

**DEPARTMENT OF AGRICULTURE****Animal and Plant Health Inspection Service****7 CFR Parts 301, 305, 318, 319, 330, and 352**

[Docket No. APHIS-2008-0022]

RIN 0579-AC94

**Phytosanitary Treatments; Location of and Process for Updating Treatment Schedules****AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Final rule.

**SUMMARY:** We are amending the phytosanitary treatment regulations in 7 CFR part 305 by removing the lists of approved treatments and treatment schedules from the regulations, while retaining the general requirements for performing treatments and certifying or approving treatment facilities. We are removing treatment schedules from other places where they are currently found in 7 CFR chapter III as well. Approved treatment schedules will instead be found in the Plant Protection and Quarantine Treatment Manual, which is available on the Internet. We are also establishing a new process to provide the public with notice and the opportunity to comment on changes to treatment schedules. Finally, we are harmonizing and combining the requirements for performing irradiation treatment for imported articles, articles moved interstate from Hawaii and U.S. territories, and articles moved interstate from an area quarantined for fruit flies. These changes will simplify and expedite our processes for adding, changing, and removing treatment schedules while continuing to provide for public participation in the process. These changes will also simplify our presentation of treatments to the public by consolidating all treatments into one document and eliminating redundant text from the regulations.

**EFFECTIVE DATE:** February 25, 2010.

**FOR FURTHER INFORMATION CONTACT:** Dr. Inder P. S. Gadh, Senior Risk Manager—Treatments, Regulations, Permits, and Manuals, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; (301) 734-0627.

**SUPPLEMENTARY INFORMATION:****Background**

The regulations in 7 CFR chapter III are intended, among other things, to prevent the introduction or dissemination of plant pests and noxious weeds into or within the United

States. Under the regulations, certain plants, fruits, vegetables, and other articles must be treated before they may be moved into the United States or interstate. The phytosanitary treatments regulations contained in part 305 of 7 CFR chapter III (referred to below as the regulations) set out standards and schedules for treatments required in parts 301, 318, and 319 of 7 CFR chapter III for fruits, vegetables, and other articles.

On May 12, 2009, we published in the **Federal Register** (74 FR 22318-22345, Docket No. APHIS-2008-0022) a proposal<sup>1</sup> to amend the regulations by removing the lists of approved treatments and treatment schedules from the regulations, while retaining the general requirements for performing treatments and certifying or approving treatment facilities. We proposed to remove treatment schedules from other places where they are currently found in 7 CFR chapter III as well, instead listing approved treatment schedules in the Plant Protection and Quarantine (PPQ) Treatment Manual, which is available on the Internet.<sup>2</sup> We also proposed to establish a new process to provide the public with notice and the opportunity to comment on changes to treatment schedules. Finally, we proposed to harmonize and combine the requirements for performing irradiation treatment for imported articles, articles moved interstate from Hawaii and U.S. territories, and articles moved interstate from an area quarantined for fruit flies.

We solicited comments concerning our proposal for 60 days ending July 13, 2009. We received 14 comments by that date. They were from nursery owners, academics, treatment facility operators, and representatives of State and foreign governments. They are discussed below by topic.

**General Comments About the Treatment Requirements**

As part of proposing to remove treatment schedules from 7 CFR chapter III, we proposed to move the general requirements for each type of treatment (chemical treatment, cold treatment, etc.) in 7 CFR part 305 to new locations within that part. We also proposed to make some minor changes to the existing treatment requirements.

One commenter suggested that we identify the common requirements for all treatments in the remaining provisions of 7 CFR part 305 and

present them in an introductory section, setting out specific requirements for the individual types of treatments in later sections. The commenter also suggested that there is a common set of mitigations for fruit flies (packaging, product movement, and location of treatment facilities) that could be contained in a separate section and referenced in the appropriate treatment requirements. The commenter stated that such changes would provide more clarity in the specific treatment requirements while creating more certainty that all regulations governing treatment in part 305 are included without unnecessary repetition.

As we proposed to move the treatment requirements but not to make any significant changes to them, making large-scale revisions to those requirements would be outside the scope of this final rule. However, we appreciate the commenter's suggestion and will consider whether to make such changes in a future rulemaking.

One commenter stated that there are inconsistencies in how the terms "approve," "authorize," and "certify" are used in the existing treatment requirements. The commenter pointed out that proposed § 305.5(a), which contains requirements for chemical treatment facilities, is headed "Certified facility," while proposed § 305.6(a), which contains requirements for cold treatment facilities, is headed "Approval of treatment facilities." (Paragraph (a) of proposed § 305.8(a), which contains requirements for heat treatment facilities, is also headed "Certified facility.") The commenter stated that authorization of a quarantine treatment facility may be a complex process that could include licenses from local, State, or Federal regulatory agencies other than the Animal and Plant Health Inspection Service (APHIS), or a foreign national plant protection organization (NPPO), in the case of foreign facilities. The commenter stated that "certification" would be a more appropriate term for the process undertaken by APHIS or a foreign NPPO to ensure that a facility can consistently perform efficacious phytosanitary treatments, including post-treatment safeguarding and documentation.

Another commenter stated that proposed § 305.9(b), which referred to approval of an irradiation facility by APHIS, should instead refer to certification of the irradiation facility by APHIS.

We agree with the first commenter's general point that a distinction should be drawn between certification of a facility as capable of performing treatment and approval of that facility to

<sup>1</sup> To view the proposed rule and the comments we received, go to (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0022>).

<sup>2</sup> At ([http://www.aphis.usda.gov/import\\_export/plants/manuals/ports/treatment.shtml](http://www.aphis.usda.gov/import_export/plants/manuals/ports/treatment.shtml)).

perform treatments. In proposed § 305.9, which contained our proposed revision of the irradiation treatment requirements, we referred to certification of a facility as part of the process for approval of a facility; the other part of that process was completing the necessary compliance agreements or workplans. Our use of the term “certification” in proposed §§ 305.5 and 305.8 was consistent with the use in proposed § 305.9. To be consistent, this final rule refers to certification, rather than approval, of cold treatment facilities in § 305.6(a). For reasons mentioned earlier, we are not making the change suggested by the second commenter.

### Definitions

We proposed to add or change the definitions of some terms in § 305.1.

The definition of *irradiation* has read: “The use of irradiated energy to kill or devitalize organisms.” We proposed to replace the reference to “irradiated energy” with a reference to “ionized energy.” We also proposed to replace the reference to “devitalize” in the definition of *irradiation* with a reference to “neutralize.”

Two commenters suggested that we refer instead to “ionizing energy,” as it is not the energy itself that is ionized; rather, the energy has the effect of ionizing atoms that are hit by the irradiation.

We agree with these commenters.

One commenter suggested that we add the word “pest” before the word “organisms” in the definition of *irradiation*.

The commenter did not provide any specific reason for making this change. We believe the suggested change is unnecessary, as any organism for which treatment is required will be a plant pest.

The International Plant Protection Convention’s (IPPC) Glossary of Phytosanitary Terms<sup>3</sup> defines *irradiation* as “treatment with any type of ionizing radiation.” As this definition is substantially similar to the proposed definition, and adopting the IPPC definition would make the regulations consistent with international standards, we are adopting the IPPC definition of *irradiation* in this final rule.

We proposed to add a definition of *neutralize* to reflect the fact that an effective irradiation treatment does not necessarily kill a plant pest. The

proposed definition of *neutralize* read: “In the case of treatments other than irradiation, to kill a plant pest; in the case of irradiation, to prevent the establishment of the pest by killing it, sterilizing it, or preventing its development from an immature stage into an adult capable of emerging from its host, reproducing, or becoming established.”

Two commenters recommended that the definition of *neutralize* make no distinction between irradiation and other treatments. One commenter noted that stating that treatments other than irradiation must result in the death of a plant pest does not provide options for other treatments that may be demonstrated to achieve a quarantine objective without causing mortality. For example, the commenter stated, the use of juvenile hormones as a treatment would prevent the development of larva into adults, while not killing the insect directly. In this case, the quarantine objective would be met, as the pest would not be able to reproduce and establish. While such treatments are not currently approved under the regulations or within the PPQ Treatment Manual, the commenter stated that, should such treatments be approved, it would be beneficial to allow for their subsequent inclusion within the PPQ Treatment Manual without having to amend the definition of *neutralize*.

We agree with these commenters and have removed the distinction between methods of treatment in the definition of *neutralize* in this final rule.

One commenter recommended that we remove the phrase “reproducing or becoming established” from the proposed definition of *neutralize* and instead refer to preventing a pest’s development from an immature stage into an adult capable of emerging from its host or pupal case. As both non-emergence of adults and sterility of any life stage would effectively prevent a pest from reproducing and thereby becoming established, the commenter stated that highlighting that both of these are potentially acceptable outcomes would allow for the different biology of the range of pests for which a quarantine treatment might be applied.

We agree with the commenter’s general point. However, with regard to the specific suggested language, “pupal case” would be inappropriately limiting, as a treatment that prevented development of pests in the larval stage would also be considered to be effective. Referring generally to preventing the development of a pest from an immature stage will encompass all of the potential successful outcomes. We have changed

the proposed definition of *neutralize* accordingly.

With these changes, the definition of *neutralize* in this final rule reads: “To prevent the establishment of a plant pest by killing it, sterilizing it, preventing its development from an immature stage, or preventing its emergence from its host.”

One commenter suggested that we add a definition of the term *monitor*, a term used in the general treatment requirements. The commenter stated that readers could be confused regarding whether *monitor* implies constant oversight of the treatment process or validation of the process at critical points in time.

The tenth edition of Merriam-Webster’s Collegiate Dictionary defines “monitor” as “to keep watch of, track, or check.” Other dictionaries provide similar definitions. This definition indicates that monitoring occurs while the treatment is occurring, but does not necessarily indicate constant oversight, which is consistent with the monitoring that officials authorized by APHIS perform for treatments. The IPPC Glossary of Phytosanitary Terms is consistent with the general definition, defining *monitoring* as “an official ongoing process to verify phytosanitary situations.” We do not see a need to add a definition of *monitor* to the regulations, since our use of *monitor* is consistent with common understanding of the term and with international standards.

### Notice-Based Process for Amending Treatments

Proposed § 305.3 set out a notice-based process for amending approved treatments. We received several comments supporting the use of such a process. One commenter noted that the addition, revision, and deletion of treatment schedules will directly affect the interests of trading partners and asked that APHIS provide notification of such changes to the World Trade Organization (WTO), with a sufficient period for comment, so that trading partners will be informed of these changes in a timely manner.

We plan to provide WTO notifications for notices published under this process, as we do for other trade-related notices. The notice will provide for a public comment period during which trading partners, as well as any other interested parties, may submit comments.

We are making two minor changes to the proposed provisions for the notice-based process. We are changing paragraph (b)(1)(iii) to refer to “articles” rather than “commodities,” because

<sup>3</sup> The Glossary of Phytosanitary Terms is International Standard for Phytosanitary Measures (ISPM) Number 5. To view this and other ISPMs on the Internet, go to (<http://www.ippc.int/>) and click on the “Adopted Standards” link under the “Core activities” heading.

“articles” is the more commonly used general term.

In addition, proposed paragraph (b)(2) stated that treatments added or revised through the process we proposed to use for immediate changes to treatment schedules would be listed in a separate section of the PPQ Treatment Manual as having been added or revised through the immediate process described in proposed paragraph (b). However, in the current PPQ Treatment Manual, all of the treatments are listed by type (chemical treatment, cold treatment, etc.), which makes it easy for facility operators and others to see all the treatments that could potentially be employed at a specific treatment facility. Listing treatments approved through the immediate process in a separate section would make the PPQ Treatment Manual less user-friendly. Therefore, we have changed this provision in this final rule to indicate that treatment schedules that have been added to the PPQ Treatment Manual or revised under this process will be identified in the PPQ Treatment Manual as having been added or revised through the immediate process. The identification will make it clear that such treatments may be subject to change pending the comments we receive on the added or revised treatments.

### Monitoring and Certification of Treatments

Section 305.3 has contained requirements for monitoring and certification of treatments. We proposed to move these requirements to § 305.4 and amend them.

Paragraph (b) of § 305.3 has required any treatment performed outside the United States to be monitored and certified by an inspector or an official from the NPPO of the exporting country. In proposed § 305.4(b), we proposed to require instead that any treatment performed outside the United States must be monitored and certified by an inspector or an official authorized by APHIS. We proposed this change to make this requirement consistent with the other requirements in part 305, which refer to officials authorized by APHIS rather than NPPO officials specifically.

Three commenters recommended that we not change the language currently in the regulations. Two commenters stated that the current regulations allow for APHIS to require preclearance, in which an APHIS inspector is present during the treatment and certifies that the treated commodity is free of quarantine pests, or certification by the NPPO; these commenters objected to what they

perceived as the removal of the latter option.

One of these commenters further noted that international agreements recognize the NPPO as the official service that certifies consignments to have been disinfected or disinfested when being moved in international trade and provides the necessary endorsements on phytosanitary certificates. This commenter also stated that, unless a risk assessment demonstrates that preclearance is necessary, requiring preclearance imposes significant additional costs to exporters without increasing the quarantine security of consignments. This commenter recommended that we change the references to “an official authorized by APHIS” in other sections of the regulations to refer to officials from the NPPO of the exporting country, to be consistent with the original text of § 305.3.

The provisions we proposed allow everything that is allowed under the current regulations; we did not propose to remove any options. Officials authorized by APHIS would include any officials of a foreign NPPO who currently certify treatments for articles exported to the United States. They would also include third parties that conduct treatments. Currently, third-party officials authorized by APHIS who monitor treatments include operators of niger seed treatment facilities, operators of wood packing material treatment facilities, officials who monitor precooling treatment temperatures for cold treatment, and others. As such, the provisions we proposed are more inclusive than those currently in the regulations and reflect current treatment activities; reverting to the original text would remove some options for exporters. In addition, the provisions we proposed continue to allow for preclearance or certification of treatment by the NPPO, as appropriate. We have made no changes in response to these comments.

We also proposed to require treated commodities to be accompanied by a phytosanitary certificate issued by the NPPO of the exporting country certifying that treatment was conducted in accordance with APHIS regulations when monitoring or certification of a treatment involves an official authorized by APHIS. The current regulations require phytosanitary certificates when treatment is monitored and certified by an official of the exporting country. We proposed to retain the requirement that the phytosanitary certificate be presented to an inspector when the commodity is offered for entry into the United States.

One commenter stated that it is inappropriate for the NPPO of the exporting country to certify that a treatment has been conducted in accordance with APHIS regulations if the treatment is not monitored by an NPPO official. This commenter also noted that some treated commodities are not required to be accompanied by phytosanitary certificates.

When treatments are conducted in a foreign country, an NPPO official is always involved in monitoring the treatment. However, the commenter is correct that many articles whose importation is authorized only if they are treated are not required to be accompanied by a phytosanitary certificate; for example, regulated wood packaging material is required under § 319.40-3(b) to be treated before importation, but a stamp on the wood packaging indicates that the treatment has been conducted. Requirements that phytosanitary certificates accompany imported articles are typically contained in APHIS permits or in the regulations in 7 CFR part 319, which contains requirements for importing various articles; it is not necessary to include a separate phytosanitary certificate requirement for treated articles in part 305, especially when there would be many exceptions to that requirement. Therefore, we will not be finalizing the phytosanitary certificate-related provisions discussed earlier that we had proposed to include in § 305.4(b).

### Chemical Treatment

We proposed to retain the requirements for chemical treatment in § 305.5, with minor changes. Paragraph (a) of § 305.5 requires fumigation treatment facilities to be certified by APHIS and to be inspected and recertified annually, or as often as APHIS directs, depending upon treatments performed, commodities handled, and operations conducted at the facility.

One commenter stated that, consistent with international agreements, the NPPO of the exporting country is capable of testing treatment facilities and certifying them as being capable of delivering the treatments required by the importing country. The commenter stated that this level of certification is not justified and presents a significant logistical and cost burden on treatment facilities, while not necessarily improving the quarantine security of consignments being exported to the United States. The commenter suggested that, at most, the certification be based on information submitted by the NPPO of the exporting country that is sufficient to demonstrate that the

facilities treating consignments are capable of meeting the requirements of § 305.5(a).

We did not propose to change the certification requirements for fumigation treatment facilities, and we would want to allow the public to comment on such a change before it was implemented. Therefore, we have made no changes to these provisions in response to this comment. However, we will consider the change the commenter suggested; if we determine that it is warranted, we will publish a proposed rule soliciting public comment on the change.

### Cold Treatment

We proposed to move the requirements for cold treatment from § 305.15 to § 305.6, with minor changes. Paragraph (d)(6) of § 305.15, which is identical to proposed § 305.6(d)(6), has stated that only the same type of fruit in the same type of package may be treated together in a container; no mixture of fruits in containers may be treated.

