

August 2000

FOOD IRRADIATION

Available Research Indicates That Benefits Outweigh Risks



GAO

Accountability * Integrity * Reliability

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Abbreviations

FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Points
IAEA	International Atomic Energy Agency
kGy	kiloGray
NRC	Nuclear Regulatory Commission
USDA	U.S. Department of Agriculture
WHO	World Health Organization



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The Honorable Tom Bliley
Chairman, Committee on Commerce
The Honorable Fred Upton
Chairman, Subcommittee on Oversight and Investigations
Committee on Commerce
House of Representatives

While the U.S. food supply is generally considered to be one of the safest in the world, foodborne illness continues to be a source of concern for consumers. Each year, millions of Americans become ill from foodborne infections and up to 5,000 people die. The economic costs are also large—the U.S. Department of Agriculture (USDA) estimates that diseases caused by seven major foodborne pathogens could result in medical costs and productivity losses of between \$6.6 billion and \$37.1 billion annually. Furthermore, recalls of contaminated food—such as the massive recalls of thousands of pounds of ground beef contaminated with *Escherichia coli* (*E. coli*) O157:H7—have resulted in severe economic losses to the affected industry.

There is no silver bullet on the horizon to eliminate foodborne illness. However, many food safety experts believe that irradiation can be an effective tool in helping to control foodborne pathogens and should be incorporated as part of a comprehensive program to enhance food safety. Irradiation, which involves exposing food briefly to radiant energy (such as gamma rays¹ or high-energy electrons), can reduce or eliminate microorganisms that contaminate food or cause food spoilage and deterioration. Nearly 40 countries worldwide have approved the use of irradiation for various types of food.

In the United States, the Food and Drug Administration (FDA) has primary regulatory responsibility for ensuring the safe use of irradiation on all foods. At the same time, USDA's Food Safety and Inspection Service is responsible for the lawful processing of meat, poultry, and some egg

¹Cobalt-60, a radioactive isotope, is one of two approved gamma ray sources for food irradiation. Cesium-137 is the other approved source; however, it is not currently being used commercially for irradiating food.

products, including the irradiation of such products. Hence the two agencies have overlapping responsibilities for ensuring the safety of certain irradiated foods. To date, irradiation has been approved by FDA (and USDA where applicable) for use on uncooked meat and poultry and fresh shell eggs, as well as a variety of other foods, including spices and fresh fruits and vegetables. Final approval for the irradiation of meat (including ground beef) took effect in February 2000. This action has heightened interest in using irradiation to reduce foodborne pathogens. Ground beef poses particular food safety concerns because the grinding process can spread pathogens present on the meat's surface throughout the product.

While federal food safety agencies have approved irradiation as safe for a variety of foods, concerns about the safety of these foods (such as toxicity and reduced nutritional quality), the impact of the irradiation process on worker safety and the environment, and consumers' willingness to purchase irradiated foods have limited their availability in the United States. In response to these concerns, you asked that we determine (1) the extent and the purposes for which food irradiation is being used in the United States and (2) the scientifically supported benefits and risks of food irradiation.

Results in Brief

To date, only limited amounts of irradiated foods have been sold in the United States. Irradiated spices, herbs, and dry vegetable seasonings constitute the largest category of irradiated food; in 1999, about 95 million pounds of these products were irradiated, accounting for about 10 percent of their total consumption. In addition, small amounts of irradiated fresh fruits, vegetables, and poultry have been available in wholesale and retail markets, primarily in Florida and several midwestern states. Irradiated frozen ground beef has recently begun to be marketed in several midwestern states and Florida. The major purchasers of irradiated foods are health care and food service establishments, which purchase them primarily to minimize the threat of foodborne illness. For example, nursing homes and hospitals serve irradiated poultry to patients with weakened immune systems to reduce the risk of contracting a foodborne illness that would further jeopardize their condition. Concerns on the part of food processors, retailers, and others about consumer acceptance of irradiated foods have limited their availability to date.

Scientific studies conducted by public and private researchers worldwide over the past 50 years support the benefits of food irradiation while indicating minimal potential risks. For example, an expert committee

convened by the World Health Organization reviewed the findings of over 500 studies and concluded that food irradiation creates no toxicological, microbiological, or nutritional problems. Cited benefits of food irradiation include (1) reducing foodborne pathogens; (2) extending the shelf life of some fruits and vegetables by preventing sprouting, deactivating mold, and killing bacteria; and (3) controlling insect pests—thus reducing the need for environmentally harmful fumigants. These studies have not borne out concerns about the safety of consuming irradiated foods. For example, the studies indicated that chemical compounds in irradiated food are generally the same as those in cooked foods, and any differences do not put consumers at risk. As for nutritional quality, the main components of food—carbohydrates, protein, and fats—undergo minimal change during irradiation, and vitamin loss corresponds to that in foods that are cooked, canned, or held in cold storage. Finally, regarding worker safety and the environment, commercial irradiation plants are strictly regulated. Worldwide, over the past 30 years, while several accidents have resulted in injury or death to workers because of radiation exposure, all of the accidents occurred because safety systems and control procedures had been bypassed. Furthermore, in North America, in over 40 years of transporting the types of radioactive isotopes used for irradiation, there has never been an accident resulting in the escape of these materials into the environment.

We provided a draft of this report to FDA for its review and comment. FDA officials, including the Director of the Division of Product Policy, Center for Food Safety and Applied Nutrition, generally agreed with the information presented in the report and provided technical clarifications, which were incorporated as appropriate.

Background

Several Processes Are Used to Irradiate Food

Food irradiation is the process of exposing food, either prepackaged or in bulk, to controlled levels of ionizing radiation. Ionizing radiation is a type of energy similar to radio and television waves, microwaves, and infrared radiation. However, the high energy produced by ionizing radiation allows it to penetrate deeply into food, killing microorganisms without significantly raising the food's temperature.

