

Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

#### 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:

**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. Section 319.56–75 is added to subpart Fruits and Vegetables to read as follows:

##### § 319.56–75 Fresh cherimoya from Chile.

Fresh cherimoya (*Annona cherimola*) fruit must be imported into the United States under the conditions listed in paragraphs (a) and (b)(1) of this section. Fresh cherimoya fruit may also be imported into the continental United States from Chile under the conditions listed in paragraph (b)(2) of this section.

(a) *Commercial consignments.* The fresh cherimoya fruit may be imported in commercial consignments only.

(b) The risks presented by *Brevipalpus chilensis* mites must be addressed in one of the following ways:

(1) The fresh cherimoya fruit are subject to treatment and certification consisting of:

(i) A soapy water and wax treatment.

(ii) Each consignment of fresh cherimoya fruit must be accompanied by documentation to validate foreign site preclearance inspection after soapy water and wax treatment completed in Chile; or

(2) The fresh cherimoya fruit are subject to a systems approach consisting of the following:

(i) *Production site registration.* The production site where the fruit is grown must be registered with the national plant protection organization (NPPO) of Chile. Harvested cherimoya must be placed in field cartons or containers that are marked to show the official registration number of the production site. Registration must be renewed annually.

(ii) *Low-prevalence production site certification.* The fruit must originate from a low-prevalence production site to be imported under the conditions in this section. Between 1 and 30 days prior to harvest, random samples of

leaves must be collected from each registered production site under the direction of the NPPO of Chile. These samples must undergo a pest detection and evaluation method as follows: The leaves must be washed using a flushing method, placed in a 20-mesh sieve on top of a 200-mesh sieve, sprinkled with a liquid soap and water solution, washed with water at high pressure, and washed with water at low pressure. The process must then be repeated. The contents of the 200-mesh sieve must then be placed on a petri dish and analyzed for the presence of live *B. chilensis* mites. If a single live *B. chilensis* mite is found, the production site will not qualify for certification as a low-prevalence production site. Each production site may have only one opportunity per season to qualify as a low-prevalence production site, and certification of low prevalence will be valid for one harvest season only. The NPPO of Chile will present a list of certified production sites to APHIS. Fruit from those production sites that do not meet the requirements for certification as low-prevalence production sites may still be imported into the continental United States subject to treatment as listed in paragraph (b)(1) of this section.

(iii) *Post-harvest processing.* After harvest, all damaged or diseased fruits must be culled at the packinghouse and remaining fruit must be packed into new, clean boxes, crates, or other APHIS-approved packing containers.

(iv) *Phytosanitary inspection.* Fruit must be inspected in Chile at an APHIS-approved inspection site under the direction of APHIS inspectors in coordination with the NPPO of Chile following any post-harvest processing. A biometric sample must be drawn and examined from each consignment. Fresh cherimoya fruit can be shipped to the continental United States under the conditions of this section only if the consignment passes inspection. Any consignment that does not meet the requirements for inspection can still be imported into the continental United States subject to treatment as listed in paragraph (b)(1) of this section. Inspection procedures are as follows:

(A) Fruit presented for inspection must be identified in the shipping documents accompanying each lot of fruit to specify the production site or sites in which the fruit was produced and the packing shed or sheds in which the fruit was processed. This identification must be maintained until the fruit is released for entry into the United States.

(B) A biometric sample of the boxes, crates, or other APHIS-approved

packing containers from each consignment will be selected by the NPPO of Chile, and the fruit from these boxes, crates, or other APHIS-approved packing containers will be visually inspected for quarantine pests. If a single live *B. chilensis* mite is found during the inspection process, the certified low-prevalence production site where the fruit was grown will lose its certification for the remainder of the harvest season.

(v) *Phytosanitary certificate.* Each consignment of fresh cherimoya fruit must be accompanied by a phytosanitary certificate issued by the NPPO of Chile that contains an additional declaration stating that the fruit in the consignment was inspected and found free of *Brevipalpus chilensis* and was grown, packed, and shipped in accordance with the requirements of § 319.56–75(b)(2).

