

**Appendices A and B**

A number of the commodities referred to in these appendices have not been used in the program for more than five years, and some for more than 20 years. To simplify and shorten the regulations and reduce printing and distribution costs, FAS proposes to delete the sections of these appendices for the following commodities: Corn meal; cracked corn; unmanufactured tobacco and tobacco products; dry edible beans; dry edible peas; lard; poultry; canned milk; nonfat dry milk, dry whole milk; butter, anhydrous milk fat, anhydrous butter fat and butteroil; cheese; ghee; and stabilized dried whole eggs.

Removing these sections from the regulations does not affect the potential for future programming of these commodities under the title I program. If any of the commodities removed from the appendices were to be programmed under title I in the future, the relevant purchase authorization would contain the updated contracting and documentary requirements.

**Paperwork Reduction Act**

The reporting and recordkeeping requirements contained in this proposed rule have been assigned OMB control number 0551-0005. This proposed rule does not impose a public reporting burden. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for further reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, AGBOX 7630, Washington, DC 20250-7630; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Paperwork Reduction Project (OMB #0551-0005), Washington, DC 20503.

**List of Subjects in 7 CFR Part 17**

Agricultural commodities; exports; finance; maritime carriers.

Accordingly, 7 CFR part 17, subpart A, is amended as follows:

1. The authority citation for part 17 continues to read as follows:

**Authority:** 7 U.S.C. 1701-1705, 1736a, 1736c, 5676; E.O. 12220, 45 FR 44245.

**§ 17.2 [Amended]**

2. In § 17.2(b), the definition of "Form CCC-106" is amended by removing the last sentence.

3. In § 17.14, the word "(white)" is removed from the first sentence of paragraph (d)(1); the last sentence of paragraph (d)(1) and all of paragraph (d)(2)(i) are revised to read as follows; and the word "(yellow)" is removed from paragraph (d)(2)(ii), as follows:

**§ 17.14 Ocean transportation.**

\* \* \* \* \*

(d) *Advice of vessel approval.* \* \* \*

(1) *For cotton.* \* \* \* If CCC finances any part of the ocean freight when cotton is shipped on an f.a.s. basis, a signed original copy of this form will be issued to the ocean carrier.

(2) *For commodities other than cotton.* \* \* \*

(i) For shipments to be made on an f.o.b. or f.a.s. basis, when CCC finances any part of the cost of ocean freight, the original of Form CCC-106-2 will be issued to the ocean carrier.

\* \* \* \* \*

**§ 17.18 [Amended]**

4. In § 17.18, the phrase "for c. & f. or c.i.f. sales" is added at the end of paragraph (c)(8)(ii).

**Appendices A and B [Amended]**

5. In Appendix A and Appendix B, existing sections (D), (E), (G), (I), (J), (L), (M), (N), (O), (P), (Q), (R), (S), (T), and (U) are removed; existing section (K) is redesignated as (G); existing section (V) is redesignated as (D); and existing section (W) is redesignated as (E).

6. In Appendix B, "Documentary Requirements," the phrase "for c. & f. or c.i.f. sales" is added at the end of the following paragraphs: (A) (1)(d) and (2)(d); (B)(4); (C) (1)(d) and (2)(d); newly redesignated (D)(4) and (E)(4); (F) (1)(d) and (2)(d); newly redesignated (G) (1)(d) and (2)(d); and (H) (1)(d) and (2)(d).

Signed at Washington, D.C. on June 12, 1995.

**Christopher E. Goldthwait,**

*General Sales Manager, Foreign Agricultural Service; and Vice President, Commodity Credit Corporation.*

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**Animal and Plant Health Inspection Service****7 CFR Part 340**

[Docket No. 95-040-1]

RIN 0579-AA73

**Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes to amend the regulations pertaining to genetically engineered plants

introduced under notification and to the petition process for the determination of nonregulated status. The proposed notification amendments would allow most genetically engineered plants that are considered regulated articles to be introduced under the notification procedure, provided that the introduction meets certain eligibility criteria and performance standards. We are also proposing to reduce the field test reporting requirements for trials conducted under notification for which no unexpected or adverse effects are observed. The proposed petition amendments would enable APHIS to extend an existing determination of nonregulated status to certain additional regulated articles that are closely related to an organism for which a determination of nonregulated status has already been made. APHIS also announces its intention to use guidelines when appropriate to provide additional information to developers of regulated articles and other interested persons regarding procedures, methods, scientific principles, and other factors that could be considered in support of actions under the regulations pertaining to genetically engineered plants introduced under notification.

