THE AMERICAN COUNCIL ON SCIENCE AND HEALTH PRESENTS

IRRADIATED FOODS

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IRRADIATED FOODS

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EXECUTIVE SUMMARY

- An overwhelming body of scientific data indicates that irradiated food is safe, nutritious, and wholesome. Health authorities worldwide, including leading national and international scientific organizations, have based their approvals of food irradiation on the results of sound scientific research. Irradiation increases the safety profile and the availability of a variety of foods.

- The safety of food irradiation has been studied more extensively than that of any other food preservation process. As is true of other food processes, irradiation can lead to chemical changes in food. Radiolytic products (compounds formed by radiation), are similar to compounds formed by heat treatment. None of these products, in the amounts found in irradiated foods, has been demonstrated to be toxic by any modern toxicological methods.

- As of December 2006, food irradiation has been approved by some 60 countries either for specific or unlimited applications, and it has been applied successfully for several types of food in more than 30 countries.

- Food irradiation is uniquely applicable to many types of fresh (raw), dried or frozen foods, either to ensure microbiological safety, or to prevent the introduction of exotic pests in or on fresh produce before they enter the United States. It offers major advantages over other treatments in providing a necessary microbiological killing step for fresh, frozen, and ready-to-eat foods. It is the only phytosanitary (produce-cleansing) treatment that has been approved (as of 2006) by the USDA Animal and Plant Health Inspection Service (APHIS) on a generic basis—regardless of commodity—with specific minimum doses for various insect pests.

- Between 1983 and 2005, U.S. Food and Drug Administration (FDA) approved the use of irradiation for antimicrobial treatments for spices and dried vegetable seasonings; destroying *Trichinella* in pork; insect disinfestations and shelf life extension of foods of plant origin; and control of pathogenic bacteria in poultry meat, red meat, shell eggs, sprouting seeds, and molluscan shellfish. A petition to permit irradiation of ready-to-eat food (deli meat, fresh produce, etc.), submitted to the FDA in 1999, is still awaiting approval.

- In 2000, electron beam and X-ray machines, energized by outside electric power, were introduced into the American food processing system. Previously, only irradiators using a cobalt-60 radioactive source had been used for food irradiation. Electron beam or X-ray machines do not use radioactive isotopes. When a cobalt-60 source is used, food irradiation facilities and transport of radioactive sources must meet stringent federal and state regulations. Both types of irradiators have been used routinely for many years to sterilize a number of medical devices and other non-food products for the U.S. market and for processing industrial products such as cables and wires. The industry has an excellent safety record.

- Major food recalls and foodborne disease outbreaks in the past decade have heightened awareness of the risks of foodborne pathogens and the utility of irradiation to ensure microbiological safety of foods. Since 2000, irradiated ground beef has been available in many supermarkets in the U.S. Some meat distribution companies have marketed only irradiated ground beef to provide an additional layer of safety for their customers. Irradiation should be as useful for ensuring the microbiological safety of fresh produce and other ready-to-eat foods, once this application is approved by the FDA.

- The United States Department of Agriculture (USDA) has estimated that the American consumer will receive approximately $2 in benefits—such as reduced spoilage and less illness—for each $1 spent on food irradiation.

- Use of irradiation will allow many tropical and sub-tropical fruits to enter the U.S. market, thus providing consumers a wide variety of fresh and nutritious food. Irradiated Indian mangoes started entering the U.S. market in April 2007. It will allow U.S. produce to enter countries such as Australia and New Zealand that have strict quarantine requirements and that have already approved irradiation as a phytosanitary treatment.

- Any irradiated food sold as such must be labeled with an internationally recognized irradiation logo and a statement such as "Treated by Irradiation" or "Treated by Ionizing Radiation." The purpose of the treatment may be displayed on the label as long as it is truthful and not misleading. In April 2007, the FDA proposed that only irradiated foods that are materially changed must be labeled. The FDA would be willing to consider a petition to use the word "pasteurization" instead of irradiation for such foods.