One commenter suggested that we define “type.” The commenter stated that a “type” of fruit, for the purpose of cold treatment, should be those fruits that are to be treated under the same schedule and that belong to the same genus. The commenter stated that different types of packaging might affect the delivery of cold treatment due to issues associated with the circulation of cold air, but different varieties of a particular species (such as Lisbon and Meyer lemons, or Washington Navel and Valencia oranges) do not affect treatment efficacy.

We agree with the commenter that varietal differences within a species do not affect the efficacy of cold treatment. However, we have determined that variations among species are significant enough that only fruit of the same species should be treated together using currently approved cold treatments; thus, we currently allow only fruit of the same species to be treated together. That said, we may determine in the future that a cold treatment schedule can be applied to fruit of the same genus. For that reason, we are not adding a definition of “type” to the regulations, but we are adding guidance on the meaning of “type” to the PPQ Treatment Manual. If we determine that a schedule could be used for fruit of the same genus, we would then be able to update the PPQ Treatment Manual to reflect that determination through the notice-based process we are adding to the regulations in this final rule.

This commenter also stated that, where the same treatment is applied and the same packaging type is used, the

inclusion of both lemons and oranges in a single treatment container should not necessarily be considered to invalidate the treatment, provided the more stringent of the two available treatments is applied. The commenter stated that these fruit are closely related, have a similar structure, and would be predicted to have a similar rate of respiration that would influence the cold treatment and the development of any “hot spots” in the treatment enclosure.

We believe that the commenter’s suggestion has some potential merit, but operational issues could make such a treatment process difficult to implement. However, we will consider the change the commenter suggested; if we determine that it is warranted, and that the operational issues associated with such a change could be adequately resolved, we will publish a proposed rule soliciting public comment on the change.

### Heat Treatment

We proposed to move the requirements for heat treatment from § 305.20 to § 305.8, with minor changes. Paragraph (a)(1) of § 305.20, which is identical to proposed § 305.8(a)(1), has stated that a certified facility must have equipment that is capable of adequately circulating air or water (as relevant to the treatment).

One commenter asked whether the interpretation of “air” in the regulations would include steam or vapor. The commenter noted that three main forms of heat treatment are generally accepted, hot water immersion, high temperature forced air, and vapor heat treatment, and suggested that the text of this section include the term “air/vapor.”

Steam and vapor are simply phases of water and, as used in treatments, are thus a mixture of air and water. As the regulations include requirements for circulation of air and water, we have determined that it is not necessary to further specify that facilities must be able to adequately circulate vapor.

### Irradiation

The regulations have contained three sections that set out requirements for performing irradiation treatment: § 305.31, for irradiation treatment of imported regulated articles; § 305.32, for regulated articles moved interstate from areas quarantined for fruit flies; and § 305.34, for regulated articles moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands. The requirements in these sections were mostly similar, and some of them were identical. We proposed to consolidate and harmonize the existing irradiation

requirements into one section that would set out irradiation requirements for all articles for which irradiation is an authorized treatment. We also proposed to make minor changes to the irradiation treatment requirements.

One commenter stated that the irradiation treatment regulations provide a much greater level of detail than the equivalent sections for other treatments. The commenter asked whether it is necessary to include this level of detail in the regulations, or whether it would be beneficial to include much of this detail in either the PPQ Treatment Manual or the other documentation specific to the irradiation treatment, such as the irradiation treatment framework equivalency workplan (FEWP). The commenter stated that reducing the level of detail in the regulations to be consistent with the other treatments would provide APHIS with more flexibility to amend the treatment requirements in the future, rather than having to complete rulemaking to do so.

The level of detail we proposed to include in the regulations reflects the level of detail that has been in the regulations. We did not propose to change the provisions of the irradiation regulations except as necessary to harmonize among the three sets of regulations and to correct errors and inconsistencies. Based on the comments we received, we will examine the irradiation regulations; if warranted, we will publish a separate proposal to amend them by removing detail and invite public comment on the proposal.

Two commenters stated that several requirements in the irradiation treatment regulations are related specifically to fruit flies. One of these commenters stated that the regulations contain requirements related to packaging, labeling, movement, and facility location that are specific to fruit flies and recommended that the regulations make it clear that irradiation is approved for many pests other than fruit flies.

The other commenter suggested that we review the proposed regulations and replace references to fruit flies with references to “pests of concern” where appropriate. This commenter specifically suggested that we change proposed § 305.9(c)(1)(i), which relates to compliance agreements for facilities treating imported articles in the United States. As proposed, this paragraph indicated that, in the facility compliance agreement, the facility operator must agree to comply with any additional requirements found necessary by APHIS to prevent the escape, prior to irradiation, of any fruit

flies that may be associated with the articles to be irradiated.

We agree with these commenters that the regulations should indicate that irradiation can be used to treat pests other than fruit flies, as irradiation is approved as a treatment for all pests of the class Insecta, other than pupae and adults of the order Lepidoptera. The proposed rule included several changes to the existing irradiation requirements to refer to pests of concern rather than to fruit flies specifically. In addition, we are taking the second commenter's suggestion to replace the reference to fruit flies in proposed § 305.9(c)(1)(i) with a reference to "pests of concern."

Some of the references to fruit flies in the regulations relate to the fact that, for articles moved within the continental United States, irradiation has only been approved as a treatment for articles moved interstate from areas quarantined for fruit flies. However, under this final rule, such facilities can treat any pest for which there is an approved dose in the PPQ Treatment Manual. We did not propose to expand the use of irradiation to facilities located in any areas quarantined for other pests in the proposal, although we may do so in the future.

Of the requirements cited by the first commenter, only the facility location requirements are specifically related to fruit flies. These are discussed in further detail in response to the next comment. However, the packaging, labeling, and movement requirements in the regulations all act as general safeguards against pests of concern, and the regulations as amended by this final rule reflect that.

Paragraph (a) of proposed § 305.9 contained the facility location requirements referred to earlier, which were taken from § 305.31(b). Under the proposed requirements, for articles that are imported or moved interstate from Hawaii or U.S. territories, irradiation facilities may be located in any State on the mainland United States except Alabama, Arizona, California, Florida, Kentucky, Louisiana, Nevada, New Mexico, South Carolina, Tennessee, Texas, and Virginia. In the States of Georgia, Mississippi, and North Carolina, irradiation facilities may only be located at the maritime ports of Gulfport, MS, or Wilmington, NC, or the airport of Atlanta, GA, and only if certain special conditions are met. Those conditions are designed to mitigate the risk of escape of fruit flies from the facility.

One commenter stated that no reason for excluding those listed States was included in the proposal and suggested that information on why these States are

excluded be added to the rule. The commenter suggested that, if it is only Federal or State legislation that prevents the use of irradiation facilities in those States for imported commodities, the additional legislation could be referenced and the specific list of States included only in the PPQ Treatment Manual, rather than the regulations. This change, the commenter stated, would prevent the need for a formal rule change should States be added to or removed from the list.

The States listed in the regulations are States where fruit flies could become established if introduced into the United States. We exclude these States to safeguard against the possibility that, despite the container and movement restrictions in the irradiation treatment regulations, fruit flies could escape from regulated articles in the United States prior to treatment. This rationale was given in the final rule establishing the irradiation treatment regulations for imported articles, which was published in the **Federal Register** and effective on October 23, 2002 (67 FR 65016-65029, Docket No. 98-030-4). As the relevant climatic conditions in these States are not expected to change, removing this list from the regulations to facilitate future changes in the list is not necessary.

One commenter noted that the regulations provide conditions for the placement of a facility in the listed States at three specific ports of entry. The commenter suggested that these provisions should not be in the regulations but in the PPQ Treatment Manual. The commenter stated that this type of detail, which might change based on specific approvals, would be better handled within the PPQ Treatment Manual. Amendments to the list could follow the same notice-and-comment process we proposed for changes to the PPQ Treatment Manual.

We are considering rulemaking to establish conditions under which facilities could be located in the States listed in paragraph (a) of proposed § 305.9. Should we decide to promulgate rulemaking to establish such conditions, we would include the list of approved facilities in the Treatment Manual, as the commenter suggests. However, making such a change in this final rule would be beyond the scope of the proposed rule.

The irradiation treatment regulations require that an irradiation treatment facility be certified by APHIS. The proposal included this requirement in paragraph (d) of proposed § 305.9. For the initial certification of a facility, the irradiation treatment regulations require that an inspector make a personal

inspection of the facility to determine whether it complies with the irradiation treatment facility requirements; the proposal included this requirement in paragraph (l) of proposed § 305.9.

One commenter stated that this level of certification is not justified and presents a significant logistical and cost burden on treatment facilities, while not necessarily improving the quarantine security of consignments being exported to the United States. The commenter stated that the key parts of the irradiation system are the dose mapping system and the routine dosimetry system. Because the regulations require these dosimetry systems to be compliant with the International Standards Organization/American Society for Testing and Materials (ISO/ASTM) standard or an equivalent standard recognized by APHIS, the commenter stated that there should be no need for specific certification visits by APHIS officials, provided that these standards are met. In this case, the commenter suggested, APHIS could use audit trails and certificates provided by accredited testing and certification laboratories to determine whether the treatment facility meets all the necessary requirements.

We have determined that, for the initial certification of a facility, it is necessary to conduct a personal inspection to ensure that the facility is in compliance with the ISO/ASTM standard. Audit trails and certificates provided by accredited testing and certification laboratories would not provide adequate assurance that the facility is in compliance with the standard. In addition, while we agree that the dose mapping and routine dosimetry systems are key components of irradiation treatment, the regulations include many other requirements that are necessary to ensure the phytosanitary security of treated articles, such as provisions to separate treated and untreated articles and to prevent the infestation of treated articles by quarantine pests after treatment. The facility's systems and processes to ensure compliance with these requirements also need to be verified by a personal inspection. We are making no changes in response to this comment.

The irradiation treatment regulations have referred to an increase or decrease in the amount of radioisotope as an event because of which recertification would be required. These events are found in the introductory text of paragraph (d) of proposed § 305.9. We proposed to add the word "significant" to better characterize the type of decrease that would require recertification, since radioisotope decreases in very small amounts during

treatment; otherwise, we did not propose to change this requirement.

Two commenters stated that increases in the amount of isotope should not necessitate recertification, and one stated that decreases in the amount of isotope should not either. Both commenters stated that if processes for maintaining the isotope have been established by the facility and approved by APHIS, changes in isotope should not require additional review by APHIS, except as necessary to confirm that the processes are being properly implemented.

As noted, the requirement for recertification in the event of a change in the amount of radioisotope has been found in all three sets of irradiation treatment facility provisions; we did not propose to change that requirement, other than making it more specific and thus more clear regarding what events require recertification. We have required recertification in the event of a change in the amount of radioisotope in order to verify that the radioisotope is at a proper level and treatment is being conducted in accordance with the ISO/ASTM standard and the facility's standard operating procedures. As discussed in more detail later in this document, it is especially important to verify that irradiation treatment is being properly conducted. We are making no changes in response to these comments.

However, we have determined that the proposed text could be more specific in describing what decreases warrant recertification. This final rule refers to a decrease in the amount of radioisotope for a reason other than natural decay, rather than to a significant decrease in the amount of radioisotope, as a reason for recertification. This reflects the intent of the proposed change more specifically and provides helpful additional information to the reader.

The irradiation treatment regulations require irradiation treatment to be monitored by an inspector. Monitoring will include inspection of treatment records and unannounced inspections of the facility by an inspector, and may include inspection of articles prior to or after irradiation. The proposal included these requirements in paragraph (e) of proposed § 305.9.

One commenter stated that such monitoring should not be required. The commenter stated that monitoring and inspection of treatment records can be performed by the NPPO of the exporting country. The commenter also stated that specific provisions for inspection prior to or after irradiation should not be included, as these should be performed during or after the issuance of a

phytosanitary certificate by the NPPO of the exporting country.

We have determined that the current level of monitoring is appropriate. Verifying that irradiation treatment is being applied properly is particularly important because an inspector looking at treated articles themselves after treatment would have no practical way to determine, based on physical evidence from the commodity itself, that the articles have been irradiated. Irradiation leaves no residue and usually causes no discernable change to an article's color or texture. In addition, as discussed earlier in this document, an effective irradiation treatment may not kill all larvae, but instead might prevent adult emergence. In cases where an inspector at the port of entry encounters live larvae of the target pest in a shipment that is documented as irradiated, it is extremely important that the inspector be able to determine with full confidence that the article was properly treated according to APHIS requirements. We are making no changes in response to this comment.

One commenter stated that provisions in proposed paragraph (e) imply that an inspector need not necessarily be present at all times during treatment. However, the commenter stated, the requirement that treatment "must be monitored by an inspector" will lead to some confusion. The commenter suggested clarifying that an inspector may not be required on site during treatment.

The commenter's interpretation that monitoring may or may not be on site is correct. Immediately after the requirement the commenter cites, the regulations go on to explain that monitoring will include inspection of treatment records and unannounced inspections of the facility by an inspector, and may include inspection of articles prior to or after irradiation. If an unannounced visit is not being conducted, monitoring would only necessarily include a review of treatment records, which could be done off site. We believe the current language is sufficiently clear on this point.

To ensure the appropriate level of monitoring for facilities treating imported articles, the regulations in § 305.31(f) have required three agreements to be signed before articles can be imported in accordance with the irradiation treatment requirements: An FEWP, a facility preclearance workplan, and a trust fund agreement. We proposed to move these requirements to proposed § 305.9(e)(1). The only change we proposed was to limit the applicability of these requirements to facilities located in foreign countries,

because ensuring that the irradiation treatment requirements are met when monitoring irradiation treatment in a foreign country involves an additional layer of complexity. Such monitoring requires us to work with foreign governments to ensure that all requirements are met, while monitoring the irradiation treatment within the United States of imported articles does not.

One commenter stated that, as specific details regarding the inspection of irradiated articles are included in the FEWP and the associated operational workplans, some of the specific details included in proposed paragraph (e) are not necessary. Similarly, the commenter suggested, as the extent of treatment oversight and monitoring would be defined in the FEWP, the text of proposed paragraph (e)(1)(iii), which contains the trust fund agreement requirements, could be simplified to remove specific references to the duties undertaken by APHIS in the exporting country.

The specific details the commenter cites are presented in the regulations as examples and not as exhaustive lists. For example, the requirements for the facility preclearance workplan that have been found in § 305.31(f)(2) and were proposed in § 305.9(e)(1)(ii) cite typical activities to be described in the workplan. These details provide helpful additional detail to the reader. We are making no changes in response to this comment.

Two commenters specifically addressed the FEWP. The regulations in § 305.31(f)(1), which we included in § 305.9(e)(1)(i) of the proposal, have required the NPPO of a country from which articles are to be imported into the United States in accordance with the irradiation treatment regulations to sign an FEWP with APHIS. In the FEWP, both the NPPO and APHIS will specify the following items for their respective countries:

- Citations for any requirements that apply to the importation of irradiated fruits and vegetables;
- The type and amount of inspection, monitoring, or other activities that will be required in connection with allowing the importation of irradiated fruits and vegetables into that country; and
- Any other conditions that must be met to allow the importation of irradiated fruits and vegetables into that country.

One commenter suggested that we revise these requirements to simply state that APHIS maintains the right to either deny the application for, or retract the approval of, an operational workplan for an irradiation facility if the

NPPO of the exporting country refuses to allow the importation of articles treated with irradiation. The commenter stated that such language would grant APHIS the legal right to determine equitable reciprocity and take appropriate action. The commenter stated that, in the case of domestic irradiation facilities that do not involve operational workplans with foreign NPPOs, reciprocity should not be required.

Another commenter requested that the requirement for the FEWP be removed. This commenter stated that the requirement for the FEWP was not based on science and thus constituted an unjustified barrier to trade. Because the requirement for the FEWP is not based on science, the commenter stated, APHIS is not authorized to impose such a requirement under the Plant Protection Act (7 U.S.C. 7701 *et seq.*), which states that decisions affecting imports, exports, and interstate movement of regulated products shall be based on sound science. The commenter stated that the requirement for the FEWP was causing costly delays in attempts by the commenter's business to establish a facility for irradiating products for export to the United States, as the government of the country in which the facility is intended to be located is reluctant to take the steps that government has determined to be necessary to agree to an FEWP.

The FEWP was originally established in the irradiation regulations to support the equivalence principle of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures by clearly stating what legislative, regulatory, and other requirements must be met, and what monitoring and other activities must occur, for irradiated articles to be imported into the United States, or into the foreign country. We did not propose to change the provisions required to be included in the FEWP requirements.

The FEWP does not obligate the government of a country in which an irradiation facility is located to agree to any specific conditions for the use of irradiation as a phytosanitary measure, but merely to document the conditions under which irradiated articles can be imported into that country. We will provide clarification regarding this point to any country that is encountering difficulty in preparing an FEWP.

