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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: Final rule.

SUMMARY: We are amending 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 will consolidate and harmonize the conditions for obtaining authorization for the importation of otherwise prohibited or restricted plant material for scientific or certain other purposes.

EFFECTIVE DATE: [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Mr. William Aley, Senior Regulatory Policy Specialist, Plant Health Programs, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1231; (301) 851-2130.

## SUPPLEMENTARY INFORMATION:

### Background

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.

On October 25, 2011, we published in the Federal Register (76 FR 65976-65985, Docket No. APHIS-2008-0055) a proposal<sup>1</sup> to amend the regulations by establishing the controlled import permit (CIP) as the permit that would be used in place of departmental permits and the other types of authorizations 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 also proposed the CIP as the form of permit required for the importation of plant materials for postentry quarantine (PEQ).

We solicited comments concerning our proposal for 60 days ending December 27, 2011. We received eight comments by that date. They were from a State department of agriculture, plant nursery associations, a biotechnology firm, an organization of State plant regulatory agencies, and a member of the general public. Two commenters supported the proposed action. One commenter opposed the establishment of the CIP without raising any issues related to the proposed rule. The remaining comments are discussed below by topic.

One commenter expressed support for the proposed rule while suggesting that the new CIP and the new regulatory category for plants for planting whose importation is not authorized pending pest risk analysis (NAPPRA) be implemented simultaneously.

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<sup>1</sup> To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0055>.

We agree that the CIP and NAPPRA are related initiatives, and we have made significant progress in implementing both. A notice adding certain taxa of plants for planting to the NAPPRA lists was published in the Federal Register on April 18, 2013 (78 FR 23209-23219, Docket No. APHIS-2011-0072), and their addition to the NAPPRA lists will be effective on May 20, 2013; this final rule, establishing the CIP program, will be effective 30 days from its date of publication.

#### Pre-shipping Conditions

We proposed to require plant material imported under a CIP to be selected from apparently disease-free sources. One commenter asked how “apparently disease free source” is defined.

“Apparently disease-free” status is specific to each type and taxon of plant material. The importer will specify how it will meet the “apparently disease-free” requirement in the CIP application, and the CIP application will be reviewed by the Animal and Plant Health Inspection Service (APHIS) before a CIP is issued.

One commenter asked if APHIS will inspect the source facility of the articles for which the CIP is issued.

In most cases, APHIS does not inspect foreign facilities. The United States is a signatory to the International Plant Protection Convention and cooperates with the national plant protection organizations (NPPO) of our trading partners to ensure that plant material exported to the United States meets any pre-export requirements that may be assigned as a condition of the permit, such as the inspection of a source facility. In some cases, APHIS may jointly inspect a facility with officials of the exporting country’s NPPO.

## Shipping Conditions

A commenter said that the proposed CIP shipping conditions, which require the plant material to be free of soil, foreign matter or debris, prohibited plants, noxious weed seeds, and living organisms, contradict the proposed definition of therapeutic purposes, which allows the application of specific processes to eliminate, isolate, or remove potential plant pests or diseases.

Unless otherwise specified under the conditions of the CIP, consignments of plant material imported under a CIP must meet certain shipping requirements, including the requirement that the plant material be free of living organisms. However, an importer of plant material intended for therapeutic purposes may specify in the CIP application different shipping conditions for the specific article (for example, an importer could apply to import material infected with a plant disease to test diagnostic techniques.). APHIS will review the proposed shipping conditions and may issue a CIP for the alternate shipping conditions.

## Mitigation of Pest Risk

Two commenters asked for clarification on how APHIS will determine that the plant pest risks associated with the plant material and its intended use can be effectively mitigated.

Mitigation of the risk associated with prohibited or restricted articles varies by commodity and origin and will be determined on a case-by-case basis. APHIS' goal is to permit importation of an otherwise prohibited or restricted plant only after scientists and risk evaluation experts have reviewed and approved the measures that the applicant proposes to reduce the likelihood of pest importation to an acceptable level. The importer will provide the proposed mitigation strategy in the CIP application. APHIS will use information provided by the permit applicant and a review of scientific literature to determine whether the proposed control measures would adequately address the identified risks. APHIS will communicate with the

importer throughout the review process. The CIP would specify the required mitigation measures that are identified as necessary by APHIS based upon the intended use of the plant material and as being adequate to prevent plant pest introduction.

