FDC date	State	City	Airport	FDC No.	Subject
03/22/01	TX	ROBSTOWN	NUECES COUNTY	1/2866	VOR/DME–A, AMDT 3
03/22/01	TX	ROBSTOWN	NUECES COUNTY	1/2867	GPS RWY 12, ORIG–B
03/22/01	UT	SALT LAKE CITY	SALT LAKE CITY INTL	1/2870	RNAV (GPS) RWY 35, ORIG
03/22/01	PA	PITTSBURGH	PITTSBURGH INTL	1/2877	2
03/22/01	NE	HASTINGS	HASTINGS MUNI	1/2882	GPS RWY 14, ORIG–B
03/22/01	OK	EL RENO	EL RENO MUNI AIR PARK	1/2894	VOR/DME RWY 35, AMDT 1A
03/23/01	FL	KEY WEST	KEY WEST INTL	1/2898	RADAR–1, AMDT 4A
03/23/01	FL	KEY WEST	KEY WEST INTL	1/2899	GPS RWY 9, ORIG–A
03/23/01	FL	KEY WEST	KEYWEST INTL	1/2900	GPS RWY 27, ORIG–A NDB OR GPS–A, AMDT
03/23/01	FL	KEYWEST	KEYWEST INTL	1/2902	15A
03/23/01	OK	NORMAN	UNIVERSITY OF OKLAHOMA WESTHEIMER.	1/2918	LOC RWY 3, AMDT 3C
03/23/01	OK	NORMAN	UNIVERSITY OF OKLAHOMA WESTHEIMER.	1/2919	VOR/DME RNAV RWY 3, ORIG–D
03/26/01	FL	ORMOND BEACH	ORMOND BEACH MUNI	1/2974	VOR OR GPS RWY 17, AMDT 1B
03/26/01	FL	ORMOND BEACH	ORMOND BEACH MUNI	1/2976	GPS RWY 8, ORIG
03/26/01	FL	ORMOND BEACH	ORMOND BEACH MUNI	1/2977	RADAR–1, AMDT 2B
03/26/01	WA	SPOKANE	SPOKANE INTL	1/2992	RNAV (GPS) RWY 3, ORIG GPS RWY 28, ORIG–B
03/26/01	NM	SANTA FE	SANTA FE MUNI	1/2993	(Replaces FDC 1/2274)
		NEW SMYRNA	NEW SMYRNA		
03/27/01	FL	BEACH	BEACH MUNI	1/3020	AMDT 1
		NEW SMYRNA	NEW SMYRNA		
03/27/01	FL	BEACH	BEACH MUNI	1/3023	RADAR–1, AMDT 3
03/27/01	AK	NOME	NOME	1/3025	GPS RWY 27, ORIG–B
03/27/01	AK	NOME	NOME	1/3026	GPS RWY 9, ORIG–B
03/27/01	AK	NOME	NOME	1/3027	GPS RWY 2, ORIG–B
			ASPEN–PITKIN COUNTY/ SARDY.		
03/27/01	CO	ASPEN	FIELD	1/3034	VOR/DME OR GPS–C AMDT 4B
03/27/01	GA	SAVANNAH	SAVANNAH INTL	1/3037	VOR OR TACAN OR GPS RWY 27, AMDT 15C
03/27/01	GA	SAVANNAH	SAVANNAH INTL	1/3038	ILS RWY 9, AMDT 25D
03/27/01	GA	SAVANNAH	SAVANNAH INTL	1/3039	HI–ILS RWY 9, AMDT 5
03/27/01	GA	SAVANNAH	SAVANNAH INTL	1/3040	HI–TACAN RWY 27, AMDT 3

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 94F–0008]

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 a machine source of high energy x-rays to inspect cargo containers that may contain food. This action is in response to a petition filed by Analytical Systems Engineering Corp. (ASEC).

DATES: This rule is effective April 10, 2001. Submit written objections and request for a hearing by May 10, 2001.

