

GAO

Report to the Honorable  
Douglas H. Bosco, House of  
Representatives

May 1990

# FOOD IRRADIATION

## Federal Requirements and Monitoring



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Human Resources Division

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May 3, 1990

The Honorable Douglas H. Bosco  
House of Representatives

Dear Mr. Bosco:

Because of your concern about the safety of food that has been exposed to radiation for preservation purposes, you asked that we provide the following information:

- federal agencies that are responsible for monitoring food irradiation activities, including inspecting firms that irradiate food;
- food products approved for irradiation;
- companies that are licensed and operating food irradiation facilities in the United States; and
- state actions to restrict food irradiation.

In performing our work, we contacted several federal and state agencies and private organizations to obtain data on food irradiation. Appendix I lists the organizations we contacted.

On February 2, 1990, we briefed your staff on the results of our work, and as requested, this report summarizes the information we provided. In short, we found that the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) have primary responsibility for regulating food irradiation. FDA has approved several food products to be irradiated, including fresh fruit and vegetables, pork, and spices. However, neither FDA nor USDA has reliable information on what food products are irradiated or who is irradiating food. FDA believes that irradiated foods pose a low health risk. However, because of consumer concerns, several states have enacted or proposed legislation restricting food irradiation.

Neither FDA nor USDA has a specific program to inspect food irradiation facilities. FDA, as a part of its routine inspections of food processing establishments between 1986 and 1989, identified four firms that irradiated food and inspected their irradiation processes. These inspections did not identify any problems. No USDA-inspected food firms are irradiating meat, poultry, or egg products. The National Coalition to Stop Food

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Irradiation has identified 16 facilities that irradiate food; this was the most comprehensive list of such facilities that we found.<sup>1</sup>

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## Background

Irradiation is used to sterilize and preserve foods. Foods are briefly exposed to a radiation source (typically cobalt-60) that penetrates the interior of the food and disrupts the organisms or processes responsible for degradation or disease.

Research on food irradiation has been going on for many years. Regulators throughout the world have been cautious in approving this process. However, with advances in radiation chemistry and increased research information, regulators are becoming increasingly satisfied that foods irradiated at low radiation doses are safe to eat.

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## Federal Agencies Responsible for Monitoring Food Irradiation Companies and Products

FDA and USDA are responsible for regulating the safety of food, which includes approving irradiation of specific foods. The Nuclear Regulatory Commission (NRC) is responsible for licensing firms to use nuclear materials to irradiate products, including foods.

Under the Federal Food, Drug, and Cosmetic Act, FDA is responsible for assuring that food products and food additives are safe to eat.<sup>2</sup> By statute, food irradiation is defined as a food additive, and as such, FDA must first determine its safety before any food may be treated with radiation. FDA issues regulations prescribing the conditions under which a food may be treated with radiation and inspects domestic firms irradiating food and imported food products. As of May 1990, FDA had approved irradiation of several food products, including spices, pork, and fresh fruits and vegetables. Appendix II lists the foods that FDA has determined can be irradiated safely, the maximum radiation dosages permitted, and the purpose for irradiating the foods.

USDA is responsible for administering the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. These laws prohibit the marketing of adulterated meat, poultry,

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<sup>1</sup>The coalition, a nonprofit organization, was established in 1984 to protest the irradiation of food, educate the public, and provide assistance to concerned groups and individuals on food irradiation.

<sup>2</sup>FDA shares responsibility with the Department of Commerce for the regulation of fish products. Commerce does not routinely inspect fish for irradiation, but upon request will certify that fish for export has not been irradiated.

and egg products. Irradiated meat, poultry, or egg products are considered adulterated and not allowed to be marketed in the United States or exported unless they are irradiated in conformity with the Federal Food, Drug, and Cosmetic Act and related regulations. Therefore, for these products, FDA makes the initial determination on safety and the conditions under which such foods may be treated with radiation and promulgates regulations. USDA then issues its own regulations, which are based on the requirements contained in FDA's regulations.