The effect of the proposed amendments would be to simplify procedures for the introduction of certain genetically engineered organisms, requirements for certain determinations of nonregulated status, and procedures for the reporting of field tests conducted under notification.

**DATES:** Consideration will be given only to comments received on or before October 23, 1995.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 95-040-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 95-040-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. Michael G. Schechtman, Domestic Programs Leader, Biotechnology Coordination and Technical Assistance, BBEP, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1237, (301) 734-7601.

## SUPPLEMENTARY INFORMATION:

**Background****I. Introduction**

The regulations in 7 CFR part 340, referred to below as the regulations, pertain to the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are derived from known plant pests (regulated articles). Before introducing a regulated article, a person is required under § 340.0 of the regulations to either (1) notify the Animal and Plant Health Inspection Service (APHIS) in accordance with § 340.3 or (2) obtain a permit in accordance with § 340.4. Introductions under notification must meet specified eligibility criteria and performance standards. Under § 340.4, a permit is granted for a field trial when APHIS has determined that the conduct of the trial, under the conditions specified by the applicant or stipulated by APHIS, does not pose a plant pest risk.

An organism is not subject to the regulations when the organism is demonstrated not to present a plant pest risk. Section 340.6 of the regulations, entitled "Petition for determination of nonregulated status," provides that a person may petition APHIS to evaluate submitted data to determine that a particular regulated article does not present a plant pest risk and should no longer be regulated. If APHIS determines that the regulated article does not present a risk of introduction or dissemination of a plant pest, the petition will be granted, thereby allowing unrestricted introduction of the article. A petition may be granted in whole or in part.

In the preamble to the final regulations published on June 16, 1987 (52 FR 22892-22915, Docket No. 87-021), APHIS stated its intention to modify or amend the regulations to ensure flexibility and to remove restrictions when warranted as experience is gained and knowledge is accrued about safe introductions of particular classes of organisms. APHIS previously demonstrated its commitment to amend the regulations by instituting exemptions for the movement, under specified conditions, of certain microorganisms that contain plant pest sequences (53 FR 12910-12913, Docket No. 88-019, April 20, 1988), and of the plant *Arabidopsis thaliana* (55 FR 53275-53276, Docket No. 90-172, December 28, 1990), and by instituting both a notification procedure for the introduction of certain regulated articles and a petition procedure for the

determination of nonregulated status (58 FR 17044-17059, Docket No. 92-156-02, March 31, 1993).

Under the current regulations, plants from six crop species, i.e., corn (*Zea mays* L.), cotton (*Gossypium hirsutum* L.), potato (*Solanum tuberosum* L.), soybean (*Glycine max* (L.) Merr.), tobacco (*Nicotiana tabacum* L.), and tomato (*Lycopersicon esculentum* L.), are eligible for notification, provided that certain eligibility criteria and performance standards are met. The notification procedure also allows for additional plant species that Biotechnology, Biologics, and Environmental Protection (BBEP) determines may be safely introduced in accordance with the eligibility criteria.

**II. Proposed Expansion of Notification**

APHIS is proposing to allow the use of the notification procedure for the introduction of most genetically engineered plants that are considered regulated articles, provided that the introduction is conducted in accordance with all other eligibility requirements and performance standards. APHIS believes that an expansion of the notification system to new plant species would simplify oversight procedures for new agricultural biotechnology products, while continuing to ensure their safe development.