Done in Washington, DC, this 29th day of March 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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#### DEPARTMENT OF AGRICULTURE

##### Animal and Plant Health Inspection Service

##### 7 CFR Part 319

[Docket No. APHIS–2015–0051]

RIN 0579–AE20

##### Importation of Lemons From Chile Into the Continental United States

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

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to amend the fruits and vegetables regulations to list lemon (*Citrus limon* (L.) Burm. f.) from Chile as eligible for importation into the continental United States subject to a systems approach. Under this systems approach, the fruit would have to be grown in a place of production that is registered with the Government of Chile and certified as having a low prevalence of *Brevipalpus chilensis*. The fruit would have to undergo pre-harvest sampling at the registered production site. Following post-harvest processing, the fruit would have to be inspected in Chile at an approved inspection site. Each consignment of fruit would have to be accompanied by a phytosanitary certificate with an additional

declaration stating that the fruit had been found free of *Brevipalpus chilensis* based on field and packinghouse inspections. This proposed rule would allow for the safe importation of lemons from Chile using mitigation measures other than fumigation with methyl bromide.

**DATES:** We will consider all comments that we receive on or before June 3, 2016.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0051>.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2015-0051, 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/#!docketDetail;D=APHIS-2015-0051> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** Mr. George Balady, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, Plant Health Programs, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851-2240.

#### SUPPLEMENTARY INFORMATION:

##### Background

Under the regulations in “Subpart-Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–74, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

The regulations in § 319.56–4(a) provide that fruits and vegetables that can be imported using one or more of the designated phytosanitary measures in § 319.56–4(b) to mitigate risk will be listed, along with the applicable requirements for their importation, on the Internet (currently in the Fruits and Vegetables Import Requirements [FAVIR] database at [www.aphis.usda.gov/favir](http://www.aphis.usda.gov/favir)). Under those

provisions, lemons from Chile (*Citrus limon* (L.) Burm. f.) are currently listed in the FAVIR database as enterable subject to treatment with methyl bromide for the pest *Brevipalpus chilensis*, the Chilean false red mite, applied either as a condition of entry treatment or applied in Chile under an APHIS preclearance program.

The regulations in § 319.56–4(a) also provide that commodities that require phytosanitary measures other than those measures cited in § 319.56–4(b) may only be imported in accordance with applicable requirements in § 319.56–3 and commodity-specific requirements contained elsewhere in the subpart. Under those provisions, other citrus fruits, including clementines (*Citrus reticulata* Blanco var. Clementine), mandarins (*Citrus reticulata* Blanco), and tangerines (*Citrus reticulata* Blanco) may be imported into the United States from Chile, and grapefruit (*Citrus paradisi* Macfad.) and sweet oranges (*Citrus sinensis* (L.) Osbeck) may be imported into the continental United States from Chile under a systems approach. The conditions applicable to the importation of citrus from Chile are listed in § 319.56–38.

In this document, we are proposing to amend § 319.56–38 to include lemons that are currently enterable into the United States subject to treatment, thereby making the lemons eligible for importation under the same systems approach as other citrus from Chile.

Our review of the information supporting the safe importation into the United States of citrus from Chile under the listed phytosanitary measures is examined in a commodity import evaluation document (CIED) titled “Importation of Fresh Lemons (*Citrus limon* (L.) Burm. F.), from Chile into the Continental United States Using a Systems Approach.” Copies of the CIED may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT** or viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for a link to Regulations.gov and information on the location and hours of the reading room).

In June 2010, APHIS recognized all of Chile as a pest-free area with respect to *Ceratitis capitata*, the Mediterranean fruit fly. Therefore, the CIED identifies one quarantine pest that could be introduced into the United States in consignments of lemon from Chile: *B. chilensis*. A quarantine pest is defined in § 319.56–2 as “a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially

controlled.” In the CIED, the likelihood and consequences of introducing this pest to the United States are considered, and *B. chilensis* is rated as having a medium pest risk potential. Pests receiving a rating within the medium range may necessitate specific phytosanitary measures in addition to standard port-of-entry inspection of the commodity being imported into the United States.