Both FDA and USDA have approved the irradiation of pork. Firms that want to irradiate pork or other products under the regulatory authority of USDA must have their quality control programs approved by USDA. As of May 1, 1990, no firm had received USDA approval to irradiate pork. On May 1, FDA approved the irradiation of fresh and frozen poultry products. However, USDA will need to issue regulations before these products can be irradiated.

NRC, under the Atomic Energy Act of 1954, is responsible for granting licenses to companies operating nuclear facilities that irradiate commercial products, including foods. These facilities are required to meet NRC design, operating, management, training, and other requirements. NRC and states inspect these facilities for compliance with NRC requirements according to a priority system.<sup>3</sup> The facilities fall into seven priority groups, with Priority 1 facilities requiring the most frequent inspections because of the nature of the operations and the kinds of material that they handle. Facilities that irradiate commercial products are in Priority 1, and these facilities are inspected every year. These inspections focus on assuring that employees of the facility using nuclear materials and the public communities surrounding the facility are adequately protected from radiation exposure. As of January 1990, NRC and the states had granted licenses for the operation of 40 facilities to irradiate commercial products.

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## Labeling Requirements

Since 1966, FDA has required that irradiated whole foods carry a label stating that they have been irradiated. Since 1986, the labels of these products have had to also include a designated logo indicating that they have been irradiated. However, no statement or logo is required for processed products containing multiple ingredients, such as herbs, spices, or seasonings, some of which may have been irradiated. USDA

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<sup>3</sup>NRC has formal agreements with 29 states to regulate certain licensees under programs comparable to NRC's.

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labeling requirements for irradiated pork are similar to FDA's regulations.

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## Federal Monitoring of Food Irradiation

FDA and USDA have little data on food irradiation activities and, therefore, do not know the extent to which food is irradiated. Neither agency has a formal procedure to collect information on food products that are irradiated, irradiated ingredients used in foods, or companies that irradiate food. The most comprehensive information we identified was contained in a 1989 survey by the National Coalition to Stop Food Irradiation. The survey showed that, as of August 1989, NRC had granted licenses for 40 facilities to use nuclear materials in the manufacturing or processing of commercial products, including foods, baby powder, and medical supplies. Of these 40 facilities, 16 reported that they were involved in irradiating food at the time of the survey. Appendix III lists the 40 facilities and notes those that reported they were irradiating foods.

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## Food Irradiation Firms Not Targeted for Special Inspection

To date, federal inspections have not targeted companies irradiating food. FDA and USDA inspect companies irradiating food as part of their regular inspection programs of domestic and foreign firms.

If, during a regular inspection of a food firm, FDA finds that the firm is irradiating food, it will inspect the firm's irradiation process. During fiscal years 1986 through 1989, FDA made over 42,000 inspections of domestic food establishments. These inspections included four firms that were irradiating foods. FDA found no violations.

In the past 12 years, FDA has sent letters of violation to two firms that were irradiating food or using irradiated food ingredients that FDA had not approved. One letter resulted from a 1978 FDA inspection that found a New Jersey firm had violated the Federal Food, Drug, and Cosmetic Act and FDA regulations because it irradiated several food products for which FDA had not approved irradiation. In 1988, FDA sent a letter to a California firm, after being advised that the firm had used, as a food ingredient, mushrooms that had been irradiated at a level exceeding FDA's approved dosage. Both firms discontinued the violative practices.

USDA has inspectors permanently stationed in domestic slaughterhouses and meat, poultry, and egg processing plants and periodically inspects foreign establishments. USDA's regular inspections have not found any of these products being irradiated. Nevertheless, a USDA official told us that

in 1985 an informant reported that a North Carolina firm had irradiated pork products without USDA approval. USDA's investigation of the reported incident confirmed this to be the case, and the firm was fined for its action.

