

(b) The ultraviolet radiation is used or intended for use as follows:

Irradiated food	Limitations	Use
Food and food products	Without ozone production; high fat-content food irradiated in vacuum or in an inert atmosphere; intensity of radiation, 1 W (of 2,537 A. radiation) per 5 to 10 ft. ² .	Surface microorganism control.
Potable water	Without ozone production; coefficient of absorption, 0.19 per cm or less; flow rate, 100 gal/h per watt of 2,537 A. radiation; water depth, 1 cm or less; lamp-operating temperature, 36 to 46 °C..	Sterilization of water used in food production.
Juice products	Turbulent flow through tubes with a minimum Reynolds number of 2,200..	Reduction of human pathogens and other microorganisms.

[42 FR 14635, Mar. 15, 1977, as amended at 65 FR 71057, Nov. 29, 2000]

§ 179.41 Pulsed light for the treatment of food.

Pulsed light may be safely used for treatment of foods under the following conditions:

(a) The radiation sources consist of xenon flashlamps designed to emit broadband radiation consisting of wavelengths covering the range of 200 to 1,100 nanometers (nm), and operated so that the pulse duration is no longer than 2 milliseconds (msec);

(b) The treatment is used for surface microorganism control;

(c) Foods treated with pulsed light shall receive the minimum treatment reasonably required to accomplish the intended technical effect; and

(d) The total cumulative treatment shall not exceed 12.0 Joules/square centimeter (J/cm².)

[61 FR 42383, Aug. 15, 1996]

Subpart C—Packaging Materials for Irradiated Foods

§ 179.45 Packaging materials for use during the irradiation of pre-packaged foods.

The packaging materials identified in this section may be safely subjected to irradiation incidental to the radiation treatment and processing of pre-packaged foods, subject to the provisions of this section and to the requirement that no induced radioactivity is detectable in the packaging material itself:

(a) The radiation of the food itself shall comply with regulations in this part.

(b) The following packaging materials may be subjected to a dose of radiation, not to exceed 10 kilograys, unless otherwise indicated, incidental to the use of gamma, electron beam, or X-radiation in the radiation treatment of prepackaged foods:

(1) Nitrocellulose-coated or vinylidene chloride copolymer-coated cellophane complying with §177.1200 of this chapter.

(2) Glassine paper complying with §176.170 of this chapter.

(3) Wax-coated paperboard complying with §176.170 of this chapter.

(4) Polyolefin film prepared from one or more of the basic olefin polymers complying with §177.1520 of this chapter. The finished film may contain:

(i) Adjuvant substances used in compliance with §§178.3740 and 181.22 through 181.30 of this chapter, sodium citrate, sodium lauryl sulfate, polyvinyl chloride, and materials as listed in paragraph (d)(2)(i) of this section.

(ii) Coatings comprising a vinylidene chloride copolymer containing a minimum of 85 percent vinylidene chloride with one or more of the following comonomers: Acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate.

(5) Kraft paper prepared from unbleached sulfate pulp to which rosin, complying with §178.3870 of this chapter, and alum may be added. The kraft paper is used only as a container for flour and is irradiated with a dose not exceeding 500 grays.

(6) Polyethylene terephthalate film prepared from the basic polymer as described in §177.1630(e)(4)(i) and (ii) of

Food and Drug Administration, HHS

§ 179.45

this chapter. The finished film may contain:

(i) Adjuvant substances used in compliance with §§178.3740 and 181.22 through 181.30 of this chapter, sodium citrate, sodium lauryl sulfate, polyvinyl chloride, and materials as listed in paragraph (d)(2)(i) of this section.

(ii) Coatings comprising a vinylidene chloride copolymer containing a minimum of 85 percent vinylidene chloride with one or more of the following comonomers: Acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate.

(iii) Coatings consisting of polyethylene conforming to §177.1520 of this chapter.

(7) Polystyrene film prepared from styrene basic polymer. The finished film may contain adjuvant substances used in compliance with §§178.3740 and 181.22 through 181.30 of this chapter.

(8) Rubber hydrochloride film prepared from rubber hydrochloride basic polymer having a chlorine content of 30–32 weight percent and having a maximum extractable fraction of 2 weight percent when extracted with *n*-hexane at reflux temperature for 2 hours. The finished film may contain adjuvant substances used in compliance with §§178.3740 and 181.22 through 181.30 of this chapter.

(9) Vinylidene chloride-vinyl chloride copolymer film prepared from vinylidene chloride-vinyl chloride basic copolymers containing not less than 70 weight percent of vinylidene chloride and having a viscosity of 0.50–1.50 centipoises as determined by ASTM method D729–81, “Standard Specification for Vinylidene Chloride Molding Compounds,” which is incorporated by reference. Copies may be obtained from

the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. The finished film may contain adjuvant substances used in compliance with §§178.3740 and 181.22 through 181.30 of this chapter.

