proposed Federal regulations preempted State regulations that were inconsistent with this rule. Three comments raised concerns or requested clarification of the statement pertaining to preemption.

In general, the comments stated that States and Federal Territories need to retain the authority to impose restrictions and advance notification requirements that are more strict than Federal standards to address local plant pest or disease conditions, to keep their constituencies informed, and to ensure their adequate protection. Federal preemption would discourage State involvement and undermine cooperation between State and Federal governments. The comments further stated that the language under Executive Order 12778 was in conflict with a recent court decision which held that Federal preemption authority was divested from the PQA by the 1926 amendment to the Act.

APHIS wishes to clarify its role in cooperating with the States during the permitting and notification processes for introduction of regulated articles. Since 7 CFR part 340 went into effect in July, 1987, APHIS has generally enjoyed a fruitful collaborative relationship in the evaluation of introductions of genetically engineered organisms, and input from officials of the States and Federal Territories has been invaluable in determining prudent courses of action with regard to proposed field trials throughout the United States. APHIS expects that this relationship will continue, and looks forward to additional assistance from the States and Territories whenever a significant issue arises.

With regard to APHIS' interpretation of its actual authority regarding plant protection issues, Congress has given to the Secretary of Agriculture, through the PQA and the FPPA, the sole responsibility for protecting the horticulture and agriculture of the United States from the importation into the United States of plant pests and diseases. Under these Acts, the States are precluded from imposing restrictions on plants and plant products while they are in foreign commerce, or which would be an unreasonable burden on such commerce. Additionally, the Secretary has been given authority under the PQA and FPPA to promulgate regulations to prevent the movement in interstate commerce of plant pests or diseases. Pursuant to those Acts, State regulations would be preempted only if they are inconsistent with any Federal orders or regulations promulgated pursuant to those Acts. It is APHIS' position that where the Secretary of Agriculture has established an interstate quarantine or regulation under either Act, neither the States nor Territories can establish additional requirements concerning the particular subject matter regulated thereby. It should be noted, however, that even where the Secretary has issued a quarantine or regulations on articles in interstate commerce, States may still establish parallel quarantines and regulations which do not impose requirements in addition to those imposed by the Secretary.

Thus, the issuance of final rules does not *per se* prohibit State regulation of the intrastate movement of genetically engineered plants. Whether State or Territorial regulation is preempted would depend on whether the State or Territorial regulation is viewed as being different than, or otherwise inconsistent with, the provisions of the final rule. The procedures adopted herein retain provisions for providing information to the States or Territories, for their review, about notifications pending within their borders. APHIS will welcome responses from the States and Territories. States and Territories are requested to inform APHIS if they have any information that gives them any reason to believe that a particular organism is not eligible for notification. APHIS looks forward to continuing its close relationship with the States or Territories as it addresses any new risk-based issues in its regulation of genetically engineered plants.

Four commenters raised the issue of preemption specifically with regard to the 1988 Court of Appeals decision in Guam Fresh, Inc. (here and after *Guam Fresh* v. *Ada*), which considered whether the 1926 amendments to the Federal Plant Quarantine Act (hereinafter, the Act) divested Federal preemptive authority from the Act. One commenter expressed the opinion that this holding allows States to regulate plant pests more strictly than they are regulated under Federal law. A reading of Guam Fresh, however, indicates that the regulatory authority of the States in a particular instance hinges on whether "the Secretary has acted" or "has found it necessary to impose a Federal quarantine in the same area". The Ninth Circuit held in Guam Fresh that States may "impose a quarantine on any articles not specifically interdicted by a Federal quarantine". The legislative history of the 1926 amendments to the Act stated:

> [t]he purpose of this measure is simply to permit the States to continue such regulations where they are not in conflict with the regulations of the United States government or where the regulations of the United States government do not cover the

particular plant or thing which the State laws undertake to cover.

The House report further noted that:

[t]he USDA advised and encouraged the placing of State quarantines [and] issued and administered its quarantines as to particular pests and diseases in the belief that the States might legally take similar action with reference to subjects not covered by a Federal quarantine.