- The American Council on Science and Health supports the use of food irradiation—a science-based technology that has been proven to be safe and effective. ACSH supports *informational*—not warning—labeling requirements for irradiated food as approved by the FDA. The use of irradiation provides American consumers with an even wider choice of safe, high-quality food.

INTRODUCTION

Why Irradiate Foods?

Foods are irradiated for two major reasons: (a) to ensure the hygienic quality of solid foods—of both animal and plant origin—that are naturally contaminated by various spoilage and pathogenic (disease-causing) microorganisms and (b) to meet strict quarantine requirements in trade in fresh produce—especially fruits of tropical origin.

The Centers for Disease Control and Prevention (CDC) estimates that some 5,000 deaths and 76 million illnesses due to food contamination occur in the U.S. annually. That toll could be substantially reduced by irradiation. Foods may be contaminated naturally during any stage of production, distribution or consumption (from farm to fork). The contamination may be in the form of microbes—including those that cause food spoilage or diseases in humans—as well as insect infestations that cause food destruction or necessitate quarantine. Some foods are seasonal and highly perishable, while others are not allowed to enter the United States because they may harbor pests and diseases that cause damage to local agriculture or illness in humans.

Traditional food processing methods such as drying, fermentation, heating, salting and smoking have been used for centuries to improve the quality, quantity, and safety of food. Newer methods such as heat pasteurization, canning, freezing, refrigeration, fumigation, ultrahigh hydrostatic pressure, electrical conductivity heating, and pulsed electrical fields have been added to the arsenal of food processing methods. Each of these methods offers specific advantages in protecting our food supplies against destruction, microbial contamination, and spoilage. None is applicable for all types of foods. Several of these methods can cause significant changes in food quality and sensory attributes.

Irradiation is a relatively new technology that can be used to inactivate spoilage and pathogenic bacteria in most solid foods in the raw, frozen, or dried state, without significantly increasing the temperature or changing sensory qualities. It can also kill or prevent further development of insect eggs and larvae in fresh fruits and vegetables. Its ability to inactivate pathogenic bacteria in frozen food is unique. Since irradiation is a “cold pasteurization” process, foods remain in the same state after irradiation as before, i.e., frozen foods stay frozen, raw foods remain raw, and volatile aromatic substances are retained.

Irradiation has been used routinely to meet microbiological standards for spices and dried vegetable seasonings in the U.S. and many other countries for the past three decades. It has been used to destroy *E. coli* O157:H7 in ground beef and other pathogens such as *Salmonella* spp. in chicken in the U.S. since 2000, and in frozen shrimp and frog legs in some European countries for the past few decades. Its effectiveness in destroying various pathogenic bacteria in foods such as shellfish, sprouting seeds, and fresh produce—especially bagged pre-cut vegetables—has been clearly demonstrated. Since 2000, irradiation has also been used as a quarantine treatment to prevent spread of tropical fruit flies and other insect pests harbored in fresh fruits and tubers from Hawaii and Florida. In 2006, the USDA's Animal and Plant Health Inspection Service (APHIS) approved irradiation as a quarantine treatment of any fresh produce against essentially all insect pests.

Today, debates about new technologies to improve food quality and safety are often fueled by the misleading claims of activists. There is thus a need to provide science-based, factual information to facilitate better understanding of the safety and benefits of unfamiliar technologies such as food irradiation. It is understood that social, political, and ideological factors may contribute to the acceptance and applications of any new technology. However, it is the results of sound scientific research that should decide the safety and benefits of any technology.

The American Council on Science and Health (ACSH) has therefore prepared this booklet to explain the process of food irradiation—including its safety and benefits—and to answer some common questions about this relatively unfamiliar food technology.

BACKGROUND

What Is Food Irradiation?

