

inspector who is supervising its enforcement whenever the inspector finds that such person has failed to comply with the provisions of this subpart or any conditions imposed pursuant thereto. If the cancellation is oral, the decision and the reasons therefore shall be confirmed in writing, as promptly as circumstances permit. Any person whose compliance agreement has been cancelled may appeal the decision, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully cancelled. The Deputy Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances permit. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of Practice concerning such a hearing will be adopted by the Deputy Administrator.

[48 FR 54580, Dec. 6, 1983, as amended at 59 FR 67608, Dec. 30, 1994; 70 FR 37254, June 29, 2005]

§ 301.64-7 Assembly and inspection of regulated articles.

(a) Any person (other than a person authorized to issue certificates or limited permits under § 301.64-5(c)), who desires to move interstate a regulated article accompanied by a certificate or limited permit shall, as far in advance as possible (should be no less than 48 hours before the desired movement), request an inspector⁷ to take any necessary action under this subpart prior to movement of the regulated article.

(b) Such article shall be assembled at such point and in such manner as the inspector designates as necessary to comply with the requirements of this subpart.

[48 FR 54580, Dec. 6, 1983, as amended at 59 FR 67608, Dec. 30, 1994; 70 FR 37254, June 29, 2005]

⁷Inspectors are assigned to local offices of Plant Protection and Quarantine, which are listed in telephone directories. Information concerning such local offices may also be obtained on the Internet at <http://www.aphis.usda.gov/ppq/>.

§ 301.64-8 Attachment and disposition of certificates and limited permits.

(a) A certificate or limited permit required for the interstate movement of a regulated article, at the times during such movement, shall be securely attached to the outside of the containers containing the regulated article, securely attached to the article itself if not in a container, or securely attached to the consignee's copy of the accompanying waybill or other shipping document; *Provided however*, That the requirements of this section may be met by attaching the certificate or limited permit to the consignee's copy of the waybill or other shipping documents only if the regulated article is sufficiently described on the certificate, limited permit, or shipping document to identify such article.

(b) The certificate or limited permit for the movement of a regulated article shall be furnished by the carrier to the consignee at the destination of the shipment.

§ 301.64-9 Costs and charges.

The services of an inspector during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, except holidays) will be furnished without cost. The user will be responsible for all costs and charges arising from inspection and other services provided outside normal business hours.

[70 FR 37254, June 29, 2005]

§ 301.64-10 Treatments.

Treatments for regulated articles must be one of the following:

(a) *Apple, grapefruit, orange, pear, plum, pomegranate, quince, and tangerine.* Cold treatment in accordance with part 305 of this chapter.

(b) *Soil within the dripline of plants that are producing or that have produced fruits listed in § 301.64-2(a).* Remove host fruits from host plants prior to treatment. Using ground equipment, drench the soil under the host plants with 5 lb a.i. diazinon per acre (0.12 lb or 2 oz avdp per 1,000 ft²) mixed with 130 gal of water per acre (3 gal per 1,000 ft²). Apply at 14- to 16-day intervals as needed. Repeat applications if infestations become established. In addition

to the above, follow all label directions for diazinon.

(c) *Premises.* A field, grove, or area that is located within the quarantined area but outside the infested core area, and that produces regulated articles, must receive regular treatments with either malathion or spinosad bait spray. These treatments must take place at 6-to 10-day intervals, starting a sufficient time before harvest (but not less than 30 days before harvest) to allow for completion of egg and larvae development of the Mexican fruit fly. Determination of the time period must be based on the day degrees model for Mexican fruit fly. Once treatment has begun, it must continue through the harvest period. The malathion bait spray treatment must be applied by aircraft or ground equipment at a rate of 2.4 oz of technical grade malathion and 9.6 oz of protein hydrolysate per acre. The spinosad bait spray treatment must be applied by aircraft or ground equipment at a rate of 0.01 oz of a USDA-approved spinosad formulation and 48 oz of protein hydrolysate per acre. For ground applications, the mixture may be diluted with water to improve coverage.

(d) *Grapefruit and oranges.* Methyl bromide in accordance with part 305 of this chapter.

(e) *Grapefruit, oranges, and tangerines.* High-temperature forced air in accordance with part 305 of this chapter.

(f) *Citrons, litchis, longans, persimmons, and white sapotes.* Cold treatment in accordance with the following schedule, which is also found in part 305 of this chapter:

| Treatment (°F) | Exposure period (days) |
|-------------------|------------------------|
| 33 or below | 18 |
| 34 or below | 20 |
| 35 or below | 22 |

(g) *Approved irradiation treatment.* Irradiation, carried out in accordance with the provisions of part 305 of this chapter, is approved as a treatment for any fruit listed as a regulated article in § 301.64-2(a).

(1) *Approved facility.* The irradiation treatment facility and treatment protocol must be approved by the Animal and Plant Health Inspection Service. In order to be approved, a facility must:

(i) Be capable of administering a minimum absorbed ionizing radiation dose of 150 Gray (15 krad) to the fruit;⁸

(ii) Be constructed so as to provide physically separate locations for treated and untreated fruit, except that fruit 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;

(iii) Complete a compliance agreement with the Animal and Plant Health Inspection Service as provided in § 301.64-6; and

(iv) Be certified by Plant Protection and Quarantine for initial use and annually for subsequent use. Recertification is required in the event that an increase or decrease in radioisotope or a major modification to equipment that affects the delivered dose. Recertification may be required in cases where a significant variance in dose delivery is indicated.