As noted above, we proposed to change the FEWP requirement so that it only applied to facilities located outside the United States. However, upon further considering the purpose of the FEWP, we have determined that the

FEWP should continue to be required for all facilities treating imported articles, whether located outside or inside the United States, as the equivalence principle applies regardless of where imported articles are treated. Therefore, this final rule contains the FEWP requirement in a separate paragraph (e)(1) that applies to all facilities treating imported articles. Paragraph (e)(2) contains the remaining requirements for facilities located in foreign countries, and paragraph (e)(3) contains the requirements for facilities located in the United States; the latter paragraph refers to the FEWP requirement in paragraph (e)(1) for facilities located in the United States that are treating imported articles.

With regard to the first commenter's suggestion, the current FEWP provisions provide helpful additional specificity regarding what information about the exporting country's irradiation requirements needs to be conveyed in order for equivalence to be established. We are making no changes in response to this comment.

Two commenters specifically addressed the facility preclearance workplan. Prior to commencing importation into the United States of articles treated at a foreign irradiation facility, APHIS and the NPPO of the country from which articles are to be imported must jointly develop a preclearance workplan that details the activities that APHIS and the foreign NPPO will carry out in connection with each irradiation facility to verify the facility's compliance with the irradiation treatment requirements of this section. Typical activities to be described in this workplan may include frequency of visits to the facility by APHIS and foreign plant protection inspectors, methods for reviewing facility records, and methods for verifying that facilities are in compliance with the requirements for separation of articles, packaging, labeling, and other irradiation treatment requirements. This facility preclearance workplan will be reviewed and renewed by APHIS and the foreign NPPO on an annual basis.

Both commenters stated that preclearance should not be mandatory in all cases and that this specific workplan should be renamed. One commenter suggested calling it the "treatment facility workplan," and the other suggested the "irradiation facility workplan." The latter commenter stated that making this change would allow the flexibility to move from a preclearance program to one in which treatments are monitored by officials authorized by APHIS and the

commodity is shipped with a phytosanitary certificate issued by the NPPO of the exporting country, given sufficient evidence regarding the success of the program.

We assume that the commenters are referring to "preclearance" as the activity in which APHIS inspectors are present in a foreign country and conduct inspections there prior to export of the inspected articles. That is how APHIS has commonly used the term in developing export programs for particular articles. However, the regulations for irradiation treatment facilities use "preclearance" in a different sense, to refer to preclearing treatments conducted at the facility. Because inspectors monitor treatment, there is no additional verification of the treatment that needs to be done at the port of entry, which is important given that there is no practical way to verify treatment, as discussed earlier.

However, articles treated in a precleared facility are not necessarily themselves precleared. Irradiated articles may be subject to mitigations besides irradiation treatment for certain pests. For example, litchi from Thailand are required by § 319.56-47 to be treated with irradiation for several insect pests and also to be inspected by the Thai NPPO and found to be free of the fungus *Peronophythora litchi*, which is not neutralized by irradiation treatment. Thus, litchi from Thailand are not precleared for entry into the United States, even though the irradiation treatment facility in which they are treated is precleared.

As discussed earlier, we need to retain the facility preclearance workplan in support of our monitoring requirements, given the difficulty associated with verifying that irradiation has been conducted properly. As the regulations refer specifically to a "facility preclearance workplan" and not a general preclearance workplan, we do not believe any further change is necessary to indicate that the preclearance discussed applies to treatments conducted in the facility and not necessarily to any articles treated by the facility.

The regulations have required in §§ 305.32(b) and 305.34(b)(3) that facilities located within the United States that carry out continual irradiation operations notify an inspector at least 24 hours before the date of operations, while facilities that carry out periodic irradiation operations must notify an inspector of scheduled operations at least 24 hours before scheduled operations. This requirement



was included in § 305.9(e)(2) of the proposal.

One commenter stated that what is meant by “continual” and “periodic” operations is not clear. The commenter suggested that we either clarify or simply change the proposed text from “...before the date of operations...” to “...before the date of initial operations...”.

Re-examining the current requirements, we note that an inspector must be notified 24 hours before scheduled operations regardless of whether operations are continual or periodic. Therefore, as the commenter suggests, we have simplified this requirement in the final rule by eliminating distinctions between the two types of facilities.

In order to ensure that inspectors have adequate notice, we are also clarifying this provision to indicate that the notification must come at least 24 hours, excluding Saturday, Sunday, and Federal holidays, before scheduled operations, so that notification for irradiation that is scheduled for the next Monday does not arrive on a Saturday, a Sunday, or a Federal holiday, which are not standard business days for APHIS inspectors. The provision thus reads as follows in this final rule: “Facilities located within the United States must notify an inspector at least 24 hours (excluding Saturday, Sunday, and Federal holidays) before scheduled operations.”

Paragraph (f) of proposed § 305.9 contained the packaging requirements of the irradiation treatment regulations. Paragraph (f)(2) contained requirements for packaging articles that are irradiated prior to arrival in the United States, prior to interstate movement from Hawaii or U.S. territories, and prior to movement from an area quarantined for fruit flies. The regulations for irradiation treatment of articles moved interstate from Hawaii and U.S. territories and from quarantined areas only allow irradiated articles to be packaged in insect-proof cartons. The regulations for irradiation treatment of imported articles allow either insect-proof cartons or noninsect-proof cartons to be used; if noninsect-proof cartons are used, the cartons must be stored immediately after irradiation in a room completely enclosed by walls or screening that completely precludes access by the pests of concern. If stored in noninsect-proof cartons in a room that precludes access by the pests of concern, prior to leaving the room, each pallet of cartons must be completely enclosed in polyethylene shrink wrap, or another solid or netting covering that completely precludes access to the cartons by the

pests of concern. We proposed in § 305.9(f)(2)(i)(B) to allow the use of noninsect-proof cartons, subject to these conditions, for articles moved interstate from areas quarantined for fruit flies and from Hawaii and U.S. territories as well.

One commenter expressed uncertainty regarding whether the complete enclosure of the pallet in polyethylene shrink wrap or other covering should include the underside of the product and, if so, how one can shrink wrap all six sides of a pallet of product.

If the bottom of a pallet was insect-proof, we would not require the bottom of the pallet to be wrapped in polyethylene shrink wrap. The requirements for the use of noninsect-proof cartons are satisfied if access to the pallet is precluded by polyethylene shrink wrap or solid or netting covering.

One commenter stated that the requirement to wrap pallets of noninsect-proof cartons to prevent access by the pests of concern may be an appropriate safeguarding measure for articles transported by air, since the pallets are almost always exposed during the loading of the aircraft, but is not appropriate for maritime shipments, when the pallets of treated articles are loaded directly into the maritime container at the packing shed under adequate safeguards and subsequently sealed by the inspector or by another official authorized by APHIS. The commenter suggested that proposed § 305.9(f)(2)(i)(B) be reworded to make a distinction between requirements for air and maritime shipment, as is the case in other programs such as the program for hot water treatment of mango, and incorporated into the PPQ Treatment Manual rather than remain in the regulations.

The intent of this requirement is to prevent the treated articles from being reinfested by the pests of concern after treatment. As articles are exposed to potential pest infestation while they are being loaded into maritime containers, it is necessary to include a requirement to address this risk for maritime shipments as well. Although the mango hot water treatment program allows for such loading to be conducted without wrapping the mangoes, as noted earlier, it is much more difficult for an inspector at a port of entry to verify that an article has been treated with irradiation; in contrast, an inspector could easily determine that live fruit flies in mangoes that have been treated with hot water represented a failure of either the treatment or the post-treatment safeguarding and take appropriate action. We will consider whether providing for supervision of the

maritime transloading process might adequately mitigate this risk; if we determine that it would, we would propose rulemaking to provide for such supervision, and take public comment on the change.

The regulations in §§ 305.31(g)(3)(ii), 305.32(c)(2), and 305.34(b)(4)(i)(B) have required each pallet-load of cartons containing irradiated articles to be wrapped before leaving the irradiation facility in one of the following ways:

- With polyethylene shrink wrap;
- With net wrapping; or
- With strapping so that each carton

on an outside row of the pallet load is constrained by a metal or plastic strap.

We included this requirement in § 305.9(f)(2)(ii) of the proposal.

One commenter stated an assumption that the concern of proposed paragraph (f)(2)(ii) is to ensure that pallets do not topple and that nontreated cartons cannot be inserted into pallets of treated articles. The commenter suggested that we substitute the word “secured” for the word “wrapped,” as it more accurately describes the process when cornices and strapping are used to stabilize the pallet. The commenter also stated that requiring the strapping to pass and constrain each carton on the outside row of the pallet load exceeds current industry practices and would increase operational costs. The commenter suggested that the requirement be reworded to indicate that pallet loads should be secured by shrink wrap, netting, or strapping, without specifying how the strapping is to be applied.

We agree with the commenter’s suggestions. Accordingly, § 305.9(f)(2)(ii) in this final rule uses the word “secured” rather than the word “wrapped,” and does not include specific instructions on how to use strapping to secure the pallet.

In addition, the packaging requirements for sweetpotatoes moved interstate from Hawaii in § 318.13-25 are similar to the packaging requirements for irradiated articles, and contain identical requirements for wrapping pallets; we are also changing those requirements in this final rule, to be consistent with the changes we are making in the irradiation regulations.

The regulations in §§ 305.31(g)(3)(iii), 305.32(c)(3), and 305.34(b)(4)(i)(C) have required packaging to be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment. We included this requirement in § 305.9(f)(2)(ii) of the proposal.

One commenter stated that this level of detail does not need to be included in the regulations and that it would be



preferable for the regulations to only state that the packaging be labeled in such a way as to enable the necessary level of traceback. The inclusion of any identifying mark on the packaging that would permit APHIS to correlate the specific shipment to a treatment certificate, import permit, or other system would provide an equivalent level of traceback. As this detail already exists in the draft operational workplans, the commenter suggested that the principle of traceback be mentioned in paragraph (f)(2)(iii) without specifically requiring treatment facility codes, dates, or other information. As the operational workplans will be more easily amended than the regulations, the commenter stated that this option would allow APHIS to more easily take into consideration the specific systems in the exporting country.

We agree with the commenter's suggestion. In this final rule, paragraph (f)(2)(iii) specifies that packaging must be labeled in a manner that allows an inspector to determine treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment. This ensures that the information necessary to conduct traceback is available while allowing flexibility in providing that information. We will approve packaging to be used at a specific facility or for a specific commodity as part of the development of the operational workplan for the facility.

In addition, the labeling requirements for sweetpotatoes moved interstate from Hawaii in § 318.13-25 contain similar requirements for labeling cartons; we are also changing those requirements in this final rule, to be consistent with the changes we are making in the irradiation regulations.

One commenter suggested that APHIS change the wording ("Treated by irradiation" or "Treated with radiation") that must be stamped or pre-printed on each carton to indicate that the articles were irradiated to mitigate pest risks.

The wording is required by the Food and Drug Administration in its regulations at 21 CFR 179.26(c). We have no authority to make changes to those regulations.

Paragraph § 305.31(h) has required containers or vans that will transport treated commodities to be free of pests prior to loading the treated commodities. We proposed to include this requirement in § 305.9(g) and to make it applicable not only to facilities treating imported articles but to facilities treating articles moved interstate from Hawaii and U.S.

territories and from areas quarantined for fruit flies as well.

One commenter requested clarification on this requirement. The commenter asked:

- Whether the intent was to prevent infestation by pests of concern or hitchhikers;
- Whether the requirement applies to product treated in an area where the pest(s) of concern are present, other areas, or both;
- If articles are treated in a domestic facility, why it is important that the container or van be pest-free after the product has been processed; and
- If the pests are not pests of concern, whether freedom would need to be established inside the container or outside the container.

The intent of the requirement is to prevent infestation by pests of concern. The requirement applies regardless of whether pests of concern are present in the area in which the articles are treated. Ensuring that containers are free of pests of concern is a basic safeguarding principle; for example, even if an irradiation facility was located in an area free of pests of concern, a container could have been used to carry infested articles, improperly cleaned, and brought to the irradiation facility to contain treated articles.

To clarify this requirement, we are changing proposed § 305.9(g) to refer specifically to pests of concern. We are also changing proposed § 305.9(g) to refer to "articles," rather than "commodities," as the term "articles" is used throughout § 305.9.

Proposed paragraph (l) of § 305.9 set out requirements for requesting certification and inspection of a facility. These requirements were taken from § 305.31(l); similar requirements are contained in §§ 305.32(g) and 305.34(c). Each of these paragraphs provides that, before the Administrator determines whether an irradiation facility is eligible for certification, an inspector will make a personal inspection of the facility to determine whether it complies with the regulations.

One commenter asked whether this paragraph also applied to recertification and, if so, suggested that we change this requirement to indicate that an inspector may make a personal inspection, rather than that an inspector will make a personal inspection. The commenter stated that a minor technical reason for recertification should not obligate APHIS to perform a personal inspection of the facility.

The requirements in proposed paragraph (l) apply only to the initial certification of a facility, not to

recertification. We have added references to initial certification to paragraph (l) to make this more clear.

We are also changing paragraph (n) of proposed § 305.9, which informs the reader that the Department is not responsible for damage to treated articles and is taken from current §§ 305.31(n), 305.32(i), and 305.34(e). This paragraph refers to "listed plant pests," which we are updating to refer to "plant pests listed in the PPQ Treatment Manual." It also refers to fruits and vegetables being authorized for treatment; however, since articles other than fruits and vegetables are authorized for treatment, "articles" is a more appropriate term, and we are changing paragraph (n) accordingly.

#### Miscellaneous Changes

One commenter pointed out two typographical errors in the proposed rule:

- In proposed § 305.6(b), the text "and located in the area north of 39° longitude and east of 104° latitude" should read "and located in the area north of 39° latitude and east of 104° longitude".

- The section for quick freeze treatments was listed in the regulatory text of the proposed rule as being § 305.8. The commenter pointed out that the section number should be § 305.7.

We have corrected both of these errors in the final rule.

We are making two other miscellaneous changes to the proposed rule. We proposed to remove the chemical treatment schedules in the appendix to the subpart for imported fire ant (§§ 301.81 through 301.81-10), retaining only the systems approach for ensuring nursery freedom from imported fire ant in a new § 301.81-11. This systems approach refers to treatment at 180-day intervals. However, as treatments for the imported fire ant are added or changed, different intervals may be required for treatment. To add flexibility to the systems approach, we are changing the references to 180-day intervals in proposed § 301.81-11 to refer instead to "the specified number of days" and "the specified interval."

Proposed § 305.6(c) set out the requirements for cold treatment enclosures that have been found in § 305.15(c). Proposed paragraph (c)(2) indicated that such enclosures must maintain fruit pulp temperatures according to treatment schedules with no more than a 0.39 °C (0.7 °F) variation in temperature. This is related to a requirement for performing cold treatment that we proposed to include in § 305.6(d)(9), which requires fruit pulp temperatures to be maintained at

the temperature specified in the treatment schedule with no more than a 0.39 °C (0.7 °F) variation in temperature between two consecutive hourly readings. To make these requirements consistent and strengthen the connection between them, we are changing paragraph (c)(2) in this final rule to indicate that the cold treatment enclosure must maintain fruit pulp temperatures with no more than the specified variation between two consecutive hourly readings as well.

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.

APHIS is amending 7 CFR parts 301, 305, 318, and 319 to streamline the process for adding, revising, and removing treatment schedules and for authorizing the use of existing treatments for additional commodities. As required by the Regulatory Flexibility Act, we have evaluated the potential economic effects of this action on small businesses, small organizations, and small governmental jurisdictions

The regulations in 7 CFR chapter III are intended, among other things, to prevent the introduction or dissemination of plant pests and noxious weeds into or within the United States. Under the regulations, certain plants, fruits, vegetables, and other articles must be treated before they may be moved into the United States or interstate. The phytosanitary treatments regulations contained in part 305 set out standards and schedules for treatments required in parts 301, 318, and 319 for fruits, vegetables, and other articles.

APHIS is amending the phytosanitary treatment regulations in 7 CFR part 305 by removing the lists of approved treatments and treatment schedules from the regulations, while retaining the general requirements for performing treatments and certifying or approving treatment facilities. We are removing treatment schedules from other places where they are currently found in 7 CFR chapter III as well. Approved treatment schedules will instead be found in the PPQ Treatment Manual, which is

available on the Internet. We are also establishing a new process to provide the public with notice and the opportunity to comment on changes to treatment schedules. Finally, we are harmonizing and combining the requirements for performing irradiation treatment for imported articles, articles moved interstate from Hawaii and U.S. territories, and articles moved interstate from an area quarantined for fruit flies. These changes will simplify and expedite our processes for adding, changing, and removing treatment schedules while continuing to provide for public participation in the process. These changes will also simplify our presentation of treatments to the public by consolidating all treatments into one document and eliminating redundant text from the regulations.