Because many foreign governments permit various food products to be irradiated, FDA and USDA review import documents at U.S. ports of entry to identify such products.<sup>4</sup> FDA and USDA have not found any irradiated foods that have been imported into the United States. However, officials of these agencies said that irradiated foods are difficult to identify and there is no practical method to test imported food products for irradiation. These officials said that unless the import documents note that a food product has been irradiated, irradiation is very difficult to detect.

## Some States Restrict Use of Food Irradiation

Eight states have taken or are considering action to restrict the use of food irradiation. Maine, New Jersey, and New York have enacted legislation restricting the use of irradiation on foods or the sale or distribution of irradiated foods, except for spices used as an ingredient in a product. Officials of these states told us that their states took the actions in response to public concern by citizen groups rather than as a result of scientific evidence questioning the safety of food irradiation. New Jersey and New York officials also said that their states' actions to restrict the use of food irradiation were taken, in part, (1) because of perceived gaps in safety data related to food irradiation and (2) to allow more time to study the process and allow a consensus to emerge on its efficacy.

Legislatures in Alaska, California, Massachusetts, New Hampshire, and Pennsylvania have introduced resolutions or legislation that would ban or restrict the irradiation of foods.<sup>5</sup>

## Views of Agency Officials

FDA and USDA officials agreed that irradiating foods with low-dose radiation is safe. An FDA official told us that food irradiation firms have not been targeted for inspection because FDA has no basis to suspect that the process poses a serious health risk. He said that if FDA was to increase its

<sup>4</sup>An April 1988 Food Irradiation Newsletter of the International Atomic Energy Agency listed 25 foreign governments that permit the irradiation of various food products, including chicken, fish products, shrimp, and coffee beans.

<sup>5</sup>Actions by state legislatures on food irradiation were reported in the Preservation of Food by Irradiation by the Congressional Research Service, Aug. 18, 1989.

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inspection effort of food irradiation firms, it would have to divert resources from issues that it believes pose a greater health concern.

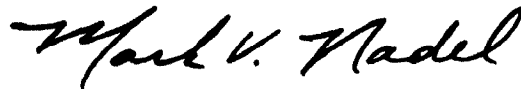
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As requested by your office, we did not provide a copy of this report for comment to FDA, USDA, or NRC. However, we discussed the information in this report with officials of these agencies and incorporated their comments where appropriate. These officials generally agreed with the report's contents.

Also, as agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to cognizant congressional committees and other interested parties, and we will make copies available to others on request.

Should you need additional information on the contents of this report, please call me on (202) 275-6195. Other major contributors to this report are listed in appendix IV.

Sincerely yours,



Mark V. Nadel  
Associate Director,  
National and Public Health Issues





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## Abbreviations

FDA	Food and Drug Administration
NRC	Nuclear Regulatory Commission
USDA	U.S. Department of Agriculture

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# Organizations GAO Contacted

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## Federal Agencies

Department of Health and Human Services:

- Food and Drug Administration

U.S. Department of Agriculture:

- Agricultural Marketing Service
- Agricultural Research Service
- Animal and Plant Health Inspection Service
- Economic Research Service
- Federal Grain Inspection Service
- Food Safety and Inspection Service

Department of Commerce:

- Chairman, Interagency Committee on Food Irradiation
- National Marine Fisheries Service

Department of Defense:

- U.S. Army, Office of Food Inspection

Nuclear Regulatory Commission

Congressional Research Service

Office of Technology Assessment

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## State Agencies

Department of Agriculture and Food, Augusta, Maine

Department of Health, Trenton, New Jersey

Department of Agriculture and Markets, Albany, New York

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## Private Organizations

Food Marketing Institute, Washington, D.C.

