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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2008–0055]

RIN 0579–AD53

Controlled Import Permits

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations concerning the importation of plants and plant products by establishing the controlled import permit as a single type of authorization for the importation into the United States of otherwise prohibited or restricted plant material for experimental, therapeutic, or developmental purposes. Currently, some sections of the regulations provide for those articles to be imported under a departmental permit, while other sections provide for their importation under administrative instructions or conditions specified by the Administrator or Deputy Administrator. This action would consolidate and harmonize the conditions for obtaining authorization for the importation of otherwise prohibited or restricted plant material for scientific or certain other purposes.

DATES: We will consider all comments that we receive on or before December 27, 2011.

ADDRESSES: You may submit comments by either of the following methods:

• Federal eRulemaking Portal: Go to http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0055-0001.

• Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2008–0055, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at http://www.regulations.gov/

The regulations contained in 7 CFR part 319, Foreign Quarantine Notices, prohibit or restrict the importation into the United States of certain plants and plant products to prevent plant pests and noxious weeds from being introduced into and spread within the United States.

These regulations are administered and enforced by the Plant Protection and Quarantine program (PPQ) of the Animal and Plant Health Inspection Service (APHIS) under the authority of the Plant Protection Act (7 U.S.C. 7701 et seg.). The regulations in part 319 designate specific articles as prohibited or restricted, and assign conditions to their movement, if allowed, into the United States according to the risks posed by each article to agriculture in the United States.

The current regulations contain provisions for several different means of authorizing the importation of plants and plant products. These means of authorization have been used to allow restricted articles to be imported under conditions that differ from the generally applicable provisions of the particular subpart; other types have been used to authorize the importation of articles that would otherwise be prohibited under the regulations.

The means of authorizing these types of movements that is most commonly found in the regulations is the departmental permit. In § 319.40–1, we define a departmental permit as “a document issued by the Administrator authorizing the importation of a regulated article for experimental, scientific, or educational purposes.” The departmental permit has been used to allow researchers and scientists affiliated with the United States Department of Agriculture (USDA) to import prohibited or restricted articles for scientific, analytical, experimental, or research purposes. It is currently available under several subparts of the regulations. In other areas of the regulations, we have referred to the departmental permit when we have stated that a regulated article may be allowed to be imported “by the U.S. Department of Agriculture for experimental or scientific purposes.” In other areas of the regulations, the regulations state that, under certain circumstances, regulated articles may be imported under conditions “modified to be less stringent” than those contained in the regulations.

In recent years, the number of requests to import, for research purposes, articles that are otherwise prohibited or restricted has increased as the number and types of possible uses for such articles in the United States has expanded. Also, entities requesting to import these articles now include private scientific and academic laboratories and researchers, and commercial and other nongovernmental organizations.

We recognize that research and investigations concerning restricted or prohibited plant material may benefit agricultural interests in the United States in several ways. Such benefits may include the introduction of plants or varieties or cultivars of plants adaptable to certain environments or resistant to domestic plant pests in the United States, suitable to consumers in the United States, or with value to certain markets. Other benefits may include the establishment of new markets, the introduction of new plant varieties, or trade opportunities.

We are committed to making our permit procedures found in the various subparts of the regulations consistent according to the plant pest risks associated with the plant material and its intended use. We are also committed to making our regulations more...
transparent and easier to use and implement.

Therefore, we are proposing to amend the regulations in part 319 to standardize the type of authorization used to permit the importation of plants and plant products for experimental, therapeutic, or developmental purposes. We would also amend these portions of the regulations that contain outdated language or that refer to procedures for importation that we believe pose unnecessary risks to agriculture in the United States.

We are proposing to establish the controlled import permit (CIP) as the permit that would be used in place of departmental permits and the other types of authorizations discussed previously that we have used to allow the importation of otherwise prohibited articles or of articles under different conditions than those found in the regulations. We are also proposing to use the CIP as the form of permit required for the importation of plant materials for postentry quarantine.

We propose to define controlled import permit as “a written or electronically transmitted authorization issued by APHIS for the importation into the United States of otherwise prohibited or restricted plant material for experimental, therapeutic, or developmental purposes, under controlled conditions as prescribed by the Administrator in accordance with §319.6.”

The CIP would be issued based on consideration of the plant pest risks of the imported plant material, whether such risks can be mitigated sufficiently, the intended use of the plant material, and the plant pest risks associated with such use. We would also consider the taxon of the plant material and country of origin. The CIP would be available to all entities in the United States and no longer limited to researchers and scientists affiliated with the USDA.

The CIP would be issued only for articles subject to the regulations in part 319; we would not provide for the issuance of a CIP for the movement of plant pests regulated under 7 CFR part 330, genetically engineered plant material regulated under 7 CFR part 340, noxious weeds regulated under 7 CFR part 360, or seeds regulated under 7 CFR part 361. We believe that the restrictions imposed on the movement of these articles by the regulations in parts 330, 340, 360, and 361 are effective in preventing the introduction and dissemination of plant pests or noxious weeds into or within the United States.

General Requirements for a Controlled Import Permit

We would add a new “Subpart—Controlled Import Permits” (§319.6) that would contain the general requirements regarding the proposed CIP.

