

Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

#### Effective Date

(h) This amendment becomes effective on August 7, 2000.

Issued in Renton, Washington, on July 13, 2000.

Donald L. Rigglin,

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 179

[Docket No. 98F-0165]

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

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ionizing radiation for the reduction of *Salmonella* in fresh shell eggs. This action is in response to a petition filed by Edward S. Josephson.

**DATES:** This rule is effective July 21, 2000. Submit written objections and requests for a hearing by August 21, 2000.

**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:** William J. Trotter, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3088.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In a notice published in the **Federal Register** of March 20, 1998 (63 FR 13675), FDA announced that a food additive petition (FAP 8M4584) had been filed by Edward S. Josephson, University of Rhode Island, Food Science and Nutrition Research Center, 530 Liberty Lane, West Kingston, RI 02892-1802. The petitioner proposed that the food additive regulations in part 179 Irradiation in the Production, Processing and Handling of Food (21 CFR part 179) be amended to provide

for the safe use of ionizing radiation for the reduction of *Salmonella* in fresh shell eggs.

##### II. Safety Evaluation

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive. The additive is not, literally, added to food. Instead, a source of radiation is used to process or treat food such that, analogous to other food processes, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is a change in the microbial load of the food, specifically, a reduction in the numbers of *Salmonella*, a human pathogen, in or on fresh shell eggs.

The petitioner submitted published articles and other study reports containing data and information related to eggs and other kinds of food in the areas of radiation chemistry, nutrition, toxicology, and microbiology. FDA has fully considered the data and studies submitted in the petition, as well as other information in its files relevant to the safety and nutritional adequacy of eggs treated with ionizing radiation.

The effects of ionizing radiation on the characteristics of treated foods are a direct result of the chemical reactions induced by the absorbed radiation. Scientists have compiled a large body of data regarding the effects of ionizing radiation on different foods under various conditions of irradiation. Research has established that the types and amounts of products generated by radiation-induced chemical reactions (hereinafter referred to as "radiolysis products") depend on the chemical constituents of the food and on the conditions of irradiation (e.g., temperature and presence or absence of air and moisture). Furthermore, the principles of radiation chemistry govern the extent of changes both in the nutrient levels and in the microbial load of irradiated foods. Key factors include the specific nutrient or microorganism of interest, the food, and the conditions of irradiation. (See the agency's final rule permitting the irradiation of meat (the meat final rule) in the **Federal Register** of December 3, 1997 (62 FR 64107) for FDA's discussion of radiation chemistry, nutrition, toxicology, and microbiology related to irradiation of foods composed primarily of water, protein, and lipids under various conditions of irradiation.)

FDA has reviewed the relevant data and information submitted in the petition regarding the radiation chemistry of fresh shell eggs, and data available in the agency's files. Fresh

whole eggs are composed mainly of water (75.3 percent), protein (12.5 percent), and lipid (10.0 percent) (Ref. 1). As discussed in the meat final rule, the radiation chemistry associated with these types of compounds is well known. FDA has concluded that the concentrations and types of radiolysis products formed by the irradiation of eggs will be comparable to those products produced by the irradiation of other foods of similar composition, such as meat (Ref. 2). In addition, the petitioner's data support the conclusion that there is little change in the levels of individual fatty acids, or in the structure, digestibility, or biological value of protein, when shell eggs are treated with ionizing radiation up to 3 kiloGray (kGy) (Refs. 2 and 3). Most of the radiolysis products are either the same as, or structurally similar to, compounds found in foods that have not been irradiated, and are formed in very small amounts. In summary, an absorbed dose of 3 kGy for the irradiation of fresh shell eggs will result in only minimal changes in the macronutrients (protein, lipid, or carbohydrate), and the chemical composition of eggs will not differ in any significant manner from eggs that have not been irradiated.