#### Post-Entry Quarantine

Under § 319.37-7, certain restricted articles from designated areas must be grown under specific post entry quarantine (PEQ) conditions and may be imported into the United States only if: The articles are destined for a State that has completed a State PEQ growing agreement; a PEQ growing agreement has been completed and submitted to the Plant Protection and Quarantine (PPQ) program; and PPQ has determined that the completed PEQ growing agreement fulfills the applicable requirements and that services by State inspectors are available to monitor and enforce the postentry quarantine.

We proposed that PEQ material be imported with a CIP, rather than the permit normally issued for planting under § 319.37-3, in addition to a PEQ growing agreement. One commenter stated that, while the proposed rule specifies that a CIP may be issued to authorize the importation of plant material for developmental purposes, experimental purposes, or therapeutic purposes, PEQ material is rarely brought in for any of these purposes. The commenter stated that PEQ material is imported because the material is not available domestically, is not available in a specific caliper or phenological state domestically, or is cheaper to acquire from a foreign source. The commenter suggested that the proposed rule be amended to exempt plants currently imported under the PEQ provisions in § 319.37-7 from the requirement that plants imported under a CIP be imported for developmental, experimental, or therapeutic purposes.

The purpose of a PEQ agreement is to allow for monitoring of consignments after entry into the country for the presence of pests, time for the expression of signs or symptoms, and, if necessary, appropriate treatment.

We proposed to define developmental purposes 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. The term is intended to be of wide scope and will not exclusively cover material for scientific or experimental uses. Given that, we continue to believe that the CIP is the appropriate type of permit for the importation of plant material that will be held in PEQ.

One commenter said that most PEQ material requires two growing season inspections, which take more than 1 year of growth in PEQ to conduct. The commenter said that, because a CIP would be valid for a period of 1 year, the CIP would require a permit renewal for most PEQ material, resulting in permit lapses and additional administrative work for both the permit holder and the agencies.

As specified in § 319.37-7(d)(7) of the regulations, most articles that are imported under a PEQ agreement must be grown in PEQ for a period of 2 years. While a CIP requires plant material to be imported within a specified 12-month period, any additional time necessary to complete the evaluation process after importation will be specified in the application and the permit. Therefore, multiple CIPs for a single shipment of PEQ material will not be necessary.

One commenter said that requiring a CIP to accompany material imported for monitoring under a PEQ agreement could result in each lot of PEQ plants having a different set of growing conditions, complicating both the inspection and production processes and increasing the rate of errors and non-compliance at the growing site.

We do not believe the problems cited by the commenter will arise. The same plant material shipped for the same purpose would by definition have the same growing conditions, which will be specified in the accompanying CIP.

#### Post-Importation Conditions

Some comments concerned the post-importation conditions associated with the CIP. As explained in the proposed rule, we may require that the plant material imported under a CIP be transported from the plant inspection station through which it is imported for release only to preapproved facilities depending on the intended purpose of the plant material and the risks associated its importation.

One commenter opposed the proposed rule citing a lack of information on what constitutes an approved facility. The commenter expressed concern about the possible risk to his State's agricultural production if appropriate containment facilities are not in place.

Because risks are specific to each taxon and type of plant material, the criteria for an approved facility will vary depending on the plant material that will be maintained in the given facility and the plant material's intended use. Prior to issuing a CIP, APHIS will consider the risks associated with imported plant material and assign conditions, including facility infrastructure and equipment requirements, determined to be sufficient. APHIS will work with the applicant to ensure that those conditions or equivalent measures can be instituted by the applicant prior to issuance of the permit. It is APHIS policy to work with State officials in order to identify and address any concerns prior to the issuance of the permit.

One commenter asked about the requirements for obtaining permission to transfer a CIP from the original permit holder to another person and if APHIS would grant permission to

transfer the material to another person only if the permit conditions remain the same, or if the material could be distributed commercially for planting or as breeding stock.

If import materials are transferred from the original CIP holder to another person, the person to whom the materials are transferred is bound by the requirements of the original CIP. Permission to move or distribute plant material that was authorized for importation under a CIP to another person can be obtained by contacting the PPQ Permit Unit. We have added language to paragraph (e)(5) of § 319.6 explaining that, should the permit holder be otherwise unavailable to maintain the plant material for which the CIP was issued, the plant material must be destroyed unless another person assumes responsibility for the continued maintenance of the plant material and such person obtains a new CIP for the plant material.

Two commenters asked if material held under CIP and/or PEQ may be commercialized once released from permit.