Eliminating the need for specific prior rulemaking for approving new treatments or treatment schedules or for revising existing ones under the notice-based process could result in considerable time savings. The rulemaking process is an inherently longer process than a notice-based process. Additionally, establishing a notice-based process for approving new treatments or treatment schedules will facilitate use of the already-established notice-based process for authorizing the importation of fruits and vegetables set out in § 319.56-4. Under § 319.56-4, APHIS can authorize the importation of fruits and vegetables via a notice-based process if APHIS makes the determination that the application of one or more designated phytosanitary measures is sufficient to mitigate the risk that plant pests or noxious weeds could be introduced into or disseminated within the United States via the imported fruits or vegetables. Currently, however, if one of the prescribed designated measures is a treatment that requires an amendment to part 305, rulemaking is still required to amend the lists of approved treatments or treatment schedules. Establishing a notice-based process to amend the lists of approved treatments or treatment schedules will streamline this process.

Consumers benefit from the opportunity to consume commodities from a variety of sources, foreign as well as domestic. Consumer expenditures for fruit and vegetables are growing faster than for any food group other than meats. In many cases, fruit and vegetable imports can occur only after those commodities have been treated to prevent the introduction or movement of plant pests. This final rule will allow treatments to be put in use more quickly when treatment changes are necessary

and when existing treatments are applied to new commodities; treated products would become available to meet consumer demand sooner than at present. Treated imports supplement domestic supplies, especially of fresh products during the winter. Treatments also allow for movement of domestically produced products to markets around the country that otherwise would not occur. This movement results in increased choices for consumers. Even where new imports compete directly with domestic production, consumers benefit when increased competition results in lower prices.

Those entities most likely to be affected by the rule are domestic importers and producers of plants and plant products. The Small Business Administration (SBA) has established guidelines for determining which establishments are to be considered small. Import/export merchants, agents, and brokers are identified within the broader wholesaling trade sector. A firm primarily engaged in wholesaling is considered small if it employs not more than 100 persons. In 2002, more than 96 percent of fresh fruit and vegetable merchant wholesalers, more than 99 percent of grain and field bean merchant wholesalers, and more than 98 percent of flower and nursery stock wholesalers were considered small by SBA standards.<sup>4</sup> All types of farms are considered small if they have annual receipts of \$0.75 million or less. In 2002, more than 99 percent of oilseed and grain farms, more than 99 percent of vegetable and melon farms, more than 99 percent of fruit and tree nut farms, more than 99 percent of greenhouse, nursery, and floriculture producers, and more than 99 percent of other crop farms were considered small by SBA standards.<sup>5</sup>

Treatments are applicable to a wide variety of products including fruits, vegetables, live plants, bulbs, seeds, grains, logs, lumber, and other plants and plant products in a wide variety of circumstances. Vast quantities of treated products move into and through the United States annually. The United States is among the top producers and

<sup>4</sup> 2002 Economic Census. Department of Commerce. U.S. Bureau of the Census. North American Industry Classification System (NAICS) Categories. 424480: Fresh fruit & Vegetable merchant wholesalers; 424510: Grain & field bean merchant wholesalers; 424930: Flower, nursery stock, and florists' supplies merchant wholesalers.

<sup>5</sup> 2002 Census of Agriculture. U.S. Department of Agriculture. National Agricultural Statistics Service. NAICS Categories. 1111: Oilseed & Grain farming; 1112: Vegetable and melon farming; 1113: Fruit and tree nut farming; 1114: Greenhouse, nursery & Floriculture production; and 1119: Other Crop farming.

consumers of plants and plant products. U.S. per-capita use of fruit and tree nuts totals nearly 300 pounds each year, ranking third in per-capita consumption

of major food groups, next to dairy and vegetables. Oranges, apples, grapes, and bananas are the most popular fruit while almonds, pecans, and walnuts are the

most preferred tree nuts. Annual per capita use of all vegetables and melons averaged 445 pounds during the first 5 years of the 2000s.

TABLE 1.—U.S. PRODUCTION VALUE OF SELECTED CROPS, 2004-2006 (\$ MILLION)

Item	2004	2005	2006
Field and miscellaneous crops:			
Cotton, tobacco, sugar	8,674	8,702	8,648
Dry beans, peas, lentils	596	650	637
Grains, hay	47,367	45,225	57,209
Oilseeds	20,115	19,681	22,412
Potatoes, misc.	4,054	4,472	4,731
Fruit and nuts:			
Apples, pears	1,696	1,969	2,567
Berries	2,082	2,300	2,668
Citrus	2,485	2,303	2,738
Grapes	3,010	3,494	3,304
Nuts, other noncitrus	4,047	4,784	4,132
Stone fruit	1,243	1,462	1,563
Fresh vegetables:			
Brassica	1,111	1,118	1,225
Lettuce, spinach	2,062	2,108	2,635
Melons	728	873	877
Onions, peppers	1,300	1,501	1,674
Tomatoes	2,445	2,609	2,670
Other vegetables	1,430	1,599	1,619

In 2006, U.S. production of field and miscellaneous crops was valued at more than \$93 billion, with grains, hay, and oilseeds accounting for the majority of this value. Fruit and tree nuts production was valued at about \$17 billion. More than 63 percent of this production was in grapes, apples, almonds, oranges, and strawberries. Commercial vegetable production for

the fresh market was valued at almost \$11 billion, with tomatoes, lettuce, onions, broccoli, and sweet corn accounting for about 60 percent of this value.

Imports have become increasingly important for domestic consumption. Imports of plants and plant products have expanded rapidly over the past two decades, and include many new

and newly traded commodities. In 2006, the United States imported approximately \$5.8 billion in fresh fruits and tree nuts, about \$2.5 billion in fresh vegetables, and about \$1.5 billion in live plants and other plant products. Logs, lumber, and other timber product imports were valued at nearly \$12 billion in 2006.

TABLE 2.—U.S. IMPORTS OF PLANTS AND PLANT PRODUCTS, 2004-2006 (\$ MILLION)

Item	2004	2005	2006
Live plants, bulbs, etc.:			
Bulbs, tubers	208	208	208
Cut flowers, dried	706	709	768
Foliage	102	114	123
Other live plants	362	352	358

TABLE 2.—U.S. IMPORTS OF PLANTS AND PLANT PRODUCTS, 2004-2006 (\$ MILLION)—Continued

Item	2004	2005	2006
Fruit and nuts:			
Bananas	1,102	1,134	1,201
Citrus, fresh	307	356	407
Coconuts, Brazil nuts	640	660	602
Dates, figs, pineapples	570	812	936
Grapes	743	980	953
Other fruits and nuts	1,127	1,174	1,297
Fresh vegetables:			
Cucumbers, gherkins	349	319	421
Melons	369	393	431
Onions, shallots	254	308	282
Tomatoes	1,054	1,075	1,234
Other vegetables	417	508	543
Logs, lumber, and other timber products:			
Wood in the rough	246	348	347
Wood, sawn or chipped	8,799	8,989	8,333
Other wood	2,894	3,074	3,235

While treatments are applicable to a wide variety of plants and plant products in a wide variety of circumstances, the changes in this final rule will not alter current treatment requirements, the manner in which new treatments are evaluated, or when and how treatments are ultimately used other than in emergency situations. The final rule will allow treatment changes to be implemented more rapidly and therefore facilitate the movement of treated products to meet consumer demand. These changes are not expected to significantly impact the total supply of plants and plant products in the United States. Therefore, we expect at most small effects on U.S. marketers and consumers.

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 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with

State and local officials. (See 7 CFR part 3015, subpart V.)

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Has no retroactive effect and (2) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### List of Subjects

7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 305

Agricultural commodities, Chemical treatment, Cold treatment, Heat treatment, Imports, Irradiation, Phytosanitary treatment, Plant diseases and pests, Quarantine, Quick freeze,

Reporting and recordkeeping requirements, Transportation.

7 CFR Part 318

Cotton, Cottonseeds, Fruits, Guam, Hawaii, Plant diseases and pests, Puerto Rico, Quarantine, Transportation, Vegetables, Virgin Islands.

7 CFR Part 319

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

7 CFR Part 330

Customs duties and inspection, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 352

Customs duties and inspection, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, we are amending 7 CFR chapter III as follows:

**PART 301—DOMESTIC QUARANTINE NOTICES**

■ 1. The authority citation for part 301 continues to read as follows:

**Authority:** 7 U.S.C. 7701-7772 and 7781-7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75-15 issued under Sec. 204, Title II, Public Law 106-113, 113 Stat. 1501A-293; sections 301.75-15 and 301.75-16 issued under Sec. 203, Title II, Public Law 106-224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. In § 301.32-10, in the introductory text, the first sentence is revised to read as follows:

**§ 301.32-10 Treatments.**

Regulated articles may be treated in accordance with part 305 of this chapter to neutralize fruit flies. \* \* \*

**§ 301.50-5 [Amended]**

■ 3. In § 301.50-5, paragraph (a)(1)(i) is amended by removing the citation “§ 301.50-10(d)” and adding the citation “§ 301.50-10(b)” in its place.

■ 4. Section 301.50-10 is amended as follows:

- a. By revising paragraph (a) to read as set forth below.
- b. By removing paragraphs (b) and (c).
- c. By redesignating paragraph (d) as paragraph (b).

**§ 301.50-10 Treatments and management method.**

(a) Regulated articles may be treated in accordance with part 305 of this chapter to neutralize the pine shoot beetle.

\* \* \* \* \*

**§ 301.75-4 [Amended]**

■ 5. In § 301.75-4, paragraph (d)(2)(i)(C) is amended by removing the words “§ 301-11(d) of this subpart” and adding the words “part 305 of this chapter” in their place; paragraphs (d)(2)(ii)(C), (d)(2)(ii)(D), (d)(2)(ii)(E), and (d)(4) are amended by removing the words “§ 301.75-11(d) of this subpart” and adding the words “part 305 of this chapter” in their place; and paragraph (d)(4) is amended by removing the words “§ 301.75-11(c) of this subpart” and adding the words “part 305 of this chapter” in their place.

**§ 301.75-6 [Amended]**

■ 6. In § 301.75-6, paragraphs (b)(5) and (b)(6) are amended by removing the words “§ 301.75-11(d)” and adding the words “part 305 of this chapter” in their place; and paragraph (b)(5) is amended by removing the words “§ 301.75-11(c)” and adding the words “part 305 of this chapter” in their place.

**§ 301.75-7 [Amended]**

■ 7. In § 301.75-7, paragraph (a)(2) is amended by removing the citation “§ 301.75-11(a)” and adding the words “part 305 of this chapter” in its place.

**§ 301.75-8 [Amended]**

■ 8. In § 301.75-8, paragraph (b) is amended by removing the words “§ 301.75-11(b) of this subpart” and adding the words “part 305 of this chapter” in their place.

**§ 301.75-11 [Removed and Reserved]**

■ 9. Section 301.75-11 is removed and reserved.

**§ 301.81-4 [Amended]**

■ 10. Section 301.81-4 is amended as follows:

- a. In paragraph (a)(2)(iii), by removing the words “the methods and procedures prescribed in the Appendix to this subpart (“III. Regulatory Procedures”)” and adding the words “part 305 of this chapter” in their place.
- b. In paragraph (b), by removing the words “the methods and procedures prescribed in the Appendix to this subpart (“III. Regulatory Procedures”), or in accordance with the methods and procedures prescribed in”.

■ 11. Section 301.81-5 is amended as follows:

- a. In paragraph (a)(3)(ii), at the end of the paragraph, by removing the word “or”.
- b. In paragraph (a)(3)(iii), by removing the words “methods and procedures prescribed in the Appendix to this subpart (“III. Regulatory Procedures”).” and adding the words “part 305 of this chapter; or” in their place.
- c. By adding a new paragraph (a)(3)(iv) to read as set forth below.

**§ 301.81-5 Issuance of a certificate or limited permit.**

- (a) \* \* \*
- (3) \* \* \*

(iv) If the article is containerized nursery stock, it has been produced in accordance with § 301.81-11.

\* \* \* \* \*

**§ 301.81-6 [Amended]**

■ 12. Section 301.81-6 is amended by removing the words “the “Imported Fire Ant Program Manual,” as set forth in the appendix to this subpart” and adding the words “part 305 of this chapter” in their place.

■ 13. A new § 301.81-11 is added to read as follows:

**§ 301.81-11 Imported fire ant detection, control, exclusion, and enforcement program for nurseries producing containerized plants.**

This detection, control, exclusion, and enforcement program is designed to keep nurseries free of the imported fire ant and provides a basis to certify containerized nursery stock for interstate movement. Participating regulated establishments must be operating under a compliance agreement in accordance with § 301.81-6. Such compliance agreements shall state the specific requirements that a shipper agrees to follow to move plants in accordance with the requirements of the program. Certificates and a nursery identification number may be issued to the nursery for use on shipments of regulated articles.

(a) *Detection.* (1) Nursery owners are required to visually survey their entire premises twice monthly for the presence of imported fire ants.

(2) Nurseries participating in this program will be inspected by Federal or State inspectors at least twice per year. More frequent inspections may be necessary depending upon imported fire ant infestation levels immediately surrounding the nursery, the thoroughness of nursery management in maintaining imported-fire-ant-free premises, and the number of previous detections of imported fire ants in or near containerized plants. Inspections by Federal and State inspectors should be more frequent just before and during the peak shipping season. Any nurseries determined during nursery inspections to have imported fire ant colonies must be immediately treated to the extent necessary to eliminate the colonies.

(b) *Control.* Nursery plants that are shipped under this program must originate in a nursery that meets the requirements of this section. Nursery owners must implement a treatment program with registered bait and contact insecticides. The premises, including growing and holding areas, must be maintained free of the imported fire ant. As part of this treatment program, all exposed soil surfaces (including sod and mulched areas) on property where plants are grown, potted, stored, handled, loaded, unloaded, or sold must be treated in accordance with part 305 of this chapter at least once every 6 months. The first application must be performed early in the spring. Followup treatments with a contact insecticide in accordance with part 305 of this chapter must be applied to eliminate all remaining colonies.

(c) *Exclusion.* (1) For plants grown on the premises, treatment of soil or potting media in accordance with part 305 of

this chapter prior to planting is required.

(2) For plants received from outside sources, to prevent the spread into a nursery free of the imported fire ant by newly introduced, infested nursery plants, all plants must be:

(i) Obtained from nurseries that comply with the requirements of this section and that operate under a compliance agreement in accordance with § 301.81-6; or

(ii) Treated upon delivery in accordance with part 305 of this chapter, and within the specified number of days be either:

(A) Repotted in treated potting soil media;

(B) Retreated in accordance with part 305 of this chapter at the specified interval; or

(C) Shipped.

(d) *Enforcement.* (1) The nursery owner must maintain records of the nursery's surveys and treatments for the imported fire ant. These records must be made available to State and Federal inspectors upon request.

(2) If imported fire ants are detected in nursery stock during an inspection by a Federal or State inspector, issuance of certificates for movement will be suspended until necessary treatments are applied and the plants and nursery premises are determined to be free of the imported fire ant. A Federal or State inspector may declare a nursery to be free of the imported fire ant upon reinspection of the premises. This inspection must be conducted no sooner than 30 days after treatment. During this period, certification may be based upon treatments for plants in accordance with part 305 of this chapter.

(3) Upon notification by the department of agriculture in any State of destination that a confirmed imported fire ant infestation was found on a shipment from a nursery considered free of the imported fire ant, the department of agriculture in the State of origin must cease its certification of shipments from that nursery. An investigation by Federal or State inspectors will commence immediately to determine the probable source of the problem and to ensure that the problem is resolved. If the problem is an infestation, issuance of certification for movement on the basis of imported-fire-ant-free premises will be suspended until treatment and elimination of the infestation is completed. Reinstatement into the program will be granted upon determination that the nursery premises are free of the imported fire ant, and that all other provisions of this subpart are being followed.

(4) In cases where the issuance of certificates is suspended through oral notification, the suspension and the reasons for the suspension will be confirmed in writing within 20 days of the oral notification of the suspension. Any person whose issuance of certificates has been suspended may appeal the decision, in writing, within 10 days after receiving the written suspension notice. The appeal must state all of the facts and reasons that the person wants the Administrator to consider in deciding the appeal. A hearing may be held to resolve any conflict as to any material fact. Rules of practice for the hearing will be adopted by the Administrator. As soon as practicable, the Administrator will grant or deny the appeal, in writing, stating the reasons for the decision. Appendix to Subpart—Imported Fire Ant [Removed]

■ 14. The Appendix to Subpart—Imported Fire Ant is removed.

#### § 301.87-5 [Amended]

■ 15. In § 301.87-5, paragraph (a)(1)(i) is amended by removing the words “§ 301.87-10 of this subpart” and adding the words “part 305 of this chapter” in their place.

#### § 301.87-10 [Removed and Reserved]

■ 16. Section 301.87-10 is removed and reserved.

#### § 301.89-5 [Amended]

■ 17. In § 301.89-5, paragraphs (a)(2)(iii) and (b) are amended by removing the words “the methods and procedures prescribed in § 301.89-13” and adding the words “part 305 of this chapter” in their place.

#### § 301.89-6 [Amended]

■ 18. In § 301.89-6, paragraph (a)(3)(iii) is amended by removing the words “methods and procedures prescribed in § 301.89-13” and adding the words “part 305 of this chapter” in their place.