(2) *Treatment monitoring.* Treatment must be carried out under the monitoring of an inspector. This monitoring must include inspection of treatment records and unannounced inspection visits to the facility by an inspector. Facilities that carry out continual irradiation operations must notify an inspector at least 24 hours before the date of operations. Facilities that carry out periodic irradiation operations must notify an inspector of scheduled operations at least 24 hours before scheduled operations.⁹

(3) *Packaging.* Fruits and vegetables that are treated within a quarantined area must be packaged in the following manner:

(i) The cartons must have no openings that will allow the entry of fruit flies and must be sealed with seals that will visually indicate if the cartons

⁸The maximum absorbed ionizing radiation dose and the irradiation of food are regulated by the Food and Drug Administration under 21 CFR part 179.

⁹Inspectors are assigned to local offices of the Animal and Plant Health Inspection Service, which are listed in telephone directories.

have been opened. They may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the fruit in the carton.¹⁰

(ii) The pallet-load of cartons must be wrapped before it leaves the irradiation facility in one of the following ways:

- (A) With polyethylene sheet wrap;
- (B) With net wrapping; or

(C) With strapping so that each carton on an outside row of the pallet load is constrained by a metal or plastic strap.

(iii) Packaging must be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment.

(4) *Dosage.* The fruits and vegetables must receive a minimum absorbed ionizing radiation dose of 150 Gray (15 krad).¹¹

(5) *Dosimetry systems.* (i) Dosimetry mapping must indicate the dose needed to ensure the fruit will receive the minimum dose prescribed.

(ii) Absorbed dose must be measured using an accurate dosimetry system that ensures that the absorbed dose meets or exceeds 150 Gray (15 krad).

(iii) When designing the facility's dosimetry system and procedures for its operation, the facility operator must address guidance and principles from American Society for Testing and Materials (ASTM) standards.¹²

(6) *Records.* Records or invoices for each treated lot must be made available for inspection by an inspector during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, except holidays). An irradiation processor must maintain records as speci-

fied in this section for a period of time that exceeds the shelf life of the irradiated food product by 1 year, and must make these records available for inspection by an inspector. 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.

(7) *Request for approval and inspection of facility.* Persons requesting approval of an irradiation treatment facility and treatment protocol must submit the request for approval in writing to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Center for Plant Health Science and Technology, 1017 Main Campus Drive, suite 2500, Raleigh, NC 27606. Before the Administrator determines whether an irradiation facility is eligible for approval, an inspector will make a personal inspection of the facility to determine whether it complies with the standards of paragraph (g)(1) of this section.

(8) *Denial and withdrawal of approval.* (i) The Administrator will withdraw the approval of any irradiation treatment facility when the irradiation processor requests in writing the withdrawal of approval.

(ii) The Administrator will deny or withdraw approval of an irradiation treatment facility when any provision of this section is not met. Before withdrawing or denying approval, 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 approval pending final determination in the proceeding, if he or she determines that suspension is necessary to prevent the spread of any dangerous insect infestation. 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

¹⁰If there is a question as to the adequacy of a carton, send a request for approval of the carton, together with a sample carton, to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Center for Plant Health Science and Technology, 1017 Main Campus Drive, suite 2500, Raleigh, NC 27606.

¹¹See footnote 8.

¹²Designation 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*.

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.

(9) *Department not responsible for damage.* This treatment is approved to assure quarantine security against Mexican fruit fly. From the literature available, the fruits 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 supervised. 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 number 0579–0088)

[63 FR 68164, Dec. 10, 1998, as amended at 64 FR 37665, July 13, 1999; 64 FR 71270, Dec. 21, 1999; 67 FR 8464, Feb. 25, 2002; 68 FR 8819, Feb. 26, 2003; 70 FR 33268, June 7, 2005; 70 FR 37254, June 29, 2005; 71 FR 4459, Jan. 27, 2006]

Subpart—Plum Pox

SOURCE: 65 FR 35264, June 2, 2000, unless otherwise noted.

§ 301.74 Restrictions on interstate movement of regulated articles.

No person may move interstate from any quarantined area any regulated article except in accordance with this subpart.¹

[65 FR 35264, June 2, 2000, as amended at 66 FR 21051, Apr. 27, 2001]

¹Any properly identified inspector is authorized to stop and inspect persons and means of conveyance and to seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of regulated articles a provided in sections 414, 421, and 434 of the Plant Protection Act (7 U.S.C. 7714, 7731, and 7754).

§ 301.74–1 Definitions.

The following definitions apply to this subpart.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service. The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture.

Departmental permit. A document issued by the Administrator in which he or she affirms that interstate movement of the regulated article identified on the document is for scientific or experimental purposes and that the regulated article is eligible for interstate movement in accordance with § 301.74–4 of this subpart.

Infestation (infested, infected). The presence of plum pox or circumstances or symptoms that makes it reasonable to believe that plum pox is present.

Inspector. Any employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or other person authorized by the Administrator to enforce this subpart.

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

Moved (move, movement). Shipped, offered for shipment, received for transportation, transported, carried, or allowed to be moved, shipped, transported, or carried.

Person. Any association, company, corporation, firm, individual, joint stock company, partnership, society, or other entity.

Plant Protection and Quarantine. Plant Protection and Quarantine, Animal and Plant Health Inspection Service, United States Department of Agriculture.

Plum pox. A plant disease caused by plum pox potyvirus that can affect many *Prunus* (stone fruit) species, including, but not limited to, almond, apricot, nectarine, peach, plum, and sweet and tart cherry. The strain of plum pox in Pennsylvania does not affect cherry trees.

Quarantined area. Any State, or any portion of a State, listed in § 301.74–3(c) of this subpart or otherwise designated