National Coalition to Stop Food Irradiation, San Francisco, California

# Food Products Approved for Irradiation by Food and Drug Administration (As of May 1, 1990)

<b>Food</b>	<b>Maximum dosage permitted</b>	<b>Purpose of irradiation</b>
Pork	100,000 RAD <sup>a</sup>	Control <i>Trichinella Spiralis</i>
Fresh and frozen poultry products	300,000 RAD	Control <i>Salmonella</i> and other bacteria
Fresh fruit and vegetables	100,000 RAD	Inhibit growth and maturation
Wheat, rice, barley, fruit, vegetables, nuts, and other foods where infestation occurs	100,000 RAD	Disinfestation of arthropod pests (insects, spiders, mites)
Dry and dehydrated enzyme preparations <sup>b</sup>	1 million RAD	Microbial disinfectior
Dry and dehydrated aromatic vegetable substances—including herbs, seeds, spices, vegetable seasonings, blends of these substances, and turmeric and paprika when used as color additives	3 million RAD	Microbial disinfectior

<sup>a</sup>RAD is a unit of measurement used by FDA to express the mount of energy (radiation) absorbed by th subject exposed to the energy.

<sup>b</sup>Enzymes are used to improve food processing and the quality of the finished food.

Source: 21 C.F.R. 179.26.

# Companies With Licenses to Operate Commercial Radiation Facilities (As of August 1989)

State and firm	Irradiating foods?
<b>Arkansas</b>	
Process Technology, Inc., West Memphis	Yes
<b>California</b>	
Radiation Sterilizers, Tustin	Yes
<b>Colorado</b>	
Cobe Laboratories, Lakewood	No
Iotech, Inc., Englewood	No
<b>Connecticut</b>	
Becton Dickenson and Company, North Canaan	No
<b>Florida</b>	
Sherwood Medical, Deland	No
<b>Georgia</b>	
Radiation Sterilizers, Decatur	Yes
<b>Illinois</b>	
Isomedix, Morton Grove	Yes
Isomedix, Liberty	Yes
Radiation Sterilizers, Shamburg	Yes
<b>Maryland</b>	
Neutron Products, Dickerson (2 facilities)	No
Terumo Medical Corporation, Elkton	No
<b>Massachusetts</b>	
Isomedix, Northborough	Yes
<b>Minnesota</b>	
Minnesota Mining and Manufacturing Company, St. Paul	No
<b>Mississippi</b>	
Isomedix, Columbus	Yes
<b>Nebraska</b>	
Becton, Dickenson and Company, Broken Bow	No
Sherwood Medical, Norfolk	No
<b>New Jersey</b>	
Isomedix, Whippany	Yes
Isomedix, Dover	Yes
Ethicon (Johnson and Johnson), Sommerville	No
Radiation Technology, Rockaway	Yes
<b>North Carolina</b>	
Processed Technology, Inc., Haw River	Yes
<b>Ohio</b>	
Isomedix, Groveport	No
Radiation Sterilizers, Westerville	No

(continued)

**Appendix III  
Companies With Licenses to Operate  
Commercial Radiation Facilities  
(As of August 1989)**

<b>State and firm</b>	<b>Irradiating foods?</b>
<b>Pennsylvania</b>	
Permagrain Products, Inc., Karthaus	No
<b>South Carolina</b>	
Becton Dickenson and Company, Sumter	No
Isomedix, Spartanburg	Yes
Bausch and Lomb, Greenville	No
<b>South Dakota</b>	
Minnesota Mining and Manufacturing Company, South Brookings	No
<b>Texas</b>	
Ethicon, Inc., San Angelo	No
Johnson and Johnson Products, Inc., South Sherman	No
Convertors (Baxter-Travenol Corp.), El Paso	No
Surgikos, Inc., Arlington	No
Surgikos, El Paso	No
Sherwood Medical, Commerce	No
Radiation Sterilizers, Fort Worth	Yes
Ansell International, El Paso	No
<b>Utah</b>	
Isomedix, Sandy	Yes
<b>Virginia</b>	
Applied Radiant Energy Corporation, Lynchburg	Yes

Note: This survey identified 40 radiation facilities, of which 16 irradiated foods.

Source: National Coalition to Stop Food Irradiation survey, August 1989.

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# Major Contributors to This Report

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