Moreover:

* * * the Secretary of Agriculture is authorized, whenever he deems such action advisable and necessary to carry out the purposes of this chapter, to cooperate with any State, Territory, or District, in connection with any quarantine. * * *

Thus, the Secretary may cooperate with the States when the Secretary deems it necessary:

* * * in order to avoid duplication of functions, facilities, and personnel, and to attain closer coordination and greater effectiveness and economy of administration of Federal and State laws and regulations.

In holding in Guam Fresh that the 1926 amendments to the Act divested the Act of its preemptive authority, there was in effect the conclusion that "the Secretary had not acted" to impose a Federal quarantine which covered the same articles as those covered by the Guam regulation. In that instance, State regulation "supplements" Federal law by restricting pests of "peculiarly local concern" and is not preempted by Federal law. With regard to the notification provisions in question, if the State identifies a specific plant or article of local concern upon which the Secretary has not acted, a State's actions would "supplement" those of the Federal government and would not be subject to preemption. However, it is APHIS' expectation that the process established under this rule will enable, with continued cooperation by the States, identification and communication of any issues of state or local concern, so that those issues will be directly considered as part of the Federal actions under notification.

Compliance With the National Environmental Policy Act

Several commenters expressed the opinion that APHIS has failed to comply with the requirements of NEPA by failing to provide an environmental analysis of its proposed rule at the time of its publication. APHIS disagrees. With regard to the notification provision of this final rule, APHIS has prepared an environmental assessment which is available upon request. The rationale for this analysis was also set forth in an abbreviated form in the preamble of the proposed rule. For organisms approved under notification, however, APHIS continues to believe that the constraints imposed by the eligibility criteria and the performance standards effectively eliminate the potential for significant impact to the environment that would occasion any case-by-case analysis.

The testing of novel organisms not fitting the eligibility criteria for notification and the use of field testing protocols not strictly in conformance with the performance standards will continue to be regulated under the permitting procedures. APHIS stated in its regulations at 52 FR 22892 on June 16, 1987, that the issuance of all permits for the introduction of a genetically engineered organism would be in accordance with NEPA, USDA regulations, and APHIS Guidelines implementing NEPA. APHIS indicated that it would prepare environmental assessments and, where necessary, environmental impact statements prior to issuing permits for the release of regulated articles into the environment.

APHIS has prepared environmental assessments (EA's) and findings of no significant impact (FONSI's) for some 365 permit applications as of March 2, 1993. Each of these assessments has entailed the evaluation of scientific data and other information submitted by interested persons, review of State comments on each proposed release, and sometimes consideration of other comments provided to APHIS by members of the public, regarding not only the potential for plant pest risk, but also a broad range of other potential effects on the human environment. Our analyses, documented in these evaluations and supported by the field trial reports submitted by applicants after the conclusion of their field trials, indicate that certain actions will not have a significant environmental effect. APHIS' action, establishing performance standards and eligibility criteria applicable to notification of introduction of a limited number of regulated articles in lieu of permitting requirements, is a reflection of our experience with these field trials. APHIS has derived the eligibility criteria and performance standards to be used for notification in this rule from the criteria that APHIS has used previously in its environmental assessments to determine that genetically engineered plants pose no significant impact on the environment. APHIS believes that full compliance with the eligibility requirements and performance standards for notification would lead to a finding of no significant impact for the introduction of such genetically engineered plants.

The D.C. Circuit's decision in *FET* v. *Heckler*, stated that "NEPA requires an agency to evaluate the environmental effects of its action at the point of commitment" (756 F.2d 143, D.C. Cir. 1985). With regard to the petition provision of this final rule, APHIS has concluded that the "point of commitment" occurs when the agency takes action on each individual petition for determination of nonregulated status of a genetically engineered plant. This petition process is similar to APHIS' actions regarding a petition for nonregulated status received from Calgene, Inc., regarding its FLAVR SAVR™ tomato. Through an analysis of data submitted from Calgene and public comments, APHIS made the determination that the FLAVR SAVR™ tomato should no longer be a regulated article. To illustrate the considerations involved in making this determination, the following conclusions are derived from that determination. FLAVR SAVR™ tomatoes were found to: (1) Exhibit no plant pathogenic properties; (2) be no more likely to become weeds than their non-engineered parental varieties; (3) be unlikely to increase the weediness potential for any other cultivated plant or native wild species with which the organisms can interbreed; (4) not cause damage to processed agricultural commodities; and (5) be unlikely to harm other organisms, such as bees, that are beneficial to agriculture. APHIS also concluded that there is no reason to believe that new progeny FLAVR SAVR™ tomato varieties bred from these lines will present a plant pest risk, i.e., have properties substantially different from those observed for the FLAVR SAVR™ tomato lines already field tested, or those observed for tomatoes in traditional breeding programs.