In the United States, three types of ionizing radiation have been approved for irradiating food—gamma rays, high-energy electrons (sometimes referred to as electron beams), and X-rays. Until recently, gamma rays—specifically, those produced by cobalt-60—have been the exclusive source of food irradiation in the United States. While the three types of ionizing radiation have the same effects on food, there are some differences in how they work. For example, electron beams and X-ray radiators are operated by electricity and do not use radioactive isotopes (e.g., cobalt-60). However, electron beams cannot penetrate as far into food as gamma rays or X-rays;² thus, they are used primarily for treating thin packages of food or a thin stream of grains or powders.

Only two gamma ray facilities in the United States are used primarily for irradiating food. However, many such facilities are used for other purposes, such as sterilizing medical, pharmaceutical, and consumer products (e.g., syringes, bandages, dairy and juice containers, and baby bottle nipples).³ The one electron beam facility that irradiates food commercially began supplying irradiated ground beef to grocery stores in Minnesota in May of this year. Additional electron beam facilities are expected to begin irradiating beef and poultry for commercial sale later this year and early next year. However, as with gamma ray facilities, other electron beam plants—primarily used for sterilizing medical supplies—have been operational for years. X-ray technology is still being tested for use in food irradiation, and a plant is being constructed in Hawaii to disinfest tropical fruit. However, at this point, X-ray technology is not as economical as gamma rays or electron beam technology.

Depending on the dose of radiation used, rapidly growing cells (such as those in foodborne pathogens, spoilage microorganisms,⁴ insects, parasites, and plant tissues) are deactivated or killed. As a result, irradiation is used for a variety of purposes, such as reducing or eliminating foodborne pathogens, disinfesting food, and extending product shelf life. However, not all foods are suitable for irradiation. For example, some fruits

²Electron beams have a maximum one-sided treatment penetration capability of about 1-½ inches in food items at the approved dose ranges; with double-sided electron beam treatment, these items can be no more than about 3-½ inches thick.

³Some of these facilities also treat food products.

⁴Spoilage microorganisms, such as certain bacteria, yeast, and mold, cause strong odors and shorten shelf life but are not generally associated with human illness.

are very sensitive to radiation and their skins are damaged, and other foods (such as cucumbers, grapes, and some tomatoes) turn mushy.

In the United States, FDA first approved irradiation for use on a food product (i.e., wheat and wheat flour) in 1963. (See app. II for a chronology of food irradiation events.) Since then, it has been approved for use on such products as vegetables, spices, fruits, poultry, and, most recently, refrigerated and frozen uncooked meat and fresh shell eggs. Worldwide, almost 40 countries permit the use of irradiation on over 50 different foods, and an estimated 500,000 tons of food are irradiated annually. However, national laws are divergent. For example, the European Union has not yet agreed on guidelines for regulating food irradiation, primarily because of resistance from Germany. On the other hand, the Netherlands, Belgium, and France irradiate many types of food, including considerable amounts of frozen seafood and frog legs and dry food ingredients. Spices are irradiated in many countries, including Argentina, Israel, Norway, France, South Africa, and Mexico.

Many Federal Agencies Regulate Food Irradiation

Many federal agencies have regulatory responsibilities related to food irradiation, including FDA, USDA, the Nuclear Regulatory Commission (NRC), the Occupational Safety and Health Administration, and the Department of Transportation—with FDA having primary regulatory responsibility for ensuring the safety of irradiated foods. These agencies regulate a range of issues, including the types of food that can be irradiated, the process by which food can be irradiated, the safe use of radiation, the safety of the workers in irradiation facilities, and the safe transportation of radioactive material.

Under the Federal Food, Drug, and Cosmetic Act, FDA has overall responsibility for regulating the safety of all foods, except for meat, poultry, and some egg products that are USDA's responsibility. FDA's specific responsibilities for food irradiation derive from the Food Additives Amendment of 1958, which gave the agency responsibility for ensuring the safety of food additives. While most food additives are substances that are added to foods, the act specifically defined the source of radiation to be a food additive.⁵ Radiation sources (i.e., cobalt-60, electron beams, and X-ray generators) are considered to be food additives because their use could affect the characteristics of food. FDA's responsibilities for food irradiation include (1) determining the safety of the radiation sources used in food processing; (2) issuing regulations that prescribe the conditions under which foods can be irradiated and the maximum permitted radiation dose, which is measured in units called kiloGray (kGy);⁶ and (3) inspecting the facilities that irradiate food products.

Food additive regulations governing the use of food irradiation are initiated either by a petition submitted to the agency or, less often, by FDA itself. In both instances, FDA must determine whether the additive is safe under all conditions of permitted use. Once FDA issues a final regulation, the additive can be used by anyone who adheres to the specified conditions of use. Since 1963, FDA has approved the use of irradiation for several foods to (1) reduce illness-causing microorganisms, (2) retard product maturation, and/or (3) meet quarantine requirements for certain insect pests. Petitions to irradiate shellfish, seeds for sprouts, nonrefrigerated meat products, and processed foods are pending. (See app. III for a list of foods and uses approved by FDA.)

USDA's Food Safety and Inspection Service (FSIS) is also responsible for ensuring the safety of certain irradiated foods. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act,⁷ FSIS is responsible for prohibiting the marketing of

⁵Under 21 U.S.C. 321(s), "a food additive is any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any source of radiation. . .)."

⁶The kiloGray is the unit of measurement for the amount of energy absorbed by food during the irradiation process. For example, FDA has approved a dose of up to 7 kiloGray for frozen meat to control pathogens and extend shelf life.

⁷21 U.S.C. 601 et. seq., 21 U.S.C. 451 et. seq., and 21 U.S.C. 1031 et. seq., respectively.

adulterated meat, poultry, and egg products. When irradiated, these products are considered adulterated and, thus, cannot be sold unless they have been irradiated in conformity with FDA's and USDA's regulations. Both FDA and USDA require that irradiated food products be labeled; in general, their labeling regulations are similar. For example, both agencies require irradiated foods to be labeled with the international food irradiation symbol—the radura. (See fig. 1)

Figure 1: The International Food Irradiation Symbol—the Radura



Source: USDA.

