Sunshine Act Meetings

Federal Register
Vol. 52, No. 115
Tuesday, June 16, 1987

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Special Meeting

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), of the forthcoming special meeting of the Farm Credit Administration Board (Board).

DATE AND TIME: The meeting is scheduled to be held at the offices of the Farm Credit Administration in McLean, Virginia, on June 10, 1987, from 2:30 p.m. until such time as the Board may conclude its business.

FOR FURTHER INFORMATION CONTACT: William A. Sanders, Jr., Secretary to the Farm Credit Administration Board, 1501 Farm Credit Drive, McLean, Virginia 22102-5090 (703-883-4010).

ADDRESS: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102-5090.

SUPPLEMENTARY INFORMATION: This meeting of the Board will be closed to the public. The matter to be considered at the meeting is:

[1] 1. Farm Credit System Collateral Issues

Dated: June 11, 1987.

William A. Sanders, Jr.,

Secretary, Farm Credit Administration Board.

[FR Doc. 87-13746 Filed 6-12-87; 9:06 am]

BILLING CODE 6705-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Changes in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its open meeting held at 2:00 p.m. on Tuesday, June 9, 1987, the Corporation's Board of Directors determined, on motion of Chairman L. William Seidman, seconded by Director C.C. Hope, Jr. (Appointive), concurred in by Director Robert L. Clarke (Comptroller of the Currency), that Corporation business required the withdrawal for the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matters:

Memorandum regarding realignment of the Division of Bank Supervision's regional offices.

Memorandum re: Proposed Statement of Policy for Disclosure of Financial and Other Information by Insured State Nonmember Banks, which policy statement would recommend that insured State nonmember banks make available to the public upon request financial data and management discussion and analysis of significant events covering the previous two calendar years as well as future plans.

The Board further determined, by the same majority vote, that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matter:

Application of Barnett Bank of Pinellas County, a proposed new bank to be located at 1901 Central Avenue, St. Petersburg, Florida, for Federal deposit insurance, for consent to merge, under its charter and title, with Barnett Bank of Pinellas County, National Association, Clearwater, Florida, and for consent to establish twenty-one existing and one approved, but unopened, offices of Barnett Bank of Pinellas County, National Association as branches of Barnett Bank of Pinellas County.

The Board further detemined by the same majority vote, that no earlier notice of the changes in the subject matter of the meeting was practicable.

Dated: June 10, 1987.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 87-13774 Filed 6-12-87; 11:02 am]

BILLING CODE 6714-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Changes in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its closed meeting held at 2:30 p.m. on Tuesday, June 9, 1987, the Corporation's board of Directors determined, on motion of Chairman L. William Seidman, seconded by Director C.C. Hope, Jr. (Appointive), concurred in by Director Robert L. Clarke (Comptroller of the Currency), that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matters:

Memorandum regarding the Corporation's corporate activities.

Matters relating to the possible failure of certain insured banks: Names and locations of the banks authorized to be exempt from disclosure pursuant to subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

A personnel matter.

The Board further determined, by the same majority vote, that no earlier notice of the changes in the subject matter of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: June 10, 1987.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 87-13775 Filed 6-12-87; 11:02 am]

BILLING CODE 6714-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 11:00 a.m., Monday, June 22, 1987.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

[1] Session closed to the public-exempt pursuant to 5 U.S.C. 552(c)(4), (8) and (9).

Dated: June 12, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-13801 Filed 6-12-87; 3:36 pm]

BILLING CODE 6210-01-M

FEDERAL TRADE COMMISSION

TIME AND DATE: 2:00 p.m., Thursday, June 18, 1987.

PLACE: Room 532, (open); Room 540 (closed), Federal Trade Commission Building, 6th Street and Pennsylvania Avenue, NW., Washington, DC 20580.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Portions Open to Public:

(1) Oral Argument in New England Motor Rate Bureau, Inc., Docket No. 9170.

Portions Closed to the Public:

(2) Executive Session to follow Oral Argument in New England Motor Rate Bureau, Inc., Docket No. 9170.

CONTACT PERSON FOR MORE INFORMATION: Susan B. Ticknor, Office of Public Affairs: (202) 326-2179; Recorded Message: (202) 326-2711.

Emily H. Rock,

Secretary.

[FR Doc. 87-13754 Filed 6-12-87; 10:07 am]

BILLING CODE 6750-01-M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of June 15, 22, 29, and July 6, 1987.

PLACE: Commissioners' Conference Room, 1717 H Street, NW., Washington, DC

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of June 15

Tuesday, June 16

2:00 p.m.
Meeting with States and Affected Indian Tribes on the Status of National High Level Waste Program (Public Meeting)

Wednesday, June 17

2:00 p.m.
Discussion/Possible Vote on Fort St. Vrain Authorization to Exceed 35 Percent Power Level (Public Meeting)

Thursday, June 18

2:00 p.m.
Briefing by Executive Branch (Closed—Ex. 1)

3:30 p.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of June 22—Tentative

Monday, June 22

3:00 p.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)

Thursday, June 25

10:00 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of June 29—Tentative

Tuesday, June 30

10:00 a.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)

2:00 p.m.
Discussion/Possible Vote on Full Power Operating License for Braidwood-1 (Public Meeting) (Tentative)

Wednesday, July 1

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of July 6—Tentative

Wednesday, July 8

2:00 p.m.
Discussion/Possible Vote on Full Power Operating License for Beaver Valley-2 (Public Meeting)

3:30 p.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

ADDITIONAL INFORMATION: Affirmation of "PSNH's Emergency Plan Submittal and Request for Low Power License," "Shoreham—Evaluation of Replies to LILCO Request for Authorization to Increase Power to 25%," and "Shoreham Intervenors' Motion to Reopen the Record" (Public Meeting) were held on June 11.

TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING): (202) 634-1498.

CONTACT PERSON FOR MORE INFORMATION: Robert McOsker (202) 634-1410.

Robert B. McOsker,

Office of the Secretary.

June 11, 1987.

[FR Doc. 87-13811 Filed 6-12-87; 3:37 pm]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: [52 FR 21409 June 5, 1987].

STATUS: Open meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE PREVIOUSLY ANNOUNCED: Tuesday, June 2, 1987.

CHANGE IN THE MEETING: Deletion.

The following item will not be considered at an open meeting for Thursday, June 11, 1987, at 10:00 a.m.

Discussion of whether and how to amend Rule 10b-4 (17 CFR 240.10b-4), the short tendering rule, in light of the Second recent decision of the Court of Appeals for the Second Circuit in *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Jack Bobker.* For further information, please contact M. Blair Corkran at (202) 272-2853.

Commissioner Grundfest, as duty officer determined that Commission business required the above changes.

At times changes in Commission priorities requre alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact; Kevin S. Fogarty at (202) 272-3195.

Jonathan G. Katz,

Secretary.

June 10, 1987.

[FR Doc. 87-13727 Filed 6-11-87; 4:14 pm]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

Agency Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of June 15, 1987:

A closed meeting will be held on Tuesday, June 16, 1987, at 2:30 p.m. An open meeting will be held on Thursday, June 18, 1987, at 10:00 a.m., in Room 1C30.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendered matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Grundfest, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, June 16, 1987, at 2:30 p.m., will be:

Settlement of administrative proceedings of an enforcement nature.

Institution of injunctive actions.

Formal orders of investigation.

Institution of administrative proceedings of an enforcement nature.

Regulatory matter regarding financial institution.

Opinions.

The subject matter of the open meeting scheduled for Thursday, June 18, 1987, at 10:00 a.m., will be:

1. Consideration of whether to publish for comment proposed amendments to Regulation S–K, Forms 8–K and N–SAR and Schedule 14A concrning disclosures related to a change in a registrant's certifying accountant. These proposals would clarify the term "disagreements" as used in these disclosure requirements, provide for more complete disclosure of potential opinion shopping situations, update such disclosures for investment companies, move the substance of the disclosure requirements for changes in accountants to Regulation S–K, extend the time frame for disclosure in proxy statements of a change in accountants to that found in Item 304 of Regulations S–K, and require the filing of a Form 8–K, when the disclosure requirements under Item 4 of that form are satisfied by filing the information in a different report, to identify the report containing that disclosure. For further information, please contact Robert Burns or John Riley at (202) 272–2130.

2. Consideration of whether to: (1) Adopt a policy permitting the multiple market trading of standardized options on exchange-listed stocks; and (2) institute proceedings under section 19(c) of the Securities Exchange Act of 1934 to amend the rules of national securities exchanges that provide a market in standardized options to prohibit any such exchange from preventing by rule or otherwise the listing of a standardized option on an exchange-listed stock by virtue of the listing of that option on another exchange. For further information, please contact Alice Rome at (202) 272–7379.

3. Consideration of whether to propose revisions to 17 CFR 200.80 and certain appendices thereto which will (1) conform the rules to changes to the Freedom of Information Act made by Congress in amendments passed on October 27, 1986; (2) ensure that as much as possible of the "direct cost" incurred in operating the Commission's Freedom of Information Act program is recouped; (3) clarify the statutory basis for dissemination of information filed with the Commission pursuant to various securities statutes; and (4) correct outdated information in the present rules. Consideration will also be given to adoption of interim rules that would be immediately effective and remain in effect pending adoption of final rules. For further information, please contact John Heine at (202) 272–7422.

4. Consideration of whether to defer application of the bank proxy processing rules with respect to employee benefit plan participants and adopt: (1) Amendments to Rule 14b–2 changing from three to five business days the time period for executing an omnibus proxy; (2) amendments to Rules 14a–1 and 14c–1 defining employee benefit plan; and (3) other clarifying and technical amendments to the shareholder communications rules. For further information, please contact Sarah A. Miller at (202) 272–2589.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Andrew Feldman at (202) 272–2091.

Jonathan G. Katz,

Secretary.

June 10, 1987.

[FR Doc. 87–13728 Filed 6–11–87; 4:14 pm]

BILLING CODE 8010–01–M

Corrections

Federal Register
Vol. 52, No. 115
Tuesday, June 16, 1987

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 272 and 273

[Amdt. No. 293]

Food Stamp Program; Higher Education Amendments of 1986

Correction

In rule document 87-12383 beginning on page 20376 in the issue of Monday, June 1, 1987, make the following correction:

On page 20377, in the second column, in the first complete paragraph, in the 12th line, "471(2)" should read "472(2)".

BILLING CODE 1505-01-D

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 273

[Amdt. 292]

Food Stamp Program; Eligible Alien Status

Correction

In rule document 87-12307 beginning on page 20055 in the issue of Friday, May 29, 1987, make the following correction:

§ 273.4 [Corrected]

On page 20058, in the second column, in § 273.4, the second line of paragraph (a)(9) should read "temporary resident status pursuant to section".

BILLING CODE 1505-01-D

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 928

[Docket No. AO-371-A1]

Papayas Grown in Hawaii; Secretary's Decision on Proposed Amendment of the Marketing Agreement and Order 928

Correction

In proposed rule document 87-12766 beginning on page 21065 in the issue of Thursday, June 4, 1987, make the following corrections:

1. On page 21065, in the first column, in the **SUMMARY**, in the seventh line, "amendment" was misspelled.

2. On the same page, in the same column, under **DATE**, in the second line, "referendum" was misspelled.

3. On the same page, in the second column, in the second line from the bottom of the column, "defied" should read "defined"; and in the last line of the column, "Flexibility" was misspelled.

4. On the same page, in the third column, in the second line, "Interested" should read "interested".

5. On the same page, in the same column, in the first complete paragraph, in the 14th line, "defied" should read "defined".

6. On the same page, in the same column, in the fourth line from the bottom of the page, "provision" was misspelled.

7. On page 21066, in the first column, in the fourth line from the bottom of the column, "characteristics" was misspelled.

8. On page 21067, in the first column, in paragraph (5), in the fourth line, "burden" should read "burdens".

§ 928.26 [Corrected]

9. On the same page, in the third column, in § 928.26, in the first line, "my" should read "any".

10. In § 928.26, on page 21068, in the first column, in the fourth line, "alternate" was misspelled.

§ 928.31 [Corrected]

11. On the same page, in the same column, in § 928.31(o), in the 16th line, "among" was misspelled.

§ 928.32 [Corrected]

12. On the same page, in the same column, in § 928.32(a), in the second line, "alternates" was misspelled.

§ 928.64 [Corrected]

13. On the same page, in the second column, in § 928.64(c), in the second line, after "end" add "of any".

14. On the same page, in the third column, in § 928.64(e), in the second line, "with" should read "within"; and in the eighth line, after "found" add "that".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[AD-FRL-3158-6]

Standards of Performance for New Stationary Sources Addition of Alternative Procedure (Critical Orifice as Calibration Standards) to Method 5, Appendix A

Correction

In rule document 87-6551 beginning on page 9657 in the issue of Thursday, March 26, 1987, make the following corrections:

1. On page 9657, in the second column, in the **SUMMARY**, in the 14th line, remove "of" after "Method 5".

Appendix A—[Corrected]

2. On page 9662, in the first column, the 23rd line should read "Average the K' values. The individual K' ".

3. In the second column, below the seventeenth line, insert "where:".

4. In the same column, in the first formula, the divisor should read "$P_{bar}T_m\Theta$".

5. In the same column, in the 19th line from the bottom of the column, "=17.64" should appear at the beginning of the 18th line from the bottom of the column.

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Disease Control

Recommendations for Protecting the Health of the Public During the Disposal of Agent VX; Request for Public Comment

Correction

In notice document 87-12133 beginning on page 19226 in the issue of Thursday, May 28, 1987, make the following corrections:

1. On page 19926, in the second column, in the **SUMMARY**, in the third line "1421" should read "1521".

2. On the same page, in the third column, in the third line, "glands" was misspelled.

3. On page 19927, in the first column, in the table, under "Level", in the seventh line, remove the ")" before "mg" and add a ")" at the end of the eighth line in place of the period.

4. On the same page, in the same column, the first sentence after the table should begin, "Certain monitoring criteria are essential to this recommendation, because any recommended ..."

BILLING CODE 1505-01-D

federal register

Tuesday
June 16, 1987

Part II

Department of Agriculture

Animal and Plant Health Inspection Service

7 CFR Parts 330 and 340

Plant Pests; Introduction of Genetically Engineered Organisms or Products; Final Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 330 and 340

[Docket No. 87-021]

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

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document establishes regulations for the introduction (Importation, interstate movement, or release into the environment) of genetically engineered organisms and products which are plant pests or for which there is reason to believe are 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. These regulations are necessary to prevent the entry into and dissemination and establishment of plant pests in the United States.

DATE: Effective date of final rule is July 16, 1987.

FOR FURTHER INFORMATION CONTACT: Terry L. Medley, Director, Biotechnology and Environmental Coordination Staff, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 406, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-7602.

SUPPLEMENTARY INFORMATION:

Background

On June 26, 1986, the Animal and Plant Health Inspection Service (APHIS) published a proposed rule entitled, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or for Which There Is Reason to Believe Are Plant Pests" (51 FR 23352-23366 hereinafter referred to as the proposed regulations). The proposed regulations set forth procedures for obtaining a permit prior to the introduction (importation, interstate movement, or release into the environment) of genetically engineered organisms or products which are plant pests or for which there is reason to believe are plant pests (regulated articles).

The provisions that appeared in the proposed regulations and adpopted in this final rule concerning the ned to obtain a permit prior to introducing a regulated article are consistent with existing permit requirements in 7CFR Parts 300-399. Such requirements are imposed by APHIS in regulating the movement of non-genetically engineered organisims, products, and certain articles which are plant pests or could harbor plant pests. The final rule extends the regulation of certain organisms not genetically engineered to certain organisms that are genetically engineered.