Food irradiation is a process of treating pre- or post-packaged foods by exposing them to carefully controlled doses of ionizing radiation, also called ionizing energy, in a specially designed chamber, to achieve desired objectives. Irradiation can kill harmful bacteria and other organisms in meat, poultry, seafood, spices, sprouting seeds, and fresh produce. It can also destroy various developmental stages of insects in fresh fruits to prevent spread of such pests to other areas and territories. Irradiation can extend the shelf life of certain fresh fruits and vegetables and control sprouting of tubers and bulbs such as potatoes and onions. Different doses of radiation are used for different purposes, as is shown in Table 1. It is a safe process that has been approved by the U.S. Food and Drug Administration (FDA) and some 60 other national food control authorities for many types of foods. Irradiation may be referred to as a "cold pasteurization" process as it does not significantly raise the temperature of the treated foods. For example, an absorbed dose of 10 kGy—the maximum dose for most applications of food irradiation—would raise the temperature of treated food by less than 4o F. As with other microbial inactivation processes, such as heat pasteurization, irradiation cannot reverse the spoilage of food. Thus, safe food handling and good manufacturing practices are required for irradiated food just as they are for foods processed by other methods.

Table 1. **Uses of Various Doses of Irradiation for Food Safety and Preservation**

Purpose	Dose Range for specified purposes (kGy*)	Products
Low Dose (up to 1 kGy)		
(a) Inhibition of sprouting	0.06-0.20	Potatoes, onions, garlic, ginger root, chestnut, etc.
(b) Insect disinfestation (including quarantine treat ment)	0.15-1.0	Cereals and legumes, fresh and dried fruits, dried fish and meat, etc.
(c) Parasite disinfection	0.3-1.0	Fresh pork, freshwater fish, fresh fruits
(d) Delay of ripening	0.5-1.0	Fresh fruits
Medium Dose (1-10 kGy)		
(a) Extension of shelf life	1.0-3.0	Raw fish and seafood, fruits, and vegetables.
(b) Inactivation of spoilage and pathogenic bacteria	1.0-7.0	Raw and frozen seafood, meat and poultry, spices, and dried vegetable seasonings
(c) Improving technical properties of foods	3.0-7.0	Increasing juice yield (grapes), reducing cooking time (dehydrated vegetables)
High Dose (above 10 kGy)		
(a) Commercial sterilization (in combination with mild heat)	30-50	Meat, poultry, seafood, sausages, prepared meals, hospital diets, etc.
(b) Decontamination of cer tain food additives and ingredients	10-50	Spices, enzyme preparations, natural gum, gel, etc.

*kGy (kilogray). For more information on the units used to measure absorbed dose of ionizing energy, see Appendix I.

Does Irradiation Make Food Radioactive?

No. Irradiation does not make food radioactive. Radiation sources approved for the treatment of foods have specific energy levels well below those that could cause any element in food to become radioactive. Like luggage passing through an airport X-ray scanner or teeth that have been X-rayed, food undergoing irradiation does not become radioactive. Although the environment naturally contains trace amounts of radioactivity (background level), irradiated food will not increase background radioactivity.

What Types of Radiation Energy Are Used to Treat Foods?

The radiation energy used to treat foods is called "ionizing radiation" because it knocks electrons out of atoms to form ions—electrically charged particles. Ionizing radiation—including X-rays, gamma rays, and beams of high-energy electrons produced by electron accelerators—has a higher energy than non-ionizing radiation such as infrared, television and radio waves, and microwaves.

Two types of radiation sources are commonly used for food treatment. The first is a tightly sealed metal container of radioactive elements—cobalt-60 or cesium-137—that emit gamma rays (cesium is not currently used for food irradiation). The gamma ray energy emitted from the sealed containers impinges upon the food being irradiated, but the food itself never comes into contact with the radioactive source. Because of the physical characteristics of these sources, no radioactivity can be induced in food thus treated, no matter how much energy (dose) is absorbed by the food or how long the food is irradiated. The second type of radiation source is a machine that produces either X-rays or high-energy electrons through the application of an outside energy source such as an electric current. This type of radiation energy is produced electronically, so no radioactive elements are used and radioactive contamination is impossible.

