

Collection Coordinator, at (301) 734-7477.

List of Subjects in 7 CFR Part 301

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

Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

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

Authority: 7 U.S.C. 7711, 7712, 7714, 7731, 7735, 7751, 7752, 7753, 7754, and 7760; 7 CFR 2.22, 2.80, and 371.3.

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

2. In § 301.64-10, a new paragraph (g) is added to read as follows:

§ 301.64-10 Treatments.

* * * * *

(g) *Approved irradiation treatment.* Irradiation, carried out in accordance with the provisions of this paragraph, 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 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

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

¹⁰ 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, Oxford Plant Protection Center, 901 Hillsboro St., Oxford, NC 27565.

¹¹ See footnote 8.

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 specified 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, Oxford Plant Protection Center, 901 Hillsboro St., Oxford, NC 27565. 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

¹² 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*.

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