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: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of February 24, 1994 (59 FR 8995), FDA announced that a food additive petition (FAP 4M4407) had been filed by Analytical Systems Engineering Corp., 5400 Shawnee Rd., suite 100, Alexandria, VA 22312. The petition proposed that the food additive regulations in § 179.21 *Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing* (21 CFR 179.21) be amended to provide for the safe use of a machine source of high energy x-rays to inspect cargo containers that may contain food. In a letter dated October 12, 2000, ASEC (now ACS Defense, Inc., 2001 North Beauregard St., Alexandria, VA 22311) informed FDA of the transfer of their rights to FAP 4M4407 to R. F. Reiter and Associates, 850 Oak Chase Circle, Fairfax Station, VA 22039.

II. Evaluation of Safety

A source of radiation used for the purpose of inspection of foods meets the definition of a food additive under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)). Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations in § 170.3(i) (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

III. Evaluation of the Safety of the Petitioned Use of a Source of Radiation

Machine sources that produce high energy x-rays may be used to screen large cargo containers for illegal drugs and other contraband. To be able to penetrate large cargo containers, these x-ray systems need to operate with x-ray energies higher than those used for screening smaller articles (Ref. 1). The present petition proposes the use of x-rays produced by an electron linear accelerator operating at energy levels of up to 10 million electron volts (MeV) to inspect large cargo containers that may contain food, provided that the maximum dose absorbed by the food does not exceed 0.5 gray (0.5 Gy). Because the probability of inducing a change in the nucleus of an atom absorbing x-rays increases with the energy of the x-ray, the potential for induced radioactivity in the finished foodstuff needs to be assessed. Current regulations authorize the use of x-rays at energies up to 0.5 MeV to inspect cargo, including food, provided the absorbed dose does not exceed 10 Gy (§ 179.21). This petition seeks to raise the energy limit for x-rays from 0.5 MeV to 10 MeV, however, the petition also proposes to limit the maximum absorbed dose to 0.5 Gy, well below the 10 Gy level previously established as safe for food inspection. Accordingly, FDA has concluded that there is no need to evaluate changes in the food subjected to x-rays other than the potential for induced radioactivity.

The petitioner submitted a number of published articles and other study reports containing data and information on the induction of radioactivity in food. One of the reports that the petitioner relied on to demonstrate that the petitioned use of the source of radiation is safe is from the World Health Organization (WHO). This WHO report concluded that no detectable radioactivity will be induced in foodstuffs by x-rays with a maximum energy level of 10 MeV when a dose of 0.5 Gy is not exceeded (Ref. 1).

As part of FDA's safety review of the petition, the agency evaluated two studies in which various foods were irradiated with either x-rays or electron beams at energies sufficient to induce radioactivity. Radioactivity is the result of changes in the nucleus of an atom induced, for example, by interaction with x-rays. Because the elemental composition of the foods that were studied is representative of foods in general, the results of the two studies may reasonably be applied to other foods subjected to these test conditions. In one study, three types of food were irradiated with high energy bremsstrahlung[1] produced by an electron linear accelerator that generated predominately 8 MeV electrons (approximately 7 percent of the electrons were in the range of 8 to 10 MeV and less than 2 percent were in the range of 10 to 12 MeV) (Ref. 2). The types of food that were irradiated were codfish, rice, and a macerated meat product. These foods received doses ranging from 8.8 to 14 kiloGy (kGy) (17,600 to 28,000 times higher than the maximum petitioned dose level of 0.5 Gy). The authors concluded that the induced activities in the foods that were observed immediately after irradiation are approximately the same as natural background levels, and that any induced activities drop quickly. According to the data presented in the paper, by 1 day after irradiation, induced levels of radioactivity were typically about 10 percent of those initially observed. Because of the extremely small level of radioactivity that was induced in foods after receiving doses thousands of times higher than the maximum petitioned dose, FDA would not expect any detectable radioactivity above background in food resulting from the petitioned use of the source of radiation at doses up to 0.5 Gy.

