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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 1993F–0357]

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 source of fast (high energy) neutrons to inspect containers that may contain food. This action is in response to a petition filed by Science Applications International Corp. (SAIC).

DATES: This rule is effective [*insert date of publication in the* **Federal Register**]. Submit written or electronic objections and requests for a hearing by [*insert date 30 days after date of publication in the* **Federal Register**]. See section VII of this document for information on the filing of objections.

ADDRESSES: You may submit written objections and requests for a hearing, identified by Docket No. 1993F–0357, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments.* Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov.* Include Docket No. 1993F–0357 in the subject line of your e-mail message.
- FAX: 301–827–6870.

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• Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1282.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of November 18, 1993 (58 FR 60860), FDA announced that a food additive petition (FAP 3M4399) had been filed by Science Applications International Corp., 2950 Patrick Henry Dr., Santa Clara, CA 95054. 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 source of fast (high energy)

neutrons to inspect cargo containers that may contain food. In a letter dated January 9, 1998, FDA was informed by Ancore Corp. that they were previously the division of SAIC responsible for this petition but had been reorganized into a separate company. The letter explained that as part of this reorganization, the rights to FAP 3M4399 had been transferred from SAIC to Ancore Corp. (same address as SAIC).

When the petition was filed on November 18, 1993, it contained an environmental assessment (EA). In the notice of filing for this petition, the agency announced that it was placing the EA submitted with this petition on display at the Division of Dockets Management for public review and comment. No comments on the EA were received. Based on the original EA, FDA prepared a finding of no significant impact to the environment dated May 31, 1994. On July 29, 1997, FDA published revised regulations under part 25 (21 CFR part 25), which became effective on August 28, 1997. On May 12, 2003, the petitioner submitted a claim of categorical exclusion under the new § 25.32(j), in accordance with the procedures in § 25.15(a) and (d). Because the environmental record for the FAP was outdated, the agency reviewed the claim of categorical exclusion under § 25.32(j) for this final rule and found it to be warranted.

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 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

A. Background on Pulsed Fast Neutron Analysis

Neutron-based techniques can be used to screen large cargo containers for contraband such as explosives, chemical warfare agents, and illegal drugs. Unlike conventional systems based on x rays or gamma rays, surveillance systems employing neutrons are able to provide more specific information on a cargo's elemental composition. When a neutron beam is directed at a target, the neutrons interact with target nuclei by either scattering or by nuclear reactions such as neutron capture by the target nuclei. Some captured neutrons result in the production of unstable isotopes that decay by emitting characteristic gamma rays, which can be detected and used to identify emitting chemical elements. Using gamma ray spectroscopy, information can be obtained on the concentration of chemical elements of the scanned object. Because the concentrations of certain elements in these types of illicit materials are characteristically different from other materials, such illicit materials can be detected. The present petition proposes the use of a pulsed fast neutron analysis system employing a beam of high energy neutrons at energies up to 9 million electron volts (MeV) to inspect large cargo containers and trucks that may contain food, provided that the maximum dose absorbed by the food does not exceed 0.01 gray (Gy). The scanning neutron beam operates in one of two modes, fast scan and directed search. Most containers would be exposed to a fast scan search only. During a fast scan, the beam impinges on any one position in the container for at most 1 second. Suspicious containers may be

subjected to a directed search. A typical directed search would focus the beam on one position in the container for 10 seconds, but it is possible that it may be necessary to dwell on one location for up to 5 minutes.

B. Radiolysis Products

One of the safety issues considered by FDA when it is evaluating a source of radiation used to inspect or treat food is the potential for formation of products generated in the food by radiation-induced chemical reactions (radiolysis products). The types and amounts of these products generated in the food depend on the chemical constituents of the food and on the conditions of irradiation. Radiation chemistry of components of food previously has been discussed in detail in the agency's final rule permitting the irradiation of meat (62 FR 64107, December 3, 1997). As stated in the meat irradiation final rule, most of the radiolysis products that are generated from food irradiation are also found in foods that have not been irradiated. Some of these compounds are also produced by heating foods, and, in the case of heating, are produced in amounts far greater than the trace amounts that result from irradiating foods.

The amount of radiolysis products generated in food increases with increasing absorbed dose of radiation. FDA has previously established that gamma rays from radionuclides of cobalt-60 or cesium-137, high-energy electrons up to 10 MeV, and x rays up to 5 MeV are safe for the treatment of different types of food at doses ranging from 0.3 kiloGray (kGy) to 30 kGy, depending on the type of food. Because the current petition proposes to limit the maximum absorbed dose to 0.01 Gy (a dose at least 30,000 times less than these approved uses), the amounts of radiolysis products generated in food from the petitioned source of radiation will be less than from these approved

sources. Accordingly, FDA has concluded that the proposed use is safe in terms of exposure to potential radiolysis products.

