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approved PCR or other molecular test must be conducted, as provided in paragraph (b)(1) of this section.

(1) *PCR or other molecular tests*—(i) *Negative results.* If the results of PCR or other molecular tests are negative for all samples in a nursery, no further testing is required. The nursery may be considered free of evidence of *Phytophthora ramorum* and plants in the nursery are eligible for interstate movement under certificate in accordance with §301.92–5.

(ii) *Positive results.* If any samples tested using PCR or other molecular tests return positive results for *Phytophthora ramorum*, the nursery from which they originate is prohibited from moving plants interstate. The nursery will be eligible to ship certain plants interstate when an inspector determines that those plants are free of evidence of *Phytophthora ramorum.*

(2) *Culture Test*—(i) *Negative results.* If the results of culture tests are other than positive for any samples taken from a single nursery, plants in the nursery must continue to be withheld from shipment in accordance with §301.92–11 and each plant sample must be tested again using a PCR or other molecular test, as described in this section.

(ii) *Positive results.* If any culture tests return positive results for *Phytophthora ramorum*, the nursery from which they originate is prohibited from moving plants interstate as directed by an inspector. The nursery will be eligible to ship certain plants interstate when an inspector determines that those plants are free of evidence of *Phytophthora ramorum.*

(c) *Other test methods.* Other test methods may be acceptable if approved by APHIS.

PART 302—DISTRICT OF COLUMBIA; MOVEMENT OF PLANTS AND PLANT PRODUCTS

Sec.

302.1 Definitions.
302.2 Movement of plants and plant products.

AUTHORITY: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

SOURCE: 66 FR 1016, Jan. 5, 2001, unless otherwise noted.

§302.1 Definitions.

Inspector. Any employee of the Animal and Plant Health Inspection Service or other person authorized by the Administrator to inspect and certify the plant health status of plants and products under this part.

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

State. The District of Columbia, Puerto Rico, the Northern Mariana Islands, or any State, territory, or possession of the United States.

§302.2 Movement of plants and plant products.

Inspection or documentation of the plant health status of plants or plant products to be moved interstate from the District of Columbia may be obtained by contacting the State Plant Health Director, Plant Protection and Quarantine, APHIS, Wayne A. Cawley, Jr. Building, Room 350, 50 Harry S. Truman Parkway, Annapolis, MD 21401–7080; phone: (410) 224–3452; fax: (410) 224–1142.

[66 FR 54641, Oct. 30, 2001]

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.

SOURCE: 75 FR 4241, Jan. 26, 2010, unless otherwise noted.

§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*) 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 highest temperature of the treatment schedule under which the fruit will be treated 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 no more than the highest temperature of the treatment schedule under 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 highest temperature of the treatment schedule under 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 highest temperature of the treatment schedule under which the fruit will be treated. 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 highest temperature of the treatment schedule under which the fruit 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 secured using measures approved by APHIS as adequate to ensure the security and integrity of cold treatment data. 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.

[75 FR 4241, Jan. 26, 2010, as amended at 75 FR 52217, Aug. 25, 2010]

§ 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 Marianas Islands (referred to collectively, in this section, as Hawaii and U.S. territories); for any berry, fruit, nut, or vegetable listed as a regulated article in § 301.32–2(a) of this chapter; and for any regulated article listed in 301.76–2 of this chapter and intended for consumption, as apparel or as a similar personal accessory, or for decorative use.

(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.

(3) For articles that are moved interstate from areas quarantined only for Asian citrus psyllid, and not for citrus greening, irradiation facilities must be located within an area that is not quarantined for citrus greening.

(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.

(4) Irradiation facilities treating articles moved interstate from areas quarantined only for Asian citrus psyllid, and not for citrus greening, must complete a compliance agreement with APHIS as provided in §301.76-8 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;[1]

(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

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

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 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.[2] 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 or Asian citrus psyllid 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;[3] 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

[2] Inspectors are assigned to local offices of the Animal and Plant Health Inspection Service, which are listed in telephone directories.

[3] 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.

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 or Asian citrus psyllid 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 Testing and Materials standard[4] 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] 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.*

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)

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PART 318—STATE OF HAWAII AND TERRITORIES QUARANTINE NOTICES

Subpart—Regulated Articles From Hawaii and the Territories

Sec.

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318.13–9 Inspection and disinfection of means of conveyance.