The petitioner submitted studies and published reports relevant to the safety of irradiated foods, in general. In addition, a variety of irradiated foods including: Red meat, chicken, fish, and eggs, have been tested in earlier animal feeding studies and genotoxicity studies; and they were previously reviewed by FDA (see, e.g., 62 FR 64107, December 3, 1997). Included in the information considered by FDA in the review of this petition are three studies conducted specifically on irradiated eggs (Ref. 4). In the first such study, rats were fed a biscuit diet containing whole eggs irradiated at 5 kGy at a dietary level of 25 percent on a dry weight basis for 3 years (two generations). No adverse effects were observed compared to the control group fed a diet containing nonirradiated eggs. In the second study, mice and rats were fed a diet containing dried eggs irradiated at 93 kGy and irradiated pork brain. No effects were observed that were attributed to the irradiated food. In the third study, rats were fed canned eggs irradiated at 5 kGy in their diet for two generations. No effects were observed that were attributed to the irradiated diet. Taken as a whole, based on the totality of evidence from all evaluated data and studies, FDA concludes that the petitioned use of

irradiation on fresh shell eggs raises no toxicity concerns (Refs. 4 and 5).

FDA also evaluated the effects of irradiation processing on micronutrients (e.g., minerals, water-soluble vitamins, and fat-soluble vitamins). Minerals are unaffected by irradiation, but the levels of some vitamins may be reduced as a result of irradiation. For example, vitamin A levels did decrease with an increasing radiation dose. Not all vitamin loss is significant, however. The extent to which a reduction in a specific vitamin level is significant depends on the relative contribution from the food in question to the dietary intake of the vitamin and the overall sufficiency of the vitamin in the diet. Based upon data in the agency's files, FDA concludes that the intake of vitamins from other foods compensates for the vitamin loss from the irradiation of eggs (Refs. 4 and 5). For example, a fresh unirradiated egg contains approximately 95 retinol equivalents (RE) of Vitamin A (Ref. 4). In a study, shell eggs irradiated at 1.0 kGy and stored for 24 days contained approximately 72 RE's (Ref. 3). In comparison, 1 tablespoon of butter contains 108 RE's, one-half cup of bran cereal contains 258 RE's, and one-half cup of canned carrots contains 1,620 RE's of vitamin A (Ref. 4). FDA, therefore, concludes, based upon all the evidence before it, that irradiation of fresh shell eggs under the conditions set forth in the regulation below will not have an adverse impact on the nutritional adequacy of a person's diet.

Increased irradiation levels can also cause organoleptic changes in the egg. For example, data in the petition showed an increased color loss in the irradiated egg yolk and a change in the egg's viscosity as the radiation dose was increased. Thus, FDA expects that the acceptability of irradiated shell eggs, based on their color and viscosity, will limit, in a practical way, the maximum dose of irradiation applied to fresh shell eggs. Therefore, FDA has determined that there is no need to limit the irradiation level based on changes in micronutrient levels or organoleptic characteristics of the eggs.

Irradiation of fresh shell eggs at the doses requested in the petition will reduce, but not entirely eliminate, microorganisms in eggs. The stated purpose of this petition is for approval of radiation of fresh shell eggs to reduce the number of *Salmonella*. The data show that low dose irradiation in the range requested by the petitioner can reduce the levels of *S. enteritidis* in fresh shell eggs (Ref. 6). *Salmonella* strains, in addition to *S. enteritidis*, in fresh shell eggs should also be reduced by irradiation since *S. enteritidis* was

found to have similar sensitivities to ionizing radiation as five other strains of *Salmonella* that were tested in various media (Ref. 7).

Based on the data and studies submitted in the petition and other information in the agency's files, FDA concludes that: (1) The proposed use of irradiation on fresh shell eggs at levels not to exceed 3.0 kGy is safe, (2) the irradiation can achieve its intended technical effect and, therefore, (3) the regulations in § 179.26 (21 CFR 179.26) should be amended as set forth below.

In accordance with § 171.1(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 § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

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

### III. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the filing notice for FAP 8M4584 (63 FR 13675, March 20, 1998). 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.

### IV. Objections

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 August 21, 2000. 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.