#### § 301.89-7 [Amended]

■ 19. Section 301.89-7 is amended by removing the citation “§ 301.89-13” and adding the words “part 305 of this chapter” in its place.

#### § 301.89-12 [Amended]

■ 20. In § 301.89-12, paragraphs (a), (b), and (c) are amended by removing the citation “§ 301.89-13” and adding the words “part 305 of this chapter” in its place.

#### § 301.89-13 [Removed and Reserved]

■ 21. Section 301.89-13 is removed and reserved.

#### § 301.92-5 [Amended]

■ 22. In § 301.92-5, paragraph (a)(1)(i) is amended by removing the words “§ 301.92-10 or”.

#### § 301.92-10 [Removed and Reserved]

■ 23. Section 301.92-10 is removed and reserved.

■ 24. Part 305 is revised to read as follows:

### PART 305—PHYTOSANITARY TREATMENTS

Sec.

305.1 Definitions.

305.2 Approved treatments.

305.3 Processes for adding, revising, or removing treatment schedules.

305.4 Monitoring and certification of treatments.

305.5 Chemical treatment requirements.

305.6 Cold treatment requirements.

305.7 Quick freeze treatment requirements.

305.8 Heat treatment requirements.

305.9 Irradiation treatment requirements.

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

#### § 305.1 Definitions.

*Administrator.* The Administrator, Animal and Plant Health Inspection Service, United States Department of Agriculture, or any person delegated to act for the Administrator in matters affecting this part.

*APHIS.* The Animal and Plant Health Inspection Service, United States Department of Agriculture.

*Cold treatment.* Exposure of a commodity to a specified cold temperature that is sustained for a specific time period to kill targeted pests, especially fruit flies.

*Dose mapping.* Measurement of absorbed dose within a process load using dosimeters placed at specified locations to produce a one-, two-, or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

*Dosimeter.* A device that, when irradiated, exhibits a quantifiable change in some property of the device that can be related to absorbed dose in a given material using appropriate analytical instrumentation and techniques.

*Dosimetry system.* A system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

*Fumigant.* A gaseous chemical that easily diffuses and disperses in air and is toxic to the target organism.

*Fumigation.* Releasing and dispersing a toxic chemical in the air so that it reaches the target organism in a gaseous state.

*Inspector.* Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

*Irradiation.* Treatment with any type of ionizing radiation.

*Methyl bromide.* A colorless, odorless biocide used to fumigate a wide range of commodities.

*Neutralize.* To prevent the establishment of a plant pest by killing it, sterilizing it, preventing its development from an immature stage, or preventing its emergence from its host.

*Plant Protection and Quarantine (PPQ).* The Plant Protection and Quarantine program of APHIS.

*PPQ Treatment Manual.* The document that contains the treatment schedules that are approved for use under this part. The Treatment Manual is available on the Internet at ([http://www.aphis.usda.gov/import\\_export/plants/manuals/index.shtml](http://www.aphis.usda.gov/import_export/plants/manuals/index.shtml)) or by contacting the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Manuals Unit, 92 Thomas Johnson Drive, Suite 200, Frederick, MD 21702.

*Quick freeze.* A commercially acceptable method of quick freezing at subzero temperatures with subsequent storage and transportation at not higher than 20 °F. Methods that accomplish this are known as quick freezing, sharp freezing, cold pack, or frozen pack, but may be any equivalent commercially acceptable freezing method.

*Section 18 of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).* An emergency exemption granted by the U.S. Environmental Protection Agency to Federal or State agencies authorizing an unregistered use of a pesticide for a limited time.

*Vacuum fumigation.* Fumigation performed in a gas-tight enclosure. Most air in the enclosure is removed and replaced with a small amount of fumigant. The reduction in pressure reduces the required duration of the treatment.

### § 305.2 Approved treatments.

(a) Certain commodities or articles require treatment, or are subject to treatment, prior to interstate movement within the United States or importation or entry into the United States. Treatment is required as indicated in parts 301, 318, and 319 of this chapter, on a permit, or by an inspector.

(b) Approved treatment schedules are set out in the PPQ Treatment Manual. Treatments may only be administered in accordance with the treatment requirements of this part and in

accordance with treatment schedules found in the PPQ Treatment Manual.

(c) APHIS is not responsible for losses or damages incurred during treatment and recommends that a sample be treated first before deciding whether to treat the entire shipment.

### § 305.3 Processes for adding, revising, or removing treatment schedules.

(a) *Normal process for adding, revising, or removing treatment schedules.* Unless there is a need to immediately add, revise, or remove a treatment schedule, as provided in paragraph (b)(1) of this section, a treatment schedule may be added to the PPQ Treatment Manual, revised, or removed from the PPQ Treatment Manual as follows:

(1) *Notice of change to treatment schedule.* APHIS will publish in the **Federal Register** a notice describing the reasons we have determined that it is necessary to add, revise, or remove a treatment schedule and, if necessary, making available the new or revised treatment schedule as it would be added to the PPQ Treatment Manual. In our notice, we will provide for a public comment period on the new or revised treatment schedule or on the removal of the treatment schedule from the PPQ Treatment Manual.

(2) *Response to comments.* (i) APHIS will issue a notice after the close of the public comment period indicating that the treatment schedule specified in the initial notice will be added to the PPQ Treatment Manual, revised as described in the notice, or removed from the PPQ Treatment Manual if:

(A) No comments were received on the notice;

(B) The comments on the notice supported our action; or

(C) The comments on the notice were evaluated but did not change our determination that it is necessary to add, revise, or remove the treatment schedule, as described in the notice.

(ii) If the notice issued after the close of the public comment period indicates that a change will be made to the PPQ Treatment Manual, APHIS will make available a new version of the PPQ Treatment Manual that reflects the addition, revision, or removal of the particular treatment schedule.

(iii) If comments present information that causes us to determine that the change described in the notice is not appropriate, APHIS will issue a notice informing the public of this determination after the close of the comment period.

(b) *Process for immediately adding, revising, or removing treatment schedules.* Treatment schedules may be

immediately added to the PPQ Treatment Manual, revised, or removed from the PPQ Treatment Manual under the circumstances described in paragraph (b)(1) of this section and in accordance with the process described in paragraphs (b)(2) and (b)(3) of this section.

(1) *Circumstances in which the immediate process may be used.*

Treatment schedules may be immediately added to the PPQ Treatment Manual, revised, or removed from the PPQ Treatment Manual if any of the following circumstances apply:

(i) PPQ has determined that an approved treatment schedule is ineffective at neutralizing the targeted plant pest(s);

(ii) PPQ has determined that, in order to neutralize the targeted plant pest(s), the treatment schedule must be administered using a different process than was previously used;

(iii) PPQ has determined that a new treatment schedule is effective, based on efficacy data, and that ongoing trade in an article or articles may be adversely impacted unless the new treatment schedule is approved for use; or

(iv) The use of a treatment schedule is no longer authorized by the U.S. Environmental Protection Agency or by any other Federal entity.

(2) *Process for immediate change to treatment schedules.* If PPQ determines that one or more of the circumstances in paragraph (b)(1) of this section applies and that it is necessary to take immediate action, APHIS will publish in the **Federal Register** a notice describing the reasons we have determined that it is necessary to immediately add, revise, or remove a treatment schedule and, if necessary, making available the new or revised treatment schedule as it has been added to the PPQ Treatment Manual. Treatment schedules that have been added to the PPQ Treatment Manual or revised under this process will be identified in the PPQ Treatment Manual as having been added or revised through the immediate process described in this paragraph (b). The PPQ Treatment Manual will indicate that these treatment schedules are subject to change or removal based on public comment. In our notice, we will provide for a public comment period on the new or revised treatment schedule or on the removal of the treatment schedule from the PPQ Treatment Manual.

(3) *Response to comments.* (i) APHIS will issue a notice after the close of the public comment period affirming the action described in the initial notice if:

(A) No comments were received on the notice;



(B) The comments on the notice supported our action; or

(C) The comments on the notice were evaluated but did not change our determination that it was necessary to add, revise, or remove the treatment schedule, as described in the notice.

(ii) If the notice issued after the close of the public comment period indicates that the initial change to the PPQ Treatment Manual is affirmed, APHIS will make available a new version of the PPQ Treatment Manual that will reflect the addition, revision, or removal of the particular treatment schedule in the main body of the PPQ Treatment Manual.

(iii) If comments present information that causes us to determine that it is necessary to change a treatment schedule added to the PPQ Treatment Manual under this process or to further revise a treatment schedule that was revised under this process, APHIS will publish a notice in the **Federal Register** informing the public of this determination after the close of the comment period and will revise the treatment schedule accordingly.

(iv) If comments present information that causes us to determine that the change described in the initial notice was not appropriate, APHIS will publish a notice in the **Federal Register** informing the public of this determination after the close of the comment period and will, if necessary, remove the new or revised treatment schedule from the separate section of the PPQ Treatment Manual.

#### **§ 305.4 Monitoring and certification of treatments.**

(a) All treatments approved under part 305 are subject to monitoring and verification by APHIS.

(b) Any treatment performed outside the United States must be monitored and certified by an inspector or an official authorized by APHIS. During the entire interval between treatment and export, the consignment must be stored and handled in a manner that prevents any infestation by pests and noxious weeds.

#### **§ 305.5 Chemical treatment requirements.**

(a) *Certified facility.* The fumigation treatment facility must be certified by APHIS. Facilities are required to be inspected and recertified annually, or as often as APHIS directs, depending upon treatments performed, commodities handled, and operations conducted at the facility. In order to be certified, a fumigation facility must:

(1) Be capable of administering the required dosage range for the required duration and at the appropriate

temperature, as specified in the treatment schedules in the PPQ Treatment Manual.

(2) Be adequate to contain the fumigant and be constructed from material that is not reactive to the fumigant.

(3) For vacuum fumigation facilities, be constructed to withstand required negative pressure.

(b) *Monitoring.* Treatment must be monitored by an official authorized by APHIS to ensure proper administration of the treatment, including that the correct amount of gas reaches the target organism and that an adequate number and placement of blowers, fans, sampling tubes, or monitoring lines are used in the treatment enclosure. An official authorized by APHIS approves, adjusts, or rejects the treatment.

(c) *Treatment procedures.* (1) To kill the pest, all chemical applications must be administered in accordance with an Environmental Protection Agency (EPA) approved pesticide label and the APHIS-approved treatment schedule prescribed in the PPQ Treatment Manual. If EPA cancels approval for the use of a pesticide on a commodity, then the treatment schedule prescribed in the PPQ Treatment Manual is no longer authorized for that commodity. If the commodity is not listed on the pesticide label and/or included in a Federal quarantine or crisis exemption in accordance with FIFRA section 18, then no chemical treatment is available.

(2) Temperature/concentration readings must be taken for items known to be sorptive or whose sorptive properties are unknown when treatment is administered in chambers at normal atmospheric pressure.

(3) Unless otherwise specified in the PPQ Treatment Manual, the volume of the commodity stacked inside the treatment enclosure must not exceed 2/3 of the volume of the enclosure. Stacking must be approved by an official authorized by APHIS before treatment begins. All commodities undergoing treatment must be listed on the label or authorized under Section 18 of FIFRA.

(4) Recording and measuring equipment must be adequate to accurately monitor the gas concentration, to ensure the correct amount of gas reaches the pests, and to detect any leaks in the enclosure. At least three sampling tubes or monitoring lines must be used in the treatment enclosure.

(5) An adequate number of blowers or fans must be used inside of the treatment enclosure to uniformly distribute gas throughout the enclosure. The circulation system must be able to

recirculate the entire volume of gas in the enclosure in 3 minutes or less.

(6) The exposure period begins after all gas has been introduced.

(7) For vacuum fumigation: The vacuum pump must be able to reduce pressure in the treatment enclosure to 1-2 inches of mercury in 15 minutes or less.

#### **§ 305.6 Cold treatment requirements.**

(a) *Certification of treatment facilities.* All facilities or locations used for refrigerating fruits or vegetables in accordance with the cold treatment schedules in the PPQ Treatment Manual must be certified by APHIS.

Recertification of the facility or carrier is required every 3 years, or as often as APHIS directs, depending on treatments performed, commodities handled, and operations conducted at the facility. In order to be certified, facilities and carriers must:

(1) Be capable of keeping treated and untreated fruits, vegetables, or other articles separate so as to prevent reinfestation of articles and spread of pests;

(2) Have equipment that is adequate to effectively perform cold treatment.

(b) *Places of treatment; ports of entry.* Precooling and refrigeration may be performed prior to, or upon arrival of fruits and vegetables in the United States, provided treatments are performed in accordance with applicable requirements of this section. Fruits and vegetables that are not treated prior to arrival in the United States must be treated after arrival only in cold storage warehouses approved by the Administrator and located in the area north of 39° latitude and east of 104° longitude or at one of the following ports: The maritime ports of Wilmington, NC; Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; and Hartsfield-Atlanta International Airport, Atlanta, GA.

(c) *Cold treatment enclosures.* All enclosures, in which cold treatment is performed, including refrigerated containers, must:

(1) Be capable of maintaining the treatment temperature specified in the PPQ Treatment Manual before the treatment begins and holding fruit at or below the treatment temperature during the treatment.

(2) Maintain fruit pulp temperatures according to treatment schedules with no more than a 0.39 °C (0.7 °F) variation in temperature between two consecutive hourly readings.

(3) Be structurally sound and adequate to maintain required temperatures.

(d) *Treatment procedures.* (1) All material, labor, and equipment for cold treatment performed on a vessel must be provided by the vessel or vessel agent. An official authorized by APHIS monitors, manages, and advises in order to ensure that the treatment procedures are followed.

(2) Refrigeration must be completed in the container, compartment, or room in which it is begun.

(3) Fruit that may be cold treated must be safeguarded to prevent cross-contamination or mixing with other infested fruit.

(4) Fruit intended for in-transit cold treatment must be precooled to the temperature at which the fruit will be treated prior to beginning treatment. The in-transit treatment enclosure may not be used for precooling unless an official authorized by APHIS approves the loading of the fruit in the treatment enclosure as adequate to allow for fruit pulp temperatures to be taken prior to beginning treatment. If the fruit is precooled outside the treatment enclosure, an official authorized by APHIS will take pulp temperatures manually from a sample of the fruit as the fruit is loaded for in-transit cold treatment to verify that precooling was completed. If the pulp temperatures for the sample are 0.28 °C (0.5 °F) or more above the temperature at which the fruit will be treated, the pallet from which the sample was taken will be rejected and returned for additional precooling until the fruit reaches the treatment temperature. If fruit is precooled in the treatment enclosure, or if treatment is conducted at a cold treatment facility in the United States, the fruit must be precooled to the temperature at which it will be treated, as verified by an official authorized by APHIS, prior to beginning treatment.

(5) Breaks, damage, etc., in the treatment enclosure that preclude maintaining correct temperatures must be repaired before the enclosure is used. An official authorized by APHIS must approve loading of compartment, number and placement of temperature probes or sensors, and initial fruit temperature readings before beginning the treatment. Hanging decks and hatch coamings within vessels may not be used as enclosures for in-transit cold treatment without prior written approval from APHIS. Double-stacking of pallets is not allowed.

(6) Only the same type of fruit in the same type of package may be treated together in a container; no mixture of fruits in containers may be treated. A numbered seal must be placed on the doors of the loaded container and may be removed only at the port of

destination by an official authorized by APHIS.

(7) Temperature recording devices used during treatment must be password-protected and tamperproof. The devices must be able to record the date, time, and sensor number and automatic and continuous records of the temperature during all calibrations and during treatment. Recording devices must be capable of generating temperature charts for verification by an inspector. If records of calibrations or treatments are found to have been manipulated, the vessel or container in which the treatment is performed may be suspended from conducting cold treatments until proper equipment is installed and an official authorized by APHIS has recertified it. APHIS' decision to recertify a vessel or container will take into account the severity of the infraction that led to suspension.

(8) A minimum of four temperature probes or sensors is required for vessel holds used as treatment enclosures. A minimum of three temperature probes or sensors is required for other treatment enclosures. An official authorized by APHIS will have the option to require that additional temperature probes or sensors be used, depending on the size of the treatment enclosure.

(9) Fruit pulp temperatures must be maintained at the temperature specified in the treatment schedule with no more than a 0.39 °C (0.7 °F) variation in temperature between two consecutive hourly readings. Failure to comply with this requirement will result in invalidation of the treatment unless an official authorized by APHIS can verify that the pulp temperature was maintained at or below the treatment temperature for the duration of the treatment.

(10) The time required to complete the treatment begins when all temperature probes reach the prescribed cold treatment schedule temperature. Refrigeration continues until the vessel arrives at the port of destination and the fruit is released for unloading by an inspector even though this may prolong the period required for the cold treatment.

(11) Temperatures must be recorded at intervals no longer than 1 hour apart. Gaps of longer than 1 hour will invalidate the treatment or indicate treatment failure unless an official authorized by APHIS can verify that the pulp temperature was maintained at or below the treatment temperature for the duration of the treatment.