(10) Nylon 11 conforming to §177.1500 of this chapter.

(c) Ethylene-vinyl acetate copolymers complying with §177.1350 of this chapter. The ethylene-vinyl acetate packaging materials may be subjected to a dose of radiation, not to exceed 30 kilogray (3 megarads), incidental to the use of gamma, electron beam, or X-radiation in the radiation treatment of packaged foods.

(d) The following packaging materials may be subjected to a dose of radiation, not to exceed 60 kilograys incidental to the use of gamma, electron beam, or X-radiation in the radiation processing of prepackaged foods:

(1) Vegetable parchments, consisting of a cellulose material made from waterleaf paper (unsized) treated with concentrated sulfuric acid, neutralized, and thoroughly washed with distilled water.

(2) Films prepared from basic polymers and with or without adjuvants, as follows:

(i) Polyethylene film prepared from the basic polymer as described in §177.1520(a) of this chapter. The finished film may contain one or more of the following added substances:

Substances	Limitations
Amides of erucic, linoleic, oleic, palmitic, and stearic acid	Not to exceed 1 pct by weight of the polymer.
BHA as described in § 172.110 of this chapter	Do.
BHT as described in § 172.115 of this chapter	Do.
Calcium and sodium propionates	Do.
Petroleum wax as described in § 178.3710 of this chapter	Do.
Polypropylene, noncrystalline, as described in § 177.1520(c) of this chapter.	Not to exceed 2 pct by weight of the polymer.
Stearates of aluminum, calcium, magnesium, potassium, and sodium as described in § 172.863(a) of this chapter.	Not to exceed 1 pct by weight of the polymer.
Triethylene glycol as described in § 178.3740(b) of this chapter	Do.
Mineral oil as described in § 178.3620 (a) or (b) of this chapter	Do.

(ii) Polyethylene terephthalate film prepared from the basic polymer as described in §177.1630(e)(4)(ii) of this chapter. The finished film may contain one or more of the added substances listed in paragraph (d)(2)(i) of this section.

(iii) Nylon 6 films prepared from the nylon 6 basic polymer as described in §177.1500(a)(6) of this chapter and meeting the specifications of item 6.1 of the table in §177.1500(b) of this chapter. The finished film may contain one or more of the added substances listed in paragraph (d)(2)(i) of this section.

(iv) Vinyl chloride-vinyl acetate copolymer film prepared from the basic copolymer containing 88.5 to 90.0 weight percent of vinyl chloride with 10.0 to 11.5 weight percent of vinyl acetate and having a maximum volatility of not over 3.0 percent (1 hour at 105 °C) and viscosity not less than 0.30 determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," Method A, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(9) of this section. The finished film may contain one or more of the added substances listed in paragraph (d)(2)(i) of this section.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter.

[42 FR 14635, Mar. 15, 1977, as amended at 49 FR 10113, Mar. 19, 1984; 54 FR 7405, Feb. 21, 1989; 54 FR 24899, June 12, 1989; 59 FR 14551, Mar. 29, 1994; 61 FR 14246, Apr. 1, 1996; 66 FR 10575, Feb. 16, 2001]

PART 180—FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY

Subpart A—General Provisions

Sec.

180.1 General.

Subpart B—Specific Requirements for Certain Food Additives

180.22 Acrylonitrile copolymers.

180.25 Mannitol.

180.30 Brominated vegetable oil.

180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

AUTHORITY: 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

EDITORIAL NOTE: Nomenclature changes to part 180 appear at 61 FR 14482, Apr. 2, 1996, and 66 FR 56035, Nov. 6, 2001.

Subpart A—General Provisions

§ 180.1 General.

(a) Substances having a history of use in food for human consumption or in food contact surfaces may at any time have their safety or functionality brought into question by new information that in itself is not conclusive. An interim food additive regulation for the use of any such substance may be promulgated in this subpart when new information raises a substantial question about the safety or functionality of the substance but there is a reasonable certainty that the substance is not harmful and that no harm to the public health will result from the continued use of the substance for a limited period of time while the question raised is being resolved by further study.

(b) No interim food additive regulation may be promulgated if the new information is conclusive with respect to the question raised or if there is a reasonable likelihood that the substance is harmful or that continued use of the substance will result in harm to the public health.

(c) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose an interim food additive regulation. A final order promulgating an interim food additive regulation shall provide that continued use of the substance in food is subject to each of the following conditions:

(1) Use of the substance in food or food contact surfaces must comply with whatever limitations the Commissioner deems to be appropriate under the circumstances.

(2) Within 60 days following the effective date of the regulation, an interested person shall satisfy the Commissioner in writing that studies adequate and appropriate to resolve the questions raised about the substance have