APHIS will make similar analyses in full compliance with NEPA to determine plant pest risk for other organisms for which petitions are received under § 340.6. APHIS expects to receive petitions concerning a wide range of organisms that exhibit a wide range of properties. By virtue of the potential variation in considerations between different petitions, each will need to be considered individually. The final rule does not irrevocably commit APHIS to any decision regarding any petition for nonregulated status.

The petition process is merely a procedural provision which may result in an organism no longer being regulated after a thorough and comprehensive plant pest and environmental analysis. As a procedural provision it advises persons what data to submit in a petition so that the

Agency can decide *if* a determination of nonregulated status can be made. This is the same rationale which appeared in the Agency's Special Environmental Assessment that was prepared analyzing the impact of 7 CFR part 340, when it was published as a final rule on June 16, 1987 (see FR 22906). Thus, APHIS is incorporating the Special Environmental Assessment into the present assessment it is preparing for this final rule.

Changes to the Final Rule Which Reflect Internal Agency Management

We have amended the rule in response to comments only in those portions addressed in the November 6, 1992, proposed rule (*See* 57 FR 53036–53043), and have made miscellaneous changes related to administrative organization within APHIS. The latter changes pertain to internal agency management and are thus exempted from notice and comment rulemaking under the Federal Administrative Procedure Act (5 U.S.C. 553).

Executive Order 12291 and Regulatory Flexibility Act

This final rule is issued in conformance with Executive Order 12291 and has been determined to be not a "major rule." Based on information compiled by the Department, it has been determined that the final rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The effect of this final rule is to (1) provide for a notification procedure for the introduction of regulated articles in accordance with performance standards, and (2) formalize a petition procedure for a determination that an article is not regulated under part 340. Currently, the regulations do not provide for such a petition procedure. The notification procedure for the introduction of a regulated article would be used in place of a permit application when the field test, interstate movement, or importation would be performed in accordance with the eligibility requirements and performance standards in this document. The petition procedure was devised in response to comments received by APHIS. The notification procedure should result in a savings of time and expense that would ordinarily be associated with the preparation of a permit application and would eliminate the delay associated with permit application review. Eighty-five percent of current field tests could be conducted under the notification procedure, with the result that the current 120-day waiting period for a release permit would be eliminated. The majority of movement that is currently conducted under permit could also be conducted under the notification procedure, with the result that the current 60-day waiting period of movement would be eliminated.

It is expected that the notification and petition procedures would affect several hundred research scientists, some of whom may be operating small businesses that would be deemed small "entities" under the Regulatory Flexibility Act. When the final rule was issued in 1987 it was estimated that the initial cost associated with submission of a permit application was $5,000. However, APHIS has subsequently learned that the cost of preparing a permit application has dropped significantly (by as much as 90%) once an applicant has made more than one permit submission to APHIS. We have estimated that the notification procedure should reduce by 95% the cost associated with permit preparation. Thus, each person utilizing the notification procedure in lieu of a permit should immediately realize an initial savings of at least $4750 for a person who is preparing a permit application for the first time. However, this savings would be less than $4750 when the cost of preparing a permit application is less than $5000.

APHIS believes that the initial cost of preparing a notification should not be significant since the type of information called for in a notification is basic data that a researcher or company has already collected. The cost of preparing a notification will further decrease as persons become more familiar with the preparation of notification letters. APHIS further believes that there should be no additional cost associated with the collection of data required for a petition for non-regulated status. The Agency believes that the data required in a petition is the data a company or researcher would routinely collect to assess the development potential of a new variety. APHIS acknowledges that there may be some slight additional cost associated with the actual preparation of the petition. APHIS believes that this cost would be minimal.