Comments Received on Proposed Regulations

APHIS attempted to solicit as many comments as possible on its proposed regulations through public hearing held in Sacramento, California, on July 29, 1986, and in Washington, DC, on August 5, 1986, and through an extension of the comment period from August 25 to September 26, 1986 (51 FR 29401, August 15, 1986). Including the comments presented at the public hearings, APHIS received 184 comments on the proposed regulations. Commenters included academicians, businesses engaged in genetic engineering, trade associations, professional organizations, private individuals/consultants, State departments of agriculture, members of the U.S. House of Representatives, and a representative from a State legislature. APHIS has carefully considered all the comments on the proposed rule.

Based on the rationale set forth in the proposed regulations and in this document, APHIS is promulgating a final rule which will become effective on July 16, 1987.

Under the final rule, a person has to obtain a permit to import, move interstate or release into the enviroment a genetically engineered organism or product only if:

(1) The organism has been altered or produced through genetic engineering from an organism (donor, vector, or recipient);

a. That is included in the list of genera and taxa in § 340.2 and such organism meets the definition of a plant pest; or

b. That is an unclassified organism and/or an organism whose classification is unknown; or

(2) The product contains such an organism (described in (1); or

(3) Any other organism or product (not included in (1) or (2) altered or produced through genetic engineering, which the Deputy Administrator determines is a plant pest or has reason to believe is a plant pest. Thus, this final rule regulates certain genetically engineered organisms and products that present plant pest risks, and, as explained in more detail below, does not regulate an article merely because of the process by which it was produced.

Many provisions, as noted below, have been changed in response to comments, which were generally constructive and often complex. Because numerous changes have been made to the regulations as originally proposed, a summary of those changes is presented at the outset of the preamble. The summary includes the number of the paragraph in which the rationale for the APHIS action is discussed. Following the summary is a detailed discussion of the relevant comments received, and APHIS' response to those comments. The preamble is organized to correspond with sections of the final rule.

SUMMARY OF CHANGES MADE IN THE FINAL RULE

Section	APHIS action	Paragraph No. of response
§ 340.1 Definitions:		
Certificate of exemption	Changed to courtesy permit	5
Classical genetics	Not adopted	6
Genetic engineering	Adopted new definition	7
Genetic manipulation	Not adopted	8
Mutagen	Not adopted	10
Organism	Amended by excluding prions and non-living components and parts	11, 21, 22
Pathogen	Not adopted	12
Plant	Amended by excluding bacteria, fungi, and prokaryotic algae	14
Regulated article	Adopted with revisions	16
§ 340.2 Groups of Organisms:		
Removed the following taxa		20, 21

SUMMARY OF CHANGES MADE IN THE FINAL RULE—Continued

Section	APHIS action	Paragraph No. of response
Prions		
Rickettsial-like organisms associated with plant disease		
Added the following taxa or groups of organisms:		
Gram-negative xylem-limited bacteria associated with plant diseases		
Gram-negative phloem-limited bacteria associated with plant diseases		
Added petition procedure in § 340.4 to amend list of organisms.		42
§ 340.3 Permits:		
§ 340.3(a)	Added provisions for designation of confidential business information (CBI) material	24, 25
§ 340.3(b)	Added permit for environmental release with provisions for State notification and review; APHIS review to be completed in 120 days.	29, 31
§ 340.3(c)	Added limited permit for interstate movement or importation with provisions for State notification and review; APHIS review to be completed in 60 days.	30, 31, 32, 34
§ 340.3(d)	Added provisions for premises inspection prior to permit issuance	36
§ 340.3(f)	Did not adopt requirement to report death of a regulated article; substituted reporting of unanticipated characteristics or unusual occurrence (excessive mortality or morbidity or unanticipated effects).	38
§ 340.4 Certification of exemption	Did not adopt; (substituted provision for courtesy permit in § 340.3(h); Section redesignated as "petition to amend the list of organisms").	34, 42
§ 340.5 Marking and identity	None	
§ 340.6 Container requirements:		
§ 340.6(c)	Added new section to allow variance from container requirements	43
§ 340.7 Costs and charges	None	

Comments on APHIS'Authority to Restrict the Introduction of a Regulated Article

1. Approximately thirty-one commenters prefaced their remarks with general statements supporting APHIS' approach in Part 340. The comments included backing for APHIS as "lead agency" and support of APHIS' authority pursuant to the Federal Plant Pest Act (FPPA) and Plant Quarantine Act (PQA) to regulate genetically engineered organisms as set forth in its proposed regulations. Seven commenters, however, alleged that APHIS lacks the authority under the provisions of the FPPA and PQA for the proposed rule. Specifically, the commenters indicated that the FPPA does not authorize APHIS to regulate "release into the environment," but only importation and interstate movement; and that the FPPA and Federal Noxious Weed Act (FNWA) and the Act of 1903 have no "beforehand testing" or pre-release review requirements to determine if new organisms might be pests, noxious weeds or contagious agents.

APHIS disagrees with the commenters who challenged APHIS' authority for the proposed rule. Is should be noted that APHIS never cited the Federal Noxious Weed Act (7 U.S.C. 2801 *et seq.*) or the Act of 1903 (21 U.S.C. 111 *et seq.*) as authority for promulgating a final rule under Part 340. Rather, APHIS cites as authority the Plant Quarantine Act (7 U.S.C. 151 *et seq.*) and the Federal Plant Pest Act (7 U.S.C. 150aa *et seq.*).

It is the Department's position that the provisions of the rule requiring a permit prior to the release into the environment of certain genetically engineered organisms or products containing such organisms is consistent with the legislative intent of the FPPA and is a reasonable construction of the Department's statutory responsibilities under the FPPA.

The FPPA was enacted to fill gaps in the Department's authority to protect American agriculture against invasion by foreign plant pests and diseases. It confers very broad authority on the Secretary of Agriculture to prevent the dissemination into the United States or interstate of plant pests.

The legislative history of the FPPA indicates that in addition to providing authority to regulate organisms that "can injure" plants or plants products, the FPPA provides authority to regulate organisms that might later be found to be injurious to cultivated crops. (See the Department's legal opinion concerning this issue, attached as Appendix G of "Issues in the Federal Regulation of Biotechnology: From Research to Release", a report prepared by the Subcommittee on Investigations and Oversight of the Committee on Science and Technology of the House of Representatives, 99th Cong., 2nd Session, December 1986).

2. One commenter who expressed the view that separate regulation of genetically engineered organisms is not authorized by the FPPA suggested that APHIS should amend its existing regulations rather than promulgate new regulations.

APHIS disagrees with this commenter and has determined that separate regulations for certain genetically engineered organisms are needed. Under the FPPA, APHIS can regulate plant pests whether they are naturally occurring or genetically engineered. APHIS' regulations in 7 CFR 330.200 are applicable to persons seeking to import, or move interstate plant pests which are naturally occurring and have not resulted from genetic engineering. APHIS believes that the regulations in 7 CFR 330.200 are not adequate to regulate the introduction (importation, interstate movement, or release into the environment) of genetically engineered organisms and products for two reasons. The regulations as presently written provide no way for the public to determine whether or not a genetically engineered organism or product would be deemed a "regulated article." Secondly, the data that is called for in a permit application under 7 CFR 330.200 would not provide APHIS with sufficient information to make a determination on the plant pest status of certain genetically engineered organisms or products. In short, APHIS determined that its existing regulations could not be readily amended to include the data elements that are needed to adequately regulate the introduction of genetically engineered organisms, and that separate regulations for genetically engineered organisms are required.

APHIS is not treating genetically engineered organisms and products which are plant pests or for which there is reason to believe are plant pests differently than so-called "established" plant pests or naturally occurring organisms which there is reason to believe are plant pests. In both cases, a permit must be obtained from APHIS prior to importation and interstate movement. In the case of certain genetically engineered organisms, APHIS has determined that the release

into the environment of certain genetically engineered organisms is tantamount to the introduction of a new organism. Further, living organisms do not acknowledge State lines. Therefore, a permit must be obtained from APHIS prior to release into the environment.

Comments on the Scope of the Proposed Regulations

3. Some commenters expressing support for APHIS' approach also expressed concern that the proposed rule was too broad and inclusive and needed modification to be practicable. Some commenters indicated that the proposed regulations would cause APHIS to be overwhelmed with applications for permits. Many commenters expressed the view that APHIS should have the ability to exclude certain products or classes of products from the regulations as experience indicates certain exemptions are justified.

APHIS agrees with commenters expressing the view that the proposed regulations were too broad and inclusive and has made several revisions to narrow the scope of the regulations.

As a means of eliminating the need for a "responsible person" to submit a new application for a limited permit for the interstate movement of a regulated article between contained facilities each time the person seeks to move the article interstate, APHIS has added provisions in § 340.3(c)(1) that would allow such movement to be made under the provisions of a single limited permit, which would be valid for one year. Such a permit could be renewed thereafter, if appropriate. This change should significantly eliminate the number of applications APHIS will have to process, and significantly reduce the number of applications that would have to be submitted. (See paragraph 32.) Further, as discussed in more detail in paragraphs 11, 16, and 19, APHIS has amended the definitions of "organism", and "regulated article", as well as the list of organisms in § 340.2. These changes narrow the scope of the final rule.

In addition, in order to facilitate the addition or removal of certain genera, species, or subspecies of organisms on the list in § 340.2, APHIS has included provisions in §340.4 of the final rule for a person to submit a petition to amend the list of organisms. (See paragraph 42.)

Comments Requesting that APHIS Not Regulate Research

4. Sixty-eight comments were received from academic researchers and/or institutions expressing opposition to APHIS' regulation of the introduction (importation, interstate movement, or release into the environment) of regulated articles. The majority of the commenters argued that this amounts to the regulation of research and that biotechnology research can be regulated by the research community itself using institutional biosafety committees and the USDA Guidelines that were set forth in the Advanced Notice of Proposed USDA Guidelines for Biotechnology Research. (See 51 FR 23367–23393) These commenters argued that a clear distinction exists between research and product development, and that APHIS should regulate only when a product is involved.

APHIS disagrees with those commenters that believe that the agency is regulating research. APHIS believes that the regulation of the introduction of certain genetically engineered organisms does not amount to regulation of research, but rather regulation of movement and release into the environment of a regulated article. The final rule does not attempt to prescribe what a person can or cannot do in a laboratory or contained greenhouse, but rather, under what conditions a regulated article can be moved or released. It should be noted that a person does not become subject to these regulations until the person seeks to *introduce* genetically engineered organisms. Thus, APHIS does not believe that the final rule is an attempt to regulate research.

APHIS also disagrees with the comments that argued that APHIS should only become involved when a "product" is involved; there is no statutory limitation in the FPPA or PQA for APHIS to regulate in such a manner. APHIS' statutory responsibility is to take those measures necessary to prevent the introduction into the United States of "plant pests."

Comments on Definitions (§ 340.1)

The definitions of key words in proposed Part 340 collectively generated the largest number of comments on a single section. Comments on the individual definitions and APHIS' response are presented in alphabetical order.

Certificate of Exemption

5. No change has been made in this definition, but the name has been changed to "courtesy permit." For a discussion of the comments and explanation of the rationale for the change see paragraph 34.

Classical Genetics

6. The six comments on this definition generally indicated that it should have included such processes as protoplast, cell, and embryo fusion, and mutagenesis, because such processes have traditionally been associated with classical genetics techniques. APHIS agrees with this assessment, and has revised the definition of "genetic engineering" to exclude reference to classical genetics as well as protoplast, cell, and embryo fusion, and mutagenesis. An examination of the literature describing the techniques used in genetics prior to the introduction of recombinant DNA technology finds that many techniques other than interspecific crosses have been in common use. The transfer of genetic traits by methods such as protoplast, cell, and embryo fusion, and mutagenesis has been an accepted part of genetics for some years prior to the development of various recombinant DNA technologies for the movement of genes. It would thus seem that the techniques in question should properly be included as a part of classical genetics, and excluded from the definition of "genetic engineering."

As a result of the change in the definition of "genetic engineering" to exclude reference to classical genetics, the definition of "classical genetics" has been deleted.

Genetic Engineering

7. The twenty-three comments on this definition generally expressed the view that such techniques as protoplast, cell, and embryo fusion, and mutagenesis encompass classical genetic processes.

For the reasons stated in paragraph 6 above on classical genetics, APHIS agrees with the comments that specific techniques such as protoplast, cell and embryo fusion, and mutagenesis should not be included in "genetic engineering." A new definition has been provided, as follows: "The genetic modification of organisms by recombinant DNA techniques." It should be noted that if a new organism or product was produced using classical genetic techniques, and the new organism was a plant pest, it would be regulated pursuant to a similar permit system found in 7 CFR 330.200.

Genetic Manipulation

8. Because the definition of genetic engineering has been modified and the term genetic manipulation is not used in the current definition of that term, APHIS has deleted the definition of genetic manipulation.

Introduce

9. Two comments were received on the definition of introduce. One commenter suggested that the definition be expanded to include "creation of a new organism or genotype" in addition to importation, interstate movement, and release into the environment. The commenter argued that the regulation of genetic engineering should begin with the development of the organism in the laboratory.

As previously stated, the final rule does not regulate laboratory research conducted at contained facilities. The responsibility at USDA for the oversight of biotechnology research is delegated to the Assistant Secretary for Science and Education. APHIS believes that if the laboratory is a contained facility, such regulation by APHIS would be unnecessary from the standpoint of preventing the introduction of genetically engineered organisms which are plant pests or which there is reason to believe are plant pests, and would, therefore, be beyond APHIS' statutory authority.

Another commenter expressed the view that the term introduce or introduction is somewhat redundant in that it overlaps with the definition of release into the environment, and that the term "release into the environment" should be dropped from the definition of introduce.

APHIS disagrees with the commenter that inclusion of the phrase "release into the environment" is redundant. Inclusion of the phrase "release into the environment" in the definition of introduce is meant to advise persons that APHIS is regulating the release into the environment of a regulated article, in addition to regulating interstate movement and importation. According to § 340.0(a) of the final rule, no person shall *introduce* (release into the environment) a regulated article unless the introduction is authorized by a permit and the introduction is in conformance with all of the applicable restrictions in this part.

Mutagen

10. Because the definition of genetic engineering has been modified and the term mutagen (mutagenesis) is not used in the current definition, APHIS is deleting the definition of mutagen.

Organism

11. The twelve comments on the definition as proposed expressed the view that it was too broad and should not include portions of organisms. APHIS agrees with these comments, and has deleted the language "and any part, copy, or analog thereof, including DNA, RNA, which is infectious."

The original definition of organism included these constituent parts, which are not included in any currently accepted concept of the nature of an organism. APHIS has reviewed this question, and determined that the separate constituent parts of an organism can not be regarded as "living", and do not present the same plant pest risk that the complete or intact organism may pose. This is not to deny that some components, such as DNA sequences, or organisms, which are plant peasts may not present some risk if they are incorporated into other organisms. However, it has been determined that it is possible to regulate the risk associated with these cell components without restoring to the inclusion of these non-living constituents as organisms. This is because a genetically engineered organism which contains these components from an organism listed in § 340.2 would be deemed a regulated article.

Prions have also been deleted from this definition, and from the list of organisms in § 340.2. The reasons for the deletion are explained in the discussion of the comments on § 340.2.

An amended definition has been adopted, as follows: "Any active, infective, or dormant stage of life form of an entity characterized as living, including vertebrate and invertebrate are animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids and viruses, or any entity characterized as living, related to the foregoing."