### V. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Nutrient Data Laboratory Food Composition Data, USDA Agricultural Research Service, available at Internet address: <http://www.nal.usda.gov/fnic/foodcomp>.
2. Memorandum from K. Morehouse, FDA, to W. Trotter, FDA, May 14, 1999.
3. Memorandum from K. Morehouse, FDA, to W. Trotter, FDA, April 11, 2000.
4. Memorandum from I. Chen, FDA, to W. J. Trotter, FDA, December 11, 1998.
5. Memorandum from I. Chen, FDA, to W. J. Trotter, FDA, March 31, 2000.
6. Memorandum from V. K. Bunning, FDA, to W. J. Trotter, FDA, April 4, 2000.
7. Thayer, D.W., et al., "Radiation Resistance of *Salmonella*," *Journal of Industrial Microbiology*, 5:383-390, 1990.

### 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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.

2. Section 179.26 is amended in the table in paragraph (b) by adding entry "9." under the headings "Use" and "Limitations" to read as follows:

#### § 179.26 Ionizing radiation for the treatment of food.

\* \* \* \* \*

(b) \* \* \*

Use	Limitations
* * * * *	* * * * *
9. For control of <i>Salmonella</i> in fresh shell eggs.	Not to exceed 3.0 kGy.

\* \* \* \* \*

Dated: July 14, 2000.  
**L. Robert Lake,**  
*Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.*  
[FR Doc. 00-18496 Filed 7-20-00; 8:45 am]  
**BILLING CODE 4160-01-F**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 524**

**Ophthalmic and Topical Dosage Form New Animal Drugs; Selamectin**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for topical veterinary prescription use of selamectin solution for the additional indication for control of intestinal hookworm and roundworm infections in cats.  
**DATES:** This rule is effective July 21, 2000.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.  
**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 141-152 that provides for topical veterinary prescription use of Revolution™ (selamectin) in dogs and cats for the additional indication for control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. The supplemental NADA is approved as of June 13, 2000, and the regulations are amended in 21 CFR 524.2098 to reflect the approval. The basis of approval is discussed in the freedom of information summary.  
In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of

safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.  
Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning June 13, 2000, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.  
The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.  
This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

**List of Subjects in 21 CFR Part 524**  
Animal drugs.  
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**  
1. The authority citation for 21 CFR part 524 continues to read as follows:  
**Authority:** 21 U.S.C. 360b.  
2. Section 524.2098 is amended by revising the third sentence in paragraph (d)(2) to read as follows:  
**§ 524.2098 Selamectin.**  
\* \* \* \* \*  
(d) \* \* \*

(2) \* \* \* Treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. \* \* \*  
\* \* \* \* \*

Dated: July 3, 2000.  
**David R. Newkirk,**  
*Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*  
[FR Doc. 00-18458 Filed 7-20-00; 8:45 am]  
**BILLING CODE 4160-01-F**

**DEPARTMENT OF STATE**  
**Bureau of Political-Military Affairs**  
**22 CFR Parts 124, 125 126**  
**[Public Notice 3365]**  
**Amendments to the International Traffic in Arms Regulation: NATO Countries, Australia and Japan**  
**AGENCY:** Bureau of Political-Military Affairs, Department of State.  
**ACTION:** Final rule.

**SUMMARY:** This rule amends the International Traffic In Arms Regulations to implement reforms announced by the Secretary of State at the NATO Ministerial in Florence, Italy on May 24, 2000. The reforms of the U.S. export controls system are available to NATO Allies, Japan and Australia and are intended to streamline the U.S. defense export control licensing process and forge closer industrial linkage between the U.S. and allied defense suppliers. It is contemplated that it will increase our mutual security by enhancing NATO member defense capabilities, promoting interoperability with our allies and friends and promoting trans-Atlantic defense industrial cooperation. Part 124 of the International Traffic In Arms Regulations is being amended to permit U.S. companies to perform, using an exemption, certain maintenance and maintenance training for NATO government, Australia and Japan on US-origin inventoried defense articles. Part 125 is amended to provide authorization, without a license, to transfer technical data to support procurement of defense articles from defense firms in NATO countries,