Currently, the regulations require that introductions of most plant species be done under permit from APHIS. The applications for permits are evaluated on a case-by-case basis. Since the APHIS permitting process for regulated articles was established in 1987, we have gained considerable experience. We have issued over 560 permits for release into the environment and over 1280 permits for movement. Most of the regulated articles field tested under permit have been plants. Through December 31, 1994, permits have been issued for a wide variety of plants. Thirty-nine different plant species have been field tested under permit, and 67 species have been moved under permit. The list of species includes a wide range of transgenic plants from 22 plant families, including flowering plants, monocots, dicots, gymnosperms, herbs, shrubs, and trees. These species exhibit a wide variety of breeding systems, including entomophily, anemophily, cleistogamy, and sexual and asexual reproduction, and exhibit seed dissemination of many different kinds. The plants have been grown in virtually all 50 States and have been moved to facilities with different laboratories, growth chambers, and greenhouses. One result of our experience with permitting has been the finding that introductions of many

different regulated articles can be conducted with little or no plant pest or environmental risk, provided that certain criteria and performance standards are met. APHIS notes in addition that even at the time that notification procedures were initially proposed in 1992, several commenters suggested that APHIS should broaden the list of organisms eligible for notification beyond the proposed list of six crops in § 340.3(b)(1)(i). After the notification procedures went into effect, APHIS has received other inquiries about adding particular additional crops to the list.

Since the APHIS notification procedure was established in 1993, we have reviewed and acknowledged over 900 notifications for field tests involving corn, cotton, potato, soybean, tobacco, and tomato. The current notification procedure involves a review of the application by APHIS to confirm that the application falls under notification, i.e., that it meets the criteria in § 340.3(b)(2) through § 340.3(b)(6). Appropriate State regulatory officials are notified. After acknowledgement of the notification by APHIS, the regulated article and site(s) of introduction are subject to inspection by APHIS and State regulatory officials. After field testing, the submission of a field test report by the applicant to APHIS is required.

One result of our experience with notification has been that such a notification procedure results in little or no plant pest or environmental risk, provided that the criteria and performance standards specified in § 340.3(b)(2) through § 340.3(b)(6) and § 340.3(c) are met. These criteria and performance standards would be retained in the proposed amendment, except that eligibility criterion in § 340.3(b)(5) would be expanded to allow the inclusion of certain additional plant virus sequences in the regulated article, as described later in this portion of the preamble.

To establish the notification procedure for additional plant species, we would revise § 340.3(b)(1), which currently lists specific crop species eligible for notification. Proposed § 340.3(b)(1) would allow the introduction under notification procedures of any plant species that is not listed as a noxious weed under regulations in 7 CFR part 360, and, for releases in the environment, is not considered a weed in the area of the proposed release into the environment.

The Agency's experience with interstate movement, importation, and release permits indicates that crop plants can be released into the

environment under notification procedures with little or no plant pest risk or potential for significant impact on the environment, if the applicant meets the performance standards given in the regulations. APHIS intends to continue its practice of consulting with appropriate State officials or other experts whenever there are questions regarding impacts on weedy populations of the plant species in question in the test area. APHIS also notes that the movement and introduction of any plant species considered a parasitic plant is subject to additional restrictions under regulations in 7 CFR parts 330 and 360 under the Federal Plant Pest Act (7 U.S.C. 150aa *et seq.*) and the Federal Noxious Weed Act (7 U.S.C. 2809), respectively.

The performance standards in § 340.3(c) of the regulations provide a description of what APHIS considers effective containment standards, typically applied on a case-by-case basis in APHIS's reviews of field trials for organisms under permit. The performance standards have, APHIS believes, effectively addressed all potential concerns with respect to nontarget effects, persistence of the regulated article in the environment, and volunteer plants. The standards also represent an enumeration of standard good agricultural practice as might be implemented by researchers and plant breeders in field trials involving the introduction of new plant material. APHIS believes that the standards apply equally well when implemented as part of a notification procedure as when implemented under a permit procedure.

The requirement that plants released into the environment are not considered weeds in the area of the field trial is not meant to supersede any State or Federal laws or regulations regarding weeds, such as the Federal Noxious Weed Act or the various laws of the States. The requirements of all such laws, acts, and regulations would be followed as part of APHIS' determination of eligibility under notification.

APHIS is also proposing to increase the range of virus resistance modifications that are included under § 340.3(b)(5), which states:

(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
- (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.