In the second study, samples of chicken, prawns, cheeses, and spices were irradiated with electron beams at energies of 10 MeV and 20 MeV and induced radioactivity was measured (Ref. 3). In this study, the mechanisms responsible for the induced radioactivity in the samples were photonuclear reactions induced by bremsstrahlung and electronuclear reactions induced by the electron beams. The authors noted that when food is irradiated with electron beams with an energy at or below 10 MeV, the induced radioactivity in food is essentially zero. Therefore, to produce measurable radioactivity in food, irradiations were also carried out at 20 MeV. The authors stated that the study with 20 MeV irradiations was intended to simulate a gross malfunction of an electron beam irradiation plant. The authors concluded that, as expected, no measurable radioactivity induced at 10 MeV was detected, and that even at energies as high as 20 MeV and doses up to 10 kGy (i.e., 20,000 times the maximum petitioned dose level of 0.5 Gy), the specific activity after 1 day was approximately 0.01 Becquerel/gram (Bq/g), which is negligible (Ref. 3).

[1] Bremsstrahlung refers to the type of radiation which is emitted when high-speed electrons are suddenly decelerated due to interactions with atomic nuclei.

IV. Conclusion of Safety

FDA has evaluated the data submitted in the petition and other relevant material and concludes that no detectable radioactivity will be induced in food when an x-ray energy of 10 MeV and a dose of 0.5 Gy are not exceeded. Therefore, the agency concludes that the proposed use of x-radiation, produced by a machine source at energies of 10 MeV or lower, to inspect food, is safe and that the conditions listed in §179.21 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.

V. Environmental Impact

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice. The agency has carefully considered the potential environmental effects of this action. FDA has concluded that this action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Paper Reduction Act of 1995

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.

VII. 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 May 10, 2001. 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.

VIII. References

The following references have been placed on display in 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. WHO, ''Food safety aspects relating to the application of X-ray surveillance equipment: Memorandum from a WHO meeting,'' Bulletin of the World Health Organization, vol. 31, pp. 297–301, 1990.

2. Wakeford, C. A. and R. Blackburn, ''Induction and Detection of Radioactivity in Foodstuffs Irradiated with 10 MeV Electrons and X-rays,'' *Radiation Physics and Chemistry*, vol. 38, No. 1, pp. 29–38, 1991.

3. Findley, D. J. S., T.V. Parson, and M. R. Sene, ''Experimental Electron Beam Irradiation of Food and the Induction of Radioactivity,'' *Applied Radiation and Isotopes*, vol. 43, pp. 567–575, 1992.

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 179.21 is amended by adding paragraphs (a)(4), (b)(1)(iii), and (b)(2)(iv) to read as follows:

§ 179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

* * * * *

(a) * * *

(4) Machine sources producing X-radiation at energies no greater than 10 million electron volts (MeV).

(b) * * *

(1) * * *

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

(2) * * *

(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).

Dated: April 3, 2001.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–8755 Filed 4–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 579

[Docket No. 99F–2799]

Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Irradiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to reflect approval of a food additive petition (FAP) filed by Sterigenics International, Inc. (now IBA Food Safety Division) that provides for irradiation of various animal feeds and feed ingredients for microbial control.

DATES: This rule is effective April 10, 2001. Submit written objections and request for a hearing by May 10, 2001.

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: John D. McCurdy, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0171.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 3, 1999 (64 FR 48409), FDA announced that a food additive petition (FAP 2243) had been filed by SteriGenics International, Inc., 4020 Clipper Ct., Fremont, CA 94538–6540. The petition proposed to amend the food additive regulations in part 21 CFR part 579 Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food to provide for the irradiation of various animal feeds and feed ingredients to control microbial contaminants. The notice of filing provided for a 60-day comment period. The agency received no comments.

FDA has evaluated data submitted by the sponsor of the petition and concludes that the data establish the safety and functionality of irradiation for use as proposed.

This final rule extends the ability to irradiate all animal feeds for the purpose of microbial disinfection, therefore, references to laboratory animals have been deleted from the regulation. Also, paragraph (b)(2) has been added to § 579.22 to make clear that as long as an irradiated feed ingredient is less than 5 percent of the final product, the final product may be irradiated without conflicting with the statement in § 579.22(b)(1) that the ionizing radiation is used or intended for use in single treatment.

In accordance with § 571.1(h) (21 CFR 571.1(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 Veterinary Medicine by appointment with the information contact person listed above. As provided in § 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

FDA has determined under 21 CFR 25.32(j) that this action is of 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.

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 May 10, 2001. 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