

Proposed Rules

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. 92-156-1]

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: Proposed rule.

SUMMARY: This document proposes to amend the regulations pertaining to the introduction of certain genetically engineered organisms and products to provide for a notification process for the introduction of certain transgenic plants with which the Animal and Plant Health Inspection Service has had considerable experience. The introduction of certain regulated articles under notification may be allowed provided that the introduction is in accordance with the provisions of this proposal.

This document also proposes to amend the regulations to provide for a petition process allowing for a determination that certain transgenic plants are no longer considered regulated articles. The proposed amendments would provide a procedure for filing a petition for determination of nonregulated status for those organisms which do not present a plant pest risk and therefore should no longer be regulated articles.

These actions would relieve unnecessary restrictions on the introduction of regulated articles based on experience. The effect of these actions is to provide standardized procedures for notification of the introduction of regulated articles in accordance with proposed performance standards and the petition requirements to release regulated articles from regulation.

DATES: Consideration will be given only to comments received on or before January 5, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92-156-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: A. Notification procedure and performance standards: Dr. Catherine M. Joyce, Biotechnologist, BBEP, APHIS, USDA, room 845, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-8761. B. Petition for nonregulated status: Dr. Frank Y. Tang, Biotechnologist, BBEP, APHIS, USDA, room 851, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7601.

SUPPLEMENTARY INFORMATION:

Background

Title 7, Code of Federal Regulations, part 340 (hereinafter the regulations), regulates 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). The regulations set forth procedures for obtaining a permit for the release into the environment of a regulated article and for obtaining a limited permit for the importation or interstate movement of a regulated article. Such permits are required before a regulated article can be introduced in the United States.

In the preamble to the final regulations published on June 16, 1987 (52 FR 22892-22915) the Animal and Plant Health Inspection Service (APHIS) stated its intention to modify or amend the regulations to ensure flexibility and to remove restrictions when warranted. APHIS previously demonstrated its commitment to amend the regulations by instituting exemptions for the movement of certain microorganisms (*Escherichia coli* strain K-12, sterile strains of *Saccharomyces cerevisiae*, or asporogenic strains of *Bacillus subtilis*) that contain plant pest sequences (53 FR 12910-12913, April 20, 1988), and plants

such as *Arabidopsis thaliana* under specified conditions (55 FR 53275-53276, December 28, 1990).

This proposed rule is consistent with the overall Federal policy for the regulation of the products of biotechnology. The proposed rule would reduce regulatory constraints on certain introductions to achieve the Federal policy goal of oversight commensurate with the risk (Office of Science and Technology Policy's biotechnology oversight policy document (February 27, 1992; 57 FR 6753-6762); the President's regulatory review initiative of January 28, 1992; and the Department's request for comments (February 25, 1992; 57 FR 6483-6484)). The proposed rule would also achieve the Federal policy goal of performance-based regulatory principles as outlined in the President's Council on Competitiveness "Report on National Biotechnology Policy" (February 1991).

The implementation of a notification system based on eligibility requirements with certain performance standards and a petition procedure for release from regulation would provide regulatory relief for the agricultural biotechnology research community and yet provide adequate oversight to assure the public of the safe development of new products. We discuss the Notification Procedures in part A and the Petition Procedures in part B below.

A. Notification Procedure for the Introduction of Regulated Articles Under the Proposed Performance Standards

In light of increased experience and scientific expertise with the products of biotechnology, we are proposing to amend the regulations to establish a notification procedure that would allow the introduction of certain regulated articles without a requirement for a permit. The notification procedure would be allowed for the introduction of most genetically modified plants that are considered regulated articles, provided that the introduction is conducted in accordance with specified eligibility requirements and performance standards.

