PART 305—PHYTOSANITARY TREATMENTS

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§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. Irradiation facilities may be located in any State on the mainland United States. For irradiation facilities located in the States of Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, and Virginia, 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 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 establishment 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, APHIS and the State will agree on a strategy to resolve the pest risk concerns prior to APHIS approval.

(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 (c)(1)(i) 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.

(vii) Regulated articles must be conveyed to the facility in a refrigerated (via motorized refrigeration equipment or other methods including ice or insulation) or air-conditioned conveyance at a temperature that minimizes the mobility of the pests of concern for the article.

(viii) 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 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 (c)(1)(i) of this section. The treatment facility must have a pest management plan within the facility.

(ix) The facility must comply with any additional requirements that APHIS may require to prevent the escape of plant pests during transport to and from the irradiation 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 (c)(1)(i) of this section.

(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. 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 approved, a facility must fulfill the requirements in paragraphs (c) and (d) of this section.

(c) *Compliance agreements.* Compliance agreements for facilities located in States listed in paragraph (a)(1) of this section may also contain additional provisions as described in paragraphs (a)(1)(i) through (a)(1)(ix) of this section. (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 or in another treatment schedule approved in accordance with §305.2 to the regulated articles;[1]

[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.

(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. Facilities must be located within the local commuting area for APHIS employees for inspection purposes.

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

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

(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

[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.

(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 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 or in another approved treatment schedule.

(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 or by another approved treatment schedule.

(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.

[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.*

(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 or the plant pests for which another treatment schedule is approved in accordance with §305.2. 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.

(o) *Substitution of irradiation for other treatments.* Treatment of fruits and vegetables that are from foreign localities, from Hawaii, Puerto Rico, and the U.S. Virgin Islands, or from domestic areas under quarantine with irradiation in accordance with this section may be substituted for other approved treatments if the target pests of the other approved treatments are approved for treatment with irradiation in the PPQ Treatment Manual or approved for treatment with irradiation in accordance with §305.2.

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