In paragraph (a) of §319.6, we would define the terms Administrator, developmental purposes, experimental purposes, and therapeutic purposes, the latter three being the purposes for which the CIP may be issued. We would define Administrator as the Administrator of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any employee of the United States Department of Agriculture delegated to act in his or her stead. Developmental purposes would be defined as the evaluation, monitoring, or verification of plant material for plant health risks and/or the adaptability of the material for certain uses or environments. Experimental purposes would be defined as scientific testing of plant material which utilizes collected data and employs analytical processes under controlled conditions to create qualitative or quantitative results. We would define therapeutic purposes as the application of specific scientific processes designed to eliminate, isolate, or remove potential plant pests or diseases.

An application for a CIP could be obtained through any of the means currently available for applying for other types of permits to import regulated plant material, i.e., through the Internet using the APHIS ePermits Web site or using applications obtained from APHIS headquarters or from local offices of PPQ; paper applications could be submitted by fax or by mail. The regulations in §319.6(c) would provide the necessary mailing address, fax number, and the address of the APHIS ePermits Web site. An application would have to be submitted at least 60 days prior to the proposed arrival of the article at the port of entry.

The application for a CIP would have to contain the following information:

- Name, address in the United States, and contact information of the applicant;
- Identity (common and botanical [genus and species] names) of the plant material to be imported; country of origin and country shipped from;
- Intended experimental, therapeutic, or developmental purpose for the importation; and
- Intended ports of departure and entry; quantity of importation; means of conveyance; estimated date of arrival.

This information would allow us to evaluate the risks associated with the proposed importation. A CIP would be issued only if APHIS determines that the plant pest risks associated with the plant material and the intended experimental, therapeutic, or developmental use of the plant material can be effectively mitigated. The CIP would contain the applicable conditions for importation and subsequent handling of the plant material if it is deemed eligible for importation into the United States.

With limited exceptions, plant material to be offered for importation under a CIP would have to be selected from apparently disease-free and pest-free sources, and be free of foreign matter or debris, other prohibited plants, noxious weed seeds, soil, living organisms such as parasitic plants, pathogens, insects, snails and mites, and other prohibited matter. The plant material would also have to be free of fungicide, insecticide, pesticide, coating, dipping, spraying, or other applied treatments that would make the consignment difficult or hazardous to inspect. Similarly, plant materials could not be wrapped or otherwise packaged in a manner that impedes or prevents adequate inspection or treatment at the port of entry.

Although we would generally require all material imported under a CIP to be apparently disease-free and pest-free, under certain circumstances and for specific purposes, we may permit plant material to be imported under a CIP for scientifically approved treatment therapies. For example, we may permit the importation under a CIP of plant material not considered free of plant pests to an approved facility capable of applying approved scientific techniques to eliminate plant pests and verifying freedom from plant pests. All plant material offered for importation under a CIP would have to be moved in an enclosed container or one completely enclosed by a covering adequate to prevent the possible escape or introduction of plant pests during shipment. Any packaging material used in the consignment would have to meet the requirements of §319.37–9, and wood packing material used in the consignment would have to meet the requirements of §§319.40–3(b) and (c). The CIP would identify the manner in which the consignment is to be shipped (e.g., as cargo, by mail, as air freight). Under certain circumstances, we may allow the plant material to be hand-carried.

The plant material would have to be offered for importation at the port of entry or plant plant inspection station specified in the CIP. A copy of the CIP and an invoice or packing list indicating...
the contents of the consignment would have to accompany each consignment. All consignments would be required to be labeled as specified in the permit, and to bear a tag provided with the CIP.

Depending on the intended purpose of the plant material presented for importation and the risks associated with such importation, we may require that the plant material be transported from the plant inspection station for release only to preapproved facilities. We would assess a facility prior to issuing a permit to ensure that it has the infrastructure and equipment identified by APHIS as being necessary to manage the risks associated with the imported plant material.

At the approved facility, the plant material imported under a CIP would have to be identified and labeled as quarantined material to be used only in accordance with a valid CIP. Such plant material would have to be maintained in a secure place and be under the supervision and control of the permit holder. The safeguards must not be moved or distributed without prior written permission. During regular business hours, properly identified officials, either Federal or State, would have to be allowed to inspect the plant material and the facility in which the plant material is maintained.

The permit holder would be required to keep the permit valid for the duration of the authorized experimental, therapeutic, or developmental activity. A CIP would be valid for a period of 1 year and could be renewed if we believed the additional time was necessary to complete the experimental, therapeutic, or developmental purpose for which the permit was issued.

In the event the permit holder leaves the institution in which the plant material is kept, another person would be required to assume responsibility for the continued maintenance of the plant material and obtain a new CIP for the material or it would have to be destroyed.

Any conditions of the CIP or assigned safeguarding or mitigation measures would be clearly explained in the CIP. Failure to comply with all of the conditions specified in the CIP or any applicable regulations or administrative instructions, or forging, counterfeiting or defacing permits or shipping labels, may result in immediate revocation of the permit, denial of future permits, and civil or criminal penalties for the permit holder.