Under the circumstances referred to above, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

In order to ensure that State regulatory programs are in harmony with this regulation, the Department will continue to consult with State regulatory officials regarding specific local ecological concerns that may be affected by plants to be introduced under the notification procedures. The Department also intends to provide the public with notice of its proposed actions and the deliberations with the States. This process should assure, with continued cooperation of the States, that State concerns will be considered as part of the Federal notification process. If newly identified issues suggest any modifications of these regulations, the Department will be able to address these concerns through the notice and comment rulemaking process, or through emergency regulation as appropriate. These cooperative measures should go far to harmonize Federal and State regulatory activities in this area.

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. Pursuant to the United States Constitution and applicable Federal statutes, any State or local laws, regulations, or policies that are inconsistent with this rule are preempted. This rule does not preempt any existing State or local law which is consistent with it. This rule has no retroactive effect. This rule does not require the exhaustion of administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

Information collection requirements contained in this document have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and have been assigned OMB control number 0579–0085.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372 which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

List of Subjects in 7 CFR Part 340

Administrative practice and procedure, Biotechnology, Genetic engineering, Imports, Packaging and

containers, Plant diseases and plant pests, Transportation.

Accordingly, we are amending 7 CFR 340 as follows:

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

1. The authority citation for 7 CFR part 340 continues to read as follows:

Authority: 7 U.S.C. 150aa–150jj, 151–167, 1622n; 31 U.S.C. 9701; 7 CFR 2.17, 2.51, and 371.2(c).

2. In § 340.0, paragraph (a) and its footnote are revised to read as follows:

§ 340.0 Restrictions on the introduction of regulated articles.

(a) No person shall introduce any regulated article unless the Director, BBEP, is:

(1) Notified of the introduction in accordance with § 340.3, or such introduction is authorized by permit in accordance with § 340.4, or such introduction is conditionally exempt from permit requirements under § 340.2(b); and

(2) Such introduction is in conformity with all other applicable restrictions in this part.[1]

* * * * *

3. In § 340.1, the definitions for *Deputy Administrator* and *Plant Protection and Quarantine* are removed; the following definitions *Animal and Plant Health Inspection Service (APHIS), Director, BBEP,* and *State regulatory official* are added in alphabetical order; and *Courtesy permit, Inspector, Permit,* and *Regulated article* are revised to read as follows:

§ 340.1 Definitions.

* * * * *

Animal and Plant Health Inspection Service (APHIS). An agency of the United States Department of Agriculture.

Courtesy permit. A written permit issued by the Director, BBEP, in accordance with § 340.4(h).

Director, BBEP. The Director, or designee of the Director, of the Biotechnology, Biologics, and Environmental Protection (BBEP) division of the Animal and Plant Health Inspection Service.

* * * * *

Inspector. Any employee of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or other person, authorized by the Director, BBEP, in accordance with law to enforce the provisions of this part.

* * * * *

Permit. A written permit issued by the Director, BBEP, for the introduction of a regulated article under conditions determined by the Director, BBEP, not to present a risk of plant pest introduction.

* * * * *

Regulated article. Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Director, BBEP, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

* * * * *

State regulatory official. State official with responsibilities for plant health, or any other duly designated State official, in the State where the introduction is to take place.

* * * * *

§ 340.1 [Amended]

4. In § 340.1 the definition heading for *Well-characterized and contains only non-coding regulatory regions (e.g. operators, promoters, origins of replication, terminators, and ribosome binding regions)* is italicized.

§ 340.2 [Amended]

5. In § 340.2, paragraph (b)(1)(i) the phrase "§ 340.6(b)(3) of this part" is revised to read "§ 340.8(b)(3)".

6. In § 340.2, paragraph (b)(2)(i) the phrase "§ 340.6(b)(1), (2), and (3) of this part" is revised to read "§ 340.8(b) (1), (2), and (3)."

§§ 340.3 through 340.7 [Redesignated as §§ 340.4, 340.5, 340.7, 340.8 and 340.9]

7. Sections 340.3, 340.4, 340.5, 340.6, 340.7 are redesignated §§ 340.4, 340.5, 340.7, 340.8, and 340.9 respectively.

8. A new § 340.3 is added to read as follows:

§ 340.3 Notification for the introduction of certain regulated articles.

(a) *General.* Certain regulated articles may be introduced without a permit, provided that the introduction is in compliance with the requirements of this section. Any other introduction of regulated articles require a permit under § 340.4, with the exception of introductions that are conditionally exempt from permit requirements under § 340.2(b) of this part.

