

Food and Drug Administration, HHS

§ 179.26

(iii) The maximum energy of X-radiation emitted by machine source.

(iv) The minimum and maximum energy of radiation emitted by neutron source.

(2) The label or accompanying labeling shall bear:

(i) Adequate directions for installation and use.

(ii) A statement that no food shall be exposed to radiation sources listed in paragraph (a) (1) and (2) of this section so as to receive an absorbed dose in excess of 10 grays.

(iii) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(3) of this section so as to receive an absorbed dose in excess of 2 milligrays.

(iv) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(4) of this section so as to receive a dose in excess of 0.5 gray (Gy).

(v) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(5) of this section so as to receive a dose in excess of 0.01 gray (Gy).

[42 FR 14635, Mar. 15, 1977, as amended at 48 FR 46022, Oct. 11, 1983; 61 FR 14246, Apr. 1, 1996; 64 FR 69191, Dec. 10, 1999; 66 FR 18539, Apr. 10, 2001; 69 FR 76404, Dec. 21, 2004]

§ 179.25 General provisions for food irradiation.

For the purposes of §179.26, current good manufacturing practice is defined to include the following restrictions:

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of part 110 of this chapter and other applicable regulations.

(b) Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use.

(c) Packaging materials subjected to irradiation incidental to the radiation treatment and processing of pre-packaged food shall be in compliance with §179.45, shall be the subject of an exemption for such use under §170.39 of this chapter, or shall be the subject of an effective premarket notification for

a food contact substance for such use submitted under §170.100 of this chapter.

(d) Radiation treatment of food shall conform to a scheduled process. A scheduled process for food irradiation is a written procedure that ensures that the radiation dose range selected by the food irradiation processor is adequate under commercial processing conditions (including atmosphere and temperature) for the radiation to achieve its intended effect on a specific product and in a specific facility. A food irradiation processor shall operate with a scheduled process established by qualified persons having expert knowledge in radiation processing requirements of food and specific for that food and for that irradiation processor's treatment facility.

(e) A food irradiation processor shall 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, up to a maximum of 3 years, whichever period is shorter, and shall make these records available for inspection and copy by authorized employees of the Food and Drug Administration. Such records shall include the food treated, 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.

[51 FR 13399, Apr. 18, 1986, as amended at 67 FR 9585, Mar. 4, 2002; 67 FR 35731, May 21, 2002]

§ 179.26 Ionizing radiation for the treatment of food.

Ionizing radiation for treatment of foods may be safely used under the following conditions:

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.

(2) Electrons generated from machine sources at energies not to exceed 10 million electron volts.

(3) X rays generated from machine sources at energies not to exceed 5 million electron volts (MeV), except as

§ 179.26

21 CFR Ch. I (4–1–12 Edition)

permitted by paragraph (a)(4) of this section.

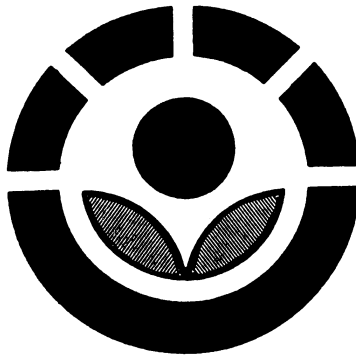
(4) X rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV).

(b) *Limitations.*

Use	Limitations
1. For control of <i>Trichinella spiralis</i> in pork carcasses or fresh, non-heat-processed cuts of pork carcasses.	Minimum dose 0.3 kiloGray (kGy) (30 kilorad (krad)); maximum dose not to exceed 1 kGy (100 krad).
2. For growth and maturation inhibition of fresh foods.	Not to exceed 1 kGy (100 krad). Do.
3. For disinfestation of arthropod pests in food.	Do.
4. For microbial disinfection of dry or dehydrated enzyme preparations (including immobilized enzymes).	Not to exceed 10 kGy (1 megarad (Mrad)).
5. For microbial disinfection of the following dry or dehydrated aromatic vegetable substances when used as ingredients in small amounts solely for flavoring or aroma: culinary herbs, seeds, spices, vegetable seasonings that are used to impart flavor but that are not either represented as, or appear to be, a vegetable that is eaten for its own sake, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as color additives. The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends.	Not to exceed 30 kGy (3 Mrad).
6. For control of food-borne pathogens in fresh or frozen, uncooked poultry products that are: (1) Whole carcasses or disjointed portions of such carcasses that are "ready-to-cook poultry" within the meaning of 9 CFR 381.1(b)(44), or (2) mechanically separated poultry product (a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses).	Not to exceed 3 kGy (300 krad); any packaging used shall not exclude oxygen.