Proposed paragraph (g) of § 319.6 would address the circumstances under which a permit application for a CIP may be denied or a CIP may be revoked after issuance. Under these provisions, the Administrator would deny an application for a CIP permit when the Administrator determines that:

- No safeguards adequate or appropriate to prevent the dissemination of a plant pest or plant disease can be implemented;
- The applicant, as a previous permittee, failed to maintain the safeguards or otherwise comply with all the conditions prescribed in a previous permit and failed to demonstrate the ability or intent to observe them in the future;
- The application for a permit is found to be false or deceptive in any material particular;
- Such an importation would involve the potential dissemination of a plant pest or plant disease which outweighs the probable benefit that could be derived from the proposed importation and use of the regulated plant material;
- The importation is adverse to the conduct of an APHIS eradication, suppression, control, or regulatory program;
- The government of the State or Territory into which the plant material would be imported objects to the proposed importation and provides a written explanation of its concerns based on plant pest risks.

The Administrator would revoke any outstanding CIP when the Administrator determines that information is received subsequent to the issuance of the CIP of circumstances that would constitute cause for the denial of an application described above, or the permittee fails to maintain the safeguards or otherwise observe the conditions specified in the CIP or in any applicable regulations or administrative instructions.

All denials of an application for a permit, or revocation of an existing permit, would be provided to the applicant or permittee in writing. The reasons for the denial or revocation would be stated in writing as promptly as circumstances permit.

We would require that, upon revocation of a permit, the permittee must either:

- Surrender all regulated plant material covered by the revoked CIP to an APHIS inspector;
- Destroy all regulated plant material covered by the revoked CIP under the supervision of an APHIS inspector;
- Remove all regulated plant material covered by the revoked CIP from the United States.

We would provide for the appeal of the denial or revocation of a CIP. Any person whose application for a permit has been denied or whose permit has been revoked may appeal the decision in writing to the Administrator within 10 days after receiving written notification of the denial or revocation. The appeal would have to state all facts and reasons upon which the person was relying to show that the CIP was wrongfully denied or revoked. The Administrator would grant or deny the appeal, in writing, as promptly as circumstances permit, and would state in writing the reason for the decision. If there is a conflict as to any material fact, a hearing would be held to resolve such conflict. Rules of practice concerning such a hearing would be adopted by the Administrator. The permit denial or revocation would remain in effect during the resolution of the appeal.

**Regulations That Would Include References to the CIP**

We are proposing to use the CIP to authorize the importation of certain prohibited or restricted plant material for experimental, therapeutic, or developmental purposes in the current regulations in part 319. In doing so, we would replace the current provisions for importations for these purposes.

In the paragraphs that follow, we discuss the changes we are proposing and cite the specific areas of the regulations we are proposing to change.

- Foreign cotton and covers regulated under §§ 319.8 through 319.8–26. In § 319.8, which establishes a notice of quarantine for parts or products of plants of the genus *Gossypium*, we would replace the current text, which is dated and difficult to follow, with a clear statement that the importation of the plants and plant products listed in the section is prohibited unless they are imported in accordance with the regulations of the subpart or imported for experimental, therapeutic, or developmental purposes under the provisions of a CIP. We would remove and reserve §§ 319.8–19 and 319.8–20, as provisions for the importation of plant material regulated by the subpart for experimental or scientific purposes would be covered in the revised § 319.8.
- Sugarcane regulated under § 319.15. In § 319.15(a), we would remove the provision that sugarcane and its related products may be imported for scientific or experimental purposes under a departmental permit only by the USDA, and provide that these articles may be moved under the conditions specified in a CIP.
- Citrus fruit and nursery stock regulated under §§ 319.19 and 319.28. In §§ 319.19(b) and 319.28(d) we would remove the provision that plants or plant parts of the botanical family Rutaceae may be imported for scientific or experimental purposes under conditions as prescribed by the APHIS.
Administrator or the PPQ Deputy Administrator, and instead provide that these articles may be moved under the conditions specified in a CIP. We would also remove the statement that the paragraph’s provisions apply only to importations by the USDA.

- Indian corn or maize and related plants and their seeds regulated under §§ 319.24 through 319.24–5 (the corn diseases subpart), and §§ 319.41 through 319.41–6 (the Indian corn or maize, broomcorn, and related plants subpart). In § 319.24(b) we would remove the provision that portions of Indian corn or maize and related plants may be imported into Guam under conditions less stringent than those of the subpart as prescribed by the Deputy Administrator, and the statement that the paragraph’s provisions apply only to USDA importers and instead provide that these articles may be moved under the conditions specified in a CIP.

- Nursery stock, plants, roots, bulbs, seeds, and other plant products regulated under §§ 319.37 through 319.37–14. In § 319.37–1 we would remove the definition of Deputy Administrator and add definitions of Administrator and controlled import permit for use in the subpart. In § 319.37–2(c)(1), we would add that importations for experimental, therapeutic, or developmental purposes may be allowed under the conditions of a CIP, and remove the statement that the paragraph’s provisions apply only to importations by the USDA. In paragraphs (c)(3) through (c)(5) we would replace references to a departmental permit with references to the CIP. In § 319.37–3, we would add a new paragraph (g) requiring that the importation of restricted articles into the United States for experimental, therapeutic, or developmental purposes would require application for a CIP in accordance with § 319.6, and add a new paragraph (h) indicating that restricted articles imported into the United States that are required to be grown under postentry quarantine provisions must be accompanied by a CIP obtained in accordance with § 319.6.