Currently, the regulations require that introductions of regulated articles must be done under permit from APHIS. In order to obtain a permit for a field test, a person must submit to APHIS a description of the regulated article to be field tested and a description of the

experimental protocol for the field test, including safeguards to limit the dissemination of the introduced organism into the environment. Similarly, applications for a permit for interstate movement or importation must contain a description of the regulated article and a description of the containment protocols to be used during shipping and at the destination facility. The applications for permits are evaluated on a case-by-case basis. Each permit request is issued or denied on the basis of the potential for any direct or indirect plant pest risk and on the potential for a significant impact on the environment.

Since the APHIS permitting process for regulated articles (7 CFR part 340) was established in 1987, we have gained considerable experience. We have issued over 300 permits for field tests and over 1000 permits for movement. One result of this experience has been the determination that introductions of many regulated articles can be conducted with little or no plant pest or environmental risk, provided that certain criteria and performance standards are met. We are now proposing to delineate those standards and to establish a notification system whereby introductions of certain regulated articles that are conducted in compliance with these standards would not require a permit from APHIS.

In order to establish the notification procedure, a new § 340.3 entitled "Notification for the Introduction of certain regulated articles" would be added to the regulations, and subsequent sections of the regulations would be redesignated accordingly. Additionally, § 340.0, which currently states that a permit is required for the introduction of a regulated article, would be amended to include the alternative of the notification procedure. The new § 340.3 would include the following:

- (a) General.
- (b) Regulated articles eligible for introduction under the notification procedure.
- (c) Performance standards for introductions under the notification procedure.
- (d) Procedural requirements for notifying APHIS.
- (e) Administrative action in response to notification. Paragraph (a) simply states that certain regulated articles may be introduced in compliance with the notification procedure of new § 340.3, and that all other introductions must be in compliance with permitting procedure (newly redesignated § 340.4). Paragraphs (b) through (e) are set forth below with explanation.

Paragraph (b) is as follows:

(b) *Regulated articles eligible for introduction under the notification procedure.* A regulated article is eligible for introduction under the notification procedure if it meets either the six requirements of paragraph (b)(1) of this section or the general criteria of paragraph (b)(2) of this section.

(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 any additional plant species that BBEP has determined may be safely introduced in accordance with the performance standards set forth in paragraph (c) of this section.

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

(iii) The introduced genetic material is well characterized and does not contain genes whose expression in the regulated article results in plant disease.

(iv) The introduced genetic material does not cause the production of:

- (A) An infectious entity or
- (B) Result in constituents that are new to the plant and are toxic to nontarget organisms.

(v) The introduced genetic material does not pose a significant risk of the creation of any new plant virus.

(vi) The plant has not been modified to contain functionally intact genes derived from human or animal pathogens.

(2) A regulated article is also eligible for introduction under the notification procedures if, after prior consultation with the Director of BBEP, an appropriate State regulatory official, or an appropriate Institutional Biosafety Committee (IBC), the researcher has determined that the introduction of the regulated article is unlikely to pose a greater risk as a plant pest in the test environment than the unmodified plant from which it was derived based on:

- (i) The characteristics of the modified plant, and
- (ii) The confinement measures to be used in the field test.

The Director of BBEP will provide guidance on factors to be considered during the consultation process, including the applicability of the eligibility criteria set forth above in § 340.3(b)(1) (ii)-(vi).

The first criterion for eligibility under the notification procedure in paragraph (1) would be that the regulated article is one of the listed plant species. There is a large body of experience from the field testing of crop plant species under good agricultural practices. Plant breeders have a long history of safe field testing and introduction of many genetically modified crops.

Additionally, we have had the most experience with evaluating field tests for these six listed crops, with percentages of total permits issued as follows: Corn (19%), cotton (10%), potato

(20%), soybean (18%), tobacco (5%), or tomato (13%), with a cumulative total of 85%. Because of extensive experience of field testing of agricultural crop plants and with the six crops listed above, the Agency was able to develop performance standards for the introduction of most regulated articles of these plant species.