This provision does not allow plants expressing sense constructs of noncapsid viral genes to qualify for introduction under notification. In its response to comments on notification in the 1993 final rule that established notification procedures, APHIS stated its commitment to "seek input from the public on the inclusion under notification of plants expressing sense constructs from all other noncapsid viral genes." On April 21–22, 1995, APHIS convened a meeting entitled "Transgenic Virus-resistant Plants and New Plant Viruses," which brought together over 50 plant virologists to elicit information regarding the safety of virus-resistant plants. The data gathered at the workshop identified no potential increased risks associated with the field testing of transgenic plants carrying specific plant virus genes other than coat protein genes, with the sole exception of genes encoding functional viral movement proteins. This information, which will be contained within proceedings to be published later this year, supports APHIS' position to expand the virus gene eligibility criterion to include all genes encoding noncapsid viral proteins except for movement proteins. Movement proteins are virus-encoded proteins that mediate cell-to-cell spread of virus. After a virus infects and multiplies in a single plant cell, it must move to adjacent cells and eventually throughout the plant in order to be a successful pathogen. Examples of known movement proteins are the 30K protein of tobamoviruses and the 24K protein of potexviruses.

Information presented at the meeting indicates that there may be some uncertainty about the effects of an introduced gene encoding a functional movement protein on viral infections of the plant. However, genes encoding movement proteins that have been modified so they no longer produce a functional product should not pose additional potential unknown risks. APHIS wishes to clarify, however, that the definition of movement protein is not intended to include the products of coat (capsid) protein genes, even though coat proteins have some involvement in long distance movement of virus in a plant in some instances. These proteins do not have a primary role in cell-to-cell virus movement.

In accordance with this information, APHIS is proposing to revise § 340.3(b)(5). Under proposed § 340.3(b)(5), to ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be noncoding regulatory sequences of known function; or sense or antisense genetic constructs derived from 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, and that do not encode any functional noncapsid gene product responsible for cell-to-cell movement of the virus.

APHIS is also proposing to amend its administrative procedures in response to notifications for interstate movement. When a regulated article is to be moved from another State under notification procedures, APHIS has requested concurrence from the receiving State prior to APHIS' acknowledgment of the notification. APHIS would continue to notify appropriate State regulatory officials of all interstate movements of regulated articles and provide the States the opportunity to provide comments or raise concerns if they so wish. APHIS would continue to ensure that any concerns raised by a State would be addressed prior to APHIS acknowledgment. Based on the history of safe interstate movement of regulated articles under notification and on a desire to lessen administrative burdens imposed on State cooperators while meeting their information requirements, however, APHIS proposes to discontinue the requirement that States in every case provide concurrences for notifications for interstate movement prior to APHIS acknowledgment. This change would be accomplished by amending § 340.3(e)(1) to indicate that the Director, BBEF, will notify the appropriate State regulatory official(s) within 5 business days of receipt for all notifications. Any additional administrative changes would only be made in full consultation with State regulatory officials. Information regarding all notifications will continue to be available on the APHIS database on the Internet. APHIS invites comment on whether this proposed change will meet the administrative needs of its State cooperators.

### III. Proposed Changes to Regulations for Determination of Nonregulated Status

APHIS is proposing to amend its regulations in § 340.6 to allow the extension of a previously issued determination of nonregulated status to

certain additional regulated articles that are closely related to an organism that was determined not to be a regulated article in the initial determination. The text of the new regulations will be placed at § 340.6(e), and entitled, "Extensions of determinations of nonregulated status."

To date, APHIS has approved, in whole or in part, eight petitions for a determination of nonregulated status under its regulations at § 340.6. Each of those determinations applied only to a specific set of plant transformation events and all progeny derived from them. In addition, with regard to one determination, we subsequently extended nonregulated status to additional transformed lines originally contained within the initial petition request, following the receipt of supplementary data (59 FR 50220, Docket No. 94-096-1, October 3, 1994; 59 FR 59746, Docket No. 94-125-1, November 19, 1994; 60 FR 15284, Docket No. 95-015-1, March 23, 1995). Several other petitions, either currently under review or being discussed as drafts with potential applicants, relate to regulated articles that are closely related to organisms that have already been granted nonregulated status.

Our expectation is that many additional petitions will be received concerning regulated articles that differ negligibly, from a safety standpoint, from others that have already been reviewed. APHIS believes that these petitions can and should be reviewed in a more streamlined manner than petitions concerning organisms that present potential plant pest risk issues that have not yet been specifically addressed.