Section 319.37–7 contains provisions governing postentry quarantine activities. Postentry quarantine is required for an established length of time following importation of certain restricted articles. Plants may be investigated and monitored for freedom from plant pests of foreign origin. Current paragraphs (a)(2) and (d) of this section require that an importer of the listed restricted articles from the designated regions complete and submit to PPQ a postentry quarantine growing agreement and an application for a written permit for the importation of the article in accordance with § 319.37–3. Section 319.37–3 designates articles whose importation requires a permit and indicates the information a permit application must contain, how a permit is issued, and under which circumstances a permit may be withdrawn.

We are proposing to amend § 319.37–7(a)(2) and (d) to state that the CIP is the form of permit required to accompany a postentry quarantine growing agreement. We believe that the information required in the application for a CIP will allow us to make a more informed decision about the specific article submitted for the postentry quarantine program, and allow us to provide more specific conditions for the issuance of the permit. It will also allow us more control over the plant material selected for the postentry quarantine program.

As noted above, current § 319.37–7(a)(2) and (d) require that the application for the written permit be made in accordance with § 319.37–3. We would add a new paragraph (h) to § 319.37–3, which would require that the importation of restricted articles into the United States be grown under the postentry quarantine provisions of § 319.37–7 must be authorized by a CIP obtained in accordance with § 319.6. Since we are proposing to change the type of permit required by § 319.37–7(a)(2) and (d) to accompany a postentry quarantine growing agreement to the CIP, we would amend those provisions to require that a CIP, as provided for in the newly added § 319.37–3(h), be obtained.

- Logs, lumber, and other unmanufactured wood articles regulated under §§ 319.40–1 through 319.40–11. In § 319.40–1 we would add a definition of controlled import permit for use in the subpart, and remove that of departmental permit. In § 319.40–2(d)(1), we would add that importations for experimental, therapeutic, or developmental purposes may be allowed under the conditions of a CIP, and we would remove the statement that the paragraph’s provisions apply only to importations by the USDA. In paragraphs (d)(2) and (d)(3), we would replace the references to a Departmental permit with references to a CIP.

- Articles restricted in order to prevent the entry of khapra beetle under §§ 319.75 through 319.75–9. In § 319.75(c), we would remove the statement that the paragraph’s provisions apply only to importations by the USDA and we would replace references to a departmental permit with references to a CIP.

We believe that these proposed changes would consolidate and harmonize requirements for obtaining a permit for the importation of plant material imported for scientific or certain other purposes, and therefore make the requirements of part 319 clearer and easier to use and implement. In addition to these specific proposed changes regarding the CIP, we are also proposing to update parts discussed above by replacing references to “Deputy Administrator” wherever
they still appear with references to the Administrator. In some subparts, this would include removing a definition of Deputy Administrator and adding one for Administrator. Most APHIS regulations refer to the Agency’s Administrator rather than the Deputy Administrators of specific programs like PPQ. This proposed change would make the regulations in part 319 consistent with other APHIS regulations.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. We have prepared an economic analysis for this proposed rule, which is set out below. The analysis provides a basis for our determination that this action would not have a significant economic impact on a substantial number of small entities.

For the purpose of this analysis and following the Small Business Administration (SBA) guidelines, we note that a major segment of entities potentially affected by the proposed changes are classified within the following industries: Nursery and Tree Production (NAICS 114211), and Floriculture Production (NAICS 111422). The nursery and floriculture industries are representative of other agricultural and nonagricultural industries in terms of being comprised largely of small entities. According to the Census of Agriculture, these two categories included 52,845 farms in 2007, and represented 3 percent of all farms in the United States. These entities are considered small by SBA standards if their annual sales are $750,000 or less. Over 93 percent of the farms in these industries had annual sales of less than $500,000.

Research and development establishments within Physical, Engineering, and Life Sciences (NAICS 541711) that provide professional, scientific, and technical services may also be affected by this proposed rule. These entities are considered small by SBA standards if they employ not more than 500 persons. According to the 2002 Economic Census, 82 percent of these establishments are small.

The CIP would replace the postentry quarantine permits and 1,012 departmental permits were issued. The proposed rule is not expected to affect the number of permits issued.

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

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2008–0055. Please send a copy of your comments to: (1) APHIS–2008–0055, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, Room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule. APHIS is proposing to amend the regulations concerning the importation of plants and plant products by establishing the controlled import permit as a single type of authorization for the importation into the United States of otherwise prohibited or restricted plant material for experimental, therapeutic, or developmental purposes. Currently, some sections of the regulations provide for those articles to be imported under a departmental permit, while other sections provide for their importation under administrative instructions or conditions specified by the Administrator or Deputy Administrator. This action would consolidate and harmonize the conditions for obtaining authorization for the importation of otherwise prohibited or restricted plant material for scientific or certain other purposes.

This proposed rule will require the use of a controlled import permit, annual inspection report, and the identification of the commodity being imported.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency’s functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.8125 hours per response.

Respondents: Researchers, for-profit organizations, and foreign government officials.

Estimated annual number of respondents: 1,200.

Estimated annual number of responses per respondent: 6,667.

Estimated annual number of responses: 8,000.

Estimated total annual burden on respondents: 6,500 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS’ Information Collection Coordinator, at (301) 851–2908.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to
E-Government Act compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 continues to read as follows:


2. A new subpart consisting of §319.6 is added to read as follows:

Subpart—Controlled Import Permits

§319.6 Controlled import permits.