Based on the findings of our CIED, we are proposing to allow the importation of fresh lemons from Chile into the United States subject to the same systems approach in place for other citrus from Chile. Under a systems approach, a set of phytosanitary conditions, at least two of which have an independent effect in mitigating the pest risk associated with the movement of commodities, is specified, whereby fruits and vegetables may be imported into the United States from countries that are not free of certain plant pests. The systems approach for lemons from Chile would require the fruit to be grown in a place of production that is registered with the national plant protection organization (NPPO) of Chile. The fruit would have to undergo pre-harvest sampling at the registered production site under the direction of the NPPO of Chile. The NPPO of Chile would present a list of production sites certified as having a low prevalence of *B. chilensis* to APHIS. Following post-harvest processing, the fruit would have to be inspected in Chile at an APHIS-approved inspection site under the direction of APHIS inspectors in coordination with the NPPO of Chile. Each consignment of the fruit would have to be accompanied by a phytosanitary certificate with an additional declaration stating that the lemons in the consignment meet the conditions of the systems approach and are free of *B. chilensis*. The mitigation measures in the proposed systems approach are discussed in greater detail below.

##### Production Site Registration

The production site where the lemons are grown would have to be registered with the NPPO of Chile. To register, the production site must provide the NPPO of Chile with the following information: Production site name, grower name, municipality, province, region, area planted to each species, number of plants/hectares/species, and approximate date of harvest. Registration would have to be renewed annually.

Registration of production sites is required to manage production site requirements and to control access to

the program to only qualified sites. Commercially grown shipments from registered production sites use good agricultural practices to reduce or eliminate pests.

#### Low-Prevalence Production Site Certification

Between 1 and 30 days prior to harvest, random samples of fruit would have to be collected from each registered production site under the direction of the NPPO of Chile. These samples would have to undergo a pest detection and evaluation method as follows: The fruit would have to be washed using a flushing method, placed in a 20-mesh sieve on top of a 200-mesh sieve, sprinkled with a liquid soap and water solution, washed with water at high pressure, and washed with water at low pressure. The washing process would then be repeated immediately after the first washing. The contents of the 200-mesh sieve would then be placed on a petri dish and analyzed for the presence of live *B. chilensis* mites. If a single live *B. chilensis* mite is found, the production site would not qualify for certification as a low-prevalence production site and would be eligible to export fruit to the United States only if the fruit is fumigated with methyl bromide either in Chile or at the port of first arrival in the United States. Each production site would have only one opportunity per season to qualify as a low-prevalence production site, and certification of low prevalence would be valid for one harvest season only. The NPPO of Chile would be required to present a list of certified production sites to APHIS annually.

#### Post-Harvest Processing

After harvest and before packing, the fruit would have to be washed, rinsed in a potable water bath, washed with detergent with brushing using bristle rollers, rinsed with a hot water shower with brushing using bristle rollers, predried at room temperature, waxed, and dried with hot air. These mitigations aid in removing any pests from the fruit.

#### Phytosanitary Inspection

The fruit would have to be inspected in Chile at an APHIS-approved inspection site under the direction of APHIS inspectors in coordination with the NPPO of Chile following any post-harvest processing. A biometric sample would be drawn from each consignment, which may represent multiple grower lots from different packing sheds. Consignments with mites will be rejected from the systems approach. Rejected lots may still be

exported to the United States but would require fumigation with methyl bromide either in Chile or at the port of first arrival in the United States in accordance with § 305.5 of the regulations.

#### Phytosanitary Certificate

Each consignment of fruit would have to be accompanied by a phytosanitary certificate issued by the NPPO of Chile that contains an additional declaration stating that the lemons in the consignment meet the conditions of the systems approach and are free of *B. chilensis*. Requiring a phytosanitary certificate ensures that the NPPO of Chile inspects the lemons for pests.

#### 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.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

The Government of Chile submitted a market access request for lemon fruit to be approved for import into the continental United States using a systems approach as an alternative to methyl bromide fumigation, to mitigate the risk of introduction of the Chilean false red mite.

