

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 179**

**[Docket No. 00F-0789]**

AMB

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Publication Date	2-16-01
Certifier	SKEESE

**Irradiation in the Production, Processing, and Handling of Food**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to expand the conditions of safe use of X-radiation and electron beam energy sources for the treatment of prepackaged foods by irradiation. This action is in response to a petition filed by the National Center for Food Safety and Technology, Illinois Institute of Technology.

**DATES:** This rule is effective *[insert date of publication in the Federal Register]*. Submit written objections and requests for a hearing by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of March 2, 2000 (65 FR 11320), FDA announced that a food additive petition (FAP 0M4711) had been filed by the National Center for Food Safety and Technology, Illinois Institute of Technology, 6502 South Archer Rd., Summit-Argo, IL 60501-1933. The petition proposed to amend the food additive

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regulations in § 179.45 *Packaging materials for use during the irradiation of prepackaged foods* (21 CFR 179.45) to expand the conditions of safe use of X-radiation and electron beam energy sources for the treatment of prepackaged foods by irradiation.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additives as sources of radiation for irradiating of prepackaged foods is safe, (2) the additives will achieve their intended technical effect, and therefore, (3) the regulations in § 179.45 should be amended as set forth below.

In accordance with § 17 1.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 17 1.1 (h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP OM47 11. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation 'may at any time file with the Dockets Management Branch (address above) written objections by *[insert date 30 days after date of publication in the Federal Register]*. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection

for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 179**

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 179 is amended as follows:

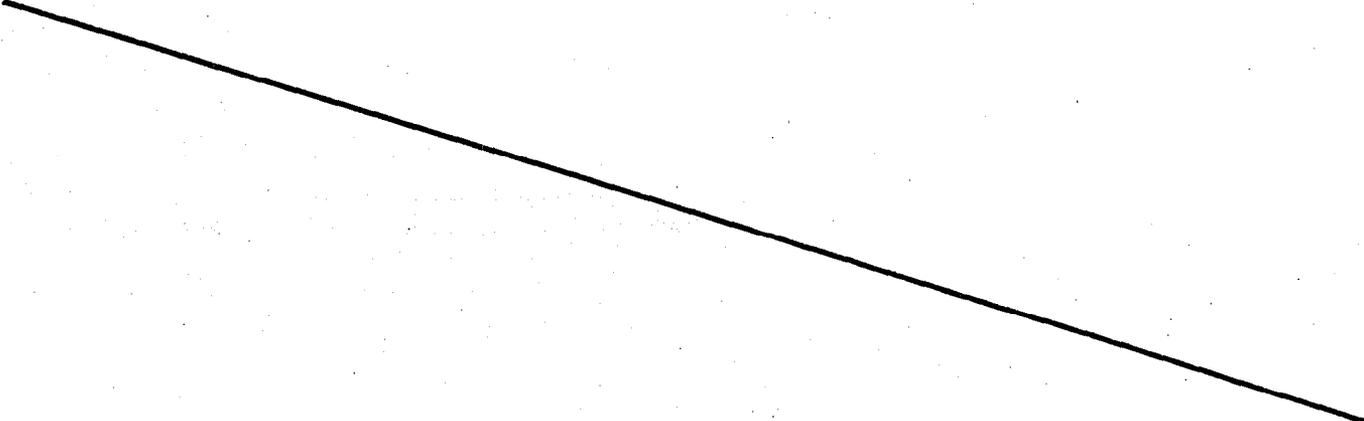
**PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD**

1. The authority citation for 21 CFR part 179 continues to read as follows:

**Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.**

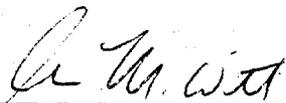
**§ 179.45 [Amended]**

2. Section 179.45 *Packaging materials for use during the irradiation of prepackaged foods* is amended in the introductory text of paragraph (b) by adding the phrase “, electron beam, or



X-" after the word "gamma" and in the introductory text of paragraph (d) by adding the phrase  
", electron beam," after the word "gamma".

Dated: January 31, 2001  
January 31, 2001



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Ann M. Witt  
Acting Associate Commissioner for Policy

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

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