The second criterion in paragraph (1) for eligibility for the notification procedure would be that the introduced genetic material is stably integrated in the plant genome. The term "stably integrated" is defined in § 340.1 of the regulations as follows: "The cloned genetic material is contiguous with elements of the recipient genome and is replicated exclusively by mechanisms used by recipient genomic DNA." We are aware that introduced genetic material that is intended to be integrated into the plant genome may show a limited degree of instability due to the site of insertion or other factors. Regulated articles with such genetic instability are still intended to be included under the notification procedure. However, such genetic instability would not include regulated articles that have been modified to result in the extrachromosomal maintenance of the genetic material; examples would include plants modified to contain novel genetic material maintained on plasmids or on viral vectors that can replicate extrachromosomally. Nor would it include regulated articles that have been modified to contain novel genetic material maintained on transposons. We believe that the introduction of such regulated articles should continue to be evaluated on a case-by-case basis under the permitting procedure.

Criteria (iii) and (iv) would require that the regulated article has not been modified to result in plant disease or to produce an infectious entity. We consider these to be sound and prudent requirements to ensure that field trials under the notification procedure will not result in plant disease or the introduction or dissemination of infectious entities. For example, criterion (iii) would ensure that if the plant pathogenic bacterium, *Argobacterium tumefaciens*, were used as a vector agent for plant transformation, it was disarmed. Criterion (iv) would ensure that the plants have not been modified to produce a plant virus, an animal virus, a viral satellite RNA molecule, or any other infectious entity. The term "well characterized", in criterion (iii), refers to data that the researcher should have regarding the introduced genetic

material. It may include nucleotide sequence data, the function of the encoded product, functional analysis of the genetic material, a restriction endonuclease map of the genetic material, or Southern and northern analysis of the genetic material when integrated into the plant genome. In addition, criterion (iv) would require that the plants do not pose a plant pest risk by requiring that they have not been modified to produce compounds toxic to nontarget organisms. For example, if a modified plant is rendered to be toxic to beneficial insects such as honeybees, the notification procedure for introduction would not be used.

Criterion (v) would avoid the creation of any new viruses by allowing only certain types of plant viral DNA sequences in plants introduced under the notification procedure. What is meant by any new virus is those viruses that would not be probable to occur in nature as a result of natural mixed virus infections of nonmodified plants. The rationale for this criterion is that APHIS has considerable experience with the introduction of regulated articles containing such sequences. Additionally, this standard is intended to preclude the use of exotic, nonendemic, and nonprevalent viruses as challenge inocula in evaluations of plant virus resistance. Furthermore, this precludes the transmission of viruses by insect vectors that would not normally come in contact with a virus encapsidated by an exotic, nonendemic, or nonprevalent coat protein derived from a virus that does not normally infect the recipient plant. This also precludes transmission to nonmodified plants that are usually not infected by these exotic, nonendemic, or nonprevalent viruses. For example, plants may contain plant viral sense and antisense coat protein genes, which are derived from plant viruses that are endemic and widely prevalent in the area of the United States where the introduction will occur, and that naturally infect plants of the same species. Another type of plant viral sequence that the regulated articles may contain are well characterized noncoding DNA regulatory sequences such as the 35S promoter of cauliflower mosaic virus. APHIS has had significant experience with the introduction of regulated articles containing such sequences, and we believe that they do not present a risk of the introduction and dissemination of a plant pest.

Criterion (vi) would require that the plants have not been modified to contain functionally intact genes from human or animal pathogens. The

Agency believes that plants modified to contain such human or animal pathogen genes should only be introduced after a thorough review by the Agency.

We are aware that many additional plant species that are regulated articles could be safely introduced with appropriate confinement measures, when there has been careful consideration of the characteristics of the modified plant. Therefore, the rule provides that such introductions may be allowed under the notification procedure provided that the Director of BBEP, an appropriate State regulatory official, or an appropriate Institutional Biosafety Committee (IBC) has been consulted by the researcher prior to the introduction to ascertain that the characteristics and confinement measures will provide that the regulated article is unlikely to pose a greater risk as a plant pest than a similar field test of the unmodified plant from which it was derived. The Director of BBEP will provide guidance on factors to be considered during the consultation process, including the applicability of the eligibility criteria set forth in § 340.3(b)(1) (ii)-(vi). The Agency solicits 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.