(a) Definitions.

Administrator. The Administrator of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any employee of the United States Department of Agriculture delegated to act in his or her stead.

Scientific purposes. Scientific purposes are defined as those purposes for which the plant material is offered for importation in order to develop or test plant material for plant health risks and/or the adaptability of the material for certain uses or environments.

Experimental purposes. Scientific testing which utilizes collected data and employs analytical processes under controlled conditions to create qualitative or quantitative results.

Therapeutic purposes. The application of specific scientific processes designed to eliminate, isolate, or remove potential plant pests or diseases.

Purpose and scope. The regulations in this part prohibit or restrict the importation into the United States of certain plants, plant products, and other articles to prevent the introduction and dissemination of plant pests and noxious weeds within and throughout the United States. The regulations in this subpart provide a process under which a controlled import permit (CIP) may be issued to authorize the importation, for experimental, therapeutic, or developmental purposes, of an article whose importation is prohibited under this part. A CIP may also be issued to authorize, for those same purposes, the importation of an article under conditions that differ from those prescribed in the relevant regulations in this part.

(c) Application process. Applications for a CIP are available without charge from the Animal and Plant Health Inspection Service, Plant Protection and Quarantine (PPQ), Permit Unit, 4700 River Road, Unit 136, Riverdale, MD 20737–1236, or from local PPQ offices. Applications may be submitted by fax, mail, or electronically and must be submitted at least 60 days prior to arrival of the article at the port of entry. Mailed applications may be submitted to the address above, faxed applications may be submitted to 301–734–4300, and electronic applications may be submitted through the ePermits Web site at https://epermits.aphis.usda.gov/epermits.

(1) The completed application for a CIP must provide the following information:

(i) Name, address in the United States, and contact information of the applicant;

(ii) Identity (common and botanical [genus and species] names) of the plant material to be imported, quantity of importation, country of origin, and country shipped from;

(iii) Intended experimental, therapeutic, or developmental purpose for the importation;

(iv) Intended ports of export and entry, means of conveyance, and estimated date of arrival.

(2) APHIS may issue a CIP if the Administrator determines that the plant pest risks associated with the plant material and its intended experimental, therapeutic, or developmental use can be effectively mitigated. The CIP will contain the applicable conditions for importation and subsequent handling of the plant material if it is deemed eligible to be imported into the United States. The plant material may be imported only if all applicable requirements are met.

(d) Shipping conditions.

Consignments of plant material to be offered for importation under a CIP must meet the following requirements, unless otherwise specified under the conditions of the CIP:

(1) The plant material must be selected from apparently disease-free and pest-free sources.

(2) The plant material must be free of soil, other foreign matter or debris, other prohibited plants, noxious weed seeds, and living organisms such as parasitic plants, pathogens, insects, snails, and mites.

(3) Fungicides, insecticides, and other treatments such as coatings, dips, or sprays must not be applied before shipment, unless otherwise specified. Plant materials may be refused entry if they are difficult or hazardous to inspect because of the presence of such treatments. Plant materials must not be wrapped or otherwise packaged in a manner that impedes or prevents adequate inspection or treatment.

(4) The plant material must be moved in an enclosed container or one completely enclosed by a covering adequate to prevent the possible escape or introduction of plant pests during shipment. Any packing material used in the consignment of the plant material must meet the requirements of §319.37–9 of this part, and wood packing material used in the consignment must meet the requirements of §319.40–3(b) and (c) of this part.

(5) Consignments may be shipped as cargo, by mail or air freight, or hand-carried, as specified in the conditions of the CIP.

(6) The plant material must be offered for importation at the port of entry or plant inspection station as specified in the conditions of the CIP.

(7) A copy of the CIP must accompany each consignment, and all consignments must be labeled in accordance with instructions in the CIP.

(8) Each consignment must be accompanied by an invoice or packing list indicating its contents.

(e) Post-importation conditions. (1) At the approved facility where the plant material will be maintained following its importation, plant material imported under a CIP must be identified and labeled as quarantined material to be used only in accordance with a valid CIP.

(2) Plant material must be stored in a secure place or in the manner indicated in the CIP and be under the supervision and control of the permit holder. During regular business hours, properly identified officials, either Federal or State, must be allowed to inspect the plant material and the facilities in which the plant material is maintained.

(3) The permit holder must keep the permit valid for the duration of the authorized experimental, therapeutic, or developmental purpose. The PPQ Permit Unit must be informed of a change in contact information for the permit holder within 10 business days of such change.

(4) Plant material imported under a CIP must not be moved or distributed to another person without prior written permission from the PPQ Permit Unit.

(5) Should the permit holder leave the institution in which the plant material
imported under a CIP is kept, the plant material must be destroyed unless, prior to the departure of the original permit holder, another person assumes responsibility for the continued maintenance of the plant material and such person obtains a new CIP for the plant material.

(f) Failure to comply with all of the conditions specified in the CIP or any applicable regulations or administrative instructions, or forging, counterfeiting, or defacing permits or shipping labels, may result in immediate revocation of the permit, denial of future permits, and civil or criminal penalties for the permit holder.