Plant material or material propagated from plant material that is imported with the intent to be used for commercial purposes would fall under the category of importation for developmental purposes. The importer must state in the CIP application that he intends to commercialize the article. If APHIS approves the CIP application with this condition, then the article may be commercialized after the CIP is closed and the imported material is released from the corresponding PEQ agreement.

#### CIP Reporting

One commenter said that she understood that the current departmental permit could be used for multiple importations of the same material and would be valid for a period of 5 years. The commenter noted that the proposed CIP would require the importer to apply for a separate and unique CIP for each and every shipment, would be valid for 1 year, and would

involve annual inspections and reporting, which have not been required for permits in the past.

While in some instances importers have imported multiple shipments under a single departmental permit, we note that the intent of the regulations always has been that a permit be issued for each importation. We are retaining this requirement for the CIP.

The time period for a valid import permit is not being changed. The existing APHIS departmental permits are valid for 1 year, not 5 years. A CIP will be valid for 1 year, and the CIP holder may request the permit be renewed for an additional 2 years. Importers will be required to conduct an annual inspection and submit an annual report in order to allow APHIS to better track the importation of plant materials for which a permit is issued.

#### Permits for Plants for Planting

One commenter asked what will happen to the provisions in §§ 319.37-3(a)(3) through 319.37-3(a)(19) when they are replaced by § 319.6. The commenter asked that the agency permitting process continue to apply these regional prohibitions to protect key plant industries and natural resources from exotic pests and pathogens.

Section 319.37-3 requires a permit for the importation of plants for planting. Paragraphs (a)(3) through (a)(19) of § 319.37-3, which specify various categories of plants for planting whose importation requires a permit, will not be replaced or changed in any way. The only changes proposed for this section are the revision of paragraph (d) and the addition of paragraphs (g) and (h). The CIP does not remove or change quarantine requirements previously established through scientific review. In paragraph (d), we are replacing the term “Deputy Administrator” with “Administrator” and making minor editorial changes. New paragraph (g) will require a CIP

for articles imported for experimental, therapeutic, or developmental purposes, while new paragraph (h) will require that materials grown under a PEQ to also have a CIP.

#### Hearings

In our proposed rule, proposed paragraph (g)(5) of § 319.6 specified the appeals process for individuals who have their application for a permit denied or permit revoked. The paragraph specified that a hearing could be held in certain instances. To reflect current Agency practices, we have removed references to such a hearing in this final rule.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

#### Executive Order 12866 and Regulatory Flexibility Act

This final 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.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on 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 this rule are classified within the following industries: Nursery and Tree Production (NAICS 111421), and Floriculture Production (NAICS 111422). The nursery and floriculture industries are representative of other agricultural and non-agricultural industries in terms of being comprised largely of small entities. According to the Census of Agriculture, these 2 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 rule. These entities are considered small by SBA standards if they employ not more than 500 persons. According to the 2007 Economic Census, 82 percent of these establishments are small.

The CIP would replace the departmental permits and other types of authorizations that we have used to allow the importation of otherwise prohibited articles or of articles under different conditions other than in the current regulations. In addition, the CIP will be used as a form of permit required for the importation of plant materials for postentry quarantine (PEQ). Because this is an administrative change, we do not anticipate that the replacement would have any significant economic impact on the concerned entities. From January 1, 2007, to December 31, 2009, a total of 108 postentry quarantine permits and 1,012 Departmental permits were issued. The final 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 will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings 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 final rule, which were filed under control number 0579-0384, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the Federal Register providing notice of what action we plan to take.

## 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 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 are amending 7 CFR part 319 as follows:

### PART 319—FOREIGN QUARANTINE NOTICES

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

Authority: 7 U.S.C. 450, 7701-7772, and 7781-7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

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.

Developmental purposes. 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. 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.

(b) 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 (APHIS), 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 mail, by fax, or electronically and must be submitted at least 60 days prior to arrival of the article at the port of entry. Mailed applications must 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;

and

(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, including the specifications for the facility where the plant will be held. 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 sprayings 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, and wood packing material used in the consignment must meet the requirements of § 319.40-3(b) and (c).

(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. Should the permit holder be otherwise unavailable to maintain the plant material for which the CIP was issued, the plant material must be destroyed unless another person assumes responsibility for the continued maintenance of the plant material and such person obtains a new CIP for the plant material.

Permission to move or distribute plant material that was authorized for importation under a CIP to another person must be obtained by contacting the PPQ Permit Unit.