(12) Cold treatment is not completed until so declared by an official

authorized by APHIS or the certifying official of the foreign country; consignments of treated commodities may not be discharged until APHIS clearance has been fully completed, including review and approval of treatment record charts.

(13) Cold treatment of fruits in break bulk vessels or containers must be initiated by an official authorized by APHIS if there is not a treatment technician who has been trained to initiate cold treatments for either break bulk vessels or containers.

(14) An official authorized by APHIS may perform audits to ensure that the treatment procedures comply with the regulations in this section and that the treatment is administered in accordance with the treatment schedules in the PPQ Treatment Manual. The official authorized by APHIS must be given the appropriate materials and access to the facility, container, or vessel necessary to perform the audits.

(15) An inspector will sample and cut fruit from each consignment cold treated for Mediterranean fruit fly (Medfly) to monitor treatment effectiveness. If a single live Medfly in any stage of development is found, the consignment will be held until an investigation is completed and appropriate remedial actions have been implemented. If APHIS determines at any time that the safeguards contained in this section do not appear to be effective against the Medfly, APHIS may suspend the importation of fruits from the originating country and conduct an investigation into the cause of the deficiency.

(16) The cold treatments required for the entry of fruit are considered necessary for the elimination of plant pests, and no liability shall attach to the U.S. Department of Agriculture or to any officer or representative of that Department in the event injury results to fruit offered for entry in accordance with these instructions. In prescribing cold treatments of certain fruits, it should be emphasized that inexactness and carelessness in applying the treatments may result in injury to the fruit or its rejection for entry.

(e) *Monitoring.* Treatment must be monitored by an inspector to ensure proper administration of the treatment. An inspector must also approve the recording devices and sensors used to monitor temperatures and conduct an operational check of the equipment before each use and ensure sensors are calibrated. An inspector may approve, adjust, or reject the treatment.

(f) *Compliance agreements.* Facilities located in the United States must operate under a compliance agreement

with APHIS. The compliance agreement must be signed by a representative of the cold treatment facility and APHIS. The compliance agreement must contain requirements for equipment, temperature, circulation, and other operational requirements for performing cold treatment to ensure that treatments are administered properly. Compliance agreements must allow officials of APHIS to inspect the facility to monitor compliance with the regulations.

(g) *Workplans.* Facilities located outside the United States may operate in accordance with a bilateral workplan. The workplan, if and when required, must be signed by a representative of the cold treatment facility, the national plant protection organization (NPPO) of the country of origin, and APHIS. The workplans must contain requirements for equipment, temperature, circulation, and other operational requirements for performing cold treatment to ensure that cold treatments are administered properly. Workplans for facilities outside the United States may also include trust fund agreement information regarding payment of the salaries and expenses of APHIS employees on site. Workplans must allow officials of the NPPO and APHIS to inspect the facility to monitor compliance with APHIS regulations.

(h) *Additional requirements for treatments performed after arrival in the United States.*

(1) *Maritime port of Wilmington, NC.* Consignments of fruit arriving at the maritime port of Wilmington, NC, for cold treatment, in addition to meeting all other applicable requirements of this section, must meet the following special conditions:

(i) Bulk consignments (those consignments which are stowed and unloaded by the case or bin) of fruit must arrive in fruit fly-proof packaging that prevents the escape of adult, larval, or pupal fruit flies.

(ii) Bulk and containerized consignments of fruit must be cold-treated within the area over which the U.S. Department of Homeland Security is assigned the authority to accept entries of merchandise, to collect duties, and to enforce the various provisions of the customs and navigation laws in force.

(iii) Advance reservations for cold treatment space must be made prior to the departure of a consignment from its port of origin.

(iv) The cold treatment facility must remain locked during non-working hours.

(2) *Maritime port of Seattle, WA.* Consignments of fruit arriving at the maritime port of Seattle, WA, for cold

treatment, in addition to meeting all other applicable requirements of this section, must meet the following special conditions:

(i) Bulk consignments (those consignments which are stowed and unloaded by the case or bin) of fruit must arrive in fruit fly-proof packaging that prevents the escape of adult, larval, or pupal fruit flies.

(ii) Bulk and containerized consignments of fruit must be cold treated within the area over which the U.S. Department of Homeland Security is assigned the authority to accept entries of merchandise, to collect duties, and to enforce the various provisions of the customs and navigation laws in force.

(iii) Advance reservations for cold treatment space must be made prior to the departure of a consignment from its port of origin.

(iv) The cold treatment facility must remain locked during non-working hours.

(v) Black light or sticky paper must be used within the cold treatment facility, and other trapping methods, including APHIS-approved fruit fly traps, must be used within the 4 square miles surrounding the cold treatment facility.

(vi) The cold treatment facility must have contingency plans, approved by the Administrator, for safely destroying or disposing of fruit.

(3) *Airports of Atlanta, GA, and Seattle, WA.* Consignments of fruit arriving at the airports of Atlanta, GA, and Seattle, WA, for cold treatment, in addition to meeting all other applicable requirements of this section, must meet the following special conditions:

(i) Bulk and containerized consignments of fruit must arrive in fruit fly-proof packaging that prevents the escape of adult, larval, or pupal fruit flies.

(ii) Bulk and containerized consignments of fruit arriving for cold treatment must be cold treated within the area over which the U.S. Department of Homeland Security is assigned the authority to accept entries of merchandise, to collect duties, and to enforce the various provisions of the customs and navigation laws in force.

(iii) The cold treatment facility and APHIS must agree in advance on the route by which consignments are allowed to move between the aircraft on which they arrived at the airport and the cold treatment facility. The movement of consignments from aircraft to a cold treatment facility will not be allowed until an acceptable route has been agreed upon.

(iv) Advance reservations for cold treatment space must be made prior to

the departure of a consignment from its port of origin.

(v) The cold treatment facility must remain locked during non-working hours.

(vi) Black light or sticky paper must be used within the cold treatment facility, and other trapping methods, including APHIS-approved fruit fly traps, must be used within the 4 square miles surrounding the cold treatment facility.

(vii) The cold treatment facility must have contingency plans, approved by the Administrator, for safely destroying or disposing of fruit.

(4) *Maritime ports of Gulfport, MS, and Corpus Christi, TX.* Consignments of fruit arriving at the ports of Gulfport, MS, and Corpus Christi, TX, for cold treatment, in addition to meeting all other applicable requirements of this section, must meet the following special conditions:

(i) All fruit entering the port for cold treatment must move in maritime containers. No bulk consignments (those consignments which are stowed and unloaded by the case or bin) are permitted.

(ii) Within the container, the fruit intended for cold treatment must be enclosed in fruit fly-proof packaging that prevents the escape of adult, larval, or pupal fruit flies.

(iii) All consignments of fruit arriving at the port for cold treatment must be cold treated within the area over which the U.S. Department of Homeland Security is assigned the authority to accept entries of merchandise, to collect duties, and to enforce the various provisions of the customs and navigation laws in force.

(iv) The cold treatment facility and APHIS must agree in advance on the route by which consignments are allowed to move between the vessel on which they arrived at the port and the cold treatment facility. The movement of consignments from vessel to cold treatment facility will not be allowed until an acceptable route has been agreed upon.

(v) Advance reservations for cold treatment space at the port must be made prior to the departure of a consignment from its port of origin.

(vi) Devanning, the unloading of fruit from containers into the cold treatment facility, must adhere to the following requirements:

(A) All containers must be unloaded within the cold treatment facility; and

(B) Untreated fruit may not be exposed to the outdoors under any circumstances.

(vii) The cold treatment facility must remain locked during non-working hours.

(viii) Black lights or sticky paper must be used within the cold treatment facility, and other trapping methods, including APHIS-approved fruit fly traps, must be used within the 4 square miles surrounding the cold treatment facility at the maritime port of Gulfport, MS, and within the 5 square miles surrounding the cold treatment facility at the maritime port of Corpus Christi, TX.

(ix) During cold treatment, a backup system must be available to cold treat the consignments of fruit should the primary system malfunction. The facility must also have one or more reefers (cold holding rooms) and methods of identifying lots of treated and untreated fruits.

(x) The cold treatment facility must have the ability to conduct methyl bromide fumigations on site.

(xi) The cold treatment facility must have contingency plans, approved by the Administrator, for safely destroying or disposing of fruit.

#### **§ 305.7 Quick freeze treatment requirements.**

Quick freeze treatment for fruits and vegetables imported into the United States or moved interstate from Hawaii or Puerto Rico must be conducted in accordance with §§ 319.56-12 or 318.13-13, respectively, of this chapter. The PPQ Treatment Manual indicates the fruits and vegetables for which quick freeze is an authorized treatment.

#### **§ 305.8 Heat treatment requirements.**

(a) *Certified facility.* The treatment facility must be certified by APHIS. Recertification is required annually, or as often as APHIS directs, depending upon treatments performed, commodities handled, and operations conducted at the facility. In order to be certified, a heat treatment facility must:

(1) Have equipment that is capable of adequately circulating air or water (as relevant to the treatment), changing the temperature, and maintaining the changed temperature sufficient to meet the treatment schedule parameters in the PPQ Treatment Manual.

(2) Have equipment used to record, monitor, or sense temperature, maintained in proper working order.

(3) Keep treated and untreated fruits, vegetables, or articles separate so as to prevent reinfestation and spread of pests.

(b) *Monitoring.* Treatment must be monitored by an official authorized by APHIS to ensure proper administration of the treatment. An official authorized

by APHIS approves, adjusts, or rejects the treatment.

(c) *Compliance agreements.* Facilities located in the United States must operate under a compliance agreement with APHIS. The compliance agreement must be signed by a representative of the heat treatment facilities located in the United States and APHIS. The compliance agreement must contain requirements for equipment, temperature, water quality, circulation, and other measures for performing heat treatments to ensure that treatments are administered properly. Compliance agreements must allow officials of APHIS to inspect the facility to monitor compliance with the regulations.

(d) *Workplans.* Facilities located outside the United States must operate in accordance with a workplan. The workplan must be signed by a representative of the heat treatment facilities located outside the United States, the national plant protection organization of the country of origin (NPPO), and APHIS. The workplan must contain requirements for equipment, temperature, water quality, circulation, and other measures to ensure that heat treatments are administered properly. Workplans for facilities outside the United States must include trust fund agreement information regarding payment of the salaries and expenses of APHIS employees on site. Workplans must allow officials of the NPPO and APHIS to inspect the facility to monitor compliance with APHIS regulations.

(e) *Treatment procedures.* (1) Before each treatment can begin, an official authorized by APHIS must approve the loading of the commodity in the treatment container.

(2) Sensor equipment must be adequate to monitor the treatment, its type and placement must be approved by an official authorized by APHIS, and the equipment must be tested by an official authorized by APHIS prior to beginning the treatment. Sensor equipment must be locked before each treatment to prevent tampering.

(3) Fruits, vegetables, or articles of substantially different sizes must be treated separately; oversized fruit may be rejected by an official authorized by APHIS.

(4) The treatment period begins when the temperature specified by the treatment schedule has been reached. An official authorized by APHIS may abort the treatment if the facility requires an unreasonably long time to achieve the required temperature.

#### **§ 305.9 Irradiation treatment requirements.**

Irradiation, carried out in accordance with the provisions of this section, is

approved as a treatment for any imported regulated article (i.e., fruits, vegetables, cut flowers, and foliage); for any regulated article moved interstate from Hawaii, Puerto Rico, the U.S. Virgin Islands, Guam, and the Commonwealth of the Northern Mariana Islands (referred to collectively, in this section, as Hawaii and U.S. territories); and for any berry, fruit, nut, or vegetable listed as a regulated article in § 301.32-2(a) of this chapter.

(a) *Location of facilities.* (1) Where certified irradiation facilities are available, an approved irradiation treatment may be conducted for any imported regulated article either prior to shipment to the United States or in the United States. For any regulated article moved interstate from Hawaii or U.S. territories, irradiation treatment may be conducted either prior to movement to the mainland United States or in the mainland United States. For articles that are imported or moved interstate from Hawaii or U.S. territories, irradiation facilities may be located in any State on the mainland United States except Alabama, Arizona, California, Florida, Kentucky, Louisiana, Nevada, New Mexico, South Carolina, Tennessee, Texas, and Virginia. In the States of Georgia, Mississippi, and North Carolina, irradiation facilities may only be located at the maritime ports of Gulfport, MS, or Wilmington, NC, or the airport of Atlanta, GA, and only if the following special conditions are met: The articles to be irradiated must be imported or moved interstate packaged in accordance with paragraph (f)(3) of this section; the irradiation facility and APHIS must agree in advance on the route by which shipments are allowed to move between the vessel on which they arrive and the irradiation facility; untreated articles may not be removed from their packaging prior to treatment under any circumstances; blacklight or sticky paper must be used within the irradiation facility, and other trapping methods, including APHIS-approved fruit fly traps, must be used within the 4 square miles surrounding the facility; and the facility must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles. Prior to treatment, the fruits and vegetables to be irradiated may not move into or through any of the States listed in this paragraph, except that movement is allowed through Dallas/Fort Worth, TX, as an authorized stop for air cargo, or as a transloading location for shipments that arrive by air but that are subsequently transloaded into trucks for overland movement from

Dallas/Fort Worth into an authorized State by the shortest route.

(2) For articles that are moved interstate from areas quarantined for fruit flies, irradiation facilities may be located either within or outside of the quarantined area. If the articles are treated outside the quarantined area, they must be accompanied to the facility by a limited permit issued in accordance with § 301.32-5(b) of this chapter and must be moved in accordance with any safeguards determined to be appropriate by APHIS.

(b) *Approved facilities.* The irradiation treatment facility must be approved by APHIS. In order to be approved, a facility must fulfill the requirements in paragraphs (c) and (d) of this section.

(c) *Compliance agreements.* (1) *Irradiation facilities treating imported articles.* (i) *Compliance agreements with importers and facility operators for irradiation in the United States.* If irradiation of imported articles is conducted in the United States, both the importer and the operator of the irradiation facility must sign compliance agreements with APHIS. In the facility compliance agreement, the facility operator must agree to comply with any additional requirements found necessary by APHIS to prevent the escape, prior to irradiation, of any pests of concern that may be associated with the articles to be irradiated. In the importer compliance agreement, the importer must agree to comply with any additional requirements found necessary by APHIS to ensure the shipment is not diverted to a destination other than an approved treatment facility and to prevent escape of plant pests from the articles to be irradiated during their transit from the port of first arrival to the irradiation facility in the United States.

(ii) *Compliance agreement with irradiation facilities outside the United States.* If irradiation of imported articles is conducted outside the United States, the operator of the irradiation facility must sign a compliance agreement with APHIS and the national plant protection organization (NPPO) of the country in which the facility is located. In this agreement, the facility operator must agree to comply with the requirements of this section, and the NPPO of the country in which the facility is located must agree to monitor that compliance and to inform the Administrator of any noncompliance.

(2) *Irradiation facilities treating articles moved interstate from Hawaii and U.S. territories.* Irradiation facilities treating articles moved interstate from Hawaii and U.S. territories must

complete a compliance agreement with APHIS as provided in § 318.13-3(d) of this chapter.

(3) *Irradiation facilities treating articles moved interstate from areas quarantined for fruit flies.* Irradiation facilities treating articles moved interstate from areas quarantined for fruit flies must complete a compliance agreement with APHIS as provided in § 301.32-6 of this chapter.

(d) *Certified facility.* The irradiation treatment facility must be certified by APHIS. Recertification is required in the event of an increase in the amount of radioisotope, a decrease in the amount of radioisotope for a reason other than natural decay, a major modification to equipment that affects the delivered dose, or a change in the owner or managing entity of the facility. Recertification also may be required in cases where a significant variance in dose delivery has been measured by the dosimetry system. In order to be certified, a facility must:

(1) Be capable of administering the minimum absorbed ionizing radiation doses specified in the PPQ Treatment Manual to the regulated articles;<sup>1</sup>

(2) Be constructed so as to provide physically separate locations for treated and untreated articles, except that articles traveling by conveyor directly into the irradiation chamber may pass through an area that would otherwise be separated. The locations must be separated by a permanent physical barrier such as a wall or chain link fence 6 or more feet high to prevent transfer of cartons, or some other means approved during certification to prevent reinfestation of articles and spread of pests.

(3) If the facility is to be used to treat imported articles and is located in the United States, the facility will only be certified if APHIS determines that regulated articles will be safely transported to the facility from the port of arrival without significant risk that plant pests will escape in transit or while the regulated articles are at the facility.

(e) *Monitoring and interagency agreements.* Treatment must be monitored by an inspector. This monitoring will include inspection of treatment records and unannounced inspections of the facility by an inspector, and may include inspection of articles prior to or after irradiation.

(1) *Irradiation facilities treating imported articles; irradiation treatment framework equivalency workplan.* The

NPPO of a country from which articles are to be imported into the United States in accordance with this section must sign a framework equivalency workplan with APHIS. In this plan, both the NPPO and APHIS will specify the following items for their respective countries:

(A) Citations for any requirements that apply to the importation of irradiated fruits and vegetables;

(B) The type and amount of inspection, monitoring, or other activities that will be required in connection with allowing the importation of irradiated fruits and vegetables into that country; and

(C) Any other conditions that must be met to allow the importation of irradiated fruits and vegetables into that country.