C. Neutron-Induced Radioactivity

Neutrons have a greater propensity to induce radioactivity in scanned materials than x rays and gamma rays of the same energy. To assess the induction of radioactivity in food by neutron irradiation from a cargo surveillance system, the petitioner submitted a 1992 report (the Harwell Report) that was prepared by Harwell Laboratory of the United Kingdom's Atomic Energy Authority (Ref. 1) and a study that was performed by the petitioner (Ref. 2). FDA contracted for an independent evaluation of the data in the petition by the U.S. Department of Energy, Oak Ridge National Laboratory (ORNL) (Ref. 3). The references provide the primary basis for FDA's conclusion regarding the safety of the petitioned use of neutron radiation.

The Harwell Report assessed the radiological implications of the use of neutron-based cargo surveillance techniques on cargoes of food. Three cargo scenarios were investigated; semi-infinite slabs (representing inspection of a large transport container of food), 1 kilogram (kg) of food in a 20-kg suitcase (representing airport inspection of a piece of luggage containing a small quantity of food (e.g., a lunch)), and 2-meter high pallets of food. Calculations were made for 17 different types of food simulating exposure to 0.5 Gy of neutrons (50 times higher than the maximum petitioned dose level of 0.01 Gy) with energies of 1, 2, 5, 8, and 14 MeV. Calculations included induced activities and the resultant doses to consumers after ingesting foods 5 minutes to 1 month after inspection. In addition, in selecting the food to be used for the cargo scenarios, three types of food were considered for the calculations based upon the chemical elements of the foods (e.g. calcium, iron, magnesium,

sodium, potassium): A single distribution representing the maximum credible concentrations of the elements in any food; a single "reference" distribution of 47 elements obtained from studies of dietary intake; and distributions corresponding to elemental concentrations in 17 common food types. Of these three distributions, the one considered the most realistic was the single "reference" distribution because it is based on the daily elemental requirements for "reference" man. For this distribution, the report provided calculations of radiation dose per unit activity intake into the body for induced activities of the neutron-irradiated "reference" food at a consumption rate of 2.88 kg of food per day and the resultant dose to reference man after ingesting the foods immediately after inspection and up to 1 month after inspection. Prior to irradiation, the ingestion dose of "reference" food is reported to be 1.823×10^{-10} Sieverts per gram (Sv/g). The authors calculated that, depending on the energy of the neutron beam and an absorbed dose in the reference food of 0.5 Gy, the ingestion doses from consuming the "reference" food 1 hour, 8 hours, and 1 day after irradiation would range from 9.2×10^{-10} to 3.2×10^{-9} Sv/g, 5.3×10^{-10} to 1.7×10^{-9} Sv/g, and 3.7×10^{-10} to 9.2×10^{-10} Sv/g, respectively. As this example and others below illustrate, any induced radioactivity is small and dissipates rapidly. Therefore, within 1 day, the ingestion dose from inspected foods would be essentially the same from natural radioactivity in the same food. FDA notes that the Harwell Report addresses a neutron dose 50 times higher than that proposed in the petition and reports radioactivity in the food within 24 hours of inspection. Because food subject to this regulation would be inspected at a far lower dose, and would unlikely be consumed within 24 hours of inspection considering the logistics of food

transportation, any residual induced radioactivity would be well below what occurs naturally.

The calculations provided by the petitioner were based on computer modeling and estimated the committed effective dose equivalents to adults, children, and infants due to ingestion of neutron-radiation inspected foods 12 hours after exposure to an 8 MeV neutron fluence rate of 5×10^5 n $cm^{-2}sec^{-1}$, for a period of 1 second, corresponding to a dose of 0.021 milliGray (mGy). The petitioner identified representative foods, the elemental composition of each food, and typical values for the annual amount of each food ingested. The calculated annual effective doses from consumption of foods that have been irradiated ranged from 3.42×10^{-11} to 2.01×10^{-8} Sv, which is significantly below the annual effective dose from natural radioactivity in food that is reported to be 3.9×10^{-4} Sv per year[1]. Although the absorbed dose in this study is approximately 500 times less than the maximum petitioned dose level of 0.01 Gy (10 mGy), the calculated annual effective dose from foods inspected with high energy neutrons is 20 thousand to 11 million times less than the annual effective dose from naturally occurring radioactivity in food.