(b) *Regulated articles eligible for introduction under the notification procedure.* Regulated articles which meet all of the following six requirements and the performance standards set forth in paragraph (c) of this section are eligible for introduction under the notification procedure.

(1) The regulated article is:

(i) One of the following plant species:

corn (*Zea mays* L.);
cotton (*Gossypium hirsutum* L.);
potato (*Solanum tuberosum* L.);
soybean (*Glycine max* [L.] Merr.);
tobacco (*Nicotiana tabacum* L.);
tomato (*Lycopersicon esculentum* L.); or

(ii) Any additional plant species that BBEP has determined may be safely introduced in accordance with the eligibility criteria set forth in paragraph (b)(2) through (b)(6) of this section and the performance standards set forth in paragraph (c) of this section.

(2) The introduced genetic material is "stably integrated" in the plant genome, as defined in § 340.1.

(3) The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease.

(4) The introduced genetic material does not:

(i) Cause the production of an infectious entity, or

(ii) Encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species, or

(iii) Encode products intended for pharmaceutical use.

(5) To ensure the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, they must be:

(i) Noncoding regulatory sequences of known function, or

[1] Part 340 regulates, among other things, the 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 introduction into the United States of such articles may be subject to other regulations promulgated under the Federal Plant Pest Act (7 U.S.C. 150aa *et seq.*), the Plant Quarantine Act (7 U.S.C. 151 *et seq.*) and the Federal Noxious Weed Act (7 U.S.C. 2801 *et seq.*) and found in 7 CFR parts 319, 321, 330, and 360. For example under regulations promulgated in 7 CFR "Subpart-Nursery Stock" (7 CFR 319.37) a permit is required for the importation of certain classes of nursery stock whether genetically engineered or not. Thus, a person should consult those regulations prior to the importation of any nursery stock.

(ii) Sense or antisense genetic constructs derived from viral coat protein genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, or

(iii) Antisense genetic constructs derived from noncapsid viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species.

(6) The plant has not been modified to contain the following genetic material from animal or human pathogens:

(i) Any nucleic acid sequence derived from an animal or human virus, or

(ii) Coding sequences whose products are known or likely causal agents of disease in animals or humans.

(c) *Performance standards for introductions under the notification procedure.* The following performance standards must be met for any introductions under the notification procedure.

(1) If the plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment.

(2) When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release.

(3) The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.

(4) There must be no viable vector agent associated with the regulated article.

(5) The field trial must be conducted such that:

(i) The regulated article will not persist in the environment, and

(ii) No offspring can be produced that could persist in the environment.

(6) Upon termination of the field test:

(i) No viable material shall remain which is likely to volunteer in subsequent seasons, or

(ii) Volunteers shall be managed to prevent persistence in the environment.

(d) *Procedural requirements for notifying APHIS.* The following procedures shall be followed for any introductions under the notification procedure:

(1) Notification should be directed to Director, BBEP, c/o Deputy Director, Biotechnology Permits, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782.

(2) The notification shall include the following:

(i) Name, title, address, telephone number, and signature of the responsible person;

(ii) Information necessary to identify the regulated article(s), including:

(A) The scientific, common, or trade names, and phenotype of regulated article,

(B) The designations for the genetic loci, the encoded proteins or functions, and donor organisms for all genes from which introduced genetic material was derived, and

(C) The method by which the recipient was transformed;

(iii) The names and locations of the origination and destination facilities for movement or the field site location for the environmental release; and the size of the introduction,

(iv) The date and, in the case of environmental release, the expected duration of the introduction (release); and

(v) A statement that certifies that introduction of the regulated article will be in accordance with the provisions of this section.

(3) Notification must be submitted to BBEP:

(i) At least 10 days prior to the day of introduction, if the introduction is interstate movement.

(ii) At least 30 days prior to the day of introduction, if the introduction is an importation.

(iii) At least 30 days prior to the day of introduction, if the introduction is an environmental release.

(4) Field test reports must be submitted to the Director, BBEP, within 12 months after the start of the field test, and every 12 months through the duration of the field test. Final reports for those field tests lasting more than 12 months are due 6 months after the termination of the field test. Field test reports shall include:

(i) The APHIS reference number; and

(ii) Methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(5) The Director, BBEP, shall be notified of any unusual occurrence within the time periods and in the manner specified in § 340.4(f)(10).