(2) *Irradiation facilities located in foreign countries.* Facilities in foreign countries that carry out irradiation operations must notify the Director of Preclearance, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737-1236, of scheduled operations at least 30 days before operations commence, except where otherwise provided in the facility preclearance workplan. To ensure the appropriate level of monitoring, before articles may be imported in accordance with this section, the following agreements must be signed, in addition to the irradiation treatment framework equivalency workplan required in paragraph (e)(1) of this section:

(i) *Facility preclearance workplan.* Prior to commencing importation into the United States of articles treated at a foreign irradiation facility, APHIS and the NPPO of the country from which articles are to be imported must jointly develop a preclearance workplan that details the activities that APHIS and the foreign NPPO will carry out in connection with each irradiation facility to verify the facility's compliance with the requirements of this section. Typical activities to be described in this workplan may include frequency of visits to the facility by APHIS and foreign plant protection inspectors, methods for reviewing facility records, and methods for verifying that facilities are in compliance with the requirements for separation of articles, packaging, labeling, and other requirements of this section. This facility preclearance workplan will be reviewed and renewed by APHIS and the foreign NPPO on an annual basis.

(ii) *Trust fund agreement.* Irradiated articles may be imported into the United States in accordance with this section only if the NPPO of the country in which the irradiation facility is located

<sup>1</sup> The maximum absorbed ionizing radiation dose and the irradiation of food is regulated by the Food and Drug Administration under 21 CFR part 179.

or a private export group has entered into a trust fund agreement with APHIS. That agreement requires the NPPO or the private export group to pay, in advance of each shipping season, all costs that APHIS estimates it will incur in providing inspection and treatment monitoring services at the irradiation facility during that shipping season. Those costs include administrative expenses and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by APHIS in performing these services. The agreement will describe the general nature and scope of APHIS services provided at irradiation facilities covered by the agreement, such as whether APHIS inspectors will monitor operations continuously or intermittently, and will generally describe the extent of inspections APHIS will perform on articles prior to and after irradiation. The agreement requires the NPPO or private export group to deposit a certified or cashier's check with APHIS for the amount of those costs, as estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the agreement further requires the NPPO or the private export group to deposit with APHIS a certified or cashier's check for the amount of the remaining costs, as determined by APHIS, before any more articles irradiated in that country may be imported into the United States. After a final audit at the conclusion of each shipping season, any overpayment of funds would be returned to the NPPO or the private export group or held on account until needed, at the option of the NPPO or the private export group.

(3) *Irradiation facilities located within the United States.* Facilities located within the United States must notify an inspector at least 24 hours (excluding Saturday, Sunday, and Federal holidays) before scheduled operations.<sup>2</sup> If the facility will be used to treat imported articles, the NPPO of the country from which the articles are to be imported into the United States in accordance with this section must also sign the irradiation treatment framework equivalency workplan required in paragraph (e)(1) of this section.

(f) *Packaging.* Articles that are irradiated in accordance with this section must be packaged in cartons in the following manner:

(1) Irradiated articles may not be packaged for shipment in a carton with nonirradiated articles.

(2) For all imported articles irradiated prior to arrival in the United States, all articles moved interstate from Hawaii or U.S. territories and irradiated prior to arrival in the mainland United States, and all regulated articles to be moved interstate from an area quarantined for fruit flies that are treated within the quarantined area:

(i) The fruits and vegetables must be packaged either:

(A) In insect-proof cartons that have no openings that will allow the entry of the pests of concern. The cartons must be sealed with seals that will visually indicate if the cartons have been opened. The cartons may be constructed of any material that prevents entry or oviposition (if applicable) by the pests of concern into the articles in the carton;<sup>3</sup> or

(B) In noninsect-proof cartons that are stored immediately after irradiation in a room completely enclosed by walls or screening that completely precludes access by the pests of concern. If stored in noninsect-proof cartons in a room that precludes access by the pests of concern, prior to leaving the room, each pallet of cartons must be completely enclosed in polyethylene shrink wrap, or another solid or netting covering that completely precludes access to the cartons by the pests of concern.

(ii) To preserve the integrity of treated lots, each pallet-load of cartons containing the fruits and vegetables must be secured before leaving the irradiation facility in one of the following ways:

(A) With polyethylene shrink wrap;

(B) With net wrapping; or

(C) With strapping.

(iii) Packaging must be labeled in a manner that allows an inspector to determine treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment.

(A) For imported articles that are treated prior to arrival in the United States, pallets that remain intact as one unit until entry into the United States may have one such label per pallet. Pallets that are broken apart into smaller units prior to or during entry into the United States, or that will be broken apart into smaller units after entry into the United States, must have the

required label information on each individual carton.

(B) For articles moved interstate from Hawaii or U.S. territories that are treated prior to arrival in the mainland United States, pallets that remain intact as one unit until entry into the mainland United States may have one such label per pallet. Pallets that are broken apart into smaller units prior to or during entry into the mainland United States, or that will be broken apart into smaller units after entry into the mainland United States, must have the required label information on each individual carton.

(3) For all articles imported to be irradiated upon arrival in the United States, moved interstate from Hawaii or U.S. territories to be irradiated upon arrival in the mainland United States, or moved interstate from areas quarantined for fruit flies to be irradiated outside the quarantined area, the articles must be packed in cartons that have no openings that will allow the exit of the pests of concern and that are sealed with seals that will visually indicate if the cartons have been opened. They may be constructed of any material that prevents the pests of concern from exiting the carton. Cartons of untreated articles must be shipped in shipping containers sealed prior to their shipment with seals that will visually indicate if the shipping containers have been opened.

(g) *Containers or vans.* Containers or vans that will transport treated articles must be free of pests of concern prior to loading the treated articles.

(h) *Certification of treatment for articles treated outside the United States.* For each consignment treated in an irradiation facility outside the United States, a phytosanitary certificate, with the treatment section completed and issued by the NPPO, must accompany the consignment.

(i) *Dosage.* The regulated articles must receive the minimum absorbed ionizing radiation dose specified in the PPQ Treatment Manual.

(j) *Dosimetry systems at the irradiation facility.* (1) Dosimetry must indicate the doses needed to ensure that all the articles will receive the minimum dose prescribed.

(2) The absorbed dose, as measured using an accurate dosimetry system, must meet or exceed the absorbed dose for the pest(s) of concern required by the PPQ Treatment Manual.

(3) When designing the facility's dosimetry system and procedures for its operation, the facility operator must address guidance and principles from the International Standards Organization/American Society for

<sup>3</sup> If there is a question as to the adequacy of a carton, send a request for approval of the carton, together with a sample carton, to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Center for Plant Health Inspection and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606-5202.

<sup>2</sup> Inspectors are assigned to local offices of the Animal and Plant Health Inspection Service, which are listed in telephone directories.

Testing and Materials standard<sup>4</sup> or an equivalent standard recognized by APHIS.

(k) *Records.* An irradiation processor must maintain records of each treated lot for 1 year following the treatment date, and must make these records available for inspection by an inspector during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, except holidays). These records must include the lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

(l) *Request for initial certification and inspection of facility.* Persons requesting initial certification of an irradiation treatment facility must submit the request for approval in writing to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Center for Plant Health Inspection and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606-5202. The initial request must identify the owner, location, and radiation source of the facility, and the applicant must supply additional information about the facility construction, treatment protocols, and operations upon request by APHIS if APHIS requires additional information to evaluate the request. Before the Administrator determines whether an irradiation facility is eligible for certification, an inspector will make a personal inspection of the facility to determine whether it complies with the standards of this section.

(m) *Denial and withdrawal of certification.* (1) The Administrator will

withdraw the certification of any irradiation treatment facility upon written request from the irradiation processor.

(2) The Administrator will deny or withdraw certification of an irradiation treatment facility when any provision of this section is not met. Before withdrawing or denying certification, the Administrator will inform the irradiation processor in writing of the reasons for the proposed action and provide the irradiation processor with an opportunity to respond. The Administrator will give the irradiation processor an opportunity for a hearing regarding any dispute of a material fact, in accordance with rules of practice that will be adopted for the proceeding. However, the Administrator will suspend certification pending final determination in the proceeding if he or she determines that suspension is necessary to prevent the spread of any dangerous insect. The suspension will be effective upon oral or written notification, whichever is earlier, to the irradiation processor. In the event of oral notification, written confirmation will be given to the irradiation processor within 10 days of the oral notification. The suspension will continue in effect pending completion of the proceeding and any judicial review of the proceeding.

(n) *Department not responsible for damage.* This treatment is approved to assure quarantine security against the plant pests listed in the PPQ Treatment Manual. From the literature available, the articles authorized for treatment under this section are believed tolerant to the treatment; however, the facility operator and shipper are responsible for

determination of tolerance. The Department of Agriculture and its inspectors assume no responsibility for any loss or damage resulting from any treatment prescribed or monitored. Additionally, the Nuclear Regulatory Commission is responsible for ensuring that irradiation facilities are constructed and operated in a safe manner. Further, the Food and Drug Administration is responsible for ensuring that irradiated foods are safe and wholesome for human consumption.

(Approved by the Office of Management and Budget under control numbers 0579-0155, 0579-0215, and 0579-0198)

**PART 318—STATE OF HAWAII AND TERRITORIES QUARANTINE NOTICES**

■ 25. The authority citation for part 318 continues to read as follows:

**Authority:** 7 U.S.C. 7701-7772 and 7781-7786; 7 CFR 2.22, 2.80, and 371.3.

**§ 318.13-3 [Amended]**

■ 26. In § 318.13-3, paragraph (b)(2) is amended by removing the words “approved in” and adding the words “approved under” in their place.

■ 27. Section 318.13-16 is amended as follows:

■ a. In the table in paragraph (a), by adding, under Hawaii, new entries for litchi and longan in alphabetical order to read as set forth below.

■ b. By adding a new paragraph (b)(1)(ii) to read as set forth below.

**§ 318.13-16 Regulated articles allowed interstate movement subject to specified conditions.**

(a) \* \* \*

State, territory, or district of origin	Common name	Botanical name	Plant part(s)	Additional requirements
Hawaii				
*	*	*	*	*
	Litchi	<i>Litchi chinensis</i>	Fruit	(b)(1)(ii), (b)(3)(ii)
	Longan	<i>Dimocarpus longan</i>	Fruit	(b)(1)(ii), (b)(3)(ii)
*	*	*	*	*

(b) \* \* \*

(1) \* \* \*

(ii) May not be moved interstate into Florida. Cartons must be stamped “Not for movement into or distribution in FL.”

\* \* \* \* \*

■ 28. Section 318.13-22 is amended by revising paragraphs (b)(1) and (b)(2) to read as follows:

**§ 318.13-22 Bananas from Hawaii.**

\* \* \* \* \*

(b) \* \* \*

(1) The bananas are irradiated in accordance with part 305 of this chapter for the Mediterranean fruit fly (*Ceratitis capitata*), the melon fruit fly (*Bactrocera curcurbitae*), the Oriental fruit fly (*Bactrocera dorsalis*), and the green scale (*Coccus viridis*) and are inspected,

<sup>4</sup> Designation ISO/ASTM 51261-2002(E), “Standard Guide for Selection and Calibration of

Dosimetry Systems for Radiation Processing,”

American Society for Testing and Materials, *Annual Book of ASTM Standards*.



after removal from the stalk, in Hawaii and found to be free of the banana moth (*Opogona sacchari* (Bojen)) by an inspector before or after undergoing irradiation treatment; or

(2) The bananas are irradiated in accordance with part 305 of this chapter for the Mediterranean fruit fly (*Ceratitidis capitata*), the melon fruit fly (*Bactrocera curcurbitae*), and the Oriental fruit fly (*Bactrocera dorsalis*) and are inspected, after removal from the stalk, in Hawaii and found to be free of the green scale (*Coccus viridis*) and the banana moth (*Opogona sacchari* (Bojen)) before or after undergoing irradiation treatment.

\* \* \* \* \*

■ 29. Section 318.13-25 is revised to read as follows:

**§ 318.13-25 Sweetpotatoes from Hawaii.**

Sweetpotatoes may be moved interstate from Hawaii in accordance with this section only if the sweetpotatoes meet the conditions in paragraph (a) or paragraph (b) of this section or if the sweetpotatoes are fumigated with methyl bromide in accordance with part 305 of this chapter.

(a) *Vapor heat treatment and inspection.* (1) The sweetpotatoes must be treated with vapor heat in accordance with part 305 of this chapter.

(2) The sweetpotatoes must be sampled, cut, and inspected and found to be free of the ginger weevil (*Elytrotreinus subtruncatus*). Sampling, cutting, and inspection must be performed under conditions that will prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with this section.

(3) The sweetpotatoes must be inspected and found to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*) and the Kona coffee-root knot nematode (*Meloidogyne konaensis*).

(4)(i) Sweetpotatoes that are treated in Hawaii must be packaged in the following manner:

(A) The cartons must have no openings that will allow the entry of the pests of concern and must be sealed with seals that will visually indicate if the cartons have been opened. They may be constructed of any material that prevents the entry of the pests of concern.<sup>5</sup>

(B) The pallet-load of cartons must be secured before it leaves the treatment facility in one of the following ways:

- (1) With polyethylene sheet wrap;
- (2) With net wrapping; or
- (3) With strapping.

(C) Packaging must be labeled in a manner that allows an inspector to determine treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment.

(ii) Cartons of untreated sweetpotatoes that are moving to the mainland United States for treatment must be shipped in shipping containers sealed prior to interstate movement with seals that will visually indicate if the shipping containers have been opened.

(5)(i) *Certification on basis of treatment.* Certification shall be issued by an inspector for the movement of sweetpotatoes from Hawaii that have been treated in accordance with part 305 of this chapter and handled in Hawaii in accordance with this section.

(ii) *Limited permit.* A limited permit shall be issued by an inspector for the interstate movement of untreated sweetpotato from Hawaii for treatment on the mainland United States in accordance with this section.

(b) *Irradiation treatment and inspection.* (1) The sweetpotatoes must be treated with irradiation in accordance with part 305 of this chapter.

(2) Sweetpotatoes that are not treated with an irradiation dose approved to neutralize the ginger weevil (*Elytrotreinus subtruncatus*) must be sampled, cut, and inspected and found to be free of the ginger weevil by an inspector in Hawaii. Sampling, cutting, and inspection must be performed under conditions that will prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with this section.

(3)(i) To be certified for interstate movement under this paragraph, sweetpotato from Hawaii must be inspected in Hawaii and found free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*) and the Kona coffee-root knot nematode (*Meloidogyne konaensis*) by an inspector before undergoing irradiation treatment in Hawaii.

(ii) To be eligible for a limited permit under this section, untreated sweetpotato from Hawaii must be inspected in Hawaii and found free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*) and the Kona coffee-root knot nematode

(*Meloidogyne konaensis*) by an inspector.

(Approved by the Office of Management and Budget under control number 0579-0281)

■ 30. A new § 318.13-26 is added to read as follows:

**§ 318.13-26 Breadfruit, jackfruit, fresh pods of cowpea, dragon fruit, mangosteen, and moringa pods from Hawaii.**

(a) *Breadfruit and jackfruit.* (1) To be eligible for interstate movement, breadfruit and jackfruit from Hawaii must be treated with irradiation in accordance with part 305 of this chapter.

(2) To be certified for interstate movement, breadfruit and jackfruit from Hawaii must be inspected in Hawaii and found free of spiraling whitefly (*Aleurodicus dispersus*), inornate scale (*Aonidiella inornata*), red wax scale (*Ceroplastes rubens*), green scale (*Coccus viridis*), gray pineapple mealybug (*Dysmicoccus neobrevipes*), pink hibiscus mealybug (*Maconellicoccus hirsutus*), spherical mealybug (*Nipaecoccus viridis*), citrus mealybug (*Pseudococcus cryptus*), melon thrips (*Thrips palmi*), and signs of thrip damage before undergoing irradiation treatment in Hawaii at a dose approved to neutralize fruit flies. Fruit treated for fruit flies also must either receive a post-harvest dip in accordance with part 305 of this chapter to treat external feeders or originate from an orchard or growing area that was previously treated with a broad-spectrum insecticide during the growing season and a pre-harvest inspection of the orchard or growing area found the fruit free of any surface pests as prescribed in a compliance agreement. Post-treatment inspection in Hawaii is not required if the fruit undergoes irradiation treatment at a dose approved to neutralize all plant pests of the class *Insecta*, except pupae and adults of the order Lepidoptera. Regardless of irradiation dose, the fruit must be free of stems and leaves and must originate from an orchard that was previously treated with a fungicide appropriate for the fungus *Phytophthora tropicalis* during the growing season and the fruit must be inspected prior to harvest and found free of the fungus or, after irradiation treatment, must receive a post-harvest fungicidal dip appropriate for *Phytophthora tropicalis*.