ORNL performed an independent assessment for a subset of foods considered by the petitioner, and ingestion doses per unit of food were found to be in general agreement with those presented in the petitioner's supportive documentation. In addition, ORNL designed three extreme-case scenarios regarding consumption of food inspected with pulsed fast neutrons. One scenario assumed the entire diet has been irradiated for 1 second and then consumed 12 hours later. This scenario, although highly conservative, is considered to be the most reasonable of the three. The second scenario

[1]This dose is based on data from the National Council on Radiation Protection and Measurements, *Ionizing Radiation Exposures of the Population of the United States*, 1987.

assumed infrequent (equivalent to 10 full days of dietary needs per year) consumption of food 5 minutes after it had been irradiated for 1 second. The third scenario assumes infrequent tasting of food immediately after it had been irradiated for 5 minutes. The calculated annual effective doses for each scenario is 4.8×10^{-8} Sv, 3.4×10^{-7} Sv, and 1.0×10^{-5} Sv, respectively, which are approximately 40 to 8,000 times less than the annual effective dose from consumption of foods due to naturally occurring radioactivity.

D. Need for a Lower Energy Limit

The petitioner proposed a range of up to 9 MeV and with no lower limit, for the source's average neutron energy. Fast neutrons with high energy (greater than 1 MeV) are necessary to penetrate large cargo containers, whereas lower energy neutrons (less than 1 MeV), including thermal neutrons, have less penetrating power and are more likely to induce radioactivity in food. Therefore, FDA considered whether the data in the petition demonstrate that a source of high energy neutrons would require a lower energy limit to ensure safe use. Although the petitioner originally proposed a neutron energy range up to 9 MeV, the Harwell Report which was submitted by the petitioner is based on neutron energy levels ranging from 1 to 14 MeV and, therefore, supports the safety of neutron energies within that range. Because the data in the petition do not adequately address the issue of induced radioactivity from neutrons of energy below 1 MeV, and because neutrons with such energy levels are not explicitly intended to be used, FDA concludes that a minimum energy level requirement of 1 MeV is appropriate. In addition to this lower energy limit, FDA has also concluded that, based on information in the petition, it is necessary to restrict the neutron source to one that produces monoenergetic neutrons. A monoenergetic source produces neutrons within a narrow energy

distribution compared to a source that is not monoenergetic. Such a restriction will limit the number of lower energy neutrons that are emitted even if the source's average neutron energy is 1 MeV.

IV. Conclusion of Safety

FDA has evaluated the data submitted in the petition and other relevant material and concludes that consumption of food inspected by a source of monoenergetic neutrons between 1 and 14 MeV 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 (see **FOR FURTHER INFORMATION CONTACT**). 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

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an EA nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data

sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Irradiation in the Production, Processing, and Handling of Food

Description: The regulation as amended requires that monoenergetic neutron sources producing neutrons at energies not less than 1 MeV but no greater than 14 MeV used for inspection of container shipments which may contain food bear a label stating the minimum and maximum energy of radiation emitted by the neutron source. The label or accompanying labeling shall also bear adequate directions for safe use and a statement that no food shall be exposed to this radiation source so as to receive a dose in excess of 0.01 Gy. This information is needed to ensure safe use of the source of radiation as a direct food additive.

Description of Respondents: Manufacturers of monoenergetic neutron radiation source.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs
179.21(a)(5), (b)(1)(iv), and (b)(2)(v)	1	1	1	1	1	$100

[1]There are no capital costs associated with this collection of information.

Estimated Annualized Cost for the Burden Hours

The operating and maintenance cost associated with this collection is $100 for preparation of labels.

The information collection requirements in this final rule have been approved under OMB control number 0910–0549. This approval expires January 31, 2005. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Division of Dockets Management and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Findlay, D. J. S., R. A. Forrest, and G. M. Smith, "Neutron-Induced Activation of Food," (Harwell Report), AEA-InTec–1051, 1992.

2. Ryge, P., I. Bar-Nir, M. Simic, "Food Safety Effects of Inspection by SAIC Pulsed Fast Neutron Analysis Explosive Detection System," SAIC, 1992.

3. Easterly, C. E., K. F. Eckerman, R. H. Ross, D. M. Opresko, "Assessment of Petition to Use Pulsed Fast Neutron Analysis (PFNA) in Inspection of Shipping Containers Containing Foods," Oak Ridge National Laboratory, Life Sciences Division, 2003.

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)(5), (b)(1)(iv), and (b)(2)(v) 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) * * *

(5) Monoenergetic neutron sources producing neutrons at energies not less than 1 MeV but no greater than 14 MeV.

(b) * * *

(1) * * *

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

(2) * * *

(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).

Dated: Dec. 14, 2004

December 14, 2004.

Leslye M. Fraser

Leslye M. Fraser,

Director,

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

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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