(6) Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field test site and any records necessary to evaluate compliance with the provisions of paragraphs (b) and (c) of this section.

(e) *Administrative action in response to notification.* (1) The Director, BBEP, will notify the appropriate State regulatory official(s) for notification and review within 5 business days of receipt of notification.

(2) The Director, BBEP, will provide acknowledgement within 10 days of receipt that the interstate movement is appropriate under notification.

(3) The Director, BBEP, will provide acknowledgement within 30 days of receipt that the importation is appropriate under notification.

(4) The Director, BBEP, will provide acknowledgement within 30 days of receipt that the environmental release is appropriate under notification.

(5) A person denied permission for introduction of a regulated article under notification may apply for a permit for introduction of that regulated article without prejudice.

9. A new § 340.6 is added to read as follows:

§ 340.6 Petition for determination of nonregulated status.

(a) *General.* Any person may submit to the Director, Biotechnology, Biologics, and Environmental Protection (BBEP), a petition to seek a determination that an article should not be regulated under this part. A petitioner may supplement, amend, or withdraw a petition in writing without prior approval of the Director, BBEP, and without affecting resubmission at any time until the Director, BBEP, rules on the petition. A petition for determination of nonregulated status shall be submitted in accordance with the procedure and format specified in this section.

(b) *Submission procedures and format.* A person shall submit two copies of a petition to the Director, BBEP, c/o the Deputy Director, Biotechnology Coordination and Technical Assistance, BBEP, APHIS, USDA, 6505 Belcrest Road, Federal Building, Hyattsville, MD 20782. The petition shall be dated and structured as follows:

Petition for Determination of Nonregulated Status

The undersigned submits this petition under 7 CFR 340.6 to request that the Director, BBEP, make a determination that the article should not be regulated under 7 CFR part 340.

(Signature) _____

A. Statement of Grounds

A person must present a full statement explaining the factual grounds why the

organism should not be regulated under 7 CFR part 340. The petitioner shall include copies of scientific literature, copies of unpublished studies, when available, and data from tests performed upon which to base a determination. The petition shall include all information set forth in paragraph (c) of 7 CFR 340.6. If there are portions of the petition deemed to contain trade secret or confidential business information (CBI), each page of the petition containing such information should be marked "CBI Copy". In addition, those portions of the petition which are deemed "CBI" shall be so designated. The second copy shall have all such CBI deleted and shall have marked on each page where the CBI was deleted: "CBI Deleted." If a petition does not contain CBI, the first page of both copies shall be marked: "No CBI."

A person shall also include information known to the petitioner which would be unfavorable to a petition. If a person is not aware of any unfavorable information, the petition should state, "Unfavorable information: NONE."

B. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which to base a determination, and that it includes relevant data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of Petitioner) _____

(Mailing Address) _____

(Telephone Number) _____

(c) *Required data and information.* The petition shall include the following information:

(1) Description of the biology of the nonmodified recipient plant and information necessary to identify the recipient plant in the narrowest taxonomic grouping applicable.

(2) Relevant experimental data and publications.

(3) A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism. Include all scientific, common, or trade names, and all designations necessary to identify: the donor organism(s), the nature of the transformation system (vector or vector agent(s)), the inserted genetic material and its product(s), and the regulated article. Include country and locality where the donor, the recipient, and the vector organisms and the regulated articles are collected, developed, and produced.

(4) A detailed description of the phenotype of the regulated article. Describe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: Plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Director believes to be relevant to a determination. Any information known to the petitioner that indicates that a regulated article may pose a greater plant pest risk than the unmodified recipient organism shall also be included.

(d) *Administrative action on a petition.*

(1) A petition for determination of nonregulated status under this part which meets the requirements of paragraphs (b) and (c) of this section will be filed by the Director, BBEP, stamped with the date of filing, and assigned a petition number. The petition number shall identify the file established for all submissions relating to the petition. The BBEP will promptly notify the petitioner in writing of the filing and the assigned petition number. If a petition does not meet the requirements specified in this section, the petitioner shall be sent a notice indicating how the petition is deficient.