During the past five years, there has been close collaboration between Federal and State officials, as well as the IBCs at colleges and universities in the review and conduct of hundreds of field trials in the United States. This close working relationship has led to the shared recognition of general principles for evaluating field trials, and a growing body of experience held in common among those partners. It is in recognition of this shared experience that the proposed requirements for notification in § 340.3(b)(2) include State officials and IBCs as appropriate reviewers for eligibility status.

This approach provides flexibility for extending the notification procedure to additional plant species without requiring an immediate, but not yet feasible, evaluation of the possible application of the performance standards to a large number of plant species. Of course, all introductions under the notification procedure, including those that are reviewed by State officials or IBCs, would require compliance with the provisions of § 340.3.

This proposed rule also includes definitions for State officials and IBC's

that would be appropriate for reviewing proposed introductions under the notification procedure. Appropriate IBCs have been defined as a committee at a university, college, or federally funded organization that was established to implement the National Institutes of Health safety guidelines for organisms produced through biotechnology, consistent with section IV-B-2 of those guidelines (51 FR 16962, May 7, 1986). The appropriate State regulatory officials have been defined as the State officials with responsibilities for plant health, generally officials within a State's department of agriculture, or any other State officials with duly designated authority.

Paragraph (c) is as follows:

(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. The destination facilities shall provide for adequate containment of the regulated article(s).

(2) When the introduction is an environmental release, the regulated article plants must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials 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 devalitized when no longer in use.

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

(5) When there is a significant probability that gene movement via pollen of the regulated article will result in viable progeny persisting in the environment, such movement must be minimized.

(6) Upon termination of the field test, no viable material shall remain which is likely to volunteer in subsequent seasons, or volunteers shall be managed to prevent persistence in the environment.

The proposed rule includes the performance standards in paragraph (c) to prevent inadvertent introductions into the environment of regulated articles that may pose a plant pest risk. Any risk posed by the introduction into the environment of a regulated article under the notification procedures is likely to be comparable to the risks posed by plants developed through more traditional plant breeding techniques. Over the years, plant breeders have developed standard agricultural practices to address these risks, and the Agency believes that such practices will be adequate to address any risk from plants introduced under this rule.

However, because some researchers doing field tests of genetically engineered organisms may not be familiar with the standard good agricultural practices followed by plant breeders, the Agency has sought to enumerate them in this rule as performance standards. We invite comment specifically on the performance standards as to whether they approximate standard good agricultural practice as practiced by researchers and plant breeders in field trials for the introduction of new plant material.

The first standard could be met, for example, by shipping the regulated article in a container that meets the requirements of 7 CFR § 340.6(b) (1) through (3). Standards (2) and (3) address biological containment during and following a field test, and could be met, for example, by returning all material to a contained facility or by destroying the material when no longer in use by incorporation into the soil, exposure to the elements, composting, or other physical or chemical means that would ensure devitalization of the material. Subsequent to the completion of the field test, the site could be monitored for the emergence of volunteer plants, which would then be destroyed. Standard (4) ensures that there will be no unintended introduction of a plant pest microorganism when a biological vector agent such as *Agrobacterium tumefaciens* is used in the development of the regulated article. The rationale for the fifth standard is based upon the fact that plants pass their genes on to successive generations via the transfer of pollen to sexually compatible recipients. Providing that the field test meets the provisions of this section, this standard (5) would not prohibit conducting controlled genetic crosses as part of a field test or controlled experiments to assess pollen dispersal.

Paragraph (d) is as follows:

(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, MD 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).

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

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

(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 postmarked, or delivered to a commercial express carrier on the day of or prior to the day of introduction. Alternatively, notification may be delivered to the Biotechnology Permits office on the day of or prior to the day of introduction, including by telephone facsimile.