The United States is a net exporter of fresh lemon; over 5 seasons (2009/10–2013/14), annual exports averaged about 102,410 metric tons (MT) (19 percent of production), compared to annual imports that averaged about 46,270 MT. Based on the Small Business Administration small-entity standards, the majority of entities that comprise industries that may be affected by this rule are small. These entities include lemon producers, packers, wholesalers, retailers, and importers.

Chile supplies about one-third of U.S. fresh lemon imports. Chile's Ministry of Agriculture estimates that approximately 60 percent of their lemon consignments to the United States will switch from methyl bromide treatment to the systems approach. Chile currently exports about 15,000 MT per year to the United States, of which the systems approach is expected to be used for 8,500 to 9,000 MT. For this reason, the

proposed rule is not expected to result in a significant increase in Chilean lemon exports to the United States or their competitiveness.

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 would allow lemon fruit to be imported into the continental United States from Chile. If this proposed rule is adopted, State and local laws and regulations regarding lemon fruit imported under this rule would be preempted while the fruit is in foreign commerce. Fresh fruits are generally imported for immediate distribution and sale to the consuming public and would remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. If this proposed rule is adopted, no retroactive effect will be given to this rule, and this rule will 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 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–2015–0051. Please send a copy of your comments to: (1) APHIS, using one of the methods described under **ADDRESSES** at the beginning of this document, and (2) Clearance Officer, OCIO, USDA, Room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250.

APHIS is proposing to amend the fruits and vegetables regulations to list lemon (*Citrus limon* (L.) Burm. f.) from Chile as eligible for importation into the continental United States subject to a systems approach. Under this systems approach, the fruit would have to be grown in a place of production that is registered with the Government of Chile and certified as having a low prevalence of *B. chilensis*. The fruit would have to undergo pre-harvest sampling at the registered production site. Following post-harvest processing, the fruit would have to be inspected in Chile at an

approved inspection site. Each consignment of fruit would have to be accompanied by a phytosanitary certificate with an additional declaration stating that the fruit had been found free of *B. chilensis* based on field and packinghouse inspections. This proposed rule would allow for the safe importation of lemons from Chile using mitigation measures other than fumigation with methyl bromide.

Implementing this rule will require permits, production site registration with low-prevalence level certification option, phytosanitary inspections, phytosanitary certificates, and chemical treatment procedures.

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 0.6917 hours per response.

**Respondents:** Producers and importers of lemons, and the NPPO of Chile.

**Estimated annual number of respondents:** 198.

**Estimated annual number of responses per respondent:** 6.71.

**Estimated annual number of responses:** 1,330.

**Estimated total annual burden on respondents:** 920 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 Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

## 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 Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

### 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:

**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.

#### § 319.56–38 [Amended]

■ 2. Section 319.56–38 is amended as follows:

■ a. In the introductory text, by adding the words “, lemons (*Citrus limon* (L.) Burm. f.),” between the words “(*Citrus paradisi* Macfad.)” and “and sweet oranges”.

■ b. In paragraph (e), by adding the word “lemons,” between the words “grapefruit,” and “mandarins,”.

■ c. In paragraph (f), by adding the word “lemons,” between the words “grapefruit,” and “mandarins,”.

Done in Washington, DC, this 29th day of March 2016.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2016–07673 Filed 4–1–16; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 56

[Docket No. FDA–2015–N–5052]

### Administrative Actions for Noncompliance; Lesser Administrative Actions

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the regulation describing lesser administrative actions that may be imposed on an Institutional Review Board (IRB) that has failed to comply with FDA's IRB regulations. We are clarifying that FDA may require the IRB to withhold approval of new FDA-regulated studies, stop the enrollment of new subjects in ongoing studies, and terminate ongoing studies, or any combination of these actions, until the noncompliance with FDA's IRB regulations is corrected. We are taking this action to ensure clarity and improve the accuracy of the regulations.

**DATES:** Submit electronic or written comments on this proposed rule or its companion direct final rule by June 20, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the