Does Irradiation Generate Radioactive Wastes?

No. The process simply involves exposing food to a source of radiation. It does not create any new radioactive material. When the strength (activity) of radioactive sources such as cobalt or cesium falls below economical usage levels, the sources are returned in a licensed shipping container to the suppliers, who have the option of either reactivating them or storing them in a regulated place. Similar procedures are followed when an irradiation plant closes down. The radiation sources can be acquired by another user or returned to the supplier, the machinery is dismantled, and the building is used for other purposes. No residual radioactivity remains inside the building.

Is Irradiation the Same Thing as Cooking in a Microwave Oven?

No. Irradiation involves the treatment of food with ionizing radiation to achieve desired effects without significantly increasing the temperature of the food. Thus, it is a non-thermal process. In contrast, microwave ovens expose foods to a non-ionizing radiation that generates heat by increasing the molecular motion of the water molecules in moist foods, thereby cooking them.

What Can Irradiation Do?

Irradiation is a versatile process: it can cause a variety of changes in living cells of microorganisms, plants and insects. Like cooking, the effect of irradiation on foods varies with the energy or dose (of heat or irradiation) applied. High-dose irradiation kills all spoilage and pathogenic microorganisms and their spores in food. Foods treated with high-dose irradiation combined with mild heat treatment (to inactivate enzymes) can be kept at room temperature as long as they have been properly packaged to prevent recontamination.

Medium doses of irradiation inactivate spoilage and pathogenic microorganisms in foods, and together with proper temperature control, extend shelf life significantly. Low doses alter biochemical reactions in food of plant origin so that their sprouting or ripening processes are significantly delayed. Low doses can interfere with cell division of some organisms, thus preventing insects or parasites in foods from either reproducing or completing their life cycles.

As with other food processes, irradiation cannot be used on all foods or under all circumstances. For example, irradiation cannot extend the shelf life of fresh foods for an unlimited time because enzymes in such foods remain active and are resistant to all but very high-dose irradiation. Such high doses of irradiation are not used on foods because they can, for instance, induce off flavors in many foods, especially those high in fat. Further, irradiated grains and legumes have to be properly packaged to prevent insects from re-infesting the products, as irradiation does not leave any toxic residue that would repel insects. Some foods, such as milk and dairy products, are not suitable for irradiation because they develop unpalatable flavors. Irradiation has an economy of scale—in other words, a sufficient volume of food is required for processing to justify the investment, although companies not wanting to build their own facilities can contract with an irradiation provider to treat smaller quantities of product.

EFFECTS OF IRRADIATION ON FOODS

How Does Irradiation Affect Microorganisms in Foods?

Irradiation damages the chromosomes of live microorganisms such as bacteria beyond repair. As a result, they cannot divide or replicate. Thus, spoilage or disease-causing (pathogenic) bacteria are inactivated or destroyed, and the onset of microbial spoilage of food is significantly delayed.

Different species of microorganisms have different sensitivities to irradiation. Spoilage and pathogenic bacteria are generally sensitive to irradiation and can be inactivated by low and medium doses of radiation (between 1 and 7 kGy). Bacterial spores are more resistant and require higher doses (above 10 kGy) for inactivation. As with any sub-sterilization process, special care must be taken when irradiating food using low and medium doses to kill spoilage and pathogenic bacteria. Processors must use good manufacturing practices, e.g., storing food products subject to radiation pasteurization at low temperature (below 40o F) to prevent spore germination and growth. Yeasts and molds, which can spoil some foods, are slightly more resistant to irradiation than bacteria and require a dose of at least 3 kGy for inactivation. Viruses are highly resistant to irradiation and require a dose of between 20 to 50 kGy to inactivate them. Thus, irradiation is unsuitable for treating virally contaminated foods.