In addition, the label must state that the product has been intentionally subjected to radiation. However, FDA's and FSIS' labeling requirements differ in at least one respect. FSIS' regulations require that irradiated meat and poultry ingredients in multi-ingredient meat and poultry products be identified on the list of ingredients. FDA does not have a similar requirement for multi-ingredient products.

In November 1997, the Congress directed FDA to reconsider its overall labeling requirement and seek public comment on possible changes. In February 1999, FDA issued a notice discussing labeling issues and invited public comments on whether changes were needed. As of June 2000, FDA had not completed analyzing the approximately 4,500 public comments it had received.

USDA's Animal and Plant Health Inspection Service regulates the use of irradiation as a pest control treatment on quarantined fruits and vegetables. Many countries (including the United States) require treatment of certain fresh produce, such as citrus, mangoes, and papayas, that often harbor nonnative insects or plant pathogenic pests that would have a negative economic, health, or environmental impact, if introduced. Currently, the Animal and Plant Health Inspection Service permits the use of irradiation to destroy these pests in certain fresh produce imported from Hawaii before their interstate distribution on the U.S. mainland.

NRC, the Department of Transportation, and the Occupational Safety and Health Administration have primary responsibilities for environmental and worker safety issues relating to radioactive materials.

- NRC is responsible for ensuring that nuclear materials are used safely within irradiation facilities. Food irradiation facilities must meet NRC's design, operating, management, training, and other requirements and are inspected yearly for compliance. In some instances, NRC relinquishes regulatory authority to state governments, which must require at least as much protection as NRC. Food irradiation facilities that use electron beams and X-ray technology are regulated by state governments.
- NRC and the Department of Transportation share primary responsibility for regulating the transport of radioactive materials. (The U.S. Postal Service, the Department of Energy, and the states are also involved in regulating the transportation of these materials.)
- The Occupational Safety and Health Administration regulates worker safety in food irradiation facilities. The agency requires that all radiation facilities operate under a worker safety program that, among other things, establishes procedures to protect workers from accidental exposure to radiation. This includes prominently displaying caution signs, labels, and signals and providing each employee with a personal device to measure radiation absorption. NRC, FSIS, and the Animal and Plant Health Inspection Service regulate aspects of worker protection in facilities that use nuclear materials, irradiate meat and poultry, and irradiate plant products, respectively.

Quantities and Uses of Irradiated Food in the United States are Limited

Despite extensive research on the safety of irradiated food and the approval of irradiation for several food products, only limited amounts of irradiated food are available in the United States. The food industry cites concerns about consumer acceptance as a major reason for the limited availability of irradiated food. While still limited, with the recent approvals of meat and fresh shell egg irradiation, the availability of irradiated food is increasing; additional increases are anticipated as a result of the expected approval of irradiation for other foods along with increased consumer education about food irradiation. Health care and food service establishments have been the primary users of irradiated food;⁸ they purchase these foods primarily to minimize the threat of foodborne illnesses.

Volume of Irradiated Food Is Small but Increasing

In the United States, an estimated 97 million pounds of food products are irradiated annually, representing a tiny fraction of the total amount of food consumed. Spices, herbs, and seasonings are the largest category of irradiated food, accounting for about 95 million pounds annually. Fruits and vegetables account for about 1.5 million pounds annually, and poultry accounts for approximately 500,000 pounds. Table 1 lists the estimated quantities and percentage of annual consumption for the types of foods that are irradiated in the United States.

Table 1: Estimated Annual Quantities and Percentage of Consumption for Irradiated Food in the United States, as of January 2000

Food product	Amount irradiated (millions of pounds)	Percentage of annual consumption
Spices and dry or dehydrated aromatic vegetable substances ^a	95.0	9.5
Fruits and vegetables	1.5	0.002
Fresh and frozen uncooked poultry	0.5	0.002
Total	97.0	

Notes: Refrigerated and frozen uncooked beef, pork, lamb, and goat have been approved for irradiation; however, as of January 2000, these products were not available commercially.

⁸This does not include spices, herbs, and dry vegetable substances that are used as ingredients in other food products.

^aRefers to substances used for flavoring or aroma (e.g., culinary herbs, seeds, spices, and vegetable seasonings).

Source: GAO's presentation of information from 21 C.F.R. 179.26 (Apr. 1, 1999, ed.) and estimates provided by the International Atomic Energy Agency and officials from the food irradiation industry.

Concerns about consumer acceptance of irradiated food are often cited by food industry officials as a major reason for the limited use of this technology. While several retail establishments, including a Chicago-area supermarket and Florida-area restaurant chain, sell irradiated chicken and some irradiated fruit, the nationwide availability of irradiated food has been extremely limited. Officials from a supplier of irradiated poultry said that, on several occasions, they tried to establish partnerships with poultry producers and retailers to expand the scope of their business but were unsuccessful. They said that retailers were reluctant to be the first to sell irradiated food in their areas.

Attitudes might be changing, however. Government and food industry officials believe that the market for irradiated food will increase following the recent approval to irradiate meat and fresh shell eggs and the anticipated approval for ready-to-eat products, such as precooked beef patties, luncheon meats, and sprouts. According to an irradiation company official, retailers and others might have more of an incentive to purchase irradiated beef, and particularly ground beef, because nonirradiated ground beef and beef are significant sources of *E. coli O157:H7*—a deadly foodborne pathogen. USDA considers raw beef products containing this pathogen to be adulterated, and the product must be destroyed. Although poultry is a source of dangerous foodborne pathogens, such as *Salmonella* (several species) and *Campylobacter jejuni*, these pathogens have not been declared adulterants, and products found to contain them are not required to be destroyed.⁹

In addition, consumers might be more inclined to purchase irradiated food as a result of the concerted public education effort that food irradiation companies have undertaken. These companies are using pamphlets, videos, and other educational tools to inform retailers and the public about the benefits of irradiation. The results of several consumer surveys indicate that as consumers become more educated about food irradiation, they are more likely to purchase these foods.