(g) Denial and revocation of a CIP. (1) The Administrator will deny an application for a CIP permit, orally or in writing, when the Administrator determines that:

(i) No safeguards adequate or appropriate to prevent the dissemination of a plant pest or plant disease can be implemented;

(ii) The applicant, as a previous permittee, failed to maintain the safeguards or otherwise comply with all the conditions prescribed in a previous permit and failed to demonstrate the ability or intent to observe them in the future;

(iii) The application for a permit is found to be false or deceptive in any material particular;

(iv) Such an importation would involve the potential dissemination of a plant pest or plant disease which outweighs the probable benefit that could be derived from the proposed importation and use of the regulated plant material;

(v) The importation is adverse to the conduct of an APHIS eradication, suppression, control, or regulatory program; or

(vi) The government of the State or Territory into which the plant material would be imported objects to the proposed importation and provides a written explanation of its concerns based on plant pest risks.

(2) The Administrator will revoke any outstanding CIP, orally or in writing, when the Administrator determines that:

(i) Information is received subsequent to the issuance of the CIP of circumstances that would constitute cause for the denial of an application under paragraph (g)(1) of this section; or

(ii) The permittee has failed to maintain the safeguards or otherwise observe the conditions specified in the CIP or in any applicable regulations or administrative instructions.

(iii) Upon revocation of a permit, the permittee must either:

(i) Surrender all regulated plant material covered by the revoked CIP to an APHIS inspector;

(ii) Destroy all regulated plant material covered by the revoked CIP under the supervision of an APHIS inspector; or

(iii) Remove all regulated plant material covered by the revoked CIP from the United States.

(4) All denials of an application for a permit, or revocation of an existing permit, will be forwarded to the applicant or permittee in writing. The reasons for the denial or revocation will be stated in writing as promptly as circumstances permit.

(5) Any person whose application for a permit has been denied or permit has been revoked may appeal the decision in writing to the Administrator within 10 days after receiving written notification of the denial or revocation. The appeal should state all facts and reasons upon which the person relies to show that the denial or revocation was wrongfully denied or revoked.

(i) The Administrator will grant or deny the appeal, in writing, as promptly as circumstances permit, and will state in writing the reason for the decision. If there is a conflict as to any material fact, a hearing will be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator. The permit denial or revocation will remain in effect during the resolution of the appeal.

(ii) [Reserved]

3. Section 319.8 is revised to read as follows:

§ 319.8 Notice of quarantine.

Pursuant to sections 411–414 and 434 of the Plant Protection Act (7 U.S.C. 7711–7714 and 7754), the Administrator of the Animal and Plant Health Inspection Service has determined that the unrestricted importation into the United States from all foreign countries and localities of any parts or products of plants of the genus *Gossypium*, including seed cotton; cottonseed; cotton lint, linters, and other forms of cotton fiber (not including yarn, thread, and cloth); cottonseed hulls, cake, meal, and other cottonseed products, except oil; cotton waste, including gin waste and thread waste; any other unmanufactured parts of cotton plants; second-hand burlap and other fabrics, shredded or otherwise, that have been used or are of the kinds ordinarily used, for containing cotton, grains (including grain products), field seeds, agricultural roots, rhizomes, tubers, or other underground crops, may result in the entry into the United States of the pink bollworm (*Pectinophora gossypiella* (Saund.)), the golden nematode of potatoes (*Heterodera rostochiensis* Wr.), the flag smut disease (*Urocystis tritici* Koern.), and other injurious plant diseases and insect pests. Accordingly, to prevent the introduction into the United States of plant pests, the importation of those articles into the United States is prohibited unless they are imported in accordance with the regulations in this subpart or their importation has been authorized for experimental, therapeutic, or developmental purposes by a controlled import permit issued in accordance with § 319.6 of this part.

4. Section 319.8–1 is amended by removing the definition of Deputy Administrator, Plant Protection and Quarantine Programs, revising the definitions of approved; approved areas of Mexico; authorized; north, northern; treatment; and utilization, including removing footnote 1, and adding, in alphabetical order, a definition for Administrator to read as follows:

§ 319.8–1 Definitions.

* * * * *

Administrator. The Administrator of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any employee of the United States Department of Agriculture delegated to act in his or her stead.

* * * * *

Approved. Approved by the Administrator.

Approved areas of Mexico. Any areas of Mexico other than Northwest Mexico and the west coast of Mexico, which are designated by the Administrator as areas in which cotton and cotton products are produced and handled under conditions comparable to those under which like cotton and cotton products are produced and handled in the generally infested pink bollworm regulated area in the United States.

* * * * *

Authorized. Authorized by the Administrator.

* * * * *

North, northern. When used to designate ports of arrival, these terms mean the port of Norfolk, VA, and all Atlantic Coast ports north thereof, ports along the Canadian border, and Pacific Coast ports in the States of Washington and Oregon. When used in a geographic sense to designate areas or locations, these terms mean any State in which cotton is not grown commercially. However, when cotton is grown commercially in certain portions of a State, as is the case in Illinois, Kansas, and Missouri, these terms include those portions of such State as may be
§ 319.19 Notice of quarantine.
(b) Plants or plant parts of all genera, species, and varieties of the subfamilies Aurantioidae, Rutidoideae, and Toddalioideae of the botanical family Rutaceae may be imported into the United States for experimental, therapeutic, or developmental purposes under the conditions specified in a controlled import permit issued in accordance with § 319.6 of this part.