In order to establish the framework under which extensions of existing determinations to certain additional regulated articles would be considered, a new term, "antecedent organism," would be added to part § 340.1, and would be defined as an organism that has already been the subject of a determination of non-regulated status by APHIS under § 340.6, and that is used as a reference for comparison to the regulated article under consideration. This term expresses the agency's intent to consider the degree of APHIS' familiarity with the types of modifications in the regulated article and with the behavior in the environment of organisms similar to the one under consideration. The antecedent organism would be used as the reference for comparison with the regulated article. The aim of making such a comparison would be to ensure that the regulated article in question raises no serious new issues meriting a

separate review under the petition process.

Under this section, requests might be made, for example, that a determination of nonregulated status be extended to new transformant lines derived by transformation of a new cultivar of the same crop species with the plasmid used in constructing the antecedent organism, or to other lines produced using a related plasmid encoding a protein of identical amino acid sequence, but in which codon usage has been modified to improve gene expression. A submitter should provide to APHIS information that describes the characteristics and identity of the regulated articles that are the subject of the request, and that describes the relatedness between the regulated article and its antecedent organism.

APHIS would publish all extensions of existing determinations of nonregulated status in the **Federal Register**. This decision will become final 30 days after publication unless the agency receives any significant comments which the agency believes warrants further consideration. This will allow time for the public to become aware of our decision and to bring to the agency's attention any additional information that might be relevant to that decision.

The proposed new provisions also provide that APHIS would inform any person, whose request for extension of an existing determination was denied, of the reasons for that denial. Such a person would be allowed to resubmit without prejudice a modified request or a separate petition for determination of nonregulated status.

APHIS believes that this approach will streamline regulatory requirements for organisms that can be straightforwardly demonstrated not to pose a potential for plant pest risk, while continuing to provide adequate oversight to assure their safe development.

#### IV. Guidelines

APHIS is committed to regulations that are adjusted as information and experience are gained. As indicated earlier, APHIS has amended its regulations several times to reflect the increasing knowledge with respect to new products of agricultural biotechnology. APHIS wishes to continue to provide additional information to developers of regulated articles and other interested persons regarding procedures, practices, and protocols that could be considered by the agency in support of actions under the regulations. A footnote has been added in §§ 340.3, 340.4, 340.5, and

340.6 to indicate that APHIS intends to prepare guidelines detailing procedures, practices, or protocols related to scientific evaluations, product identity standards, and other technical or policy considerations. Guidelines will state procedures, practices, or protocols relevant to matters under this part that fall under the Federal Plant Pest Act and the Plant Quarantine Act. A person may follow an APHIS guideline or may follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed, a person may, but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS.

The first guidelines that will be prepared are intended to help submitters establish the level of similarity or relatedness between a regulated article and its antecedent organism, by illustrating procedures and methods that would be acceptable to the agency to establish such similarity or relatedness, and principles or issues of potential concern that might be considered by the agency. APHIS does not believe it is appropriate to establish rigid rules for determining similarity or relatedness, in view of the rapid pace of technological change that is expanding the potential for developing plants with new types of desirable modifications. However, the agency believes that it can provide guidance on the types of factors that should be relevant for a submitter to consider.

#### V. Simplifications to Reporting Requirements Under Permit or Notification

APHIS is proposing to simplify the reporting requirements on the performance characteristics of regulated articles in field trials that have been conducted under permit or notification, while leaving unchanged recordkeeping requirements for those trials. The regulations at § 340.4(f)(9) require that permit holders submit to BBEP monitoring reports on the performance characteristics of the regulated article, in accordance with any monitoring reporting requirements that may be specified in a permit. Starting with field trials in the 1988 growing season, APHIS incorporated into its Supplemental Permit Conditions for all field trials conducted under permit, a reporting requirement for data on the fate of the genetically engineered organisms in the environment. In addition, § 340.4(f)(10) specifies the time and manner for rapid notification of BBEP in the event of accidental or unauthorized release of the regulated

article, or upon finding that the regulated article or associated host has characteristics substantially different from those listed in the application, or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms).

For field trials conducted under notification procedures, § 340.3(d)(4) requires that field test reports 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. It also requires that final reports for those field tests lasting more than 12 months are due 6 months after the termination of the test. Field test reports shall include the APHIS reference number and methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment. In addition, § 340.3(d)(5) stipulates that the requirements in § 340.4(f)(10), for reporting of unusual occurrences in field trials conducted under permit, also apply to field trials conducted under notification.