Pathogen

12. Because the definition of regulated article has been modified and the term pathogen (pathogenic) is not used in the current definition, APHIS is deleting the definition of pathogen.

Person/Responsible Person

13. One commenter noted that the proposed regulations contained definitions of the terms "person" and "responsible person." The commenter asked, "who is responsible, the individual or the individual and his corporation?

The final rule aplies to either a single person when acting alone when there is no corporation or other legal entity, or the person designated by the corporation or other legal entity to be the responsible person and the corporation or other legal entity, when the responsible person is acting within the scope of his or her employment of the corporation.

Plant

14. The majority of the seventeen commenters on this definition pointed out that it was not consistent with the classification of organisms in § 340.2 of the proposed regulations. These comments noted that the definition of plant included bacteria, but that bacteria was not listed under the Kingdom Plantae; bacteria had been listed under the Kingdom Monera. The commenters argued that bacteria should not be included in the definition of plant.

Other commenters objected to the inclusion of fungi and prokaryotic algae in the plant kingdom. One commenter noted that the inclusion of such organisms in the plant kingdom fails to consider the results of twenty-five years and more of comparative biochemistry concerned with the structure and function of cells.

APHIS agrees with these comments, and has accordingly deleted bacteria, fungi, and prokaryotic algae from the definition.

An amended definition has been adopted, as follows: Any living stage or form of any member of the plant kingdom including, but not limited to eukaryotic algae, mosses, club mosses, ferns, horsetails, liverworts, angiosperms, gymnosperms, and lichens (which contain algae) including any parts (e.g., pollen, seeds, cells, tubers, stems) thereof, and any cellular components (e.g., plasmids, ribosomes, etc.) thereof.

Plant Pest

15. Nine comments were received on the definition of plant pest. The commenters indicated that the definition was very broad and overly inclusive, that it included numerous examples of nonpathogenic organisms, and that it failed to adequately notify applicants of the characteristics or criteria to enable a determination of non-pest status.

APHIS acknowledges that the definition of plant pest is very broad. However, APHIS disagrees that the definition is overly inclusive, and the definition has been adopted as proposed. The definition of plant pest comes from the definition of plant pest found in the FPPA (7 U.S.C. 150aa *et seq.*). As discussed in response to paragraph 1, the definition of plant pest was deliberately made broad by Congress to include those organisms that might *later* be found to be injurious to plants. APHIS has determined that all of the types of organisms included in the definition of plant pest have been

known to directly or indirectly injure or cause either disease or damage in plants, or in plant parts, or in processed, manufactured, or other products of plants. APHIS believes that the definition of plant pest indicates to a person that an organism that does not have plant pest status would be one that does not directly or indirectly injure or cause disease or damage in any plants, or plant parts, or any processed, manufactured, or other products of plants.

Regulated Article

16. Thirty-four comments were received on the definition of regulated article. Fifteen of these comments expressed the opinion that the proposed definition of regulated article was too broad. Some commenters stated that as defined "regulated article" could be interpreted in a way that would include many organisms that the commenters did not consider to be plant pests. In many cases commenters identified specific organisms that they stated were not plant pests, and thus should not be subject to regulation. Other commenters stated that the inclusion of non-living components of plant pest organisms should not be included as a regulated article.

APHIS agrees with these comments, and has modified the final rule in several respects to narrow the scope of regulated article.

First, the list of organisms in § 304.2, which would cause a genetically engineered organism or product to be deemed a "regulated article," has been modified, by deleting certain organisms and by clearly stating how the list is to be utilized. Secondly, the definition of organism has been modified to exclude non-living components or parts of organisms listed in § 340.2. Lastly, APHIS has modified the definition of regulated article to indicate that an organism which belongs to any genera or taxa designated in § 340.2 must meet the definition of "plant pest" or be an unclassified organism and/or an organism whose classification is unknown, or contain such an organism, or any other organism which the Deputy Administrator determines is a plant pest or has reason to believe is a plant pest. The change is significant since it would affect whether the genetically modified organism is deemed a regulated article.

The following new definition has been adopted: "Any organism which has been altered or produced through genetic engineering if the donor organism(s), recipient organism(s), or vector or vector agent(s) belongs to a genera or taxa designated in § 340.2 of this part and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Deputy Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions." (The rationale for the exclusion for certain microorganisms is discussed in paragraph 18).

Several commenters suggested that APHIS add procedures which would provide for the exclusion of organisms altered by recombinant methods, which are not plant pests.

APHIS agrees with the commenters and believes that the petition procedure discussed in paragraph 42 is responsive to the commenters' concerns.

Several commenters suggested that the delegation of authority to the Deputy Administrator to designate an organism as a "regulated article" based upon "reason to believe" was a standardless delegation of authority.

APHIS disagrees with these comments. The provision for the Deputy Administrator to designate an organism as a regulated article based upon "reason to believe" has been retained.

Section 105 of the FPPA grants the emergency authority to regulate an organism, where there is reason to believe it is a plant pest or in order to prevent the dissemination into the United States of a plant pest. With regard to conventional plant pests, the Deputy Administrator of APHIS has used this authority when it was necessary to regulate an organism that was likely to be a plant pest and was not otherwise specified because of plant pest risk as a regulated article. "Reason to believe" is based on scientific information, such as taxonomic association and biological data. This standard is an objective, not subjective one.

An example of the use of "reason to believe" occurred in 1982 when a previously undescribed disease was observed on lime trees in Southwestern Mexico. APHIS regulations prohibit entry of citrus fruit from countries where citrus canker is present. Initially it proved difficult to make a specific identification of the pathogen associated with this disease. Because the pathogen belonged to the bacterial genus *Xanthomonas*, and because the disease caused lesions on citrus leaves, it was determined that there was reason to believe that the disease in Mexico was citrus canker, and that the organism associated with the disease was a plant pest. This resulted in various actions being taken to prevent the introduction of the disease into the United States. Subsequent research conducted in the United States and Mexico confirmed that the organism causing the disease in Mexico was *Xanthomonas campestris* pv. *citri*, a regulated plant pest.

The decision by APHIS to designate an organism as a regulated article based upon the "reason to believe" provision will be an objective, informed decision made after review of substantive information regarding demonstrated plant pest risks. It will not be an arbitrary one.

Release into the Environment

17. Of the eighteen comments on this definition, the largest number concerned the fact that the proposed definition relied only on physical containment, and ignored biological containment. Other commenters requested a definition of contained greenhouse, expressed approval of the definition, or suggested various approaches to the evaluation of containment.

One commenter indicated that a general understanding of this term has been that release occurs if an experiment does not take place within the confines of a laboratory where the organism can be physically contained and remedial measures taken in the event of an accident. APHIS agrees with the commenter and believes that the concept of release should be based on the concept of a release from the confines of physical containment. One commenter suggested regulating release only if there is a deleterious alteration of the environment. APHIS believes that what is "deleterious" to the environment is too subjective a standard. USDA believes that a release from physical confinement is more understandable and a practical standard.

APHIS has adopted the definition of "release into the environment" as originally proposed. APHIS believes biological and greenhouse containment are key issues in discussions concerning this definition. While the definition of release into the environment does not formally include the concept of biological containment (i.e. the inability of the regulated article to survive outside specific environmental or host conditions) APHIS believes that biological containment is one important factor in determining the prescribed level of physical containment. Since greater scrutiny is needed to judge the

efficacy of biological containment than physical containment, APHIS does not believe a claim of biological containment is sufficient to exempt a party from the requirement of having to obtain a permit for the release of a regulated article into the environment. In APHIS' review of permit applications, determinations of the adequacy of biological containment will vary according to the subject organism and quality of scientific evidence, and will be made on a case-by-case basis. In its review process, APHIS will allow biological containment in lieu of physical containment if it determines this will prevent the dissemination and establishment of plant pests in the United States.

APHIS does not believe it is practical to try to define what is a "contained greenhouse", since what is considered adequate physical containment will vary according to the subject organism, and that such determination must be made on a case-by-case basis. For example, physical containment will depend upon combinations of laboratory practices, containment equipment, and special laboratory design. APHIS will review the data submitted in a permit application concerning the description of a "contained facility" in determining whether the contained facility is adequate to prevent the release into the environment of the genetically engineered organism. A person should consult the NIH Guidelines at 51 FR 16958, "Appendix G—Physical Containment", for guidance on what are appropriate methods of physical containment.

APHIS acknowledges that the Biotechnology Science Coordinating Committee, the National Institutes of Health, and the Environmental Protection Agency are all attempting to define what constitutes release into the environment. If a uniform definition is adopted by these groups APHIS shall consider proposing to amend the final rule to incorporate such a definition.

Well-Characterized and Contains Only Non-Coding Regulatory Regions; Exclusion for Certain Microorganisms

18. A total of nineteen comments were received on this exclusion from the definition of regulated article. It was proposed to exclude microorganisms that are "non-pathogenic, non-infectious, and otherwise not plant pests that have resulted from the addition of genetic material that is well characterized and contains only non-coding regulatory regions."

The comments on this provision ranged from doubt about the scientific soundness of such an exclusion to requests that the exclusion be retained and expanded to include other non-coding regions.

Based upon a review of these comments and the scientific literature, it was determined that there is no evidence that the addition of well-characterized non-coding regulatory genes from a prokaryote or eukaryote to a prokaryote has resulted in the *de novo* appearance of a gene product which did not exist prior to the acquisition of the new genetic material. The scientific literature indicates that regulatory, transcriptional or translational ambiguities are not found in the transfer of well characterized genetic material between prokaryotes, or from eurkaryote to prokaryote, but do occur in prokaryote to eukaryote transfers.

One commenter indicated that some pathogens have the capacity to increase in virulence or change in host range in response to a single gene mutation and that some avirulent derivatives of pathogens have the potential to regain pathogenicity by mutation. The commenter stated that such microorganisms need to be examined before release to the environment. However, the commenter noted that a distinction must be made between a derivative of a pathogen, potentially harmful, and a nonpathogenic organism bearing an introduced gene from a pathogen.

APHIS agrees with the commenter that if the recipient microorganism is not a pathogen or a plant pest the microorganism after the addition of genetic material which is well characterized and contains only non-coding regulatory regions, will also not be a pathogen or a plant pest. Therefore, as adopted in the final rule, recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism which is "well characterized and contains only non-coding regulatory regions" are not regulated articles. However, if the recipient microorganism was a plant pest, the addition of such genetic material would not lessen the fact that the recipient microorganisms presents a plant pest risk, and as such, would be a regulated article.

One commenter suggested that other non-coding regions such as ribosomal RNAs, tRNAs, and RNAs as required for replication also be exempted from review because these do not encode proteins.

APHIS disagrees with the commenter. The reason that the exclusion cannot be currently extended to other specific non-coding, non-regulatory regions such as ribosomal RNAs, tRNAs, and RNAs required for replication is that most of these aforementioned genes are part of a complex interdependent system of operons. These operons generally contain a very wide array of disconnected functions which interact with other related and unrelated operons to poroduce critical non-structural proteins which are needed in equimolar amounts. Therefore, the consequences of the genetic transfer of this level of genetic complexity, even between bacteria, are not well understood, and could have unforeseen results. APHIS believes there may be significant potential plant pest problems present in this type of gene transfer if the exclusion were more extensive.

Commenters argued that "knowing the exact nucleotide base sequence of a regulatory element or the transfer of non-coding regulatory sequences" does not allow one to predict the biological role of this element when placed in another organism.

APHIS disagrees with the commenters. In the case of (the transfer between prokaryotes or eukaryotes to prokaryotes) "well-characterized non-coding regulatory genes," there is absolute predictability of the biological role of these genetic elements, and it can only execute its original predetermined regulatory function.

One commenter argued that it did not make sense to exempt only non-coding sequences. The commenter indicated that almost all "coding" sequences should be given exempt status such as cloned sequences. Another commenter noted that there are many well-characterized *coding* regions, which have no known or expected hazard to health or the environment, which should also be excluded.

APHIS disagrees with the commenters who believe that microorganisms which have resulted from the addition of genetic material which contains coding regions should also be exempt.

With the exclusion for microorganisms as modified in the final rule, it is impossible for the benign recipient to acquire new structural genes or gene products. The exclusion of well-characterized *coding* genes could result in the acquisition of deleterious new or novel gene products in a benign recipient. Therefore, the commenter's suggestion has not been accepted.

One commenter suggested modifying the definition of well-characterized and contains only non-coding regulatory regions. The commenter suggested modifying the definition by eliminating section (c) of the definition because it is redundant to sections (a) and (b) and by revising section (c) to indicate that the

transferred genetic material must be non-coding in the new host microorganism.

The modification of the definition as suggested by the commenter is unnecessary. There is no evidence to support the commenter's suggestions that a non-coding gene from a donor microorganism could be a coding gene in a recipient microorganism.

One commenter noted that the precision in molecular biological experiments must not be confused with precision in predicting their ecological consequences. The commenter indicated that this alteration of the organism as a whole or its relationship to other organisms in the environment would be unknown, and that such regulatory changes in the organism can create "novel" organisms which are eminently suited to disrupt ecological niches.

APHIS disagrees with the commenter's assertion that a novel or new organism would be created as a result of the addition of genetic material that contains only well-characterized non-coding regulatory regions. APHIS believes that in this specific case, the absolute understanding of the underlying molecular genetic mechanism is the sole determinant in being able to predict the plant pest characteristics of the modified microorganism. It is APHIS' position that when donor genetic material from an organism which is well characterized and contains only non-coding regulatory regions is placed into a benign receipient microorganism, the recipient will not acquire plant pest traits or become a plant pest.

Furthermore, APHIS believes that the genetic manipulations which create such a microorganism would be similar to the same type of genetic manipulations which occur in nature through mutation and natural selection (the higher or lower production of a pre-existing structural gene) or through classical breeding techniques which man has been using for the past 10,000 years. In short, such a modified microorganism would be so close to ones produced by natural mutational events or selective breeding programs (classical techniques) that there is no reason to believe that such a microorganism would be a plant pest. Furthermore, APHIS believes that the possibililty of harmful ecological consequences would not be considered significant.

Comments Concerning the List of Organisms in (§ 340.2)

19. Fifty-two comments were received on the list of organisms in § 340.2, which are or may contain known plant pests or for which the Department has reason to believe are plant pests. The commenters generally expressed the view that the list was overly broad and inclusive, and that only organisms known to be plant pests should be included. Other comments were received which objected to the inclusion of various taxa or groups of organisms which commenters argued were not plant pests.

APHIS agrees with those commenters that believe that the list was overly broad and inclusive, and agrees that only organisms from any genera or taxa listed in § 340.2 and that meet the definition of "plant pest" should be regulated. APHIS has made several revisions in the final rule to implement this change.

APHIS has revised the prefatory language in § 340.2 of the rule, which explains how to determine if an organism classified in an unlisted taxa which comes under a higher listed taxa would be deemed to be a plant pest. Further, APHIS has amended the definition of "regulated article" to indicate that an organism which belongs to any genera or taxa designated in § 340.2 must meet the definition of plant pest before it is deemed a regulated article. In addition, APHIS has added the following new footnote 4 to § 340.2 which explains the conditions that must be met before an organism is deemed a plant pest.

> An organism belonging to any taxa contained within any listed genera or taxa is only considered a plant pest if the organism "can directly or indirectly injure, cause disease, or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants." Thus, a particular unlisted species within a listed genus would be deemed a plant pest for purposes of § 340.2 if the scienfitic literature refers to the organism as a cause of direct or indirect injury, disease, or damage to any plants, plant parts, or products of plants. (If there is any question concerning the plant pest status of an organism belonging to any listed genera or taxa, the person proposing to introduce the organism in question should consult with APHIS to determine if the organism is subject to regulation.)