There is a misperception that food irradiation produces harmful mutant strains of pathogenic microorganisms that might flourish in the absence of the bacteria killed by irradiation. However, at the radiation doses used to control spoilage and pathogenic bacteria, any surviving ones are significantly injured and they cannot reproduce or cause harm.

How Does Irradiation Affect Insects in Foods?

Insects at various developmental stages cause enormous damages to food crops, both during production in the field and after harvesting. Several insect species, such as the tephretid fruit fly, and mango seed weevil, actually develop inside some fruits while they are still on the tree. Other pests, such as weevils and beetles, normally infest foods such as grains after harvesting—especially during storage.

Insects are relatively sensitive to irradiation. As a general rule, the earlier the developmental stage, the more sensitive the insect is to radiation. Thus, eggs are more sensitive to radiation than larvae, which are more sensitive than pupae, which in turn are more sensitive than adults. Thus, irradiating food at the earliest stage possible not only eliminates the insects but permits the use of the lowest effective dose. In general, a dose below 1 kGy will either kill or prevent further development of insects in food.

Many crops are quarantined to prevent the spread of various types of insect pest—to protect local agriculture from insect damage. For example, crops carrying certain species of fruit fly are quarantined in the mainland U.S, which is essentially free from these insects. Such crops must be treated to ensure that the insects do not survive or become established in a non-endemic area.

How Does Irradiation Affect the Nutrients in Foods?

A common consumer concern is whether irradiation adversely affects the nutritional value of food. In general, irradiation changes the nutritional quality of foods no more than most other methods of food processing, such as cooking, freezing, or canning.

The possibility of irradiation-induced changes in nutritional value depends on a number of factors: radiation dose, the type of food, the temperature and atmosphere in which irradiation is performed (e.g., presence or absence of oxygen), packaging, and storage time. Main components of foods such as proteins, fats, and carbohydrates are changed very little by irradiation, even at doses higher than 10 kGy. Similarly, the essential amino acids, minerals, trace elements and most vitamins are not significantly altered by irradiation. Some vitamins—riboflavin, niacin, and vitamin D—are fairly resistant to irradiation, but vitamins A, B1 (thiamine), E, and K are relatively sensitive. Their sensitivities depend on the complexity of the food system, whether the vitamins are soluble in water or fat, and the atmosphere in which irradiation occurs. For example, a solution of vitamin B1 (thiamine) in water lost 50% of the vitamin activities after irradiation at 0.5 kGy. In contrast, irradiation of dried whole egg at the same dose caused less than 5% destruction of the same vitamin. Thiamine is more sensitive to heat than it is to irradiation. Research has demonstrated that pork and beef sterilized by irradiation retain much more thiamine than canned meat sterilized by heat. In general, the effects of irradiation on vitamin C in fruits and vegetables are insignificant—although the research reports often are conflicting. Some studies reported only the effect on ascorbic acid, while others reported on the effect on total ascorbate, a mixture of ascorbic and dehydroascorbic acid, both of which provide vitamin C activity.

In general, the effects of irradiation on the nutritional value of foods are insignificant for low doses (up to 1 kGy), but may be greater at medium doses (1-10 kGy) if food is irradiated in the presence of air. At high doses (above 10 kGy), losses of sensitive vitamins such as thiamine may be significant. Vitamin losses can be mitigated by protective actions, such as using low temperatures and air exclusion during processing and storage. Irradiated foods are normally consumed as part of a mixed diet and the process will have little impact on the total intake of specific nutrients. The effect of irradiation on nutrient value is one of the factors evaluated prior to approval of this process on specific foods.

How Does Irradiation Affect Foods' Sensory Qualities?

Irradiation may cause chemical changes in some foods that can affect its sensory quality. Milk and dairy products are among the most radiation-sensitive foods. A dose as low as 0.1 kGy will impart an off-flavor to milk that most consumers find unacceptable, making dairy products unsuitable for radiation processing. Irradiation of some fresh fruits and vegetables may cause softening because of damage to the cell walls. High-dose irradiation sterilization can induce "off" flavors in many types of meat products if they are not properly processed.