The vast majority of data reports received by APHIS for field trials under either permit or notification have identified no deleterious effects of the regulated article on plants, nontarget organisms, or the environment. Less than one percent of all field trial reports have noted any unusual occurrences of the types indicated in § 340.3(d)(5). Occasional crop lines have exhibited substandard agronomic performance, i.e., they were wilted, or were smaller or less sturdy than controls. No event in any field trial has resulted in any known unmanaged dissemination of a regulated article.

APHIS proposes to amend the requirements for submission of field data reports for field trials under notification procedures so that only reports documenting unusual occurrences would need to be submitted within the intervals previously specified. Persons submitting petitions for determination of nonregulated status would, however, be required to submit all data reports for field trials completed prior to petition submission and submit appropriate data reports for ongoing field trials lasting more than one year. This would effect a change in reporting requirements but not recordkeeping requirements. All records documenting the safety of field trials would need to be maintained by persons responsible for the conduct of those trials, but, apart from instances in which deleterious effects on plants, nontarget organisms, or the environment are observed, those data would only be needed to be

considered by APHIS at the time of petition. Submission of field trial reports documenting the absence of deleterious effects on plants, nontarget organisms, or the environment in completed field trials under notification procedures would no longer be required prior to submission of subsequent notifications for the same regulated article(s). The existing provisions in § 340.4(f)(10) for rapid communication with BBEP in the event of certain unusual circumstances would remain unchanged, and the proposed regulation continues to require routine reporting of other deleterious effects that might be observed.

To implement these changes, § 340.3(d)(4) would be amended. It would require that responsible persons maintain records of the conduct and status of all field trials under notification procedures, that field test records include the APHIS reference number, and methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment. For field tests in which deleterious effects on plants, nontarget organisms, or the environment are observed, proposed § 340.3(d)(4) would also require that field test reports 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. For field tests lasting more than 12 months, final reports would be due 6 months after the termination of the field test. Field test reports would have to include all data required in field test records for the trial.

A new § 340.6(c)(5) would also be added, amending the list of required data and information in a petition to indicate the requirement to submit all field test reports at the time of petition submission. We would require the submission of field test reports for all trials conducted under permit or notification procedures, involving the regulated article, that were completed prior to petition submission. For ongoing trials longer than 12 months in duration, interim field test reports are required for each year. Field test reports would have to include the APHIS reference number, and methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

APHIS is also proposing to clarify the requirements for data reporting for those field trials that remain under permit. These field trials involve traits that do not meet the eligibility criteria set forth in § 340.3(b)(2) through § 340.3(b)(6) or field testing protocols that deviate from

the requirements of the performance standards set forth in § 340.3(c). Submission of data reports for field trials under permit, which has to date been required via Supplemental Permit Conditions attached to the APHIS permits for conduct of the trials, would now be explicitly required in the regulation. This proposed rule change should not alter the content of field test reports that are being submitted by permit recipients under the current regulations. APHIS, however, believes that the formal requirement for submission of field data reports should be included within the permit regulations in current § 340.4 to emphasize the importance of these reports in establishing the safety of field tests using particular classes of organisms. Under the proposed changes to our notification procedure, such safety information would be used to establish that new crop species can be safely field tested under notification, and could also help establish that crop plants having other types of modifications can be safely field tested under notification.

Accordingly, § 340.4(f)(9) would be amended to require that a person who has been issued a permit submit to the Director, BBEP, field test reports within 12 months after the start of the field test, and every 12 months through the duration of the field test. For field tests lasting more than 12 months, proposed § 340.4(f)(9) would require final reports 6 months after the termination of the field test. The field test reports would have to include the APHIS reference number, and methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

## VI. Rulemaking Analyses

### *Executive Order 12866 and Regulatory Flexibility Act*

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.<sup>1</sup>

<sup>1</sup> The agricultural biotechnology industry is still in a relatively early stage of development. Each year, as the industry continues to grow, it is anticipated there will be growth in experimentation, ultimately resulting in an increase in agricultural production and a broadening of international trade. The potential benefits could be significant, but are speculative at this time. APHIS anticipates that this Proposed Rule will be generally welcomed by public and private researchers, because it is estimated that it could save the industry as a whole perhaps \$50,000 in costs associated with preparing submissions to APHIS.