As the language in the footnote indicates, an organism is not necessarily considered to be a plant pest, and thus subject to regulation, simply because the organism is a member of any listed genera or taxa. The list of genera or taxa in § 340.2 is presented as a list of all taxa which may contain plant pests. Within any listed genus or taxon, the organisms subject to regulation as plant pests are only those organisms that meet the statutory definition of plant pest (i.e., causes injury, disease, or damage in plants, plant parts, or products of plants). In most cases, organisms that are known to be plant pests will be referred to or discussed in the scientific literature. APHIS' reveiew of the scientific literature involves a search of the relevant agricultural data bases which include, but are not limited to Agricola, Biosis Previews, Cab Astracts, Agris International, Life Sciences Collection, and Supertech.

In addition to all those species for which the plant pest status can be determined by reference to the scientific literature, there will be certain other species or organisms for which the plant pest status will be unclear, due to such things as problems with taxonomic designation. If there is any question concerning the plant pest status of any species or organism belonging to any listed genera or taxa, the person proposing to introduce the organism in question should consult with APHIS to determine if the organism is subject to regulation.

This procedure for determining if an organism is subject to regulation under Part 340 is the same type of determination that must be made when a person proposes to import or move interstate non-genetically engineered organisms that may be subject to regulations promulgated under the FPPA and PQA and found in 7 CFR 330.200.

Lastly, for the reasons discussed in the proposed regulations of June 26, 1986, published in the **Federal Register** at 51 FR 23355, unclassified organisms and/or organisms whose classification is unknown are also included in § 340.2.

20. Many comments contained statements that various groups of organisms listed in § 340.2 should be removed from the list because these organisms are not plant pests. The groups of organisms most frequently mentioned in these comments were the bacterial genera *Rhizobium* and *Bradyrhizobium*, and various groups of mycorrhizal fungi.

However, those commenters did not present sufficient data to justify excluding *Rhizobium*, *Bradyrhizobium*, and various groups of mycorrhizal fungi from the list of organisms in § 340.2.

These taxa or groups of organisms contain organisms that are able to infect plants and survive at the expense of the host plant. The interaction between the infecting organism and the host plant is usually regarded as a symbiotic one, with the plant benefiting from the increased availability of essential nutrients. However, because the groups of organisms in question contain species that are well adapted to infecting and surviving in their plant hosts, it was determined necessary to retain these groups on the list in § 340.2. It should be noted that new § 340.4 provides the

procedures for amending the list of organisms in § 340.2.

The list in § 340.2 is composed of all those genera or taxa which may contain organisms that are plant pests. Within any taxonomic series, the lowest unit of classification actually listed is the group which is composed of, or includes, organisms that are regulated. Organisms belonging to all lower taxa contained within the group that is listed are included as organisms which are or may contain plant pests, if they otherwise meet the definition of plant pest as explained above. For example, when the lowest unit listed of a particular series is an order, then members of all families, genera, and species belonging to that order are meant to be included as organisms which are or may contain plant pests, if such organisms meet the statutory criteria for being a plant pest.

In a second example, if an order is included on the list, but is followed by a listing of one or more of the families belonging to that order, then only the members (all genera and species) of those families listed that meet the definition of plant pest are intended to be regulated. Members of any other families within that order that are not listed are not regulated.

It is crucial to note that an organism of any genera or taxa listed in § 340.2 is significant only when the organism meets the definition of a plant pest and two additional conditions are met. The organism must have been modified in some way through the process of genetic engineering (as defined in § 340.1), and there must be the intention to import the organism, to move the organism interstate, or to release the organism in the environment. If an organism is listed in § 340.2 but does not meet both the condition of movement or release to the environment, and of being modified by a process of genetic engineering, it is not regulated under Part 340.

Finally, it should be noted that all other regulations which affect the importation or movement of an organism which is a plant pest or could harbor a plant pest remain in effect regardless of the status of the organism under Part 340. To remind persons of this fact the following language has been added to footnote 1.

Under regulations promulgated in 7 CFR "Subpart-Nursery Stock" 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.

21. Several comments were received which contained statements that the list of organisms in § 340.2 includes groups which have an incorrect taxonomic designation or that the list is incomplete with regard to the Kingdom Monera. In response to these comments, APHIS scientists reviewed the list of organisms and determined that certain changes were appropriate.

Taxonomy is a dynamic branch of the biological sciences, and is particularly so when the organisms being classified are in taxa or genera that have only recently been identified. After consulting the current literature, the following changes are made in the list of organisms in § 340.2.

Prions have been removed from the list of organisms which are or contain plant pests in § 340.2. There is no evidence at the present time that any prion is associated with a plant pest. All of the prions identified to date have been associated with diseases in animals. If in the future a prion should be found to be associated with a plant pest or suspected of causing a plant disease that organism could be added to the list.

The group of organisms previously referred to as Rickettsial-like organisms associated with plant disease are correctly described as gram-negative xylem-limited bacteria associated with plant diseases. Examples of diseases associated with these pathogens are Pierce's disease of grape and phony disease of peach.

Some organisms previously thought to be mycoplasma-like organisms (MLO) are in fact true bacteria and should be correctly listed as gram-negative phloem-limited bacteria associated with plant diseases. Examples of organisms in this group are the bacteria which are associated with citrus greening disease and clover club leaf disease.

Concerning those comments that the list is incomplete, APHIS is conducting a further examination of the plant pest status of members of various taxa in the Kingdom Monera to determine if additional taxa should be added to the list or if a more specific and exact listing can be proposed for members of some of the genera listed. If APHIS' research indicates additional taxa should be included in § 340.2 or if the list should be made more specific, a document shall be published in the **Federal Register** proposing to add such taxa or otherwise to revise the list.

Items Exempt From Regulation and Procedures for Removing Organisms From the List

22. Thirty-nine comments contained statements objecting to the inclusion of various organisms or portions or constituents of organisms as plant pests. Many comments contained statements that various portions (plasmids, DNA fragments, etc.) of plant pests be exempted from regulation if these components are "non-pathogenic." Some comments contained the suggestion that "disabled" pathogens not be regulated as plant pests.

In response to these comments, APHIS has modified the definition of organism so that this definition as amended now excludes parts or components of organisms listed in § 340.2. As previously stated, the definition proposed by APHIS for organism has been revised, and now excludes non-living components of living organisms. The reasons for this change have been previously explained in paragraph 11. Any organism containing these parts or components would be regulated if the parts or components were incorporated into the organism through the process of genetic engineering (as defined in § 340.1).

The movement of killed organisms that are included in the list of organisms in § 340.2 is not regulated. The movement of non-living components (including, but not limited to, DNA, RNA, and plasmids) of organisms included on the list of organisms in 340.2 is not regulated. However, if certain components of regulated plant pest organisms, including DNA and RNA sequences, organelles, and plasmids retain their identity and are incorporated as part of an organism, then the introduction of this organism would be regulated under Part 340. It was not APHIS' intent to imply that all species, biotypes, lines, or races of the taxa listed in proposed § 340.2 were plant pests. For example, *Erwinia caritovora* is a bacterial plant pathogen causing soft rot diseases. All members of the genus *Erwinia* are included in the list of organisms in § 340.2. If this organism is modified by the process of genetic engineering, the modified bacteria are subject to regulation under Part 340. If genetically engineered bacteria of this species are killed, then the killed cells and/or any parts or components (including DNA and RNA sequences) that might be extracted from them are not subject to regulation. Should any genetic material from these killed bacteria, including DNA and RNA or other component as noted at the beginning of § 340.2, be introduced into any living organism by the process of genetic engineering, then that organism would be subject to regulation under Part 340.

23. Many comments expressed concern about the inclusion of certain organisms as plant pests. In many cases these organisms are members of a group containing many plant pests, such as the

bacterial genera *Pseudomonas, Xanthomonas,* and *Erwinia.* Commenters frequently requested that specific organisms belonging to these groups which were believed not to be plant pests be removed from the list. These requests were based on conclusions and opinions, rather than any complete submission of factual material.

Organisms or groups of organisms are considered to be on the list of organisms in § 340.2 if they meet the statutory definition of plant pest. To determine if a particular species is a plant pest, a person should consult the scientific literature or APHIS to determine if the species has plant pest characteristics, as discussed in footnote 4 above.

APHIS recognizes that there may be instances when it may be appropriate to remove specific organisms from the list because they do not appear to be plant pests. Provisions for submitting a petition to remove a specific organism or group of organisms from the list are discussed in § 340.4. Any person may submit a petition to remove an organism or group of organisms from the list in § 340.2. The petition should include full and factual information supporting the request for removal.

Comments on Permits for the Introduction of a Regulated Article (§ 340.3)

Numerous comments were received on § 340.3 of the regulations pertaining to the issuance of a permit for the introduction of a regulated article. The comments pertained to: The need for additional provisions to protect confidential business information; the 180 day review period for processing permit applications; data required in applications; the need for state involvement in the review process; certificate of exemption/courtesy permits; the need for additional safeguards to be added to the final rule; and the standard permit conditions.

Confidential Business Information

24. One commenter suggested that it would be beneficial if the regulations contained specific instructions to an applicant in order to identify and protect confidential business information (CBI).

APHIS agrees with the commenter, and has revised § 340.3(a) of the final rule to include provisions advising applicants how CBI should be designated and submitted. Under § 340.3(a) the responsible person should submit two copies of a permit application. If there is CBI information contained in the application, then each page of the application containing such information should be marked "CBI Copy." In addition, those portions of the application deemed CBI should be so designated. The second copy of the application should have all such CBI deleted and should be marked on each page of the application where CBI was deleted "CBI Deleted." If an application does not contain CBI, then the first page of both copies of the application should be marked "No CBI."

APHIS believes that such procedures will readily identify those applications which contain CBI and will specifically designate those portions which the applicant feels must be protected. In addition, by requiring that an applicant submit a second copy of an application with CBI deleted, this will provide APHIS with a copy of the application which can be routinely sent to the State departments of agriculture for their notification, and review of the application and to requesting public interest groups without concern that CBI data might not be properly safeguarded.

25. Other comments acknowledged that the APHIS policy statement on CBI (See 50 FR 38561–38563, September 23, 1985) was an important element in USDA's regulatory program, but that it is important that these same procedures apply equally to any individual outside of APHIS, at other USDA agencies, that handle CBI in connection with an APHIS action.

APHIS agrees with these commenters. It should be noted that if CBI is made available to other government employees at other USDA agencies, such employees are prohibited under the Trade Secrets Act (18 U.S.C. 1905 *et seq.*) from disclosing such information. The Trade Secrets Act imposes serious criminal penalties for violating its provisions, and those government employees handling CBI are aware of the need to safeguard CBI. In addition, the USDA is drafting CBI materials specifically for the Office of Agricultural Biotechnology (OAB) which is the office which coordinates biotechnology research for the Science and Education Administration. These CBI materials will include a "Guide for the Control of Confidential Business Information Relating to Proposals for Approval of Biotechnology Research," and a "Commitment to Protect Confidential Business Information Form," to be signed by any person who receives CBI in an official capacity through the OAB.

180 Day Review Period for Processing Permit Applications

26. Fifty-three comments were received on the proposed provisions of the regulations which provided for a 180 day period for the review of permit applications.

The comments ranged from the observation that 180 days was "too long" to more strongly worded statements that such a delay was "unreasonable, unacceptable, and untenable." Approximately half the commenters (25) on the 180 day review period suggested a shorter review period and/or structured review procedures.

One commenter suggested that the review period should be no longer than 60 days. Other commenters expressed the view that applications should be reviewed for their completeness within 45 days, with a final decision being made in 90 days. The commenters suggested that for complicated applications, there could be a provision for an extended review of up to 120 days if the applicant and APHIS so agreed.

Most commenters suggested that a 90 day review period would be reasonable and in accord with the processing time for a pre-manufacturing notification (PMN) submitted to EPA under the Toxic Substances Control Act.

Nearly a quarter of the comments on this issue objected to the fact that in the proposed review period, APHIS did not distinguish between the different types of permits people would be requesting. These comments expressed the view that release into the environment and interstate movement or importation were separate activities and should be treated as such. One commenter suggested that 14 days would be a more appropriate period for the issuance of a movement permit.

APHIS agrees with the commenters that believe the proposed 180-day review period should be reduced and that the review period should vary according to the type of permit being issued.

APHIS has adopted a 120-day period, rather than a 60-day or 90-day time period time to review an application for release into the environment for two reasons. First, before APHIS issues a permit for release, a thorough and comprehensive environmental assessment must be prepared. Because of the doctrine of "Functional Equivalency," the EPA, which by statute must review a PMN within 90 days from receipt of a complete PMN, does not have to prepare an environmental assessment during the review period. APHIS has determined it necessary to prepare environmental assessments pursuant to the National Environmental Policy Act (NEPA) prior to issuance of a permit for release into the environment. Therefore, APHIS believes that it needs 120 days to review a permit application for environmental release. In the event an environmental impact statement

(EIS) has to be prepared, the review period would be extended. Secondly, the final rule, as revised, provides that before APHIS issues a permit for environmental release it shall submit a copy of the application for State notification and review. Because of the necessity to coordinate and consult with the State where release shall occur, APHIS believes it's advisable to allow for more than a 60-day review period.

It should be noted that 120 days would be the *maximum* time APHIS would need to review a complete application for environmental release that does not involve the preparation of an EIS, and is the period an applicant should use for planning purposes. APHIS shall make every attempt to complete its final review in less than 120 days. One hundred and twenty days will also allow APHIS to schedule an inspection of the site where the release is to occur prior to the issuance of a permit, as provided for in new § 340.3(d). It should be further noted that § 340.3(b) of the final rule is being revised to indicate that APHIS will complete its initial review within 30 days of receipt and shall advise the responsible individual if any additional information is needed within 30 days of receipt of the application.

APHIS disagrees with the commenter who suggested that a 14-day review period would be a sufficient period to process an application for a permit for interstate movement. As explained in more detail below, because of the need to consult with State officials and possibly to conduct an inspection of the contained facility where the regulated article is to be stored, APHIS has amended the final rule in § 340.3(b) to provide for a 60-day review period. For the review of applications for interstate movement or importation into a contained facility, APHIS will, however, complete its initial review within 15 days of receipt and advise the responsible individual if additional information is required. It should also be noted that 60 days is the *maximum* time USDA will take to review a complete permit application for interstate movement or importation to a contained facility and is the period an applicant should use for planning purposes. In all possible cases, APHIS will try to complete its final review in less than 60 days.

Data Required in an Application

27. One commenter noted that a significant amount of genetic information is required in advance of approval of experimentation. The commenter noted that the level of documentation required by these regulations is usually generated as a result of the research.

As revised, the final rule calls for less data in an application for a limited permit for interstate movement or importation than must be submitted in an application for environmental release. APHIS believes that the data that is required for an application for environmental release should have been obtained before release is requested, and can be obtained from the scientific literature and/or by doing research within a contained facility.

28. One commenter indicated that there is no need for APHIS to require extensive documentation on proposed experiments after the work has been approved elsewhere. The commenter suggested that documentation of other approvals, a brief description of the materials, and a statement of the level of containment should be enough to quickly be granted a permit to receive cultures that are to be used in a contained facility.

APHIS believes that the provisions of the final rule which provide for the issuance of a limited permit for interstate movement of a regulated article into a contained facility address many of the concerns raised by the commenter. As revised, APHIS will issue limited permits for interstate movement in less time by requiring less data than a permit for release into the environment.