(4) Field test reports must be submitted to the Deputy Director within 12 months after the start of the field test, and every 12 months thereafter for the duration of the field test. Field test reports shall include accurate observations regarding any deleterious effects on plants, nontarget organisms, or the environment.

(5) The Director, BBEP, shall be notified upon termination or an unexpected disruption of the field test.

(6) Access shall be allowed for APHIS and State plant regulatory officials to contained 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.

Requirements (1) through (3) would provide that APHIS will receive timely notification of the introduction and that the notification will contain sufficient information to determine that the regulated article is eligible for the notification procedure. Requirement (4) ensures that APHIS is informed of the progress of the field tests and that any information about deleterious effects on plants, nontarget organisms, or the environment is reported in a timely fashion. The reporting of such information is important for the purpose of enabling Agency scientists to determine whether continuation of the field test presents a plant pest risk. Requirement (5) also ensures that the Agency is informed of the progress of the field trial and of any unexpected disruptions of the field trial (e.g., those resulting from severe weather conditions). Requirement (6) addresses the appropriateness of retaining authority for inspections by APHIS and State plant regulatory officials or other duly designated State officials to ensure compliance with the notification provisions. During the five year of field tests conducted under the permitting procedure, we have conducted inspections and found an extremely high level of compliance with permit conditions.

Paragraph (e) would be as follows:

(e) Administrative action in response to notification.

(1) The Director, BBEP, will notify the appropriate State regulatory officials where the introductions are to take place.

(2) The Director, BBEP, will acknowledge receipt of notification.

In the current permitting procedure for introduction, State officials are advised of permit applications for introductions in their State, and comments from State officials are requested. Action (1) in this subsection provides that this important exchange of information with State officials continues under the notification procedure. Action (2) in this subsection provides that APHIS will acknowledge receipt of notification to the responsible person. We anticipate that most people will want to receive confirmation that notification was received by the Agency.

B. Petition for Determination of Nonregulated Status

Current APHIS regulations provide for a petition to amend the list of regulated articles in § 340.2. The regulations provide a petition process to add or remove an organism from the list of organisms which are or contain plant pests. APHIS has recently received two petitions requesting that the Agency certify certain data, obtained from field trials which APHIS had permitted, regarding the lack of plant pest risk of a particular genetically engineered plant and that the Agency make a determination as to the regulatory status of such plant. In response to these petitions, APHIS published notices of proposed interpretive rulemaking in the *Federal Register* (See 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. For each petition, APHIS prepared an interpretive ruling based upon a review of the data submitted by the petitioners, comments received from the public in response to the notice of interpretive rulemaking, and information that APHIS has in its own files. The APHIS interpretive rule for the first of these petitions, along with the determination document, was published in the *Federal Register* on October 19, 1992. APHIS stated in the determination document that it was preparing a proposal to amend 7 CFR part 340 to "formalize" the petition process. The petition process described below is intended to provide a procedure for seeking a determination that an article is not regulated under 7 CFR part 340.

Section 340.6(c) proposes data and information requirements in support of a petition for release from regulation. The

data and information are necessary in order for APHIS to determine that the regulated article that is the subject of the petition does not present a plant pest risk. This is not to imply a zero risk standard, but rather the regulated article is unlikely to pose a greater plant pest risk than the unmodified plant from which it was derived. The biology of the nonmodified recipient organism serves as a basis with which to compare the final product (regulated article). Relevant experimental data and publications should support claims made about the nonmodified recipient and the regulated article. The identification of the source of the regulated article, the transformation system, the inserted genetic material and its products are essential for a determination that the regulated article does not present a plant pest risk.

Of paramount importance in determining that no plant disease, injury, or damage to plants or plant products will result from an introduction of the regulated article is a detailed description of the observed biological and chemical properties of the regulated article as compared to those of the unmodified recipient organism. The required information should allow APHIS to determine that the regulated article or its progeny presents no new plant pest properties, i.e., properties substantially different from those observed for the nonmodified recipient organism when used in traditional breeding programs.

Section 340.6(d) describes APHIS' administrative procedures for preparing a determination and notification of the petitioner within 120 days of receipt of a completed petition.