(3) To be eligible for a limited permit, breadfruit and jackfruit from Hawaii must be free of stems and leaves and must originate from an orchard that was previously treated with a fungicide appropriate for the fungus *Phytophthora tropicalis* during the growing season

<sup>5</sup> If there is a question as to the adequacy of a carton, send a request for approval of the carton, together with a sample carton, to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Center for Plant Health Science and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606.

and the fruit must be inspected prior to harvest and found free of the fungus or, after irradiation treatment, must receive a post-harvest fungicidal dip appropriate for *Phytophthora tropicalis*.

(b) *Fresh pods of cowpea*. (1) To be eligible for interstate movement, fresh pods of cowpea and its relatives from Hawaii must be treated with irradiation in accordance with part 305 of this chapter.

(2) To be certified for interstate movement, fresh pods of cowpea and its relatives from Hawaii must be inspected in Hawaii and found free of the cassava red mite (*Oligonychus biharensis*) and adults and pupae of the order Lepidoptera before undergoing irradiation treatment. The pods must be free of stems and leaves.

(3) To be eligible for a limited permit, fresh pods of cowpea and its relatives from Hawaii must be free of stems and leaves and must be inspected in Hawaii and found free of the cassava red mite (*Oligonychus biharensis*) and adults and pupae of the order Lepidoptera.

(c) *Dragon fruit*. To be certified for interstate movement, dragon fruit from Hawaii presented for inspection must have the sepals removed and must be inspected in Hawaii and found free of gray pineapple mealybug (*Dysmicoccus neobrevipes*), pink hibiscus mealybug (*Maconellicoccus hirsutus*), and citrus mealybug (*Pseudococcus cryptus*) before undergoing irradiation treatment in Hawaii at a dose approved to neutralize fruit flies. Fruit treated for fruit flies also must either receive a post-harvest dip in accordance with part 305 of this chapter to treat external feeders or originate from an orchard or growing area that was previously treated with a broad-spectrum insecticide during the growing season and a pre-harvest inspection of the orchard or growing area found the fruit free of any surface pests as prescribed in a compliance agreement. Post-treatment inspection in Hawaii is not required if the fruit undergoes irradiation treatment at a dose approved to neutralize all plant pests of the class *Insecta*, except pupae and adults of the order Lepidoptera. Regardless of irradiation dose, the fruit must be free of stems and leaves.

(d) *Mangosteen*. To be certified for interstate movement, mangosteen from Hawaii must have the sepals removed and must be inspected in Hawaii and found free of gray pineapple mealybug (*Dysmicoccus neobrevipes*), pink hibiscus mealybug (*Maconellicoccus hirsutus*), citrus mealybug (*Pseudococcus cryptus*), and *Thrips floridum* before undergoing irradiation treatment in Hawaii at a dose approved to neutralize fruit flies. Fruit treated for

fruit flies also must either receive a post-harvest dip in accordance with part 305 of this chapter to treat external feeders or originate from an orchard or growing area that was previously treated with a broad-spectrum insecticide during the growing season and a pre-harvest inspection of the orchard or growing area found the fruit free of any surface pests as prescribed in a compliance agreement. Post-treatment inspection in Hawaii is not required if the fruit undergoes irradiation treatment at a dose approved to neutralize all plant pests of the class *Insecta*, except pupae and adults of the order Lepidoptera. Regardless of irradiation dose, the fruit must be free of stems and leaves.

(e) *Melon*. To be certified for interstate movement, melon from Hawaii must be inspected in Hawaii and found free of spiraling whitefly (*Aleurodicus dispersus*) before undergoing irradiation treatment in Hawaii at a dose approved to neutralize fruit flies. Fruit treated for fruit flies also must either receive a post-harvest dip in accordance with part 305 of this chapter to treat external feeders or originate from an orchard or growing area that was previously treated with a broad-spectrum insecticide during the growing season and a pre-harvest inspection of the orchard or growing area found the fruit free of any surface pests as prescribed in a compliance agreement. Post-treatment inspection in Hawaii is not required if the fruit undergoes irradiation treatment at a dose approved to neutralize all plant pests of the class *Insecta*, except pupae and adults of the order Lepidoptera. Regardless of irradiation dose, melons must be washed to remove dirt and must be free of stems and leaves.

(f) *Moringa pods*. To be certified for interstate movement, moringa pods from Hawaii must be inspected in Hawaii and found free of spiraling whitefly (*Aleurodicus dispersus*), inornate scale (*Aonidiella inornata*), green scale (*Coccus viridis*), and citrus mealybug (*Pseudococcus cryptus*) before undergoing irradiation treatment in Hawaii at a dose approved to neutralize fruit flies. Fruit treated for fruit flies also must either receive a post-harvest dip in accordance with part 305 of this chapter to treat external feeders or originate from an orchard or growing area that was previously treated with a broad-spectrum insecticide during the growing season and a pre-harvest inspection of the orchard or growing area found the fruit free of any surface pests as prescribed in a compliance agreement. Post-treatment inspection in Hawaii is not required if the fruit undergoes

irradiation treatment at a dose approved to neutralize all plant pests of the class *Insecta*, except pupae and adults of the order Lepidoptera.

#### § 318.47-3 [Amended]

■ 31. In § 318.47-3, paragraph (a) is amended by adding the words “in accordance with part 305 of this chapter” after the word “origin”.

#### PART 319—FOREIGN QUARANTINE NOTICES

■ 32. 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.

■ 33. In § 319.8-23, paragraph (a)(1) is revised to read as follows:

#### § 319.8-23 Treatment.

(a)(1) Vacuum fumigation as required in this subpart must be conducted in accordance with part 305 of this chapter.

\* \* \* \* \*

#### § 319.28 [Amended]

■ 34. Section 319.28 is amended as follows:

■ a. In paragraph (b)(5), by adding the words “treated in accordance with part 305 of this chapter” after the words “fumigated with methyl bromide”; and by removing the second sentence.

■ b. In paragraphs (b)(7)(i) and (b)(7)(ii), by removing the words “paragraph (b)(5) of this section” and adding the words “part 305 of this chapter” in their place.

#### § 319.37-13 [Amended]

■ 35. In § 319.37-13, paragraph (c) is amended by removing the words “the Plant Protection and Quarantine Treatment Manual” and adding the words “7 CFR part 305” in their place.

■ 36. In § 319.40-3, paragraph (b)(1) is revised to read as follows:

#### § 319.40-3 General permits; articles that may be imported without a specific permit; articles that may be imported without either a specific permit or an importer document.

\* \* \* \* \*

(b) \* \* \*

(1) The wood packaging material must have been treated in accordance with part 305 of this chapter.

\* \* \* \* \*

■ 37. Section 319.40-5 is amended as follows:

■ a. In paragraph (b)(1)(i)(C), by removing the citation “§ 319.40-7(f)(1)” and adding the words “part 305 of this chapter” in its place.

■ b. In paragraph (b)(1)(i)(D), by removing the citation “§ 319.40-7(d)”

and adding the words “part 305 of this chapter” in its place.

■ c. In paragraph (b)(1)(iii)(A), by removing the citations “§ 319.40-7(c)” and “§ 319.40-7(d)” and adding the words “part 305 of this chapter” in their place.

■ d. In paragraph (b)(1)(iii)(C), by removing the citations “§ 319.40-7(c)”, “§ 319.40-7(d)”, and “§ 319.40-7(f)(3)” each time they occur and adding the words “part 305 of this chapter” in their place.

■ e. In paragraph (b)(2)(i), by removing the citation “§ 319.40-7(f)(2)” and adding the words “part 305 of this chapter” in its place.

■ f. In paragraph (b)(2)(ii), by removing the citations “§ 319.40-7(c)” and “§ 319.40-7(d)” and adding the words “part 305 of this chapter” in their place.

■ g. In paragraph (c)(2), by removing the citation “§ 319.40-7(f)(1)” and adding the words “part 305 of this chapter” in its place.

■ h. In paragraph (d), by removing the citation “§ 319.40-7(f)” and adding the words “part 305 of this chapter” in its place.

■ i. In paragraph (f), by removing the citation “§ 319.40-7(c)” and adding the words “part 305 of this chapter” in its place.

■ j. By revising paragraph (l)(3) to read as set forth below.

■ k. In paragraph (m)(2)(iv)(A)(1), by removing the citation “319.40-7(f)” and adding the words “part 305” in its place.

■ l. In paragraph (m)(2)(iv)(A)(4), by removing the citation “§ 319.40-6” and adding the words “7 CFR part 305” in its place.

■ m. In paragraph (n)(1)(ii), by removing the citation “§ 319.40-7(c)” and adding the words “part 305 of this chapter” in its place.

**§ 319.40-5 Importation and entry requirements for specific articles.**

\* \* \* \* \*

(1) \* \* \*

(3) Are fumigated in accordance with part 305 of this chapter prior to arrival in the United States.

\* \* \* \* \*

**§ 319.40-6 [Amended]**

■ 38. Section 319.40-6 is amended as follows:

■ a. In paragraph (a), by removing the citation “§ 319.40-7(c)” and adding the words “part 305 of this chapter” in their place.

■ b. In paragraphs (b)(1) introductory text, (b)(1)(i), (b)(1)(ii), (b)(2)(ii), (c)(2)(i)(B), (c)(2)(iii), (c)(2)(iv), and (d), by removing the citation “§ 319.40-7(c)” each time it occurs and adding the words “part 305 of this chapter” in its

place; and by removing the citation “§ 319.40-7(d)” each time it occurs and adding the words “part 305 of this chapter” in its place.

■ c. In paragraph (c)(1)(i)(A), by removing the citation “§ 319.40-7(e)” each time it occurs and adding the words “part 305 of this chapter” in its place.

■ d. In paragraphs (c)(2)(i)(B), (c)(2)(iii), (c)(2)(iv), and (d), by removing the citation “§ 319.40-7(f)(3)” each time it occurs and adding the words “part 305 of this chapter” in its place.

■ 39. Section 319.40-7 is amended as follows:

■ a. By removing paragraphs (c) through (f).

■ b. By adding a new paragraph (c) to read as set forth below.

■ c. By redesignating paragraph (g) as paragraph (d).

**§ 319.40-7 Treatments and safeguards.**

\* \* \* \* \*

(c) *Treatments.* Treatment of regulated articles under this subpart must be conducted in accordance with part 305 of this chapter.

\* \* \* \* \*

**§ 319.41-5 [Amended]**

■ 40. Section 319.41-5 is amended as follows:

■ a. In paragraph (a), second sentence, by removing the words “other necessary”; and by adding the words “in accordance with part 305 of this chapter,” after the word “treatment”.

■ b. In paragraph (a), third sentence, by adding the words “in accordance with part 305 of this chapter” after the word “treatment”.

■ c. In paragraphs (b), (c), (d)(1), and (d)(3), by adding the words “in accordance with part 305 of this chapter” after the words “other treatment” each time they occur.

**§ 319.41-5a [Removed]**

■ 41. Section 319.41-5a is removed.

**§ 319.55-6 [Amended]**

■ 42. Section 319.55-6 is amended as follows:

■ a. In paragraph (a), in the first sentence, by adding the words “in accordance with part 305 of this chapter” after the word “disinfection”; and in the second sentence, by adding the words “in accordance with part 305 of this chapter” after the word “treatment”.

■ b. In paragraph (b)(1), in the first sentence, by adding the words “in accordance with part 305 of this chapter” after the word “treatment.”

**§ 319.56-3 [Amended]**

■ 43. In § 319.56-3, paragraph (c)(2) is amended by removing the citation “§ 305.15” and adding the words “part 305” in its place.

**§ 319.56-7 [Amended]**

■ 44. In § 319.56-7, paragraph (b)(1)(ii) is amended by removing the words “with an approved treatment listed in” and adding the words “in accordance with” in their place.

**§ 319.56-11 [Amended]**

■ 45. In § 319.56-11, paragraph (b)(1) is amended by removing the words “with an approved treatment listed in” and adding the words “in accordance with” in their place.

**§ 319.56-12 [Amended]**

■ 46. Section 319.56-12 is amended by removing in the second sentence the words “at a temperature not higher than 20 °F during shipping and upon arrival in the United States, and”; and by removing the third sentence.

**§ 319.56-13 [Amended]**

■ 47. Section 319.56-13 is amended as follows:

■ a. In paragraph (b)(1)(ii), by removing the words “an approved treatment listed in”.

■ b. In paragraphs (b)(5)(xiii) and (b)(5)(xv), by removing the words “with an approved treatment listed in 7 CFR” and adding the words “in accordance with” in their place; and by adding the words “of this chapter” after the words “part 305”.

**§ 319.56-21 [Amended]**

■ 48. In § 319.56-21, paragraphs (b)(2) and (d)(2) are amended by removing the words “an approved treatment listed in”.

■ 49. In § 319.56-22, paragraph (g)(2) is revised to read as follows:

**§ 319.56-22 Apples and pears from certain countries in Europe.**

\* \* \* \* \*

(g) \* \* \*

(2) Treatments must be conducted in accordance with part 305 of this chapter.

\* \* \* \* \*

■ 50. Section 319.56-23 is amended as follows:

■ a. In footnote 3, by removing the words “a treatment listed in”.

■ b. By revising paragraph (f)(2) to read as set forth below.

**§ 319.56-23 Apricots, nectarines, peaches, plumcot, and plums from Chile.**

\* \* \* \* \*

(f) \* \* \*

(2) Treatments must be conducted in accordance with part 305 of this chapter.

\* \* \* \* \*

**§ 319.56-38 [Amended]**

■ 51. In § 319.56-38, paragraph (d)(4)(ii)(B) is amended by removing the words “an authorized treatment for the pest is available in” and adding the words “a treatment for the pest is authorized by” in their place.

**§ 319.56-46 [Amended]**

■ 52. In § 319.56-46, paragraph (a) is amended by removing the words “by receiving a minimum absorbed dose of 400 Gy” and adding the words “for plant pests of the class Insecta, except pupae and adults of the order Lepidoptera” in their place; and by removing the citation “§ 305.31” and adding the words “part 305” in its place.

**§ 319.56-47 [Amended]**

■ 53. Section 319.56-47 is amended as follows:  
 ■ a. In paragraph (b), by removing the citation “§ 305.31” and adding the words “part 305” in its place.  
 ■ b. In paragraph (d), by removing the citation “§ 305.31” and adding the words “part 305 of this chapter” in its place.  
 ■ 54. In § 319.59-4, paragraph (d)(3) is revised to read as follows:

**§ 319.59-4 Karnal bunt.**

\* \* \* \* \*

(d) \* \* \*

(3) Items that require disinfection prior to entry into the United States must be disinfected in accordance with part 305 of this chapter.

\* \* \* \* \*

■ 55. Section 319.74-2 is amended as follows:

■ a. By redesignating the introductory text to paragraph (c)(1) as the introductory text to paragraph (c); removing paragraph (c)(2); and redesignating paragraphs (c)(1)(i) and (c)(1)(ii) as paragraphs (c)(1) and (c)(2), respectively.

■ b. In the newly redesignated introductory text of paragraph (c), by removing the words “paragraph (c)(2) of this section” and adding the words “part 305 of this chapter” in their place.

■ c. By revising the first two sentences of paragraph (e) to read as set forth below.

**§ 319.74-2 Conditions governing the entry of cut flowers.**

\* \* \* \* \*

(e) *Irradiation.* Cut flowers and foliage that are required under this part to be treated or subjected to inspection to control one or more of the plant pests for which irradiation is an approved treatment under part 305 of this chapter may instead be treated with irradiation. Irradiation treatment must be conducted in accordance with the requirements of part 305 of this chapter. \* \* \*

\* \* \* \* \*

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

■ 56. The authority citation for part 330 continues to read as follows:

**Authority:** 7 U.S.C. 450, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

**§ 330.106 [Amended]**

■ 57. In § 330.106, paragraph (a) is amended by adding in the fourth sentence the words “in accordance with part 305 of this chapter” after the word “treatment.”

**§ 330.300 [Amended]**

■ 58. In § 330.300, paragraph (a) is amended by removing the words “methods of” and by adding the words “in accordance with part 305 of this chapter” after the word “treatment.”

**PART 352—PLANT QUARANTINE SAFEGUARD REGULATIONS**

■ 59. The authority citation for part 352 continues to read as follows:

**Authority:** 7 U.S.C. 7701-7772 and 7781-7786; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

**§ 352.10 [Amended]**

■ 60. In § 352.10, paragraph (b)(2)(viii) is amended by adding the words “in accordance with part 305 of this chapter” after the word “treatment.”

**§ 352.30 [Amended]**

■ 61. In § 352.30, paragraph (a)(4)(iii) is amended by removing the word “such” and by adding the word “any” in its place; and by adding the words “in accordance with part 305 of this chapter” after the word “treatment.”

Done in Washington, DC, January 19, 2010.

**Kevin Shea**

*Acting Administrator, Animal and Plant Health Inspection Service.*

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