Other commenters argued that the proposed regulations were too restrictive as they pertained to the interstate movement of low risk genetically engineered organisms. One commenter indicated that prior approval should not have to be obtained for the interstate movement of organisms shipped between laboratories which comply with NIH containment guidelines. The commenter argued that in such situations a simple notification to USDA pertaining to the movement of such organisms would suffice. These commenters did not present specific examples of the types of organisms and under what conditions certain organisms would not pose a risk of plant pest dissemination.

It appears that there are circumstances under which certain genetically engineered organisms such as those employed as "libraries" or biological containers can be moved interstate between contained facilities under conditions which would not present a risk of plant pest dissemination, and for which no permit would be required. It appears that such organisms are *E. coli* K–12 or other bacterial strains with similar characteristics, containing genetic material from any plant pest, except when such genetic material contains genes which code for: substances toxic to plants and organisms in the agro-ecosystem; or substances influencing plant growth; or genes for disease susceptability; or substances or characteristics associated with resistance to pesticides.

Likewise, a unique synthetic nucleotide sequence added as a "marker" for identification of a specific microorganism, when constructed to not constitute an open reading frame in any register, also poses no risk and is completely benign.

In accordance with notice provisions of the Administrative Procedure Act, APHIS intends to publish a proposed rule in the **Federal Register** within the next 30 days which would amend Part 340 to include these exclusions.

The fact that APHIS intends to publish a document which would propose to make certain changes to the final rule, shortly after its publication, reflects APHIS' belief that the regulations should be malleable and keep pace with the scientific "state of the art." It is anticipated that the APHIS regulations will parallel the NIH Guidelines in the sense that these regulations will continue to evolve and be updated as experience is gained and more information becomes available on the plant pest risk presented by the introduction of genetically engineered organisms. In short, APHIS believes that when it can be shown that the interstate movement between contained facilities of certain organisms does not present a risk of plant pest introduction or dissemination, then the regulations should be amended to exclude such movement from the permit requirements.

Lastly, to facilitate receipt of current data relative to the plant pest status of certain organisms from outside sources, APHIS has included the petition process in § 340.4 of the final rule.

Permit Processing Procedures

29. Section 340.3(b) of the final rule is a new section and is entitled, "Permit for release into the environment." If an application for environmental release is complete when received, APHIS shall notify the responsible individual of the date of receipt of the application for purposes of advising the applicant when the 120 day review period commenced. If an application is not complete, APHIS will advise the responsible individual what additional information must be submitted and shall commence the 120 day review period upon the receipt of the additional information, assuming the

additional data requested is adequate. When it is determined that an application is complete, APHIS shall submit to the State department of agriculture where the release is planned, a copy of its initial review and a copy of the application marked "CBI Deleted" or "No CBI" for State notification and review. Pursuant to APHIS' CBI Policy Statement of September 23, 1985 (50 FR 38561–38563), the requirements of Section VIII(b) must be complied with by a State prior to disclosure by APHIS to the State of CBI material. This section requires that the request be for an official purpose; that the requester have security procedures equivalent to those of APHIS; and that the person submitting the material determined by APHIS to be CBI be notified of the request prior to any disclosure.

An application for release into the environment must include the information required by § 340.3(b)(1)–(14). These are the same 14 data elements that appeared in the proposed regulations under § 340.3(a).

30. Section 340.3(c) of the final rule is a new section and is entitled, "Limited permits for the interstate movement or importation of a regulated article." This section provides for a 60 day review period with an initial review being performed by APHIS within 15 days of receipt of an application. Like an application for release into the environment, if an application is incomplete and additional information must be requested, APHIS will commence the 60 day review period upon receipt of the additional information. Section 340.3(c) of the final rule also provides that when APHIS determines that an application is complete, APHIS shall submit a copy of its initial review and the "CBI Deleted" or "No CBI" copy of the application to the State department of agriculture located in the State of destination of the regulated article, for State notification and review of the application.

State Involvement in the Review Process

31. Several comments were received from State departments of agriculture concerning the need for State involvement and participation when APHIS is deciding whether to issue a permit for release into the environment. A comment from the State of New Mexico indicated that notification of the State where release will be accomplished is necessary to minimize last minute complications. The State of California indicated that it has regulations that mandate certain review procedures prior to the release of certain genetically engineered organisms into the environment, and that APHIS' permit application for the introduction of genetically engineered organisms contains no provisions for State recommendations on the application. The State of North Carolina further indicated that the State where a person intends to release a regulated article should be given an opportunity to review the application, and that the State should be notified of any exemptions that may be granted, or if a permit is withdrawn.

APHIS agrees with these commenters that State notification and review of an application for the introduction of a regulated article is essential. To ensure that the affected State has been notified and has an opportunity to review a permit application for release or interstate movement or importation, APHIS has modified §§ 340.3(b) and (c) to include provisions that call for State notification and review of a permit application. These provisions which ensure State involvement and participation in the permitting process for genetically engineered organisms is totally consistent with existing procedures for the issuance of a permit for the movement of plant pests under 7 CFR 330.200. It is envisioned that State regulatory officials will play a significant role in providing site specific and other environmental and ecological data on the location where a genetically engineered organism is to be released, and otherwise assist in the enforcement of the Federal regulations, on a cooperative basis.

Provisions for the Issuance of a Single Permit for Multiple Interstate Movements

32. New § 340.3(c)(1) provides that the responsible person may apply for a single limited permit that would be valid for the interstate movement of multiple regulated articles moving between contained facilities in lieu of having to submit an application for each individual interstate movement. Such a limited permit for interstate movement would be valid for one year from the date of issuance. The purpose of this provision is to eliminate the need for a person to have to go to APHIS for approval each time the person proposes to ship a regulated article, when this information can be made available to APHIS in advance of the shipments, all at one time. APHIS has added provisions allowing for multiple shipments to multiple locations under a single limited permit in response to comments that it would be too burdensome to require a person to submit a new application for each new shipment. New § 340.3(c)(1) further provides that a limited permit for interstate movement of a regulated article shall only be valid for the movement of those regulated articles moving between those locations specified in the application. If a person seeks to move regulated articles other than those specified in the application or to locations other than those specified in the application, a supplemental application must be submitted to APHIS.

Section 340.3(c)(1) of the final rule further provides that the responsible person shipping a regulated article interstate shall keep records for one year demonstrating that the regulated article reached its intended destination. The purpose of this requirement is for the shipper of the regulated article and APHIS to be able to verify that the regulated article, in fact, reached its intended destination, and to provide the capacity to trace a regulated article in the event it is delivered to the wrong location. This provision can be satisfied when using the mail by sending a regulated article, "certified mail, return receipt requested," or by using a carrier that requires the consignee sign for the delivery. If a person does not use the mail or a carrier to deliver a regulated article, then the consignee should keep a log of when the regulated article is received, and a duplicate copy of the log should be maintained by the responsible individual. This section also requires that no person move a regulated article interstate unless the number of the limited permit appears on the outside of the shipping container.

A person must submit data required by §§340.3(b) (1), (2), (4), (6), (7), (9), and (11–14) in an application for a permit for multiple interstate movements. This is the same information that would have to be submitted in an application for a limited permit for a single interstate movement. This data would provide APHIS with necessary information about the nature of the regulated article(s), the method of movement, and how it shall be contained during movement and at the article's destination(s). Such information will enable APHIS to decide whether or not a permit can be issued. If a permit is issued, such data will be used in determining what conditions, if any, should be imposed as part of the permit to eliminate or reduce the possibility of dissemination of a plant pest.

Limited Permits for Importation

33. New § 340.3(c)(2) of the final rule provides that the responsible person seeking a permit for the importation of a regulated article to a contained facility must submit an application for a permit

at least 60 days prior to the importation of *each shipment* of regulated articles.

Unlike a limited permit for interstate movement, APHIS is requiring that a person submit a separate application for each importation of regulated articles rather than issuing a "single" permit for importation that would be valid for multiple importations for a specified period.

APHIS has traditionally allowed persons moving regulated articles interstate to do so repeatedly under the provisions of a single limited permit, for movement to specified destinations for utilization or processing. Such a system would not be practicable for the importation of regulated articles because the entry status of many imported articles frequently changes depending on the plant pest status of the article's country of origin. Because the entry status of a regulated article is subject to change, APHIS needs to review each permit application for importation prior to importation so that a decision whether to allow importation can be made on a case-by-case basis.

APHIS anticipates that in many cases, a request for the renewal of a limited permit for importation can be processed in less than 60 days. APHIS has added the following new footnote 7 to § 340.3 (c)(2) to reflect this fact.

Renewals may receive shorter review. In the case of a renewal for a limited permit for importation that was issued less than one year earlier, APHIS will notify the responsible person within 15 days that either: (1) The renewal permit is approved or (2) that a 60 day review period is necessary because the conditions of the original permit have changed.

APHIS is also requiring that the responsible person importing a regulated article keep records for one year that demonstrate that the regulated article arrived at its intended destination. The one year recordkeeping requirement is consistent with the recordkeeping requirement for limited permits for interstate movement. A person must submit data required by §§ 340.3(b)(1),(2),(4),(6),(7),(9), and (11)–(14) in an application for a limited permit for importation. This is the same data that must be submitted in an application for a limited permit to move a regulated article interstate. APHIS believes that such data will enable it to properly evaluate the risk of allowing the regulated article to be imported. This data will provide APHIS with necessary information about the country of origin of the regulated article, the nature of the regulated article, the method of movement, and how it shall be contained during movement and at its final destination. As with limited permits for interstate movement, because the regulated article is moving under containment into a contained facility, APHIS is requiring that the same data be submitted in an application to import the regulated article as is required in an application for interstate movement.

Certificate of Exemption/Courtesy Permits

34. Six comments were received on § 340.4 of the proposed regulation entitled, "Certificate of Exemption." Several commenters suggested that the term "exemption" is not appropriate because it implies that APHIS is exempting the introduction of a regulated organisms from the provisions of the regulation, rather than providing an indication that the organism was never subject to the regulation to begin with. These commenters suggested that the appropriate name for such a document should be a "courtesy permit," as found in 7 CFR 330.208. One commenter suggested that a certificate of exemption be issued in situations where a regulated article is biologically contained.

APHIS agrees with commenters that argued the name "certificate of exemption" is a misnomer, and has changed the name of the document that will be issued to "courtesy permit." APHIS will issue a courtesy permit under the same circumstances that were proposed for the issuance of a "certificate of exemption," i.e., the organism was never subject to regulation under Part 340, but is similar to other organisms regulated under Part 340.

APHIS also added new § 340.3(h)(3) which indicates that a courtesy permit will be issued within 60 days from the receipt of a complete application, or the applicant will be advised that a permit is required under § 340.3(b) or (c). APHIS will conduct its initial review of a courtesy permit application within 15 days of receipt of a complete application and advise the applicant within this period if any additional information is required. It should be noted that 60 days is the maximum time it will take for the issuance of a courtesy permit, and that every effort will be made to issue such permits in less than 60 days.

Since courtesy permits are issued for organisms which are not regulated articles, the issue of containment, whether biological or physical, is not material.

35. One commenter believed that a person would be required to obtain a "certificate of exemption" (now courtesy permit) when organisms are produced through classical genetics.

APHIS wishes to stress that a courtesy permit is an *option* that an applicant may seek if it believes that such a permit would facilitate the movement of an organism through a USDA port of entry, because the movement might otherwise be impeded because of its similarity to a regulated article.

Lastly, one commenter suggested that a certificate of exemption should be extended to those genetically engineered organisms otherwise subject to regulation under Part 340, that can be documented not to be plant pests.

In such cases, APHIS would issue a permit without conditions (restrictions) for the introduction of the regulated article.

The preceding discussion on APHIS permits can be summarized as follows:

APHIS PERMITS FOR THE INTRODUCTION OF A REGULATED ARTICLE[1]

Type of permit	Application elements	USDA review period	USDA action	State notification and review required
Environmental release	§ 340.3(b)(1)–(14)	120 days (maximum time from receipt of complete application;[1] initial review within 30 days).	Issue permit with conditions; request additional data; or deny permit with reasons.	Yes.
Limited Permit for Interstate Movement or Importation into a Contained Facility.	§ 340.3(b) (1), (2), (4), (6), (7), (9), (11)–(14).	60 days (maximum time from receipt of complete application; initial review within 15 days).	Same as above	Yes.

APHIS PERMITS FOR THE INTRODUCTION OF A REGULATED ARTICLE[1]—Continued

Type of permit	Application elements	USDA review period	USDA action	State notification and review required
Courtesy Permit[1] (not required; may be sought at the option of an applicant; organism not a regulated article).	§ 340.3(b) (1), (2), (5), (7) and statement why not a regulated article.	60 days with initial review within 15 days.	Issue courtesy permit; request additional data; or advise applicant that another permit is required.	No (if courtesy permit issued). Yes (if another permit issued).

[1] The 120 day review period would be extended if preparation of an environmental impact statement was required.

Need for Additional Safeguards

36. Three comments were received on the need for additional safeguards to be added to the rule. One commenter indicated that the proposed regulations did not contain the safeguards already present in 7 CFR 330.202(b) applicable to the movement of plant pests. The commenter noted such provisions allows USDA to inspect at its discretion, any site or premises prior to the issuance of a permit, to determine the adequacy of the site or premises for purposes of containment.

APHIS agrees with the commenter and believes that the final rule should contain provisions giving APHIS the option to conduct a site or premises inspection prior to the issuance of a permit. Accordingly, APHIS has added new § 340.3(d) entitled, "Premises inspection," which is consistent with 7 CFR 330.202(b) of its existing plant pest regulations. Section 340.3(d) provides that an inspector may inspect the site or facility where regulated articles are proposed to be released or contained under permit.

This section further provides that failure to allow the inspection of a premises prior to the issuance of an environmental release or limited permit shall be grounded for the denial of the permit.

37. Other commenters suggested that USDA publish guidelines for academic investigators that would be useful in determining what constitutes a pathogenic or environmental hazard, and recommendations for commensurate containment levels. One commenter further suggested that APHIS publish a laboratory safety monograph which addresses feasible greenhouse containment, and construction and utilization of growth chambers. Another commenter suggested that USDA include in its regulations minimal safety precautions for biotechnology research. The commenter further noted that not all personnel have the desirable training in anti-contamination and containment techniques.

APHIS believes that it would be beyond the scope of the regulations to include minimal safety precautions for biotechnology research. These comments pertain to worker safety and do not address the issue of plant pest dissemination and establishment. APHIS believes that such information should be made available by other Federal agencies whose responsibility is to regulate Federally funded research or worker safety, e.g., the National Institutes of Health, the Science and Education Administration of USDA, or the Occupational Safety and Health Administration (OSHA).

For reasons discussed in paragraph 17, APHIS does not believe the issuance of a monograph for greenhouse containment is appropriate because of the need to make such determinations on a case-by-case basis.

Standard Permit Conditions

38. Several commenters objected to the wording of some of the standard permit conditions. These commenters argued that the phrase "as determined necessary by the Deputy Administrator" is vague and open-ended.

In an attempt to provide more specificity to the standard permit conditions, APHIS has moved the phrase "as determined necessary by the Deputy Administrator" from the conditions in §§ 340.3(f) (1) and (2) and has inserted the phrase, "in a manner so as to prevent the establishment and dissemination of plant pests." APHIS believes this change makes these conditions more specific.