The effect of the proposed amendments would be to simplify procedures: (1) for the introduction of certain genetically engineered organisms by expanding the scope of organisms that would be included under notification procedures and lessening certain administrative requirements for State concurrence on interstate movements under notification procedures; (2) for determination of nonregulated status for certain organisms by allowing for extension of determinations of nonregulated status to other regulated articles closely related to those for which the initial determination was made; and (3) for reporting requirements by focusing on reporting only of unusual events for field tests conducted under notification, while maintaining recordkeeping requirements.

The expansion of the scope of organisms included under notification procedures would eliminate the need for a permit to conduct field tests for many crops that currently fall under the permitting regulations. This would allow researchers to conduct field tests for most crops with greatly simplified regulatory requirements. At present, approximately 87 percent of all field trials are conducted under notification procedures. Based on trials to date, APHIS estimates that less than 0.5 percent of the transgenic plants field tested would not qualify for notification procedures based on the local weed status of the crop species. In addition, nearly 99 percent of all introduced genes in plants field tested to date have qualified under notification procedures. Most of the donor genes that have not met the eligibility criteria have been virus-derived genes that could potentially also qualify for notification under the proposed § 340.3(b)(5). APHIS therefore estimates that about 99 percent of all field trials would be conducted under notification procedures under these proposed modifications. APHIS estimates that the cost savings for preparation of notification over preparation of a permit application is approximately 95 percent.

APHIS also estimates that extension of existing determinations would potentially be applicable to perhaps half of all regulated articles for which a determination of nonregulated status might be sought. The amount of time required to establish similarity with an antecedent organism, APHIS estimates, might be about one-fourth of that required for preparation of a petition for determination of nonregulated status. In

These savings are expected to increase as the number of submissions to APHIS continues to grow.

addition, there would be time savings for applicants for field tests under notification, who would not be required to submit field data reports on other than adverse events until the time of petition for determination of nonregulated status. Much of this data is data that the researcher should already have acquired while conducting field tests of genetically engineered crops.

This proposed rule is consistent with the risk- and product-based philosophy underlying the Federal policy for the regulation of the products of biotechnology, as announced by the Office of Science and Technology Policy in the Coordinated Framework for the Regulation of the Products of Biotechnology (51 FR 23303-23350, June 26, 1986). It is also consistent with the principles of regulation expressed in Executive Order 12866, specifically that the agency consider the degree and nature of risks posed by the activities under its jurisdiction, and tailor its regulations to achieve the least burden on society consistent with obtaining its regulatory objectives. The proposed option of allowing applicants to submit protocols for product identity standards is also consistent with the Presidential Memorandum to heads of Departments and Agencies of March 4, 1995, on the Regulatory Reform Initiative which, among other things, directs agencies to consider the question, "Could private business, setting its own standards and being subject to public accountability, do the job as well?"

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

#### *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.)

#### *Executive Order 12778*

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

#### *Paperwork Reduction Act*

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule will be submitted for approval to the Office of Management and Budget. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please send a copy of your comments to: (1) Docket No. 95-040-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OIRM, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250.

#### **List of Subjects in 7 CFR Part 340**

Administrative practice and procedure, Biotechnology, Genetic engineering, Imports, Packaging and containers, Plant diseases and pests, Transportation.

Accordingly, we are proposing to amend 7 CFR part 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 part 340 would continue to read as follows:

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

2. In § 340.1, the following definition would be added in alphabetical order to read as follows:

#### **§ 340.1 Definitions.**

\* \* \* \* \*

*Antecedent organism.* An organism that has already been the subject of a determination of nonregulated status by APHIS under § 340.6, and that is used as a reference for comparison to the regulated article under consideration under this part.

\* \* \* \* \*

#### **Footnotes 5 through 7, 8 and 9 [Redesignated as Footnotes 7 through 9, 12 and 13]**

3. In part 340, footnotes 5 through 7 and 8 and 9 would be redesignated as footnotes 7 through 9 and 12 and 13, respectively.

4. In § 340.3, a new footnote 5 would be added at the end of the section heading and paragraphs (b)(1), (b)(5),

(d)(4), and (e)(1) would be revised to read as follows:

**§ 340.3 Notification for the introduction of certain regulated articles.<sup>5</sup>**

\* \* \* \* \*

(b) \* \* \*

(1) The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Federal Noxious Weed Act (7 U.S.C. 2809), and, when being considered for releases into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment.

