

approved treatment schedule, the volume of the commodity stacked inside the treatment enclosure must not exceed  $\frac{2}{3}$  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.

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#### § 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 or in another treatment schedule approved in accordance with § 305.2 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. A facility will only be certified or recertified if the Administrator determines that the location of the facility is such that those Federal agencies involved in its operation and oversight have adequate resources to conduct the necessary operations at the facility, that the pest risks can be

managed at that location, and that the facility meets all criteria for approval. Other agencies that have regulatory oversight and requirements must concur in writing with the establishment of the facility prior to APHIS approval. 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) Be capable of preventing the escape and spread of pests while regulated articles are at the facility; and

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

(b)(1) *Location of facilities.* Where certified cold treatment facilities are available, an approved cold 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, cold treatment may be conducted either prior to movement to the mainland United States or in the mainland United States. Cold treatment facilities may be located in any State on the mainland United States. For cold treatment facilities located in the area south of 39° latitude and west of 104° longitude, the following additional conditions must be met:

(i) Prospective facility operators must submit a detailed layout of the facility site and its location to APHIS. APHIS will evaluate plant health risks based on the proposed location and layout of the facility site. APHIS will only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from the port of entry or points of origin in the United States.

(ii) The government of the State in which the facility is to be located must concur in writing with the location of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, APHIS and the State must agree on a strategy to resolve the pest risk

concerns prior to APHIS approval. If the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

(iii) Untreated articles may not be removed from their packaging prior to treatment under any circumstances.

(iv) The facility must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles if the facility is unable to properly treat a shipment.

(v) The facility may only treat articles approved by APHIS for treatment at the facility. Approved articles will be listed in the compliance agreement required in paragraph (f) of this section.

(vi) Arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States. APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility. If APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached.

(vii) Regulated articles must be conveyed to the facility in a refrigerated (via motorized refrigeration equipment) conveyance at a temperature that minimizes the mobility of the pests of concern for the article.

(viii) The facility must apply all post-treatment safeguards required for certification under paragraph (a) of this section before releasing the articles.

(ix) The facility must remain locked when not in operation.

(x) The facility must maintain and provide APHIS with an updated map identifying places where horticultural or other crops are grown within 4 square miles of the facility. Proximity of host material to the facility will necessitate trapping or other pest monitoring activities, funded by the facility, to help prevent establishment of any escaped pests of concern, as approved by APHIS; these activities will

be listed in the compliance agreement required in paragraph (f) of this section. The treatment facility must have a pest management plan within the facility.

(xi) The facility must comply with any additional requirements including, but not limited to, the use of pest-proof packaging and container seals, that APHIS may require to prevent the escape of plant pests during transport to and from the cold treatment facility itself, for a particular facility based on local conditions, and for any other risk factors of concern. These activities will be listed in the compliance agreement required in paragraph (f) of this section.

(2) For articles that are moved interstate from areas quarantined for fruit flies, cold treatment 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.

(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 or in another approved treatment schedule 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 ap-

proval 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 or in accordance with another approved treatment schedule. 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 after it has been cold treated to monitor treatment effectiveness. If a single live pest of concern 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 ef-

fective against the pests of concern, APHIS may suspend the importation of fruits from the originating country and conduct an investigation into the cause of the deficiency. APHIS may waive the sampling and cutting requirement of paragraph (d)(15) of this section, provided that the national plant protection organization (NPPO) of the exporting country has conducted such sampling and cutting in the exporting country as part of a biometric sampling protocol approved by APHIS.

(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. Facilities must be located within the local commuting area for APHIS employees for inspection purposes. Facilities treating imported articles must also be located within an area over which the U.S. Department of Homeland Security is assigned authority to accept entries of merchandise, to collect duties, and to enforce the provisions of the customs and navigation laws in force.

(f) *Compliance agreements.* Any person who operates a facility where cold treatment is conducted for phytosanitary purposes must sign a compliance agreement with APHIS.

(1) *Compliance agreements with importers and facility operators for cold treatment in the United States.* If cold treatment of imported articles is conducted in the United States, both the importer and the operator of the cold treatment facility or the person who conducts the

cold treatment must sign compliance agreements with APHIS. 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 treated during their transit from the port of first arrival to the cold treatment facility in the United States. In the facility compliance agreement, the facility operator or person conducting the cold treatment must agree to comply with the requirements of this section and any additional requirements found necessary by APHIS to prevent the escape of any pests of concern that may be associated with the articles to be treated.

(2) *Compliance agreements with cold treatment facilities outside the United States.* If cold treatment of imported articles is conducted outside the United States, the operator of the cold treatment facility must sign a compliance agreement or an equivalent agreement with APHIS and the 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 inform the Administrator of any noncompliance.

(3) *Cold treatment facilities treating articles moved interstate from Hawaii and U.S. territories.* Cold treatment facilities treating articles moved interstate from Hawaii and the U.S. territories must complete a compliance agreement with APHIS as provided in §318.13-3(d) of this chapter.

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### § 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 fruits and vegetables for which quick freeze is an authorized treatment. Requests to authorize quick freeze as a treatment for other fruits and vegetables may be made in accordance with §305.2(c).

[75 FR 4241, Jan. 26, 2010, as amended at 76 FR 60361, Sept. 29, 2011]

### § 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 or in another treatment schedule approved in accordance with §305.2.

(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.