Sections 340.3(f) (7) and (8) still retain the phrase, "as determined necessary by the Deputy Administrator." The language in § 340.3(7) gives APHIS the authority to specify in a permit any special conditions that might be deemed necessary to ensure the regulated article will not be accidentally released or that there will not be an unauthorized release. APHIS believes that such determinations can only be made on a case-by-case basis, and that retention of this phrase gives APHIS the flexibility need to ensure against an accidental or unauthorized released of the regulated article.

Section 340.3(f)(8) provides that a regulated article shall be subject to the application of remedial measures (including disposal) determined by the Deputy Administrator to be necessary to prevent the spread of plant pests. Such authority would only be exercised in the event of an accidental release of the regulated article, and gives APHIS the necessary authority to prevent the dissemination of plant pests. Such emergency authority is found in 7 U.S.C. 150dd of the FPPA.

APHIS has revised § 340.3(f)(9) to now read, "a person who has been issued a permit shall submit to Plant Protection and Quarantine monitoring reports on the performance characteristics of the regulated article in accordance with any monitoring reporting requirements that may be specified in a permit. This condition previously specified that such reports would have to be submitted, "as deemed necessary by the Deputy Administrator." The decision to require the submission of monitoring reports will be made on a case-by-case basis, and will depend on the nature of the regulated article. Monitoring reports will not be required of all permittees.

39. Six commenters objected to the time periods for reporting specified events to APHIS (i.e., unauthorized release (24 hours)), characteristics substantially different from those in an application (5 working days), and death of the regulated article (5 working days). Several commenters also objected to having to report the death of the regulated article, believing that death is not an unusual occurrence. One commenter objected to the fact that oral notification was required immediately, and, in every case, followed by the submission of written notification. In response to these comments, APHIS has made the following changes to the reporting requirements in § 340.3(f)(10).

Oral reporting to APHIS is now only required in the event of any accidental or unauthorized release. Because of the potential consequences of such an event, APHIS believes that such

occurrence must be orally reported, immediately upon discovery, and in writing within 24 hours. If immediate oral notification is impossible, then reporting should occur on the first working day after discovery of the release. APHIS has eliminated the requirement of oral notification for all reportable events other than unauthorized or accidental release.

40. One commenter suggested that the rule should vary the time within which an accidental or unauthorized release must be reported, depending on the nature of the regulated article.

While not all regulated articles present the same risk of plant pest dissemination, APHIS believes that in the event of an unauthorized or accidental release, it needs to know about such events as quickly as possible and that reporting times should be uniform (24 hours) regardless of the nature of the regulated article.

41. In response to several comments, APHIS has eliminated the requirement of having to report the death of a regulated article in proposed § 340.3(c)(10)(iii). Under § 340.3(f)(10)(ii) of the final rule, a person need only report in writing, as soon as possible, but not later than 5 working days, if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the permit application or suffers any unusual occurrence (excessive mortality or morbidity or an unanticipated effect on non-target organisms). APHIS believes that the death of a regulated article, as discussed above, should not be a reportable event.

APHIS believes that, as modified, having to report excessive mortality or morbidity or an unanticipated effect on a non-target organism as soon as possible but not later than 5 working days, is a reasonable requirement. APHIS believes that this requirement will advise the Agency of any disease or pest that may be of significance.

It should be noted that APHIS has added the phrase "as soon as possible" to clarify the agency's intent that the reporting should be prompt. However, APHIS has not changed the requirement which appeared in the proposed regulations that the reporting must not occur later than 5 working days from the observance of such events.

Denial of a Permit

APHIS, to fully inform permittees of their appeal rights, has included provisions in §§ 340.3(e) and (g) which provide appeal provisions in the event a permit is denied.

Petition To Amend the List of Organisms (§ 340.4)

42. Several commenters suggested that USDA should include a mechanism which would allow persons to petition for the "delisting" or removal of organisms from the list of organisms in § 340.2 of the final rule, if it could be demonstrated that such organisms are not plant pests. Other commenters indicated that USDA should include a mechanism that would allow a person to seek the addition of organisms to the list, if it could be shown that such organisms were plant pests.

USDA agrees with the commenters and has added a new § 340.4 to the final rule, entitled "Petition to Amend the List of Organisms." USDA believes that the petition mechanism will afford interested persons the opportunity to readily bring information to USDA's attention, as new information becomes available about existing or newly discovered organisms. The petition process in § 340.4 is in accord with section 4(e) of the Administrative Procedure Act (5 U.S.C. 553(e)) for the issuance, amendment, or repeal of a rule and with USDA's Departmental Proceedings in 7 CFR 1.28.

Under § 340.4(a) of the final rule, any person may submit a petition to the Deputy Administrator of Plant Protection and Quarantine to amend the list or organisms in § 340.2 by adding or removing any genus, species, or subspecies. Section 340.4(a) further provides that a petitioner may supplement, amend, or withdraw a petition, in writing, without prior approval of the Deputy Administrator and without prejudice to resubmission at any time, until the Deputy Administrator rules on the petition.

Section 340.4(b) specifies the submission procedures and format of a petition. This section requires that a petitioner provide two copies of a petition to the Deputy Administrator in care of the Director of the Biotechnology and Environmental Coordination Staff.

Section 340.4(b) also specifies what must be included in the "Statement of Grounds" of the petition. A person must include a full statement explaining the factual grounds why the genus, species, or subspecies to be added to § 340.2 is a plant pest or why there is reason to believe the genus, species, or subspecies is a plant pest. In the case of a petition to remove a genus, species, or subspecies from the list, a person must include a full statement explaining why the genus, species, or subspecies is not a plant pest or why there is no reason to believe the genus, species, or subspecies is not a plant pest. The petition should include copies of scientific literature which the petition is relying upon, copies of unpublished studies, or date from tests performed. Because the petition and any accompanying data will be made available for public inspection, the petition should not include trade secret or confidential business information.

A person must also include in the "Statement of Grounds" representative information known to the petitioner which would be unfavorable to a petition to add or remove organisms. Section 340.4(b) also requires that a petitioner sign a short certification that must be included as part of the petition.

Section 340.4(c) specifies the administrative action that will be taken on a petition. Under § 340.4(c), a petition which appears to be complete will be filed by the Director of the Biotechnology and Environmental Coordination Staff, stamped with the date of filing, and assigned a docket number. The Director of the Biotechnology and Environmental Coordination Staff will notify the petitioner in writing of the filing and the docket number of the petition. If a petition is incomplete, the petitioner shall be sent a notice indicating how the petition is deficient.

After a complete petition is filed, USDA shall publish a proposal in the **Federal Register** to amend § 340.2 and soliciting comments thereon from the public. Any written comments submitted shall become part of the docket file. The Deputy Administrator shall furnish a written response to each petitioner within 180 days of the receipt of the petition. The decision shall be placed in the public docket file in the offices of the Biotechnology and Environmental Coordination Staff.

The response will either: (1) Approve the petition in whole or in part, in which case the Deputy Administrator shall concurrently take appropriate action (publication of a document in the **Federal Register** amending § 340.2 of this part); or (2) deny the petition in whole or in part.

APHIS has chosen 180 days as the time period in which to respond to a petition for the following reasons: (1) A 180 day review period would provide APHIS reviewers sufficient time to perform thorough and comprehensive research on the material presented in a petition and to consult with other scientists at other institutions both domestically and internationally; (2) a 180 day review period provides APHIS with sufficient time to schedule public hearings during the petition process should that be necessary, and (3) a 180

day review period is consistent with the petition procedures utilized by other Federal agencies, namely, the Food and Drug Administration in their regulations in 21 CFR 10.30.

Container Requirements (§ 340.6)

43. Eight comments were received on the proposed container requirements in § 340.6 of the regulations. The commenters generally expressed the view that the container requirements were overly stringent and too restrictive, or in other cases inappropriate.

One commenter indicated that to assume that an organism is dangerous simply because it has been genetically modified is not justified. Another commenter indicated that in certain instances one may wish to carry plant seedlings a short distance across a State line in an open flat in a car. The commenter further indicated that in such an instance, there would be essentially no chance of dispersal of the plant since it would be devoid of any reproductive parts, and presumably all plant parts could be collected and accounted for in case of an accident.

USDA disagrees with the comment that a presumption exists that an organism is dangerous because it has been genetically modified. Consistent with stated USDA policy, the final rule does not regulate an organism because of the process by which it is modified. USDA believes that if a person is seeking to introduce an organism that is engineered from organisms which are known plant pests, then certain precautions are necessary. One precaution that must be taken is that until the plant pest status of the organism is established, special container requirements are required. The container requirements set forth in the final rule are no more stringent than what would be required for the movement of plant pests under permit in 7 CFR 330.200. However, USDA agrees with the commenter that argued that for certain organisms and in certain instances the container requirements may be inappropriate due to unique circumstances (the volume, nature, or life stage of the regulated article).

In order to remedy this situation on a case-by-case basis, APHIS has included a procedure whereby a person seeking to move a regulated article may seek a variance from the container requirements if the responsible individual believes the container requirements are inappropriate.

Section 340.6(b) of the final rule entitled, "Request for a variance from container requirements" provides that a person may submit a short statement describing why the applicable container requirements are inappropriate for the regulated article to be moved and what the individual would use in lieu thereof. USDA shall advise the responsible individual in writing at the time a permit is granted on the individual's request for a variance.

Cost of Preparing a Permit Application

Twenty comments were received on the APHIS analysis made pursuant to E.O. 12291 on the economic impact of the regulations. APHIS stated that it anticipated the cost of preparing a permit application to be not greater than $5,000 per application. Many of these commenters erroneously interpreted the statement to mean the APHIS would charge applicants not more than $5,000 as the fee for processing permit applications.

APHIS wishes to explain the $5,000 represented the maximum *in-house cost* to an applicant of submitting an application for a permit to APHIS. The $5,000 estimated cost was based on the salary of a Ph.D. researcher earning $60,000 per year. It was estimated that it would take approximately two weeks to prepare an application. The $5,000 figure also includes the cost of clerical support and reproduction costs. With the exception of reproduction and postage or handling costs, these costs are ordinary salary costs that must be paid regardless of whether a person is submitting a permit application to APHIS. Five thousand dollars for the most part represents the upper limit of the in-house costs. APHIS believes that in many cases, the cost will be significantly less than $5,000. It should be noted that one producer of genetically engineered organisms indicated that the $5,000 figure was accurate based on the cost of submitting an application for the field testing of a genetically engineered organism.

It should be further noted that under the final rule the $5,000 figure is only applicable to the cost of preparing an application for a permit for release into the environment. An application for a limited permit for the interstate movement or importation of a regulated article into a contained facility requires the submission of less data, and the time and cost required to prepare such an application should be less than $5,000.

Comments Concerning Joint Jurisdiction

Several comments were received on the issue of overlapping jurisdiction between USDA and EPA. Dual or redundant reviews of the same organism or product were mentioned as an unwelcome possibility.

During the months since the "Coordinated Framework" was first published as a proposed policy by the OSTP and Federal agencies in December 1984 (49 FR 50856–50907) the components of EPA and USDA that have jurisdiction in the same area have been in communication on a regular basis. USDA through its Biotechnology and Environmental Coordination Staff and EPA through its Office of Toxic Substances and Office of Pesticide Programs have identified principal liaisons who have the responsibility to share information, coordinate data requests, and keep one another informed of communications with submitters. These individuals will ensure that data requests are not duplicated.

Compliance With the National Environmental Policy Act

APHIS indicated in its proposed regulations at 51 FR 23359 on June 26, 1986, that the issuance of all permits for the introduction of a genetically engineered organism would be in accordance with National Environmental Policy Act (NEPA), USDA regulations, and APHIS Guidelines implementing NEPA.

APHIS shall prepare environmental assessments and, where necessary, environmental impact statements prior to issuing a permit for the release into the environment of a regulated article. The D.C. Circuit's decision in *FET* v. *Heckler*, stated that "NEPA requires an agency to evaluate the environmental effects of its action at the point of commitment." 756 F.2d 143 (D.C. Cir. 1985) With regard to this final rule, APHIS has concluded that the "point of commitment" occurs when the agency takes action on each individual application to issue a permit for the release into the environment of a genetically engineered organism.

The final rule does not irrevocably commit APHIS to any decision concerning issuance of any permits for release. APHIS retains the authority to grant or deny a permit for release on a case by case basis. However, APHIS has prepared a special environmental assessment on the effect of these regulations.

The special environmental assessment for the final rule discusses alternatives that were considered in lieu of promulgation of this rule and is available from the person listed under "FOR FURTHER INFORMATION CONTACT."

Editorial Changes

APHIS has also made minor editorial changes, where necessary.

Executive Order 12291 and Regulatory Flexibility Act

This final rule is issued in conformance with Executive Order 12291 and has been determined to be not a "major rule." Based on information compiled by the Department, it has been determined that the proposed rule will not have a significant effect on the economy; will 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 have 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.

As explained above, regulations regulate the introduction (importation, interstate movement, and release into the environment) of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests. Such organisms and products are deemed regulated articles for which either a limited or environmental release permit would have to be obtained prior to its introduction.

It is anticipated that the cost of preparing a permit application for the release into the environment of a regulated article will be no more than $5,00 per application. The cost of preparing an application for a limited permit which requires less data than an environmental release permit should be less than $5,000. The required information about the organism, and the way it was altered or produced should be available from documents pertaining to the research and development of the regulated article. Thus, a person seeking to obtain a permit should not have to generate any new data, but rather submit to APHIS, what should be, existing data. The $5,000 estimated cost is based on the salaries of a Ph.D. researcher and the necessary clerical staff working for approximately 2 weeks in preparing an application for a permit for environmental release. During the first year, the Department does not expect to receive more than 50 applications for release into the environment. Most other costs associated with complying with the regulations, e.g., container requirements, are merely incidental to a person complying with sound laboratory and research practices. The only other costs associated with complying with the regulations would arise if a supplemental report were required, e.g., an accidental or unauthorized release of a regulated article, the regulated article is found to have substantially different characteristics than those listed in the application, or if APHIS otherwise believes monitoring reports are required. It is anticipated that the cost of such reports in most instances would be minimal.

APHIS is requiring that an application for a permit be submitted 120 days prior to the time a person seeks to release a regulated article into the environment. APHIS believes that the 120 day time period required to process a permit application will not be an unreasonable delay in the marketing of organisms or products subject to regulations under Part 340. It is anticipated that if USDA receives only 50 applications the first year for the release into the environment, the average time to process any application will be considerably less than the maximum processing periods of 120 days. APHIS does not believe that the applications will come all at once. In the short term, we anticipate receiving 50 applications the first year, growing to perhaps 3,000 by 1989. The experience gained during the first year should help expedite the review of future applications. As more applications are processed, shorter review times could be achieved through the use of data previously submitted.

Since the timing of when to submit an application to USDA is left to an applicant, USDA believes that both large and small business entities will be able to incorporate the review period into their planning process so as not to disrupt the marketing of organisms or products that are subject to regulation.

Under the circumstances referred to above, 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.

Paperwork Reduction Act

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

Executive Order 12372

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

List of Subjects

7 CFR Part 330

Customs duties and inspection, Garbage, Imports, Plant diseases, Plant pests, Plants (Agriculture), Quarantine, Soil, Stone and quarry products, Transportation.

7 CFR Part 340

Agricultural commodities, Biotechnology, Genetic engineering, Plant diseases, Plant pests, Plants (Agriculture), Quarantine, Transportation.