⁹In addition, poultry is more likely than beef to be thoroughly cooked prior to consumption; proper cooking kills most pathogens, thus making the product safer to eat.

Earlier this year, two food irradiation companies collaborated with several large food producers to test irradiated foods for consumer acceptance and marketability. One of the companies aligned with a beef processor to introduce irradiated beef patties into Minnesota supermarkets in May 2000. According to a company official, the patties were introduced into 84 stores on the first day, and over 250 supermarkets in five states were receiving irradiated beef patties by June 2000. The second company has established a partnership with a beef processor in Florida. As of June 2000, a few small food retailers have purchased irradiated beef products from this company.

Irradiated Foods Are Purchased Primarily for Their Food Safety Benefits

According to consumer surveys,¹⁰ irradiated food is purchased primarily for food safety benefits. These benefits are particularly important to health care and food service establishments—the primary purchasers of irradiated foods. For example, nursing homes and hospitals serve irradiated poultry to patients with weakened immune systems to reduce the risk of contracting a foodborne illness that would further jeopardize their health. In addition, a restaurant chain in Florida serves irradiated chicken to reduce its risk of having an outbreak of a foodborne illness. With the recent outbreaks of *Listeria monocytogenes* (a foodborne pathogen most commonly found in processed meats and soft cheeses), food processors are expected to become major users of food irradiation if the petition to allow irradiating ready-to-eat, processed food is approved.

Scientific Evidence Supports the Benefits of Food Irradiation and Indicates that Risks are Minimal

Irradiation has been studied extensively, and the consensus emerging from these studies is that food irradiation is a safe, effective tool for reducing foodborne pathogens. Other benefits of food irradiation include extending the shelf life of certain foods, decontaminating spices and other seasonings, and controlling insect infestation in grain products, fruits, and vegetables.

Moreover, the risks that have sometimes been attributed to irradiated food—such as the creation of potentially harmful chemical by-products and the loss of nutrients—have been shown to be minimal. Worker and environmental safety issues, particularly with respect to the use of cobalt-

¹⁰ *Consumer Expectations Regarding Irradiated Foods*, Christine Bruhn, Director, Center for Consumer Research, University of California-Davis, Apr. 2000; *Consumer Perceptions of Meat Irradiation*, Marjorie Troxel, Research Specialists, Sosland Research Services, Apr. 2000.

60 (a source of gamma rays) in food irradiation, have also raised concerns. However, irradiation facilities are subject to strict federal and state regulations. Worldwide, over the past 30 years, while several accidents have injured or killed workers because of radiation exposure, all of these accidents occurred because safety systems and control procedures had been bypassed. Furthermore, in North America, in over four decades of transporting the types of radioactive isotopes used for irradiation, there has never been an accident resulting in the escape of radioactive materials into the environment. (See app. IV for commonly asked questions and answers on the benefits, the risks, and other issues relating to food irradiation.)

Numerous national and international health and scientific organizations—including the American Medical Association, FDA, the World Health Organization, and the Food and Agriculture Organization—have endorsed food irradiation. Most major U.S. food-related consumer groups cautiously support or are neutral on the use of food irradiation, particularly for vulnerable populations. However, several groups—such as Public Citizen and Food and Water, Inc.—oppose its use because they believe that FDA has not sufficiently proven that irradiation can safely be used on food and that more long-term research on the effects of consuming irradiated food is needed.

Irradiation Reduces Foodborne Pathogens, Extends Shelf Life, Decontaminates Spices, and Controls Insect Infestation

A major benefit of food irradiation is its effectiveness as a tool in reducing foodborne pathogens, according to numerous studies conducted worldwide for over 50 years. Irradiation, within approved dosages, has been shown to destroy at least 99.9 percent of common foodborne pathogens, such as *Salmonella (various species)*, *Campylobacter jejuni*, *E. coli O157:H7*, and *Listeria monocytogenes*, which are associated with meat and poultry.¹¹ However, irradiation at the approved doses does not sterilize food nor make it shelf-stable (i.e., capable of being stored without refrigeration); FDA officials and others emphasize that irradiation does not replace proper food handling—irradiated food must still be properly refrigerated and cooked prior to consumption.

¹¹Viruses, bacterial spores, some mold and yeasts, mycotoxins produced by certain types of bacteria and mold, and prion particles (the agent thought to be responsible for bovine spongiform encephalopathy, or “mad cow” disease) are highly resistant to irradiation.

Because of irradiation's effectiveness in controlling common foodborne pathogens and in treating packaged food (thereby minimizing the possibility of cross-contamination prior to consumer use), federal food safety officials and others view irradiation as an effective critical control point in a Hazard Analysis and Critical Control Points (HACCP) system.¹² According to a food scientist who is currently the director of the Food Chemicals Codex at the National Academies Institute of Medicine, irradiation fulfills several conditions necessary for a critical control point. In addition to its pathogen-reducing abilities, appropriate radiation doses are well-known, and compliance can be monitored by accurately measuring the absorbed radiation dosage.

A second important benefit of irradiation is that it can prolong the shelf life of many fruits and vegetables. It does this by reducing spoilage bacteria and mold and inhibiting sprouting and maturation. As a result, products can be harvested when fully ripened and can be transported and displayed for longer periods while maintaining desirable sensory qualities longer than nonirradiated products. For example, according to the Council for Agricultural Science and Technology,¹³ irradiating strawberries extends their refrigerated shelf life to 3 weeks without decay or shrinkage. Irradiation can also be used as an alternative to chemical sprout inhibitors for tubers, bulbs, and root crops. These inhibitors are considered by some to be harmful, and many countries have prohibited their use. The softening and browning associated with the ripening of certain fruits and vegetables, such as bananas, mangoes, and mushrooms, can be delayed with irradiation.