\* \* \* \* \*

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

(i) Noncoding regulatory sequences of known function; or

(ii) Sense or antisense genetic constructs derived from 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, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.

\* \* \* \* \*

(d) \* \* \*

(4) Responsible persons shall maintain records of the conduct and status of all field trials under notification procedures. Field test records shall include the APHIS reference number. Field test records shall also include methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(i) For field tests in which deleterious effects on plants, nontarget organisms, or the environment are observed, field test reports must be submitted to the Director, BBEP, within 12 months after the start of the field test, and every 12 months thereafter throughout the duration of the field test. For field tests lasting more than 12 months, final reports are due 6 months after the termination of the field test.

<sup>5</sup> APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations. A person may follow an APHIS guideline or follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed, a person may, but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS.

(ii) Field test reports shall include all data required in field test records for the trial.

\* \* \* \* \*

(e) \* \* \*

(1) The Director, BBEP, will notify the appropriate State regulatory official(s) within 5 business days of receipt for all notifications.

\* \* \* \* \*

5. In § 340.4, a new footnote 6 would be added at the end of the section heading and paragraph (f)(9) would be revised to read as follows:

**§ 340.4 Permits for the introduction of a regulated article.<sup>6</sup>**

\* \* \* \* \*

(f) \* \* \*

(9) A person who has been issued a permit shall submit to the Director, BBEP, field test reports within 12 months after the start of the field test, and every 12 months thereafter throughout the duration of the field test. For field tests lasting more than 12 months, final reports are due 6 months after the termination of the field test. Field test reports shall include the APHIS reference number. Field test reports shall also include methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment;

\* \* \* \* \*

6. In § 340.5, a new footnote 10 would be added at the end of the section heading to read as follows:

**§ 340.5 Petition to amend the list of organisms.<sup>10</sup>**

\* \* \* \* \*

7. In § 340.6, a new footnote 11 would be added at the end of the section heading, a new paragraph (c)(5) would be added, paragraph (e) would be redesignated as paragraph (f), and a new paragraph (e) would be added to read as follows:

**§ 340.6 Petition for determination of nonregulated status.<sup>11</sup>**

\* \* \* \* \*

(c) \* \* \*

(5) Field test reports for all trials conducted under permit or notification procedures, involving the regulated article, that were completed prior to petition submission. For ongoing trials longer than 12 months in duration, interim field test reports for each year. Field test reports shall include the APHIS reference number. Field test reports shall also include methods of

<sup>6</sup> See footnote 5 at § 340.3.  
<sup>10</sup> See footnote 5 at § 340.3.  
<sup>11</sup> See footnote 5 at § 340.3.

observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

\* \* \* \* \*

(e) *Extensions to determinations of nonregulated status.* (1) The Director, BBEP, may determine that a regulated article does not pose a potential for plant pest risk, and should therefore not be regulated under this part, based on the similarity of that organism to an antecedent organism.

(2) A person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question.

(3) APHIS will announce in the **Federal Register** all extensions of determinations of nonregulated status 30 days before their effective date.

(4) If a request to APHIS to extend a determination of nonregulated status under this part is denied, APHIS will inform the submitter of that request of the reasons for denial. The submitter may submit a modified request or a separate petition for determination of nonregulated status without prejudice.

\* \* \* \* \*

Done in Washington, DC, this 15th day of August 1995.

**Terry Medley,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 95-20547 Filed 8-21-95; 8:45 am]

BILLING CODE 3410-34-P

**9 CFR Part 113**

[Docket No. 93-039-3]

**Viruses, Serums, Toxins, and Analogous Products; Standard Requirement for Escherichia Coli Bacterins**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of reopening and extension of comment period.

**SUMMARY:** We are reopening and extending the comment period for the proposed rule to add a Standard Requirement for *Escherichia coli* bacterins. This extension will provide interested persons with additional time in which to prepare comments on the proposed rule.

**DATES:** Consideration will be given only to written comments on Docket No. 93-039-1 that are received on or before September 14, 1995.

**ADDRESSES:** Please send an original and three copies of your comments to