12. In § 319.24, paragraph (b) is amended by removing the second and third sentences and adding a new sentence in their place to read as follows:

§ 319.24 Notice of quarantine.
(b) * * * * * However, this prohibition does not apply to importations of such items for experimental, therapeutic, or developmental purposes under the conditions specified in a controlled import permit issued in accordance with § 319.6 of this part.

16. Section 319.37–2 is amended as follows:

a. By revising paragraph (c)(1) to read as set forth below.

b. In paragraphs (c)(3), (c)(4), and (c)(5), by removing the word “Departmental” each time it appears and adding the words “controlled import” in its place.

c. In paragraph (c)(4), by removing the word “Deputy”.

§ 319.37–2 Prohibited articles.
(c) * * * * (1) Imported for experimental, therapeutic, or developmental purposes under the conditions specified in a controlled import permit issued in accordance with § 319.6 of this part;

17. Section 319.37–3 is amended by revising paragraph (d) and adding new paragraphs (g) and (h) to read as follows:

§ 319.37–3 Permits.
(d) Any permit which has been issued may be withdrawn by an inspector or the Administrator if he or she determines that the holder of the permit has not complied with any condition for the use of the document. The reasons for the withdrawal will be confirmed in writing as promptly as circumstances permit. Any person whose permit has been withdrawn may appeal the decision in writing to the Administrator within 10 days after receiving the written notification of the withdrawal. The appeal must state all of the facts and reasons upon which the person relies to show that the permit was wrongfully withdrawn. The Administrator will grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances permit. If there is a conflict as to any material fact, a hearing will be held to resolve such conflict.

(g) Persons wishing to import restricted articles into the United States for experimental, therapeutic, or
developmental purposes must apply for a controlled import permit in accordance with § 319.6 of this part.

(h) The importation of restricted articles required to be grown under the postentry quarantine provisions of § 319.37–7 must be authorized by a controlled import permit obtained in accordance with § 319.6 of this part.

§ 319.37–7 [Amended]

18. Section 319.37–7 is amended as follows:

a. In paragraph (a)(2), in the second sentence, by removing the word “written” and adding the words “controlled import” in its place, and by removing the citation “§ 319.37–3” and adding the words “§ 319.6 of this part” in its place.

b. In paragraph (d) introductory text, in the first sentence, by removing the word “written” and adding the words “controlled import” in its place, and by removing the citation “§ 319.37–3” and adding the words “§ 319.6 of this part” in its place.

19. Section 319.40–1 is amended by removing the definition of departmental permit and by adding, in alphabetical order, a definition for controlled import permit to read as follows:

§ 319.40–1 Definitions.

* * * * *

Controlled import permit. A written or electronically transmitted authorization issued by APHIS for the importation into the United States of otherwise prohibited or restricted plant material for experimental, therapeutic, or developmental purposes, under controlled conditions as prescribed by the Administrator in accordance with § 319.6 of this part.

* * * * *

20. Section 319.40–2 is amended as follows:

a. By revising paragraph (d)(1) to read as set forth below.

b. In paragraphs (d)(2) and (d)(3) by removing the word “Departmental” each time it appears and adding the words “controlled import” in its place.

§ 319.40–2 General prohibitions and restrictions; relation to other regulations.

* * * * *

(d) * * *

(1) Imported for experimental, therapeutic, or developmental purposes under the conditions specified in a controlled import permit issued in accordance with § 319.6 of this part.

* * * * *

21. In § 319.41, paragraph (c) is revised to read as follows:

§ 319.41 Notice of quarantine.

* * * * *

(c) The Administrator may authorize the importation of articles otherwise prohibited under paragraph (b) of this section under conditions specified in a controlled import permit issued in accordance with § 319.6 of this part.

* * * * *

§ 319.41–3 [Amended]

22. In § 319.41–3, paragraphs (a) and (b) are amended by removing the words “Deputy Administrator of the Plant Protection and Quarantine Programs” each time they appear and adding the word “Administrator” in its place.

23. In § 319.55, paragraph (c) is revised to read as follows:

§ 319.55 Notice of quarantine.

* * * * *

(c) The Administrator may authorize the importation of articles otherwise prohibited by this subpart under conditions specified in a controlled import permit issued in accordance with § 319.6 of this part.

* * * * *

24. Section 319.59–1 is amended by adding, in alphabetical order, a definition for controlled import permit to read as follows:

§ 319.59–1 Definitions.

* * * * *

Controlled import permit. A written or electronically transmitted authorization issued by APHIS for the importation into the United States of otherwise prohibited or restricted plant material for experimental, therapeutic, or developmental purposes, under controlled conditions as prescribed by the Administrator in accordance with § 319.6 of this part.

§ 319.59–2 [Amended]

25. Section 319.59–2 is amended as follows:

a. In paragraph (b) introductory text, by removing the words “by the U.S. Department of Agriculture for experimental or scientific purposes” and adding the words “for experimental, therapeutic, or developmental purposes” in their place.

b. In paragraphs (b)(2), (b)(3), and (b)(4), by removing the word “departmental” each time it appears and adding the words “controlled import” in its place.

26. Section 319.69 is amended as follows:

a. In paragraph (b) introductory text, by removing the words “supplemental to this quarantine” and adding the words “in this subpart” in their place.

b. By revising paragraph (c) to read as set forth below.