Irradiation is also an effective means to decontaminate certain food products, thereby eliminating or reducing the use of toxic or environmentally harmful fumigants. Spices, herbs, and dry vegetable seasonings are the most commonly irradiated food products in the United States. These products are frequently dried in the open air and become

¹²A HACCP system is a science-based process intended to identify potential sources of pathogen contamination and establish procedures to prevent contamination. All state and federally inspected meat and poultry slaughter and processing plants are required to have HACCP plans. A critical control point is a point, step, or procedure at which control can be applied and a food safety hazard can be prevented or reduced to an acceptable level.

¹³The Council is a nonprofit organization composed of 38 scientific societies and other members (e.g., individuals, companies, and nonprofits). Its mission is to identify food and fiber, environmental, and other agricultural issues and interpret related scientific research information for public policy decisionmakers.

severely contaminated by air- and soil-borne microorganisms and insects. Food processors often fumigate spices, herbs, and dry vegetable seasonings with ethylene oxide to reduce or eliminate pathogens and with methyl bromide to reduce insects. However, both of these products are extremely toxic and/or damaging to the environment—ethylene oxide has been banned in many countries and methyl bromide is being phased out globally for environmental reasons.

Finally, irradiation can be used as a pest control treatment on quarantined fruits and vegetables to prevent the importation of harmful pests—such as the Mediterranean fruit fly. To minimize this risk, USDA's Animal and Plant Health Inspection Service's quarantine procedures require the use of fumigation or heat (hot water or hot air) or cold treatment of fruit that is not ripe. Irradiation treatment is an effective alternative for many types of fresh produce because it can be used on riper fruit and on fruit that cannot tolerate heat treatment. Moreover, a number of past quarantine treatments have recently been prohibited—an example being fumigation with ethylene dibromide. In 1997, the Inspection Service issued a final rule allowing the use of irradiation as a quarantine treatment for papayas, carambola, and litchi coming from Hawaii to the U.S. mainland. In May 2000, the Inspection Service proposed a rule to allow irradiation for use in killing fruit flies and mango seed weevils on fruits and vegetables imported into the United States. If approved, this rule will further expand the use of irradiation in pest control.

Scientific Studies Indicate Minimal Risks Are Associated With Food Irradiation

Despite the benefits of irradiation, the widespread use of irradiated food hinges largely on consumer confidence in the safety and the wholesomeness of these products. The cumulative evidence from over four decades of research—carried out in laboratories in the United States, Europe, and other countries worldwide—indicates that irradiated food is safe to eat. The food is not radioactive; there is no evidence of toxic substances resulting from irradiation; and there is no evidence or reason to expect that irradiation produces more virulent pathogens among those that survive irradiation treatment. In addition, nutritional losses from food irradiation are similar to other forms of food processing and would not adversely affect a food's nutritional value. In particular:

-
- Radioactivity in irradiated foods is not seen as a concern because the energy in the currently approved radiation sources (cobalt-60, cesium-137, electron beams, and X-rays) is too low to induce radioactivity. According to the International Consultative Group on Food Irradiation,¹⁴ irradiation cannot increase the normal trace amounts of background radioactivity of food at approved energy levels—no matter how long the food is exposed to the radiation source or how much of the energy dose is absorbed.
 - With regard to toxicity, the evidence from numerous studies conducted worldwide over the past 50 years indicates that the compounds formed in irradiated food are generally the same as those produced during cooking, canning, pasteurization, and other forms of food preparation and that any differences do not put consumers at risk.¹⁵ Three United Nations agencies—the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the International Atomic Energy Agency (IAEA)—convened Joint Expert Committees on the Wholesomeness of Irradiated Foods in 1964, 1969, 1976, and 1980 to evaluate studies on the safety of irradiated foods and other irradiation-related issues. These committees' evaluations, along with independent evaluations by experts in Denmark, France, the Netherlands, Japan, the United Kingdom, and the United States, found no toxic effects as a result of consuming irradiated food. In 1992, WHO had an expert committee evaluate all the literature and data available since 1980—over 500 studies—on the safety of irradiated food. This committee reiterated earlier findings that food irradiation causes no toxicological, microbiological, or nutritional problems that adversely effect human health.
 - Finally, FDA has found no evidence that food irradiation results in pathogenic bacteria that are more virulent or more resistant to heat (e.g., less likely to be destroyed in cooking). In fact, pathogenic bacteria that survive irradiation are destroyed at lower cooking temperatures than those that have not been irradiated.

¹⁴The International Consultative Group on Food Irradiation, established under the aegis of the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the International Atomic Energy Agency (IAEA) provides information to these three United Nations agencies and their member nations on the safe and proper use of food irradiation technology.

¹⁵The standard procedure in these studies is to feed laboratory animals the irradiated food product and look for health indicators, such as impacts on longevity, reproductive capacity, and tumor incidence.

In addition to safety issues, nutritional loss has been a concern. While some nutrient losses are associated with irradiation, they are less than those associated with cooking or many other food-processing methods, according to the Institute of Food Technologists' Expert Panel on Food Safety and Nutrition. Furthermore, carbohydrates, proteins, and fats—the main components of food—are not significantly affected by irradiation doses even greater than those currently approved by FDA. Food processors minimize nutrient loss by irradiating food in a cold or frozen state and under reduced levels of oxygen.

There is also some vitamin loss associated with irradiation—with certain vitamins, such as thiamin (B1), ascorbic acid (C), and alpha-tocopherol (E)—more affected by irradiation than others. However, according to the Institute of Food Technologists, it is highly doubtful that there would ever be any vitamin deficiency resulting from eating irradiated food. For example, thiamin is the most radiation-sensitive, water-soluble vitamin. With regard to this vitamin, the American Dietetic Association's position statement on food irradiation notes that FDA evaluated an extreme case in which all meat, poultry, and fish were irradiated at the maximum permissible dose under conditions resulting in the maximum destruction of thiamin. Even in these circumstances, the average thiamin intake was above the Recommended Dietary Allowance, leading FDA to conclude that there was no deleterious effect on the total dietary intake of thiamin as a result of irradiating foods. In its 1980 evaluation of food irradiation, the Joint Expert Committee convened by FAO, WHO, and IAEA concluded that irradiation caused no special nutritional problems in food. Another meeting of experts in 1997—organized by the same three international organizations—concluded that even high doses of irradiation (i.e., over 10 kGy) would not result in nutrient losses that could adversely affect a food's nutritional value.

Worker and Environmental Safety Is a Concern, but the Record Has Been Good

Worldwide, there are about 170 industrial gamma irradiation facilities, about 40 of which are in the United States. While some of these facilities process food, most are used to sterilize medical equipment and consumer goods. However, the technology and equipment used in these facilities are similar, regardless of the product that is being irradiated. While all industrial activities typically pose certain risks to human beings and the environment, reports by the Council for Agricultural Science and Technology and the International Consultative Group on Food Irradiation state that the radiation processing industry is considered to have a strong

safety record.¹⁶ According to the International Consultative Group on Food Irradiation, over the past 30 years worldwide, several accidents have resulted in injury or death to workers because of radiation exposure; however, all of these accidents occurred because safety systems had been bypassed and proper control procedures had not been followed. Furthermore, none of the accidents endangered public health or environmental safety.

To decrease the risk of accidental exposure to ionizing radiation, irradiation facilities are built with several layers of redundant protection to detect equipment malfunctions and protect employees from accidental exposure. Potentially hazardous areas are monitored; a system of interlocks prevents unauthorized entry while products are being irradiated; and a maze constructed of thick concrete walls protects workers from radiation. Furthermore, all irradiation facilities must be licensed and are subject to regular inspections, audits, and other reviews to ensure that they are safely and properly operated.¹⁷ In the United States, NRC has exempted facilities that use radioisotopes (such as cobalt-60 and cesium-137) from having to prepare an environmental impact statement (which is required for nuclear facilities) because it found that these facilities do “not individually or cumulatively have a significant effect on the human environment.”

All radioactive materials required for irradiation facilities are transported in lead-shielded steel casks. The containers meet stringent national and international government standards designed to withstand the most severe accidents, including collisions, punctures, and exposure to fire and water. In North America, in over 40 years of transporting the types of radioactive isotopes used for irradiation, there has never been an accident resulting in the escape of radioactive materials into the environment. According to the International Consultative Group on Food Irradiation, this excellent safety record exceeds that of other industries shipping hazardous materials, such as toxic chemicals, crude oil, or gasoline.

¹⁶*Issue Paper: Radiation Pasteurization of Food*, Council for Agricultural Science and Technology, No. 7, Apr. 1996; *Facts About Food Irradiation*, the International Consultative Group on Food Irradiation, 1999.

¹⁷As discussed, U.S. facilities using gamma ray sources must be licensed by NRC; those using electron beams and X-rays are licensed by the states.

While Major Health and Scientific Organizations Endorse Food Irradiation, Some U.S. Consumer Groups Have Reservations About, or Oppose, the Practice

Many prominent health and scientific organizations have agreed that food irradiation is an effective tool for enhancing food safety. Trade groups, such as the American Meat Institute, the Grocery Manufacturers of America, and the National Food Processors Association, also support irradiation. In addition, nearly 40 countries, including the United States, Canada, the United Kingdom, France, Germany, the Netherlands, South Africa, Argentina, Brazil, China, India, and Russia, have approved food irradiation for certain types of food.

Following are some of the major scientific and health-related organizations that consider food irradiation to be safe:

- **U.S. government agencies**
 - Food and Drug Administration
 - Department of Agriculture
 - Public Health Service
 - Centers for Disease Control and Prevention
- **U.S. scientific and health-related organizations**
 - American Dietetic Association
 - American Medical Association
 - American Veterinary Medical Association
 - Council for Agricultural Science and Technology
 - Institute of Food Technologists
 - National Association of State Departments of Agriculture
- **International scientific and health-related organizations**
 - Food and Agriculture Organization
 - International Atomic Energy Agency
 - World Health Organization
 - Codex Alimentarius Commission
 - Scientific Committee of the European Union

At the same time, however, FDA officials and others caution that irradiation should not be seen as a panacea but as an intervention strategy that can be used as part of a comprehensive food safety program. When irradiation is used to control bacteria, it should be part of a well-designed HACCP system.

Major U.S. consumer food groups, including the Center for Science in the Public Interest, Safe Tables Our Priority, the National Consumer League, and the Consumer Federation of America, for the most part, cautiously support or are neutral regarding the limited use of food irradiation. In

general, the groups acknowledge that irradiation can be an effective tool to eliminate pathogens in food, particularly for consumers with compromised or vulnerable immune systems, but they are concerned that the process could be used at the “end of the line to mask inadequate sanitation practices in processing plants.” They generally believe there is a continuing need for strong government food safety inspection programs and clear labeling of irradiated foods, and some groups advocate stronger labeling requirements. However, several consumer groups, such as Food and Water, Inc. and Public Citizen, strongly oppose food irradiation. Among other things, they believe that FDA has not sufficiently proven that irradiation can safely be used on food and that more long-term research on the effects of consuming irradiated food is needed.

Agency Comments

We provided the Food and Drug Administration with a draft of this report for its review and comment. We met with the Director of the Division of Product Policy, Center for Food Safety and Applied Nutrition, and several officials from the Center’s Office of the Director as well as representatives from the Office of Legislation and the Office of the Chief Counsel. These officials generally agreed with the substance of the report and provided technical and clarifying comments that we have incorporated as appropriate.

We conducted our work from January through July 2000 in accordance with generally accepted government auditing standards. Appendix I discusses our scope and methodology.

As arranged with your offices, unless you publicly announce the contents earlier, we plan no further distribution of this report until 30 days after the date of this letter. At that time, we will provide copies to interested congressional committees; the Honorable Dan Glickman, Secretary of Agriculture; the Honorable Donna E. Shalala, Secretary of Health and Human Services; and other interested parties. We will also make copies available to others on request.

If you or your staffs have any questions about this report, please contact me at (202) 512-5138. Key contributors to this report are listed in appendix V.

A handwritten signature in black ink that reads "Robert Robertson". The signature is written in a cursive style with a large initial "R".

Robert E. Robertson
Associate Director,
Food and Agriculture Issues

Scope and Methodology

To determine the extent and the purposes for which food irradiation is being used, we interviewed representatives from the federal government, the food irradiation and food processing industries, and food industry organizations. Specifically, we interviewed and obtained information from officials from the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), Animal and Plant Health Inspection Service, Economic Research Service, and Agricultural Research Service. We interviewed officials from five major North American irradiation firms—Food Technology Service, Inc., Titan Corporation, IBA Food Safety Division, STERIS Corporation-Isomedix Services, and MDS Nordion—as well as the National Food Processors Association; the American Spice Trade Association; and the American Meat Institute. We also obtained data on the quantities of irradiated food from the five irradiation firms, the American Spice Trade Association, the International Atomic Energy Agency, the International Consultative Group on Food Irradiation, and USDA.

To determine the scientifically supportable benefits and risks of food irradiation, we reviewed reports, journal articles, position papers, and other documents prepared by public and private organizations in the United States and other countries, international organizations, and individual scientists. Many of these documents draw upon scientific studies conducted in the United States and elsewhere over the past 50 years. These documents were prepared by the following organizations:

1. **Federal agencies**, including USDA's Economic Research Service, FSIS, and Agricultural Research Service; the Centers for Disease Control and Prevention; and FDA's Center for Food Safety and Applied Nutrition;
2. **U.S. food and health-related organizations, public policy organizations, and universities**, including the American Council on Science and Health; the Council for Agricultural Science and Technology; the Foundation for Food Irradiation Education; the Institute of Food Technologists; the American Enterprise Institute-Brookings: Joint Center for Regulatory Studies; the American Dietetic Association; the American Medical Association; Iowa State University; Massachusetts Institute of Technology; and the universities of California-Davis, Connecticut, Florida, Georgia, and Michigan;

3. **International food and health-related organizations**, including the Joint Expert Committee on the Wholesomeness of Irradiated Foods, sponsored by the International Atomic Energy Agency, the Food and Agriculture Organization, and the World Health Organization; the International Consultative Group on Food Irradiation; and the International Food Information Council;
4. **Consumer and public interest organizations**, including Public Citizen; Safe Tables Our Priority; Food and Water, Inc.; the Center for Science in the Public Interest; and the International Organization of Consumers Unions; and
5. **Industry trade associations**, including the National Food Processors Association, the Grocery Manufacturers of America, the American Meat Institute, and the American Spice Trade Association.

In addition, we reviewed texts by scientists and others including *Safety of Irradiated Foods*, by J.F. Diehl, Marcel Dekker, Inc., second edition, 1995; *Biology of Food Irradiation*, by David R. Murray, Research Studies Press, LTD and John Wiley and Sons, Inc., 1990; and *Food Irradiation: Who Wants It?* by Tony Webb, Tim Lang, and Kathleen Tucker, Thorsons Publishers, Inc., 1987.

Our examination of the benefits and the risks of food irradiation also included a review of FDA's and FSIS' final rules relating to the irradiation of fresh foods, spices, poultry, and refrigerated or frozen meat. We also reviewed a petition to irradiate raw and preprocessed vegetables and fruits and certain multi-ingredient food products for which a final rule has not yet been issued. Among other things, these documents evaluate the safety of irradiation and include assessments of the chemical reactions that occur as a result of irradiation, toxicity studies of irradiated foods, studies of the nutritional adequacy of irradiated products, and studies of the effects of irradiation on microorganisms. We also reviewed FSIS' *Review of Risk Analysis Issues* for information relating to environmental impact and worker and transportation safety issues and reviewed comments proponents or opponents of food irradiation have provided to FDA on its proposed rules.

Finally, for added perspective on the stated positions of some of these organizations, we interviewed the Director, Division of Product Policy, FDA Center for Food Safety and Applied Nutrition; the Director, Regulations Development and Analysis Division, FSIS; executives from the five major

Appendix I
Scope and Methodology

North American irradiation firms; officials from consumer and public interest organizations, including the Center for Science in the Public Interest, the Consumer Federation of America, Food and Water, Inc., Public Citizen, and Safe Tables Our Priority; and representatives from two food industry organizations, the American Meat Institute and the National Food Processors Association. We also attended the international food irradiation conference held in Arlington, Virginia, in April 2000.

We conducted our review from January through July 2000 in accordance with generally accepted government auditing standards.

Chronology of Food Irradiation Events

Year	Event
1905	Scientists receive patents for a food preservative process that uses ionizing radiation to kill bacteria in food.
1921	U.S. patent is granted for a process to kill <i>Trichinella spiralis</i> in meat by using X-ray technology.
1953-1980	The U.S. government forms the National Food Irradiation Program. Under this program, the U.S. Army and the Atomic Energy Commission sponsor many research projects on food irradiation.
1958	The Food, Drug, and Cosmetic Act is amended and defines sources of radiation intended for use in processing food as a new food additive. Act administered by FDA.
1963	FDA approves irradiation to control insects in wheat and flour.
1964	FDA approves irradiation to inhibit sprouting in white potatoes.
1964-1968	The U.S. Army and the Atomic Energy Commission petition FDA to approve the irradiation of several packaging materials.
1966	The U.S. Army and USDA petition FDA to approve the irradiation of ham.
1971	FDA approves the irradiation of several packaging materials based on the 1964-68 petition by the U.S. Army and the Atomic Energy Commission.
1976	The U.S. Army contracts with commercial companies to study the wholesomeness of irradiated ham, pork, and chicken.
1980	USDA inherits the U.S. Army's food irradiation program.
1985	FDA approves irradiation at specific doses to control <i>Trichinella spiralis</i> in pork.
1986	FDA approves irradiation at specific doses to delay maturation, inhibit growth, and disinfect foods, including vegetables and spices. The Federal Meat Inspection Act is amended to permit gamma radiation to control <i>Trichinella spiralis</i> in fresh or previously frozen pork. Law is administered by USDA.
1990	FDA approves irradiation for poultry to control salmonella and other foodborne bacteria.
1992	USDA approves irradiation for poultry to control salmonella and other foodborne bacteria.
1997	FDA's regulations are amended to permit ionized radiation as a source of radiation to treat refrigerated or frozen uncooked meat, meat byproducts, and certain food products to control foodborne pathogens and to extend shelf life.
2000	USDA's regulations are amended to allow the irradiation of refrigerated and frozen uncooked meat, meat byproducts, and certain other meat food products to reduce the levels of foodborne pathogens and to extend shelf life. FDA's regulations are amended to permit the irradiation of fresh shell eggs to control salmonella.

Food Products Approved for Irradiation in the United States

Food product	Agency and approval date	Purpose for irradiation	Maximum permitted dosage (kiloGray)
Wheat and wheat powder	FDA – August 21, 1963	Insect Deinfestation	0.20 to 0.50
White potatoes	FDA – July 8, 1964	Inhibit sprout development	0.05 to 0.15 ^a
Spices and dry vegetables	FDA – July 5, 1983	Microbial disinfection and insect deinfestation ^b	10.0
Dry or dehydrated enzyme preparations	FDA – June 10, 1985	Microbial disinfection	10.0
Pork carcasses or fresh nonheated processed cuts	FDA – July 22, 1985	Control <i>Trichinella spiralis</i>	0.30 to 1.00
Fresh foods	FDA – April 18, 1986	Delay maturation	1.0
Dry or dehydrated aromatic vegetable substances ^c	FDA – April 18, 1986	Microbial disinfection	30.0
Fresh, frozen uncooked poultry	FDA – May 2, 1990 USDA – October 21, 1992	Control foodborne pathogens	3.0
Refrigerated and frozen uncooked beef, lamb, goat, and pork	FDA – December 3, 1997 USDA – February 22, 2000	Control foodborne pathogens and extend shelf life	4.5 (refrigerated) 7.0 (frozen)
Fresh shell eggs	FDA – July 21, 2000	Control salmonella	3.0

^aMaximum dose increased from 0.10 to 0.15 on November 9, 1965.

^bInsect deinfestation approved June 1984.

^cRefers to substances used as ingredients for flavoring or aroma (e.g., culinary herbs, seeds, spices, and vegetable seasonings). Includes turmeric and paprika when used as color additives.

Source: 21 C.F.R. 179.26 (Apr. 1, 1999, ed.) and FDA and USDA/FSIS officials.

Commonly Asked Questions and Answers About Food Irradiation

How does food irradiation work to reduce or eliminate foodborne microorganisms and insects?

Exposing food to radiation energy disrupts the organic processes essential to life and the reproduction of organisms. During the irradiation process, energy waves from gamma rays, electrons, or X-rays break molecular bonds inside the genetic material of pathogens, spoilage organisms, and insects, which causes them to die or prevents them from replicating.

Do microorganisms that survive irradiation treatment at low or medium doses pose a more serious threat than if they had not been irradiated at all?

FDA has found no evidence that food irradiation results in pathogens that are more virulent or more resistant to heat after treatment. To the contrary, research shows that radiation is more likely to reduce the virulence of any surviving pathogens. For example, bacteria that survive irradiation are destroyed at a lower cooking temperature than bacteria that have not been irradiated.

Does the dose of irradiation required for destroying microorganisms in food differ for electron beam, gamma ray, and X-ray processing?

The absorbed dose, measured in kiloGray, delivered by the three processes has the same effects on microorganisms and food. The absorbed dose is controlled by the intensity of radiation and the length of time the food is exposed.

Does irradiated food need to be refrigerated?

At the approved doses, irradiation does not eliminate the need for refrigeration or the need for careful handling, storage, and cooking of perishable foods. For example, the levels of irradiation approved for poultry can reduce the numbers of pathogenic and spoilage bacteria. However, the product is not sterilized and still requires proper refrigeration and handling by retailers and consumers.

Can irradiation make spoiled or dirty food marketable?

Irradiation cannot reverse the spoilage process—the bad appearance, taste, and/or smell will remain the same after irradiation. In addition, current

regulations do not allow food processors to use doses of irradiation on meat, poultry, fruits, and vegetables that would be high enough to sterilize extremely contaminated food. If a processor attempted to use a sterilization dose on many of these products, the odor, flavor, taste, and texture would be seriously impaired and the consumer would reject such products.

Will irradiated food be more expensive?

While there have been relatively few irradiated products marketed to date, those that have been sold have been more expensive than their counterparts. According to food irradiation industry officials, meat and poultry could be 3 to 8 cents a pound more; fruits and vegetables could cost 2 to 3 cents a pound more. However, as a facility irradiates more food, the cost per pound should decline over time.

Does USDA accept imported meat and poultry that have been irradiated in other countries for distribution in the United States?

Yes, provided they are treated and labeled consistent with USDA's regulations.

Can an accident at a gamma ray facility lead to the "meltdown" of the irradiator and the release of radioactivity into the atmosphere?

It is impossible for a meltdown to occur in an irradiation facility or for the radiation source to explode. The source of radiation used at irradiation facilities cannot produce neutrons, which can make materials radioactive, so no chain reaction can occur. Similarly, nothing inside the irradiation facility—the food being processed, the machinery, or the walls—can become radioactive.

Is food irradiated with nuclear waste materials?

None of the gamma irradiators in the United States use radioactive waste materials. All U.S. gamma irradiation facilities use cobalt-60 as the irradiation source. This source does not produce radioactive waste material because it can be returned to the supplier for reactivation or reuse in another application.

GAO Contacts and Staff Acknowledgments

GAO Contacts

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In addition to those named above, Rebecca Johnson and John Smith made key contributions to this report.

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