Use	Limitations
7. For the sterilization of frozen, packaged meats used solely in the National Aeronautics and Space Administration space flight programs.	Minimum dose 44 kGy (4.4 Mrad). Packaging materials used need not comply with § 179.25(c) provided that their use is otherwise permitted by applicable regulations in parts 174 through 186 of this chapter.
8. For control of foodborne pathogens in, and extension of the shelf-life of, refrigerated or frozen, uncooked products that are meat within the meaning of 9 CFR 301.2(rr), meat byproducts within the meaning of 9 CFR 301.2(tt), or meat food products within the meaning of 9 CFR 301.2(uu), with or without nonfluid seasoning, that are otherwise composed solely of intact or ground meat, meat byproducts, or both meat and meat byproducts.	Not to exceed 4.5 kGy maximum for refrigerated products; not to exceed 7.0 kGy maximum for frozen products.
9. For control of <i>Salmonella</i> in fresh shell eggs..	Not to exceed 3.0 kGy.
10. For control of microbial pathogens on seeds for sprouting..	Not to exceed 8.0 kGy.
11. For the control of <i>Vibrio</i> bacteria and other foodborne microorganisms in or on fresh or frozen molluscan shellfish..	Not to exceed 5.5 kGy.
12. For control of food-borne pathogens and extension of shelf-life in fresh iceberg lettuce and fresh spinach..	Not to exceed 4.0 kGy.

(c) *Labeling.* (1) The label and labeling of retail packages of foods irradiated in conformance with paragraph (b) of this section shall bear the following logo along with either the statement



“Treated with radiation” or the statement “Treated by irradiation” in addition to information required by other regulations. The logo shall be placed prominently and conspicuously in conjunction with the required statement. The radiation disclosure statement is not required to be more prominent than the declaration of ingredients required under §101.4 of this chapter. As used in this provision, the term “radiation disclosure statement” means the written statement that discloses that a food has been intentionally subject to irradiation.

(2) For irradiated foods not in package form, the required logo and phrase “Treated with radiation” or “Treated by irradiation” shall be displayed to the purchaser with either (i) the labeling of the bulk container plainly in view or (ii) a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. As an alternative, each item of food may be individually labeled. In either case, the information must be prominently and conspicuously displayed to purchasers. The labeling requirement applies only to a food that has been irradiated, not to a food that merely contains an irradiated ingredient but that has not itself been irradiated.

(3) For a food, any portion of which is irradiated in conformance with paragraph (b) of this section, the label and labeling and invoices or bills of lading shall bear either the statement “Treated with radiation—do not irradiate again” or the statement “Treated by irradiation—do not irradiate again”

when shipped to a food manufacturer or processor for further processing, labeling, or packing.

[51 FR 13399, Apr. 18, 1986, as amended at 53 FR 12757, Apr. 18, 1988; 53 FR 53209, Dec. 30, 1988; 54 FR 32335, Aug. 7, 1989; 55 FR 14415, Apr. 18, 1990; 55 FR 18544, May 2, 1990; 60 FR 12670, Mar. 8, 1995; 62 FR 64121, Dec. 3, 1997; 63 FR 43876, Aug. 17, 1998; 65 FR 45282, July 21, 2000; 65 FR 64607, Oct. 30, 2000; 69 FR 76846, Dec. 23, 2004; 70 FR 48072, Aug. 16, 2005; 73 FR 49603, Aug. 22, 2008]

§ 179.30 Radiofrequency radiation for the heating of food, including microwave frequencies.

Radiofrequency radiation, including microwave frequencies, may be safely used for heating food under the following conditions:

(a) The radiation source consists of electronic equipment producing radio waves with specific frequencies for this purpose authorized by the Federal Communications Commission.

(b) The radiation is used or intended for use in the production of heat in food wherever heat is necessary and effective in the treatment or processing of food.

§ 179.39 Ultraviolet radiation for the processing and treatment of food.

Ultraviolet radiation for the processing and treatment of food may be safely used under the following conditions:

(a) The radiation sources consist of low pressure mercury lamps emitting 90 percent of the emission at a wavelength of 253.7 nanometers (2,537 Angstroms).