Section 340.6(e) provides a procedure for appeal of a petition decision by the Director, BBEP.

APHIS believes that for regulated articles, field testing may be required to verify that they exhibit the expected biological properties, and to demonstrate that although derived using components from plant pests, they do not possess plant pest characteristics. However, an organism is no longer subject to the permitting requirements of 7 CFR part 340, when it is demonstrated not to present a plant pest risk. APHIS is proposing to amend § 340.6 by allowing for a "petition for Determination of Nonregulated Status" under part 340. We are also proposing to add definitions for "APHIS" and Director, BBEP.

Executive Order 12291 and Regulatory Flexibility Act

This proposed rule is issued in

conformance with Executive Order 12291 and has been determined not to be a "major rule." Based on information compiled by the Department, it has been determined that this proposed rule would have an effect on the economy of less than \$100 million; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and would 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 proposed rule would (1) provide for a notification procedure for the introduction of regulated articles in accordance with proposed 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 proposed 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 proposed in this document. The proposed petition procedure is based on 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 for movement would be eliminated.

It is expected that the proposed 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 would be basic data that a researcher or company would have 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 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 should not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule would preempt any State or local laws, regulations, or policies that are inconsistent with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the regulations under this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501), the information collection provisions that are included in the proposed rule will be submitted for approval to the Office of Management and Budget (OMB). Written comments concerning

any information collection provisions should be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. A duplicate copy of such comments should be submitted to: (1) Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782 and (2) Clearance Officer, (ORIM) USDA, room 404-W, 14th Street and Independence Avenue, SW., Washington, DC 20250.

Regulatory Reform: Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use, or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed the regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this notice.

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 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 7 CFR part 340 would continue 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) would be 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 following definitions would be added in alphabetical order to read as follows:

§ 340.1 Definitions.

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

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.

Institutional Biosafety Committee (IBC). A committee at a university, college, or federally funded organization that was established to implement the

¹ Part 340 regulates the introduction of organisms developed using genetic sequences from known 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.

National Institutes of Health safety guidelines for organisms produced through biotechnology, as consistent with Section IV-B-2 of those guidelines (51 FR 16962, May 7, 1986).

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.

§§ 340.3-340.7 [Redesignated as §§ 340.4, 340.5, 340.7-340.9]

4. Sections 340.3, 340.4, 340.5, 340.6, 340.7 would be redesignated §§ 340.4, 340.5, 340.7, 340.8, 340.9 respectively; and new §§ 340.3 and 340.8 would be 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 requirement for a permit, provided that the introduction is in compliance with the requirements of this section. Any other introductions 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).

(b) *Regulated articles eligible for introduction under the notification procedure.* A regulated article is eligible for introduction under the notification procedure if it meets either the six requirements of paragraph (b)(1) of this section or the general criteria of paragraph (b)(2) of this section.

(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

any additional plant species that BBEP determines may be safely introduced in accordance with the performance standards set forth in paragraph (c) of this section.

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

(iii) The introduced genetic material is well characterized and does not contain genes whose expression in the regulated article results in plant disease.

(iv) The introduced genetic material does not cause the production of:

- (A) An infectious entity or
(B) Result in constituents that are new to the plant and toxic to nontarget organisms.

(v) The introduced genetic material does not pose a significant risk of the creation of any new plant virus.

(vi) The plant has not been modified to contain functionally intact genes derived from human or animal pathogens.

(2) A regulated article is also eligible for introduction under the notification procedures if, after prior consultation with the Director of BBEP, an appropriate State regulatory official, or an appropriate Institutional Biosafety Committee (IBC), the researcher has determined that the introduction of the regulated article is unlikely to pose a greater risk as a plant pest in the test environment than the unmodified plant from which it was derived based on:

(i) The characteristics of the modified plant, and

(ii) The confinement measures to be used in the field test.

The Director of BBEP will provide guidance on factors to be considered during the consultation process, including the applicability of the eligibility criteria set forth in § 340.3(b)(1)(iii)-(vi).