PART 330—FEDERAL PLANT PEST REGULATIONS; GENERAL; PLANT PESTS; SOIL, STONE AND QUARRY PRODUCTS; GARBAGE

Accordingly, 7 CFR Part 330 is amended to read as follows:

1. The authority citation for 7 CFR Part 330 is revised to read as follows:

Authority: 7 U.S.C. 147a, 150bb, 150dd–150ff, 161, 162, 450, 2260; 19 U.S.C. 1306; 21 U.S.C. 111, 114a; 31 U.S.C. 9701; 7 CFR 2.17, 2.51, and 371.2(c).

2. Paragraph (h) § 330.100 is revised to read as follows:

§ 330.100 Definitions.

* * * * *

(h)(1) *Plant pest.* Except for §§ 330.200 through 330.212, "Plant Pest" means any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants.

(2) *Plant pest.* For purposes of §§ 330.200 through 330.212, "Plant Pest" means any living stage of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances of the aforementioned which are not genetically engineered as defined in 7 CFR 340.1 which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants.

* * * * *

Accordingly, 7 CFR, Chapter III, is amended by adding Part 340 to read 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

Sec.

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).

§ 340.0 Restrictions on the introduction of regulated articles.

(a) No person shall introduce any regulated article unless: (1) Such introduction is authorized by a permit; and (2) such introduction is in conformity with all of the other applicable restrictions in this part.[1]

(b) Any regulated article introduced not in compliance with the requirements of this part shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of such plant pests.[2]

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

[2] Pursuant to section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd) the Secretary of Agriculture is authorized to order prompt removal from the United States or to seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of, in such manner as the Secretary deems appropriate, certain regulated articles which are believed to be infested or infected by or contain a plant pest.

§ 340.1 Definitions.

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

Courtesy permit. A written permit issued by the Deputy Administrator in accordance with § 340.3(h) of this part.

Deputy Administrator. The Deputy Administrator for Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or any other officer or employee of the Department to whom authority to act in his/her stead has been or may hereafter be delegated.

Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism.

Environment. All the land, air, and water; and all living organisms in association with land, air and water.

Genetic engineering. The genetic modification of organisms by recombinant DNA techniques.

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

Interstate. From any State into or through any other State.

Introduce or introduction. To move into or through the United States, to release into the environment, to move interstate, or any attempt thereat.

Move (moving, movement). To ship, offer for shipment, offer for entry, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved into, through, or within the United States.

Organism. Any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

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

Person. Any individual, partnership, corporation, company, society, association, or other organized group.

Plant. Any living stage or form of any member of the plant kingdom [3] including, but not limited to, eukaryotic algae, mosses, club mosses, ferns, angiosperms, gymnosperms, and lichens (which contain algae) including any parts (e.g. pollen, seeds, cells, tubers, stems) thereof, and any cellular components (e.g. plasmids, ribosomes, etc.) thereof.

Plant pest. Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

Plant Protection and Quarantine. The organizational unit within the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, delegated responsibility for enforcing provisions of the Plant Quarantine Act, the Federal Plant Pest Act, and related legislation, and quarantine and regulations promulgated thereunder.

Product. Anything made by or from, or derived from an organism, living or dead.

Recipient organism. The organism which receives genetic material from a donor organism.

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

Release into the environment. The use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained

[3] The taxonomic scheme for the plant kingdom is that found in Synopsis and Classification of Living Organisms by S.P. Parker, McGraw Hill (1984).

greenhouse, or a fermenter or other contained structure.

Responsible person. The person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and requirements in this part are complied with. A responsible person shall be a resident of the United States or designate an agent who is a resident of the United States.

Secretary. The Secretary of Agriculture, or any other officer or employee of the Department of Agriculture to whom authority to act in his/her stead has been or may hereafter be delegated.

State. Any State, the District of Columbia, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and any other Territories or Districts of the United States.

United States. All of the States.

Vector or vector agent. Organisms or objects used to transfer genetic material from the donor organism to the recipient organism.

Well-characterized and contains only non-coding regulatory regions (e.g. operators, promoters, origins of replication, terminators, and ribosome binding regions). The genetic material added to a microorganism in which the following can be documented about such genetic material: (a) The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides; (b) The regulatory region and any inserted flanking nucleotides do not code for protein or peptide; and (c) The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

§ 340.2 Groups of organisms which are or contain plant pests.

The organisms that are or contain plant pests are included in the taxa or group of organisms contained in the following list. Within any taxonomic series included on the list, the lowest unit of classification actually listed is the taxon or group which may contain organisms which are regulated. Organisms belonging to all lower taxa contained within the group listed are included as organisms that may be or may contain plant pests, and are regulated *if they meet the definition of plant pest in § 340.1*[4]

Note.—Any genetically engineered organism composed of DNA or RNA sequences, organelles, plasmids, parts, copies, and/or analogs, of or from any of the groups of organisms listed below shall be deemed a regulated article if it also meets the definition of plant pest in § 340.1.

GROUP

Viroids

Superkingdom Prokaryotae

Kingdom Virus

All members of groups containing plant viruses, and all other plant and insect viruses

Kingdom Monera

Division Bacteria

Family Pseudomonadaceae
- Genus Pseudomonas
- Genus Xanthomonas

Family Rhizobiaceae
- Genus Rhizobium
- Genus Bradyrhizobium
- Genus Agrobacterium
- Genus Phyllobacterium

Family Enterobacteriaceae
- Genus Erwinia

Family Streptomycetaceae
- Genus Streptomyces

Family Actinomycetacease
- Genus Actinomyces

Coryneform group
- Genus Clavibacter
- Genus Arthrobacter
- Genus Curtobacterium
- Genus Corynebacteria

Gram-negative phloem-limited bacteria associated with plant diseases

Gram-negative xylem-limited bacteria associated with plant diseases

And all other bacteria associated with plant or insect diseases

Rickettsiaceae
- Rickettsial-like organisms associated with insect diseases

Class Mollicutes

Order Mycoplasmatales
Family Spiroplasmataceae
- Genus Spiroplasma

Mycoplasma-like organisms associated with plant diseases

Mycoplasma-like organisms associated with insect diseases

Superkingdom Eukaryotae

Kingdom Plantae

Subkingdom Thallobionta

Division Chlorophyta
- Genus Cephaleuros
- Genus Rhodochytrium
- Genus Phyllosiphon

Division Myxomycota

Class Plasmodiophoromycetes

Division Eumycota

Class Chytridiomycetes

Order Chytridiales

Class Oomycetes

Order Lagenidiales
Family Lagenidiaceae
Family Olpidiopsidaceae
Order Peronosporales
Family Albuginaceae
Family Peronosporaceae
Family Pythiaceae
Order Saprolegniales
Family Saprolegniaceae
Family Leptolegniellaceae

Class Zygomycetes

Order Mucorales
Family Choanephoraceae
Family Mucoraceae
Family Entomophthoraceae

Class Hemiascomycetes

Family Protomycetaceae
Family Taphrinaceae

Class Loculoascomycetes

Order Myriangiales
Family Elsinoeaceae
Family Myriangiaceae
Order Asterinales
Order Dothideales
Order Chaetothyriales
Order Hysteriales
Family Parmulariaceae
Family Phillipsiellaceae
Family Hysteriaceae
Order Pleosporales
Order Melanommatales

Class Plectomycetes

Order Eurotiales
Family Ophiostomataceae
Order Ascophaerales

Class Pyrenomycetes

Order Erysiphales
Order Meliolales
Order Xylariales
Order Diaporthales
Order Hypocreales
Order Clavicipitales

Class Discomycetes

Order Phacidiales
Order Helotiales
Family Ascocorticiceae
Family Hemiphacidiaceae
Family Dermataceae
Family Sclerotiniaceae
Order Cytarriales
Order Medeolariales
Order Pezziales
Family Sarcosomataceae
Family Sarcoscyphaceae

[4] Any organism belonging to any taxa contained within any listed genera or taxa is only considered to be a plant pest if the organism "can directly or indirectly injure, or cause disease, or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants." Thus a particular unlisted species within a listed genus would be deemed a plant pest for purposes of § 340.2, if the scientific literature refers to the organism as a cause of direct or indirect injury, disease, or damage to any plants, plant parts or products of plants. (If there is any question concerning the plant pest status of an organism belonging to any listed genera or taxa, the person proposing to introduce the organism in question should consult with APHIS to determine if the organism is subject to regulation.)

Class Teliomycetes

Class Phragmobasidiomycetes

Family Auriculariaceae
Family Ceratobasidiaceae

Class Hymenomycetes

Order Exobasidiales
Order Agaricales
Family Corticiaceae
Family Hymenochaetaceae
Family Echinodontiaceae
Family Fistulinaceae
Family Clavariaceae
Family Polyporaceae
Family Tricholomataceae

Class Hyphomycetes

Class Coelomycetes

And all other fungi associated with plant or insect diseases

Subkingdom Embryobionta

Note.—*Organisms listed in the Code of Federal Regulations as noxious weeds are regulated under the Federal Noxious Weed Act*

Division Magnoliophyta

Family Balanophoraceae—parasitic species
Family Cuscutaceae—parasitic species
Family Hydnoraceae—parasitic species
Family Krameriaceae—parasitic species
Family Lauraceae—parasitic species
  Genus Cassytha
Family Lennoaceae—parasitic species
Family Loranthaceae—parasitic species
Family Myzodendraceae—parasitic species
Family Olacaceae—parasitic species
Family Orobanchaceae—parasitic species
Family Rafflesiaceae—parasitic species
Family Santalaceae—parasitic species
Family Scrophulariaceae—parasitic species
  Genus Alectra
  Genus Bartsia
  Genus Buchnera
  Genus Buttonia
  Genus Castilleja
  Genus Centranthera
  Genus Cordylanthus
  Genus Dasistoma
  Genus Euphrasia
  Genus Gerardia
  Genus Harveya
  Genus Hyobanche
  Genus Lathraea
  Genus Melampyrum
  Genus Melasma
  Genus Orthantha
  Genus Orthocarpus
  Genus Pedicularis
  Genus Rhamphicarpa
  Genus Rhinanthus
  Genus Schwalbea
  Genus Seymeria
  Genus Siphonostegia
  Genus Sopubia
  Genus Striga
  Genus Tozzia
Family Viscaceae—parasitic species

Kingdom Animalia

Subkingdom Protozoa

  Genus Phytomonas

  And all Protozoa associated with insect diseases

Subkingdom Eumetazoa

Phylum Nemata

Class Secernentea

Order Tylenchida
Family Anguinidae
Family Belonolaimidae
Family Caloosiidae
Family Criconematidae
Family Dolichodoridae
Family Fergusobiidae
Family Hemicycliophoridae
Family Heteroderidae
Family Hoplolaimidae
Family Meloidogynidae
Family Nacobbidae
Family Neotylenchidae
Family Nothotylenchidae
Family Paratylenchidae
Family Pratylenchidae
Family Tylenchidae
Family Tylenchulidae
Order Aphelenchida
Family Aphelenchoididae

Class Adenophorea

Order Dorylaimida
Family Longidoridae
Family Trichodoridae

Phylum Mollusca

Class Gastropoda

Subclass Pulmonata
Order Basommatophora
  Superfamily Planorbacea
Order Stylommatophora
  Subfamily Strophocheilacea
Family Succineidae
  Superfamily Achatinacae
  Superfamily Arionacae
  Superfamily Limacacea
  Superfamily Helicacea
Order Systellommatophora
  Superfamily Veronicellacea

Phylum Arthropoda

Class Arachnida

Order Parasitiformes
  Suborder Mesostigmata
  Superfamily Ascoidea
  Superfamily Dermanyssoidea
Order Acariformes
  Suborder Prostigmata
  Superfamily Eriophyoidea
  Superfamily Tetranychoidea
  Superfamily Eupodoidea
  Superfamily Tydeoidea
  Superfamily Erythraenoidea
  Superfamily Trombidioidea
  Superfamily Hydryphantoidea
  Superfamily Tarsonemoidea
  Superfamily Pyemotoidea
Suborder Astigmata
  Superfamily Hemisarcoptoidea
  Superfamily Acaroidea

Class Diplopoda

Order Polydesmida

Class Insecta

Order Collembola
Family Sminthoridae
Order Isoptera
Order Thysanoptera
Order Orthoptera
Family Acrididae
Family Gryllidae
Family Gryllacrididae
Family Gryllotalpidae
Family Phasmatidae
Family Ronaleidae
Family Tettigoniidae
Family Tetrigidae
Order Hemiptera
Family Thaumastocoridae
Family Aradidae
  Superfamily Piesmatoidea
  Superfamily Lygaeoidea
  Superfamily Idiostoloidea
  Superfamily Coreoidea
  Superfamily Pentatomoidea
  Superfamily Pyrrhocoroidea
  Superfamily Tingoidea
  Superfamily Miroidea
Order Homoptera
Order Coleoptera
Family Anobiidae
Family Apionidae
Family Anthribidae
Family Bostrichidae
Family Brentidae
Family Bruchidae
Family Buprestidae
Family Byturidae
Family Cantharidae
Family Carabidae
Family Cerambycidae
Family Chrysomelidae
Family Coccinellidae
  Subfamily Epilachninae
Family Curculionidae
Family Dermestidae
Family Elateridae
Family Hydrophilidae
  Genus Helophorus
Family Lyctidae
Family Meloidae
Family Mordellidae
Family Platypodidae
Family Scarabaeidae
  Subfamily Melolonthinae
  Subfamily Rutelinae
  Subfamily Cetoniinae
  Subfamily Dynastinae
Family Scolytidae
Family Selbytidae
Family Tenebrionidae
Order Lepidoptera
Order Diptera
Family Agromyzidae
Family Anthomyiidae
Family Cecidomyiidae
Family Chloropidae
Family Ephydridae
Family Lonchaeidae
Family Muscidae
  Genus Atherigona
Family Otitidae
  Genus Euxeta
Family Syrphidae
Family Tephritidae
Family Tipulidae
Order Hymenoptera
Family Apidae
Family Caphidae
Family Chalcidae
Family Cynipidae
Family Eurytomidae
Family Formicidae
Family Psilidae
Family Siricidae
Family Tenthredinidae

Family Torymidae
Family Xylocopidae

Unclassified organisms and/or organisms whose classification is unknown.

§ 340.3 Permits for the introduction of a regulated article.

(a) *Application for permit.* Two copies of a written application for a permit to introduce a regulated article shall be submitted by the responsible person on an application form obtained from Plant Protection and Quarantine, to the Biological Assessment Support Staff (Biotech Unit), Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782. If there are portions of the application deemed to contain trade secret or confidential business information (CBI), each page of the application containing such information should be marked "CBI Copy". In addition, those portions of the application which are deemed "CBI" shall be so designated. The second copy shall have all such CBI deleted and shall be marked on each page of the application where CBI was deleted, "CBI Deleted". If an application does not contain CBI then the first page of both copies shall be marked "No CBI".

(b) *Permit for release into the environment.* An application for the release into the environment of a regulated article shall be submitted at least 120 days in advance of the proposed release into the environment. An initial review shall be completed by Plant Protection and Quarantine within 30 days of the receipt of the application. If the application is complete, the responsible individual shall be notified of the date of receipt of the application for purposes of advising the applicant when the 120 day review period commenced.[5] If the application is not complete, the responsible individual will be advised what additional information must be submitted. Plant Protection and Quarantine shall commence the 120 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. When it is determined that an application is complete, Plant Protection and Quarantine shall submit to the State department of agriculture of the State where the release is planned, a copy of the initial review and a copy of the application marked, "CBI Deleted", or "No CBI" for State notification and review. The application shall include the following information: [6]

(1) Name, title, address, telephone number, signature of the responsible person and type of permit requested (for importation, interstate movement, or release into the environment);

(2) All scientific, common, and trade names, and all designations necessary to identify the: Donor organism(s); recipient organism(s); vector or vector agent(s); constituent of each regulated article which is a product; and, regulated article;

(3) Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article;

(4) A description of the means of movement (e.g., mail, common carrier, baggage, or handcarried (and by whom));

(5) A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics);

(6) A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article;

(7) Country and locality where the donor organism, recipient organism, vector or vector agent, and regulated article were collected, developed, and produced;

(8) A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design;

(9) The quantity of the regulated article to be introduced and proposed schedule and number of introductions;

(10) A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: Donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article;

(11) A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location);

(12) A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations;

(13) A detailed description of any biological material (e.g., culture medium, or host material) accompanying the regulated article during movement; and

(14) A detailed description of the proposed method of final disposition of the regulated article.