(6) CIPs issued by APHIS are valid for a period of 1 year. The permittee may request the existing permit be renewed for up to an additional 2 years prior to the expiration of the CIP and if no adverse indications exist from the previous year.

(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 may deny an application for a CIP, 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.

(3) 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. 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.

(Approved by the Office of Management and Budget under control number 0579-0384)

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.

4. Section 319.8-1 is amended as follows:

a. By removing the definition of Deputy Administrator, Plant Protection and Quarantine Programs;

b. By revising the definitions of approved; approved areas of Mexico; authorized; north, northern; treatment; and utilization, including removing footnote 1; and

c. By adding, in alphabetical order, a definition of Administrator.

The revisions and addition 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 determined by the Administrator as remote from the main area of cotton production.

\* \* \* \* \*

Treatment. Procedures administratively approved by the Administrator for destroying infestations or infections of insect pests or plant diseases, such as fumigation, application of chemicals or dry or moist heat, or processing, utilization, or storage.

\* \* \* \* \*

Utilization. Processing or manufacture, in lieu of fumigation at time of entry, at a mill or plant authorized by APHIS through a compliance agreement for foreign cotton processing or manufacturing.

\* \* \* \* \*

§§ 319.8-2, 319.8-8, 319.8-11, and 319.8-17 [Amended]

5. Sections 319.8-2, 319.8-8, 319.8-11, and 319.8-17 are amended by redesignating footnotes 2 through 6 as footnotes 1 through 5, respectively.

§ 319.8-3 [Amended]

6. In § 319.8-3, paragraphs (a) and (b) are amended by removing the word "Deputy" each time it appears.

§ 319.8-8 [Amended]

7. In § 319.8-8, paragraphs (a)(2)(v) and (a)(4) 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 their place.

§ 319.8-12 [Amended]

8. In § 319.8-12, paragraphs (d) and (f) are amended by removing the word "Deputy" each time it appears.

§§ 319.8-19 and 319.8-20 [Removed and Reserved]

9. Sections 319.8-19 and 319.8-20 are removed and reserved.

10. In § 319.15, paragraph (a) is revised to read as follows:

§ 319.15 Notice of quarantine.

(a) The importation into the United States of sugarcane and its related products, including cuttings, canes, leaves and bagasse, from all foreign countries and localities is prohibited, except for importations for experimental, therapeutic, or developmental purposes under the conditions specified in a controlled import permit issued in accordance with § 319.6.

\* \* \* \* \*

11. In § 319.19, paragraph (b) is revised to read as follows:

§ 319.19 Notice of quarantine.

\* \* \* \* \*

(b) Plants or plant parts of all genera, species, and varieties of the subfamilies Aurantioideae, Rutoideae, 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.

\* \* \* \* \*

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.

\* \* \* \* \*

§ 319.24-1 [Amended]

13. Section 319.24-1 is amended by removing the words "Deputy Administrator of the Plant Protection and Quarantine Programs" and adding the words "Administrator, Animal and Plant Health Inspection Service" in their place.

14. Section 319.28 is amended as follows:

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

b. In paragraphs (i) and (j), by removing the word "Deputy" each time it occurs.

§ 319.28 Notice of quarantine.

\* \* \* \* \*

(d) This prohibition shall not apply to importations for experimental, therapeutic, or developmental purposes under the conditions specified in a controlled import permit issued in accordance with § 319.6.

\* \* \* \* \*

15. Section 319.37-1 is amended by removing the definition of Deputy Administrator and by adding, in alphabetical order, definitions of Administrator and controlled import permit to read as follows:

§ 319.37-1 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.

\* \* \* \* \*

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.

\* \* \* \* \*

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;

\* \* \* \* \*

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.

\* \* \* \* \*

(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.

(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.

\* \* \* \* \*

§ 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” 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” 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.

\* \* \* \* \*

20. Section 319.40-2 is amended as follows:

a. In the heading of paragraph (d), by removing the words “scientific or educational” and adding the words “therapeutic, or developmental” in their place.

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

c. 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;

\* \* \* \* \*

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.

\* \* \* \* \*

§ 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 their 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.

\* \* \* \* \*

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.

\* \* \* \* \*

§ 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 under a controlled import permit issued in accordance with § 319.6" 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.

\* \* \* \* \*

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.

\* \* \* \* \*

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 conditions specified in a controlled import permit issued in accordance with § 319.6.

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;

(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; 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 of 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 26<sup>th</sup> day of April 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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