(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. The destination facilities shall provide for adequate containment of the regulated article(s).

(2) When the introduction is an environmental release, the regulated article plants must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials 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) When there is a significant probability that gene movement via pollen of the regulated article will result in viable progeny persisting in the environment, such movement must be minimized.

(6) Upon termination of the field test, no viable material shall remain which is likely to volunteer in subsequent seasons, or 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, 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);

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

(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 postmarked, or delivered to a commercial express carrier on the day of or prior to the day of introduction. Alternatively, notification may be delivered to the Biotechnology Permits office on the day of or prior to the day of introduction, including by telephone facsimile.

(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 thereafter for the duration of the field test. Field test reports shall include accurate observations regarding any deleterious effects on plants, nontarget organisms, or the environment.

(5) The Director, BBEP, shall be notified upon termination or an unexpected disruption of the field test.

(6) Access shall be allowed for APHIS and State plant regulatory officials to contained 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 plant regulatory officials, or other duly designated State officials, where the introductions are to take place.

(2) The Director, BBEP, will acknowledge receipt of notification.

§ 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, or 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 organism.

(2) Relevant experimental data and publications.

(3) A detailed description of the genotype of the article. 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 article. Include country and locality where the donor, the recipient, and the vector organisms and the articles are collected, developed, and produced.

(4) A detailed description of the phenotype of the 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.

(d) *Administrative action on a petition.* (1) A petition for determination of nonregulated status under this part which meets the requirements of paragraph (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 petition, APHIS shall publish a notice in the *Federal Register*. 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 120 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.

Done in Washington, DC, this 30th day of October 1992.

Lonnice J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 92-28918 Filed 11-5-92; 8:45 am]

BILLING CODE 3410-34-M

Agricultural Marketing Service

7 CFR Part 907

[Docket No. FV-92-907-5]

Navel Oranges Grown in Arizona and Designated Part of California; Proposed Weekly Volume Regulations

AGENCY: Agricultural Marketing Services, USDA.

ACTION: Proposed rule; correction.

SUMMARY: This action amends a proposed rule which invites comments on the quantities of fresh California-Arizona navel oranges that may be shipped weekly to domestic markets.

FOR FURTHER INFORMATION CONTACT: Christian D. Nissen, (202) 720-5127.

SUPPLEMENTARY INFORMATION: This action amends a proposed rule which appeared in the *Federal Register* (57 FR 48340, October 23, 1992). The meeting time and location on page 48343, item 3, are changed to read as follows:

3. Committee Meeting Date: November 10, 1992. Time: 9:30 a.m., Location: Visalia Elks Lodge, 3100 West Main, Visalia, California 93291.

The meeting times on pages 48344 and 48345, items 4 through 10, are changed to read as follows: Time: 9:30 a.m.

Dated: November 4, 1992.

Robert C. Keeney,
Deputy Director, Fruit and Vegetable Division.

[FR Doc. 92-27119 Filed 11-5-92; 8:45 am]

BILLING CODE 3410-02-M

Rural Electrification Administration

7 CFR Part 1755

Review and Revision of Architectural Services Contract—Telephone

AGENCY: Rural Electrification Administration, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Rural Electrification Administration (REA) is considering possible revisions that may be desirable in the form and content of REA contract Form 185 "Architectural Services Contract—Telephone". Several years have passed since this document was last revised and changes in common contract language have occurred. Revising the document at this time will allow contracts to be more consistent with common practice. Suggestions are invited on the document.

DATES: Comments must be received by REA or carry a postmark or equivalent by December 7, 1992.

ADDRESSES: Written comments should be addressed to Donald M. Van Bellingier, Director, Telecommunications Standards Division, U.S. Department of Agriculture, Rural Electrification Administration, room 2835-S, 14th & Independence Avenue, SW., Washington, DC 20250-1500. REA requires a signed original and three copies of all comments (7 CFR 1700.30(e)). All comments received will