(c) *Limited permits for interstate movement or importation of a regulated article.* An application for the interstate movement or importation of a regulated article shall be submitted at least 60 days in advance of the first proposed interstate movement and at least 60 days prior to each importation. An initial review shall be completed by Plant Protection and Quarantine within 15 days of the receipt of the application. If the application is complete, the responsible person shall be notified of the date of receipt of the application for purposes of advising the applicant when the 60 day review period commenced. If the application is not complete, the responsible person will be advised what additional information must be submitted. Plant Protection and Quarantine shall commence the 60 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. When it is determined that an application is complete, Plant Protection and Quarantine shall submit to the State department of agriculture of the State of destination of the regulated article a copy of the initial review and the application marked, "CBI Deleted", or "No CBI" for State notification and review.

(1) *Limited permit for interstate movement.* The responsible person may apply for a single limited permit for the interstate movement of multiple regulated articles in lieu of submitting an application for each individual interstate movement. Each limited permit issued shall be numbered and shall be valid for one year from the date

[5] The 120 day review period would be extended if preparation of an environmental impact statement in addition to an environmental assessment was necessary.

[6] Application forms are available without charge from the Biological Assessment Support Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, or from local offices which are listed in telephone directories. A person should specify in requesting the application that the permit is for the introduction of a regulated article subject to regulation under Part 340.

of issuance. If a permit is sought for multiple interstate movements between contained facilities the responsible individual shall specify in the permit application all the regulated articles to be moved interstate; the origins and destinations of all proposed shipments; a detailed description of all the contained facilities where regulated articles will be utilized at destination; and a description of the containers that will be used to transport the regulated articles. A limited permit for interstate movement of a regulated article shall only be valid for the movement of those regulated articles moving between those locations specified in the application. If a person seeks to move regulated articles other than those specified in the application, or to a location other than those listed in the application, a supplemental application shall be submitted to Plant Protection and Quarantine. No person shall move a regulated article interstate unless the number of the limited permit appears on the outside of the shipping container. The responsible person shipping a regulated article interstate shall keep records for one year demonstrating that the regulated article arrived at its intended destination. The responsible person seeking a limited permit for interstate movement shall submit on an application form obtained from Plant Protection and Quarantine the data required by § 340.3(b)(1), (2), (4), (6), (7), (9), and (11)–(14).

(2) *Limited permit for importation.* The responsible person seeking a permit for the importation of a regulated article shall submit an application for a permit prior to the importation of *each* shipment of regulated articles. The responsible person importing a regulated article shall keep records for one year demonstrating that the regulated article arrived at its intended destination. The responsible person seeking a limited permit for importation shall submit on an application form obtained from Plant Protection and Quarantine data required by § 340.3(b)(1), (2), (4), (6), (7), (9), and (11)–(14).[7]

(d) *Premises inspection.* An inspector may inspect the site or facility where regulated articles are proposed, pursuant to a permit, to be released into the environment or contained after their interstate movement or importation. Failure to allow the inspection of a premises prior to the issuance of a permit or limited permit shall be grounds for the denial of the permit.

(e) *Administrative action on applications.* After receipt and review by Plant Protection and Quarantine of the application and the data submitted pursuant to paragraph (a) of this section, including any additional information requested by Plant Protection and Quarantine, a permit shall be granted or denied. If a permit is denied, the applicant shall be promptly informed of the reasons why the permit was denied and given the opportunity to appeal the denial in accordance with the provisions of paragraph (g) of this section. If a permit is granted, the permit will specify the applicable conditions for introduction of the regulated article under this part.

(f) *Permit conditions.* A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Deputy Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit;

(4) The regulated article shall be maintained only in areas and premises specified in the permit;

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article;

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation;

(7) The regulated article shall be subject to the application of measures determined by the Deputy Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article;

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Deputy Administrator to be necessary to prevent the spread of plant pests;

(9) A person who has been issued a permit shall submit to Plant Protection and Quarantine monitoring reports on the performance characteristics of the regulated article, in accordance with any monitoring reporting requirements that may be specified in a permit;

(10) Plant Protection and Quarantine shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37–14(b);

(ii) Notify Plant Protection and Quarantine promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with § 340.5 of this part.

(g) *Withdrawal or denial of a permit.* Any permit which has been issued may be withdrawn by an inspector or the Deputy Administrator if he/she determines that the holder thereof has not complied with one or more of the conditions listed on the permit. APHIS will confirm the reasons for the withdrawal of the permit in writing within ten (10) days. Any person whose permit has been withdrawn or any person who has been denied a permit may appeal the decision in writing to the Deputy Administrator within ten (10) days after receiving the written notification of the withdrawal or denial. The appeal shall state all of the facts and reasons upon which the person relies to show that the permit was wrongfully withdrawn or denied. The Deputy Administrator shall grant or

[7] Renewals may receive shorter review. In the case of a renewal for a limited permit for importation that has been issued less than one year earlier, APHIS will notify the responsible person within 15 days that either: (1) The renewal permit is approved or (2) that a 60 day review period is necessary because the conditions of the original permit have changed.

deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator.

(h) *Courtesy permit*—(1) *Issuance.* The Deputy Administrator may issue a courtesy permit for the introduction of organisms modified through genetic engineering which are not subject to regulation under this part to facilitate movement when the movement might otherwise be impeded because of the similarity of the organism to other organisms regulated under this part.

(2) *Application.* A person seeking a courtesy permit shall submit on an application form obtained from Plant Protection and Quarantine data required by §§ 340.3(b)(1), (2), and (5) of this part and shall indicate such data is being submitted as a request for a courtesy permit. A person should also include a statement explaining why he or she believes the organism or product does not come within the definition of a regulated article. The application shall be submitted at least 60 days prior to the time the courtesy permit is sought.

(3) *Administrative action.* Plant Protection and Quarantine shall complete an initial review within 15 days of the date of receipt of the application. If the application is complete, the responsible individual shall be notified of the date of receipt of the application for purposes of advising the applicant when the 60 day review period commenced. If the application is not complete, the responsible individual will be advised what additional information must be submitted, and shall commence the 60 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. Within 60 days from the date of receipt of a complete application, Plant Protection and Quarantine will either issue a courtesy permit or advise the responsible individual that a permit is required under § 340.3(b) or (c).

§ 340.4 Petition to amend the list of organisms.

(a) *General.* Any person may submit to the Deputy Administrator a petition to amend the list of organisms in § 340.2 of this part by adding or deleting any genus, species, or subspecies. A petitioner may supplement, amend, or withdraw a petition in writing without prior approval of the Deputy Administrator and without prejudice to resubmission at any time until the Deputy Administrator rules on the petition. A petition to amend the list of organisms shall be submitted in accordance with the procedures and format specified by this section.

(b) *Submission procedures and format.* A person shall submit two copies of a petition to the Deputy Administrator of Plant Protection and Quarantine, in care of the Director of the Biotechnology and Environmental Coordination Staff, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, 6505 Belcrest Road, Room 406, Federal Building, Hyattsville, Maryland 20782. The petition should be dated, and structured as follows:

Petition To Amend 7 CFR 340.2

The undersigned submits this petition under 7 CFR 340.4 to request the Deputy Administrator of Plant Protection and Quarantine, to [add the following genus, species, or subspecies to the list of organisms in 7 CFR 340.2] or [to remove the following genus, species, or subspecies from the list of organisms in § 340.2].

A. Statement of Grounds

[A person must present a full statement explaining the factual grounds why the genus, species, or subspecies to be added to § 340.2 of this part is a plant pest or why there is reason to believe the genus, species, or subspecies is a plant pest or why the genus, species, or subspecies sought to be removed is not a plant pest or why there is reason to believe the genus, species, or subspecies is not a plant pest. The petition should include copies of scientific literature which the petitioner is relying upon, copies of unpublished studies, or data from tests performed. *The petition should not include trade secret or confidential business information.*

A person should also include representative information known to the petitioner which would be unfavorable to a petition for listing or delisting. [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 the petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____
(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____

(c) *Administrative action on a petition.* (1) A petition to amend the list of organisms which meets the requirements of paragraph (b) of this section will be filed by the Director of the Biotechnology and Environmental Coordination Staff, stamped with the date of filing, and assigned a docket number. The docket number shall identify the file established for all submissions relating to the petition. The Biotechnology and Environmental Coordination Staff, will promtply notify the petitioner in writing of the filing and docket number of a petition. If a petition does not meet the requirements of paragraph (b) of this section, the petitioner shall be sent a notice indicating how the petition is deficient.

(2) After the filing of a petition to amend the list or organisms USDA shall publish a proposal in the **Federal Register** to amend § 340.2 and solicit comments thereon from the public. An interested person may submit written comments to the Director of the Biotechnology and Environmental Coordination Staff on a filed petition, which shall become part of the docket file.

(3) The Deputy Administrator shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either: (i) Approve the petition in whole or in part in which case the Deputy Administrator shall concurrently take appropriate action (publication of a document in the **Federal Register** amending § 340.2 of this part; or (ii) deny the petition in whole or in part. The petitioner shall be notified in writing of the Deputy Administrator's decision. The decision shall be placed in the public docket file in the offices of the Biotechnology and Environmental Coordination Staff, and in the form of a notice published in the **Federal Register.**

§ 340.5 Marking and identity.

(a) Any regulated article to be imported other than by mail, shall, at the time of importation into the United States, plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated or cultured;

(3) Name and address of shipper, owner, or person shipping or forwarding the organism;

(4) Name, address, and telephone number of consignee;

(5) Identifying shipper's mark and number; and

(6) Number of written permit authorizing the importation.

(b) Any regulated article imported by mail, shall be plainly and correctly addressed and mailed to Plant Protection Quarantine at a port of entry designated by an asterisk in 7 CFR 319.37–14(b) and shall be accompanied

by a separate sheet of paper within the package plainly and correctly bearing the name, address, and telephone number of the intended recipient, and shall plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated, or cured;

(3) Name and address of shipper, owner, or person shipping or forwarding the regulated article; and

(4) Number of permit authorizing the importation;

(c) Any regulated article imported into the United States by mail or otherwise shall, at the time of importation or offer for importation into the United States, be accompanied by an invoice or packing list indicating the contents of the shipment.

§ 340.6 Container requirements for the movement of regulated articles.

(a) *General requirements.* A regulated article shall not be moved unless it complies with the provisions of paragraph (b) of this section, unless a variance has been granted in accordance with the provisions of paragraph (c) of this section. [8]

(b) *Container requirements*—(1) *Plants and plant parts.* All plants or plant parts, except seeds, cells, and subcellular elements, shall be packed in a sealed plastic bag of at least 5 mil thickness, inside a sturdy, sealed, leak-proof, outer shipping container constructed of corrugated fiberboard, corrogated cardboard, wood, or other material of equivalent strength.

(2) *Seeds.* All seeds shall be transported in a sealed plastic bag of at least 5 mil thickness, inside a sealed metal container, which shall be placed inside a second sealed metal container. Shock absorbing cushioning material shall be placed between the inner and outer metal containers. Each metal container shall be independently capable of protecting the seeds and preventing spillage or escape. Each set of metal containers shall then be enclosed in a sturdy outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(3) *Live microorganisms and/or etiologic agents, cells, or subcellular elements.* All regulated articles which are live (non-inactivated) microorganisms, or etiologic agents, cells, or subcellular elements shall be packed as specified below:

(i) *Volume not exceeding 50 ml.* Regulated articles not exceeding 50 ml shall be placed in a securely closed, watertight container (primary container, test tube, vial, etc.) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(ii) *Volume greater than 50 ml.* Regulated articles which exceed a volume of 50 ml. shall comply with requirements specified in paragraph (b)(3)(i) of this section. In addition, a shock absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. single primary containers shall not contain more than 1,000 ml. of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml. may be placed in a single, secondary container. The maximum amount of microorganisms or etiologic agents, cells, or subcellular elements which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

(iii) *Dry ice.* If dry ice is used as a refrigerant, it shall be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbing material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(4) *Insects, mites, and related organisms.* Insects, mites, and other small arthropods shall be packed for shipment as specified in this paragraph or in paragraph (b)(3) of this section. Insects (any life stage) shall be placed in an escape-proof primary shipping container (insulated vacuum container, glass, metal, plastic, etc.) and sealed to prevent escape. Such primary container shall be placed securely within a secondary shipping container of crushproof styrofoam or other material of equivalent strength; one or more rigid ice packs may also be placed within the secondary shipping container; and sufficient packing material shall be added around the primary container to prevent movement of the primary shipping container. The secondary (styrofoam or other) container shall be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(5) *Other macroscopic organisms.* Other macroscopic organisms not covered in paragraphs (b) (1), (2), and (4) of this section which do not require continuous access to atmospheric oxygen shall be packaged as specified in paragraph (b) (3) or (4) of this section. All macroscopic organisms which are not plants and which require continuous access to atmospheric oxygen shall be placed in primary shipping containers constructed of a sturdy, crush-proof frame of wood, metal, or equivalent strength material, surrounded by escape-proof mesh or netting of a strength and mesh size sufficient to prevent the escape of the smallest organism in the shipment, with edges and seams of the mesh or netting sealed to prevent escape or organisms. Each primary shipping container shall be securely placed within a larger secondary shipping container constructed of wood, metal, or equivalent strength material. The primary and secondary shipping containers shall then be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength, which outer container may have air holes or spaces in the sides and/or ends of the container, provided that the outer shipping container must retain sufficient strength to prevent crushing of the primary and secondary shipping containers.

(c) *Request for a variance from container requirements.* A responsible person who believes the container requirements normally applicable to the movement of the person's regulated article(s) are inappropriate due to unique circumstances (such as the nature, volume, or life stage of the regulated article) may submit in an application for a permit, a request for a variance from the container requirements. The request for a variance under this section shall consist of a short statement describing why the

[8] The requirements of this section are in addition to and not in lieu of any other packing requirements such as those for the transportation of etiologic agents prescribed ty the Department of Transportation in Title 49 of the Code of Federal Regulations or any other agency of the Federal government.

normally applicable container requirements are inappropriate for the regulated article which the person proposes to move and what container requirements the person would use in lieu of the normally prescribed container requirements. USDA shall advise the responsible person in writing at the time a permit is granted on the person's request for a variance.

§ 340.7 Cost and charges.

The services of the inspector during regularly assigned hours of duty and at the usual places of duty shall be furnished without cost.[9] The U.S. Department of Agriculture will not be responsible for any costs or charges incident to inspections or compliance with the provisions of this part, other than for the services of the inspector.

[9] The Department's provisions relating to overtime charges for an inspector's services are set forth in 7 CFR Part 354.

Done at Washington, DC, this 10th day of June, 1987.

D. Husnik,

Acting Deputy Administrator, Plant Protection and Quarantine, Animal and Plant Health Inspection Service.

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