(2) After the filing of a completed petition, APHIS shall publish a notice in the **Federal Register**. This notice shall specify that comments will be accepted from the public on the filed petition during a 60 day period commencing with the date of the notice. During the comment period, any interested person may submit to the Director, BBEP, written comments, regarding the filed petition, which shall become part of the petition file.

(3) The Director, BBEP, shall, based upon available information, furnish a response to each petitioner within 180 days of receipt of a completed petition. The response will either:

(i) Approve the petition in whole or in part; or

(ii) deny the petition.

The petitioner shall be notified in writing of the Director's decision. The decision shall be placed in the public petition file in the offices of BBEP and notice of availability published in the **Federal Register**.

(e) *Denial of a petition; appeal.* (1) The Director's written notification of denial of a petition shall briefly set forth the reason for such denial. The written notification shall be sent by certified mail. Any person whose petition has been denied may appeal the determination in writing to the Administrator within 10 days from receipt of the written notification of denial.

(2) The appeal shall state all of the facts and reasons upon which the person relies, including any new information, to show that the petition was wrongfully denied. The Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. An informal hearing may be held by the Administrator if there is a dispute of a material fact. Rules of Practice concerning such a hearing will be adopted by the Administrator.

§ 340.4 [Amended]

10. In newly redesignated § 340.4 the words "Plant Protection and Quarantine" are removed and the phrase "Biotechnology, Biologics, and Environmental Protection" is added in its place:

a. Paragraph (a), both times it appears.

b. Paragraph (b), three times it appears.

c. Footnote 6.

d. Paragraph (c), introductory paragraph, three times it appears.

e. Paragraph (c)(1), in the 5th and 8th sentences.

f. Paragraph (c)(2).

g. Paragraph (e), both times it appears.

h. Paragraph (f)(9).

i. Paragraph (f)(10).

j. Paragraph (f)(11)(ii).

k. Paragraph (h)(2).

l. Paragraph (h)(3), both times it appears.

11. In newly redesignated § 340.4 the words "Deputy Administrator" are removed and the words "Director, BBEP" are added in their place:

a. Paragraph (f), introductory paragraph.

b. Paragraph (f)(7).

c. Paragraph (f)(8).

d. Paragraph (g), the three times it appears.

e. Paragraph (h)(1).

12. In newly redesignated § 340.4, paragraph (a) first sentence, the words "the Biological Assessment Support Staff, (Biotech Unit)" are removed and the words "Biotechnology Permit Unit" are added in their place.

13. In newly redesignated § 340.4, footnote 6, the words "the Biological Assessment Support Staff" are removed and the words "Biotechnology Permit Unit" are added in their place.

§ 340.5 [Amended]

14. In newly redesignated § 340.5, paragraph (b), in the introductory paragraph and under the subheading PETITION TO AMEND 7 CFR 340.2, the words "Plant Protection and Quarantine" are removed and the phrase "Biotechnology, Biological, and Environmental Protection" are added in their place.

15. In newly redesignated § 340.5 the words "Deputy Administrator" are removed and the words "Director, BBEP" are added in their place:

a. Paragraph (a), the three times it appears.

b. Paragraph (b), in the introductory paragraph and under the subheading PETITION TO AMEND 7 CFR 340.2.

c. Paragraph (c)(3) the introductory text and (c)(3)(i).

16. In newly redesignated § 340.5, paragraph (c)(3)(ii) the words "Deputy Administrator's" are removed and the words "Director, BBEP's" are added in their place.

17. In newly redesignated § 340.5, paragraph (b), the words "in care of the Director of the Biotechnology and Environmental Coordination Staff" are removed.

18. In newly redesignated § 340.5 the words "the Biotechnology and Environmental Coordination Staff" are removed and the words "Biotechnology, Biologics, and Environmental Protection" are added in their place.

a. Paragraph (c)(1), both times it appears.

b. Paragraph (c)(2).

c. Paragraph (c)(3)(ii).

§ 340.7 [Amended]

19. In newly redesignated § 340.7, paragraph (b) the words "Plant Protection and Quarantine" are removed and the phrase "Biotechnology, Biologics, and Environmental Protection" are added in its place.

Done in Washington, DC, this 29th day of March 1993.

Kenneth C. Clayton,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–7517 Filed 3–30–93; 8:45 am]

BILLING CODE 3410–34–M