§ 319.69 Notice of quarantine.

* * * * *

(c) The importation of plants and plant products that are prohibited or restricted under paragraphs (a) and (b) of this section may be authorized for experimental, therapeutic, or developmental purposes under conditions specified in a controlled import permit issued in accordance with § 319.6 of this part.

* * * * *

27. Section 319.74–1 is amended by adding, in alphabetical order, a definition for controlled import permit to read as follows:

§ 319.74–1 Definitions.

* * * * *

Controlled import permit. A written or electronically transmitted authorization issued by APHIS for the importation into the United States of otherwise prohibited or restricted plant material for experimental, therapeutic, or developmental purposes, under controlled conditions as prescribed by the Administrator in accordance with § 319.6 of this part.

* * * * *

28. Section 319.74–3 is revised to read as follows:

§ 319.74–3 Importations for experimental or similar purposes.

Cut flowers may be imported for experimental, therapeutic, or developmental purposes under such conditions as specified in a controlled import permit issued in accordance with § 319.6 of this part.

29. In § 319.75, paragraph (c) is revised to read as follows:

§ 319.75 Restrictions on importation of restricted articles; disposal of articles refused importation.

* * * * *

(c) A restricted article may be imported without complying with other restrictions under this subpart if:

(1) Imported for experimental, therapeutic, or developmental purposes under the conditions specified in a controlled import permit issued in accordance with § 319.6 of this part.

(2) Imported at the National Plant Germplasm Inspection Station, Building 580, Beltsville Agricultural Research Center East, Beltsville, MD 20705, or through any USDA plant inspection station listed in § 319.37–14 of this part; and

(3) Imported with a controlled import tag or label securely attached to the outside of the container containing the
article or securely attached to the article itself if not in a container, and with such tag or label bearing a controlled import permit number corresponding to the number of the controlled import permit issued for such article.

30. Section 319.75–1 is amended as follows:

a. By removing the definition of Deputy Administrator.

b. In the definition of inspector, by removing the word “Deputy”.

c. By adding, in alphabetical order, a definition for Administrator to read as set forth below.

§ 319.75–1 Definitions.

Administrator. The Administrator of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any employee of the United States Department of Agriculture delegated to act in his or her stead.

§ 319.75–3 [Amended]

31. In § 319.75–3, paragraph (d) is amended by removing the word “Deputy” each time it appears.

§ 319.75–8 [Amended]

32. Section 319.75–8 is amended by removing the word “Deputy”.

Done in Washington, DC, this 19th day of October 2011.

Kevin Shea,
Acting Administrator, Animal and Plant Health Inspection Service.

FOR FURTHER INFORMATION CONTACT:
Ms. Claudia Ferguson, Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road, Unit 113, Riverdale, MD 20737–1236; (301) 734–0754.

SUPPLEMENTARY INFORMATION:

Background

The regulations in “Subpart-Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–52, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests within the United States.

The national plant protection organization (NPPO) of Vietnam has requested that the Animal and Plant Health Inspection Service (APHIS) amend the regulations to allow fresh litchi (Litchi chinensis Sonn.) and longan (Dimocarpus longan Lour.) to be imported from Vietnam into the continental United States. The NPPO of Vietnam also proposed that the litchi and longan fruit be treated with irradiation at the 400 Gy dose approved to neutralize most insect pests, except pupae and adults of the order Lepidoptera.

As part of our evaluation of that request, we prepared a pest risk assessment identifying all quarantine pests of litchi and longan in Vietnam and a risk management document (RMD) that recommends risk mitigation measures to prevent the quarantine pests associated with these commodities from being introduced into the United States. Copies of the pest risk assessment and the RMD may be obtained from the person listed under FOR FURTHER INFORMATION CONTACT or viewed on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov).

The pest risk assessment identified 16 pests of quarantine significance present in Vietnam that could be introduced into the United States through the importation of fresh litchi:

Lepidopteran Pests:
- Conopomorpha sinensis
- Conogethes punctiferaria
- Cryptophlebia ombrodelta

Non-Lepidopteran Insect Pests:
- Bactrocera cucurbitae
- Bactrocera dorsalis
- Ceroplastes rubens
- Coccus viridis
- Dymococcus neobrevipes
- Nipaecoccus viridis
- Paracoccus interceptus
- Planococcus lilacinus
- Planococcus litchi
- Planococcus minor
- Pseudococcus cryptus
- Mite Pest:
- Aceria litchii
- Fungi Pest:
- Phytophthora litchii

The pest risk assessment also identified 17 pests of quarantine significance present in Vietnam that could be introduced into the United States through the importation of fresh longan:

Lepidopteran Pests:
- Conopomorpha sinensis
- Conogethes punctiferaria
- Cryptophlebia ombrodelta

Non-Lepidopteran Insect Pests:
- Bactrocera dorsalis
- Ceroplastes rubens
- Coccus viridis
- Drepacoccus chiton
- Dymococcus neobrevipes
- Exallomochlus hispidus
- Maconellicoccus hirsutus
- Nipaecoccus viridis
- Paracoccus interceptus
- Planococcus lilacinus
- Planococcus litchi
- Planococcus minor
- Pseudococcus cryptus
- Mite Pest: