

AMERICAN ACADEMY OF PEDIATRICS

Katherine M. Shea, MD, MPH, and the Committee on Environmental Health

Technical Report: Irradiation of Food

ABSTRACT. Recent well-publicized outbreaks of foodborne illness have heightened general interest in food safety. Food irradiation is a technology that has been approved for use in selected foods in the United States since 1963. Widespread use of irradiation remains controversial, however, because of public concern regarding the safety of the technology and the wholesomeness of irradiated foods. In this report, we describe the technology, review safety and wholesomeness issues, and give a historical perspective of the public controversy regarding food irradiation.

ABBREVIATIONS. Gy, gray (international units); FDA, Food and Drug Administration; USDA, US Department of Agriculture; WHO, World Health Organization; IPIF, International Project on Food Irradiation; IAEA, International Atomic Energy Agency; FAO, Food and Agriculture Organization.

Irradiation of foods can reduce the risk of foodborne illness.^{1,2} Foodborne pathogens cause millions of illnesses, hundreds of thousands of hospitalizations, and thousands of deaths per year in the United States.³ Estimated annual costs from medical expenses and productivity loss secondary to foodborne illness are between \$5 and \$23 billion per year.⁴ Rates of foodborne illnesses are increasing dramatically in the United States and other industrialized countries, and children represent a particularly susceptible population.⁵ *Escherichia coli* O157:H7, which is sometimes found in beef and other foods, can cause hemorrhagic diarrhea and hemolytic-uremic syndrome, both of which can be fatal in young children. Other foodborne pathogenic bacteria to which children may be particularly susceptible include *Campylobacter*, *Listeria*, *Salmonella*, *Shigella*, and *Staphylococcus* species. Parasites found in foods can also have a disproportionate effect on children by compromising nutrition during growth and development. Prenatally acquired infections with certain foodborne pathogens (eg, *Listeria*, *Toxoplasma* species) can cause miscarriage, neonatal death, or lifelong morbidity.⁶

WHAT IS IRRADIATION OF FOOD?

Technical Explanation

Food irradiation is a process by which food is exposed to a controlled source of ionizing radiation to prolong shelf life and reduce food losses, improve

microbiologic safety, and/or reduce the use of chemical fumigants and additives.^{7,8} It can be used to reduce insect infestation of grain, dried spices, and dried or fresh fruits and vegetables; inhibit sprouting in tubers and bulbs; retard postharvest ripening of fruits; inactivate parasites in meats and fish; eliminate spoilage microbes from fresh fruits and vegetables; extend shelf life in poultry, meats, fish, and shellfish; decontaminate poultry and beef; and sterilize foods and feeds.⁹

The dose of the ionizing radiation determines the effects of the process on foods. Radiation doses are measured in international units called gray (Gy [1 Gy = 100 rad]). Food is generally irradiated at levels from 50 Gy to 10 kGy (1 kGy = 1000 Gy), depending on the goals of the process. Low-dose irradiation (up to and including 1 kGy) is used primarily to delay ripening of produce or kill or render sterile insects and other higher organisms that may infest fresh food. Medium-dose irradiation (1–10 kGy) pasteurizes food and prolongs shelf life. High-dose irradiation (>10 kGy) sterilizes food.¹⁰

Irradiation kills microbes primarily by fragmenting DNA.¹⁰ The sensitivity of organisms increases with the complexity of the organism. Thus, viruses are most resistant to destruction by irradiation, and insects and parasites are most sensitive. Spores and cysts are quite resistant to the effects of irradiation, because they contain little DNA and are in highly stable resting states. Toxins and prions, which have few chemical bonds to disrupt, are resistant to irradiation. The conditions under which irradiation takes place (ie, temperature, humidity, and atmospheric content) can affect the dose required to achieve the food processing goal, but these are well-described and easily controlled.¹⁰

In the United States, the irradiation source for food is most commonly cobalt 60, a gamma radiation emitter, which is produced by exposing naturally occurring cobalt 59 to neutrons in a nuclear reactor. Food is sent through a maze of stainless steel rods containing cobalt 60 on a conveyor belt; the speed used determines the dose received by the food.¹⁰

Regulatory Explanation

Food irradiation is considered a “process” by many nations. The US Congress explicitly included sources of irradiation as “food additives” under the 1958 Food Additives Amendment to the Federal Food, Drug and Cosmetic Act of 1938.^{11,12} This designation places food irradiation under the same regulatory umbrella of the US Food and Drug Administration (FDA) as other food additives. Thus,

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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irradiated food is defined as adulterated and illegal to market unless irradiation conforms to specified federal rules. The FDA has authorized the following 4 sources of ionizing radiation for food treatment: cobalt 60, cesium 137, machine-generated accelerated electrons not to exceed 10 million electron volts, and machine-generated x-rays not to exceed 5 million electron volts.⁸ All petitioners for FDA approval of food irradiation must satisfy technical requirements that limit dose and specify conditions under which the food will be irradiated. The technical effect on the food, dosimetry, and environmental controls must be defined and in compliance with the Federal Food, Drug and Cosmetic Act. Facilities must also pass an environmental impact study to comply with the National Environmental Policy Act of 1969. Nutritional adequacy, as well as radiologic, toxicologic, and microbiologic safety, must be ensured under FDA regulations. In addition, the US Department of Agriculture (USDA) has regulatory responsibilities for some types of foods irradiated for defined purposes. For example, as part of its inspection services, USDA regulates irradiation when used as a quarantine procedure for fruits. Under federal meat and poultry inspection laws, USDA has responsibility for ensuring safety and wholesomeness of irradiated meat and poultry.

Radiologic Safety

All foods are radioactive to some extent as a result of exposure to natural background radiation.¹³ Irradiation of food does not induce additional radioactivity, because the sources of radiation approved for use in food irradiation are limited to those producing energy too low to induce subatomic particles.^{13,14} Chain reactions cannot occur; therefore, no radioactivity is added. Neither the food nor the packaging materials become radioactive.¹⁵

Toxicologic Safety

Unique Radiolytic Products

During early reviews of the safety of irradiated foods, the FDA coined the term “unique radiolytic products” to describe the theoretical possibility that molecules unique to the process of food irradiation could be generated.¹⁶ The process of irradiation essentially adds a small amount of energy to food. As such, many radiolytic products are generated, but in very small numbers. Heat processing forms the same general types of molecules, but in larger numbers, because the amount of energy added to foods is often greater than with irradiation. The FDA review concluded that there is no cause for concern that toxic unique radiolytic products are generated during irradiation.¹⁷

Feeding Studies

Hundreds of animal feeding studies of irradiated food, including multigenerational studies, have been performed since 1950.¹⁸ Endpoints investigated have included subchronic and chronic changes in metabolism, histopathology, and function of most systems; reproductive effects; growth; teratogenicity; and mu-

tagenicity. Because a large number of studies has been performed, some have demonstrated adverse effects of irradiation, but no consistent pattern has emerged.^{18,19} Independent reviews of the scientific evidence by a series of expert committees, including the Joint Food and Agriculture Organization, the International Atomic Energy Agency, and the World Health Organization (WHO) International Consultative Group on Food Irradiation, as well as the FDA have concluded that irradiation of foods under specified conditions is safe.^{14,17,20}

Chemiclearance Approach

Chemiclearance is the term used to refer to the toxicologic analysis and safety clearance of irradiated food. Chemiclearance applies only to questions of toxicology, not microbiologic safety or nutritional adequacy. Chemical analysis of irradiated foods and analytical technology enable scientists to predict the types and numbers of radiolytic products that can be formed in foods irradiated at a given dose under specified conditions. At the national level, in 1979 an FDA advisory committee concluded that any foods irradiated at levels up to 1 kGy or foods comprising no more than 0.01% of the daily diet irradiated up to 50 kGy are safe for human consumption without any toxicologic testing.^{10,12} At the international level, in 1980, the WHO joint committee concluded that the irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicologic hazard; hence, toxicologic testing of foods so treated is no longer required.²¹ Current WHO recommendations impose no upper dose limit, because doses required to eliminate biological hazards are below doses that might compromise the sensory quality of food.²⁰

Microbiologic Safety

Microbes in food fall into three categories. Some microorganisms, such as those that produce fermentation, create desirable changes in foods. Spoilage microorganisms change the color, odor, and texture of food, rendering it unpalatable, but they do not cause human illness. Pathogens cause human disease and include invasive and toxigenic bacteria, toxigenic molds, viruses, and parasites. All food production techniques from the farm to the table are concerned with minimizing spoilage, eliminating pathogens, and prolonging shelf life.¹⁰

Radiation Resistance and Mutational Changes

Induction of radiation-resistant microbial populations occurs when cultures are experimentally exposed to repeated cycles of radiation.^{22,23} Mutations in bacteria and other organisms develop with any form of food processing, including ionizing radiation, heat, drying, and ultraviolet light. Ionizing radiation does not produce mutations by unique mechanisms.²⁴ Further, mutations from any cause can result in greater, less, or similar levels of virulence or pathogenicity from parent organisms. Although it remains a theoretical risk, several major international reviews cite no reports of the induction of novel pathogens attributable to food irradiation.^{14,25,26}

Viruses, spores, prions, and preformed toxins are resistant to radiation. Irradiation is unlikely to affect the safety of food with respect to these categories of contaminants. The possibility of differential response of bacteria, fungi, and molds to irradiation and subsequent threats to food safety merits examination.

Gram-negative spoilage bacteria tend to be more sensitive to radiation than are pathogens, whereas gram-positive spoilage bacteria can be more resistant to radiation than are pathogens. The range of radiation sensitivities, however, is narrow.²⁷ Initial counts of spoilage bacteria (bacteria that alter the color, flavor, texture, or smell of food but do not cause human disease) are much higher in foods than are counts of pathogens (bacteria that cause human disease). At approved levels of irradiation, surviving bacteria are significantly more likely to be spoilage types than pathogenic types. Thus, irradiated food would most likely spoil long before becoming pathogenic.²⁸

There is some concern regarding irradiation and sporulating toxin-producing bacteria. These may thrive in nonacidic, perishable high-protein foods and are about 10 times more resistant to radiation than are nonspore formers. For example, *Clostridium botulinum* type E, which is found in fish and seafood, can survive nonsterilizing doses of irradiation intended to extend shelf life. When refrigerated long enough at 10°C or higher, toxin formation can occur.²⁹ Thus, it may be possible for food to become toxic with botulinum toxin before it is obviously spoiled. Conditions that allow for toxin formation before spoilage, such as inadequate refrigeration, are well-understood, and regulations can be designed to mitigate against such occurrences. This concern also applies to other nonsterilizing food processing technologies, such as heat, to which spore-forming bacteria are also relatively resistant.

Similar concerns exist about mycotoxins. Experimental data are conflicting, but some studies show an increase in mycotoxin formation after irradiation. One theory is that the higher radioresistance of molds and yeasts compared with bacteria results in a loss of competitive inhibition of mold and yeast growth. The author of one study concludes that, "any mold surviving treatment with irradiation may be expected to grow more rapidly in the absence of competitors and eventually dominate the mycoflora."²⁷ The author of another study draws the somewhat different conclusion that in the absence of temperature abuse in storage, "the available evidence indicates that treating products with ionizing energy does not add to that [mold growth] hazard."²⁹ Other explanations include the possibility that more nutrients are made available for fungi by irradiation. This is an area in which additional study would be useful.⁹

Nutritional Adequacy

All forms of food processing affect nutritional content, and irradiation is no exception. Changes in food attributable to irradiation are similar to those that

result from cooking, canning, pasteurizing, blanching, and other forms of heat processing.²⁴ Vitamin loss is the largest nutritional concern with respect to food irradiation. Water-soluble vitamins, such as the B vitamins and vitamin C, can be oxidized during irradiation. In pure solution, thiamin is the most sensitive to radiation, followed by vitamin C, pyridoxine (B₆), riboflavin (B₂), and niacin. Of the fat-soluble vitamins, vitamin E is the most radiosensitive, followed by vitamins A and K. Vitamin D is relatively radiostable.²⁴ These sensitivities may vary significantly in whole foods. Because food irradiation is a nonthermal process, loss of heat-sensitive vitamins is no greater than with conventional heat processing, and is often less. Vitamins are lost at the time of irradiation and afterward during storage. Storage loss can be minimized by excluding oxygen. Finally, there is synergism between irradiation and heat (cooking) loss of certain vitamins in some foods. Vitamin deficiencies could develop if irradiated food were significantly deficient in an essential vitamin and that food represented a large proportion of the dietary source of that essential vitamin.^{18,30}

Carbohydrates and proteins are not significantly affected during irradiation at approved levels. A change in the bioavailability or quantity of minerals or trace elements has not been identified as a result of irradiation. Fats can be oxidized, leading to rancidity and odor or color changes. Polyunsaturated fatty acids generally are not altered at low to medium irradiation doses.²⁴

WHAT IS THE CURRENT STATUS OF FOOD IRRADIATION IN THE UNITED STATES?

In 1991, Food Technology Services Incorporated opened the first dedicated food irradiation facility in North America near Tampa, Florida. Strawberries, tomatoes, and citrus fruit from this facility have been marketed directly to consumers in Florida and Illinois since 1992. Fruits from Hawaii, including papaya and lychees, were irradiated and sold in several states during 1995. Although irradiated spices and herbs have been approved for use since 1963, they have only been marketed in the United States since 1995. Vidalia onions irradiated in Florida have been marketed at the retail level in Chicago since 1992. Since 1993, small quantities of irradiated chicken have been available in retail outlets in Florida, Illinois, Iowa, and Kansas.¹³ Very little irradiated food is currently sold to consumers in the United States.

About 40 large-scale gamma facilities are in operation in the United States for sterilization of medical, surgical, and pharmaceutical products and packaging materials.¹⁰ In addition, 4 dedicated food irradiation facilities are currently in operation. Table 1 shows which foods are approved for irradiation in the United States market.

Labeling

All irradiated food sold in the United States must be clearly labeled with the international irradiation symbol, the Radura (Fig 1), and the words, "treated by irradiation, do not irradiate again" or "treated with radiation, do not irradiate again." The labeling

TABLE 1. Rules From US FDA for Food Irradiation*

Food	Purpose of Irradiation	Dose Permitted, kGy	Date of Rule
Spices, dry vegetable seasoning	Decontamination/disinfest insects	30 (maximum)	7/15/63
Wheat, wheat powder	Disinfest insects	0.2–0.5	8/21/63
White potatoes	Extend shelf life	0.05–0.15	11/1/65
Dry or dehydrated enzyme preparations	Control insects and microorganisms	10 (maximum)	6/10/85
Pork carcasses or fresh noncut processed cuts	Control <i>Trichinella spiralis</i>	0.3 (minimum)–1.0 (maximum)	7/22/85
Fresh fruit	Delay maturation	1	4/18/86
Dry or dehydrated enzyme preparations	Decontamination	10	4/18/86
Dry or dehydrated aromatic vegetable substances	Decontamination	30	4/18/86
Poultry	Control pathogens	3	5/2/90
Red meat	Control pathogens and prolong shelf life	4.5 (fresh)–7 (frozen)	12/3/97
Fresh shell eggs	Control <i>Salmonella</i> species	3.0	7/12/00

*USDA rules may have a different timeline.



Fig 1. International Radura.

law was amended in November 1997 and new labeling rules are currently in the public comment phase of rule making.^{31–33}

Packaging

One great advantage of irradiation is that it can be accomplished after foods are packaged, preventing recontamination during subsequent handling.¹¹ Although studies have been completed that document the safety of this practice, they have been performed largely at higher doses than are currently used and with packaging materials available 10 to 30 years ago.²⁰ Studies of the effects of irradiation on foods packaged in modern materials are ongoing.^{2,32}

WHY IS FOOD IRRADIATION CONTROVERSIAL?

New food technologies traditionally have been met with resistance. When pasteurization was first developed in the late 19th century, it was considered highly suspect.²⁶ Many of the objections raised to its dissemination were similar to arguments made today about food irradiation.²⁶ Opponents worry that irradiation might be used to mask spoilage and enable the sale of unsafe food. However, the chemical and physical changes that are characteristic of spoiled food cannot be reversed by irradiation. Odor, color, and texture changes would remain despite destruction of spoilage microorganisms.¹⁰ In addition to health and food safety concerns, irradiation of

food also has raised concerns related specifically to expansion of the nuclear technology itself.^{34–36}

Historical Links to the Military

Use of ionizing radiation in food preservation was proposed shortly after x-rays were discovered in 1895, and experiments began as early as 1896. The first US patent for food irradiation was awarded for a device to irradiate organic materials including pork for control of *trichinae*.³⁷ It was not until after World War II, however, that large-scale attention was paid to food irradiation technology as part of President Eisenhower's "Atoms for Peace" program.²⁴ In the 1950s, experiments using spent fuel rods for food irradiation were conducted, but the rods were found to be unsuitable radiation sources.³⁸ The US Army sponsored many studies on food irradiation between 1953 and 1980, resulting in a linking of the technology with the military in the minds of the public.³⁹ Internationally as well as in the United States, however, most research on food irradiation has been conducted by universities, nonmilitary government agencies, and commercial laboratories.¹⁸

In 1970, the International Project on Food Irradiation (IPIF) was begun by 19 countries, later increased to 24, under the joint sponsorship of the International Atomic Energy Agency (IAEA) in Vienna and the Food and Agriculture Organization (FAO) in Rome. The WHO participated in an advisory capacity. The IPIF pooled international resources and coordinated chemical and animal studies on a variety of topics and in numerous foods. In 1981, the FAO/IAEA/WHO joint committee published the recommendation that the irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicologic hazards; hence, toxicologic testing of foods so treated is no longer required.²¹ In 1982, the participating governments terminated the project. Despite the wide international base of research funded in a variety of ways, the perception remains that irradiation of food is supported disproportionately by the military. In the United States, this has added to the controversy surrounding the technology.

Concerns Specific to Nuclear Technology

Critics are concerned that food irradiation facilities could fail and release radiation into the environment, harm workers, or generate nuclear waste. Similar concerns about accidents during the transport of radioactive sources to and from irradiation facilities have been proposed.³⁴ Acceptance for nuclear technology is reflected in different national policies on food irradiation in various developed and developing countries.⁴⁰

About 170 gamma facilities exist worldwide. Most facilities are used for medical, surgical, or pharmaceutical sterilization or the preparation of packaging materials. Just as with an x-ray machine, meltdown in a gamma irradiator is impossible, because no radioactivity is created. The food, machinery, and the facility itself do not become radioactive. As a result, the general public could use a shutdown facility without any cleanup once the radioactive source was removed. Finally, because cobalt 60 degrades to non-radioactive nickel, very little waste is produced, and this waste has very low-level radioactivity. When a cobalt 60 source has lost approximately 90% of its radioactivity (which takes 15 to 20 years), it is returned to the supplier for reactivation or storage as low-level radioactive waste. In the United States, the manufacturer is responsible for complying with federal regulations of transport, installation, maintenance, and return of cobalt after use.¹³

CONCLUSIONS

The science of food irradiation is mature, and the scientific consensus on its efficacy and safety is strong. The FDA has taken a protective stance on regulation of food irradiation compared with much of the rest of the world, allowing doses only up to 1 kGy to be approved without toxicologic testing. Even petitioners requesting use below 1 kGy must satisfy all other FDA requirements. Although questions and uncertainties will always remain in an area as complex as food technology, the following conclusions are justified.

Irradiation of food cannot substitute for excellent food production, processing, and preparation (Table 2).^{4,41} Irradiated food is safe and nutritious and produces no unusual toxicity as long as best management practices are followed. Irradiation is a complement to established techniques that can add to food safety, increase shelf life, reduce loss from spoilage, and increase the diversity of foods available to the population. The technology of food irradiation is the most intensely studied of all food processing tech-

TABLE 2. WHO Golden Rules for Safe Food Preparation

1.	Choose foods processed for safety.
2.	Cook food thoroughly.
3.	Eat cooked foods immediately.
4.	Store cooked foods carefully.
5.	Reheat cooked foods thoroughly.
6.	Avoid contact between raw foods and cooked foods.
7.	Wash hands repeatedly.
8.	Keep all kitchen surfaces meticulously clean.
9.	Protect food from insects, rodents, and other animals.
10.	Use pure water.

niques.¹⁸ In the United States, it is regulated for safety by federal agencies. Widespread use of food irradiation would necessitate construction of irradiation facilities in the United States and other countries. The benefits of expanding this technology and the risks involved must be thoroughly debated. Health care professionals should participate in the dialogue. As with any technology, unforeseen consequences are possible; therefore, careful monitoring and continuous evaluation of this and all food processing techniques are prudent precautions.

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