For optimum results, food irradiation requires the proper conditions and dose for each food. Too high a dose may affect the food's sensory qualities, while one too low will not achieve the intended sanitary effect. Food scientists have determined that the foods most suitable for irradiation are: roots and tubers, cereals and legumes, meat, poultry, fish and seafood, most fruits and vegetables, and spices and seasonings. Fat-containing foods such as meat and fish should be irradiated under low temperature and in proper atmospheric packaging to avoid off-flavors.

SAFETY OF IRRADIATED FOODS

Are Irradiated Foods Safe to Eat?

Yes. Food irradiation safety has been thoroughly studied and comprehensively evaluated for over 50 years—both in the United States and elsewhere—to an extent seen for no other food technology. The pertinent research involved many animal feeding tests in rats, mice, dogs, and monkeys. These included lifetime and multi-generation studies to determine if any changes in growth, blood chemistry, histopathology, or reproduction occurred that might be attributable to consumption of different types of irradiated foods. Data from these studies were systematically evaluated by panels of experts that included toxicologists, nutritionists, microbiologists, radiation chemists, and radiobiologists. Such review panels have been convened repeatedly by the Food and Agricultural Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), and the World Health Organization (WHO) in 1964, 1969, 1976, 1980, and 1997. In 1980, the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food (JECFI) concluded that "Irradiation of any food commodity up to an overall average dose of 10 kGy introduces no toxicological hazard; hence, toxicological testing of food so treated is no longer required." The JECFI also stated that irradiation of food up to a dose of 10 kGy introduces no special microbiological or nutritional problems.

These conclusions were supported by subsequent investigations. For example, a small feeding trial was run in China in which 21 men and 22 women volunteers consumed 62 to 71% of their total caloric intake as irradiated foods for 15 weeks. No adverse effect on their health could be demonstrated. Since 1980, no credible scientific evidence, either from animal feeding studies or from human consumption of several types of irradiated foods in several countries, has suggested such foods pose a health hazard.

In 1997, FAO, IAEA and WHO convened a Joint Study Group to evaluate studies of food irradiated with doses above 10 kGy. Based on available scientific evidence, they concluded that food irradiated with any dose is both safe and nutritionally adequate. No upper dose limit therefore needs to be imposed as long as food is irradiated based on prevailing good manufacturing practices. The safety of irradiated foods is also supported by data on extensive experience with laboratory animal diets that had been sterilized by irradiation. Over the past few decades, millions of laboratory animals including rats, mice, and other species have been bred and reared exclusively on radiation-sterilized diets. Several generations of these animals were fed diets irradiated with doses ranging from 25 to 50 kGy—considerably higher than doses used for human foods. No transmittable genetic defects—teratogenic or oncogenic—were observed that could be attributed to the consumption of irradiated diets.

Determining the Safety of Irradiated Foods

Establishing the safety of irradiated foods has involved the input of experts in radiation chemistry, toxicology, nutrition, microbiology, and packaging.

Radiation Chemistry

Scientists have collected substantial information on the chemical changes that occur when foods are irradiated. Many of the substances produced by irradiation (radiolytic products) have been identified through the use of sensitive analytical techniques. "Radiolytic" does not mean radioactive or toxic in any way. It simply means that these substances are produced by irradiation in the same manner as heat processing produces "thermolytic products." Most of these radiolytic products are familiar substances that occur in non-irradiated foods or that are also produced in foods by conventional processes such as cooking. The safety of radiolytic products has been examined very thoroughly, and no evidence of a hazard has been found. A claim by some scientists and groups opposed to food irradiation about the potential toxicity of 2-alkyl cyclobutanones (2-ACBs), a group of radiolytic products formed in irradiated fat-containing foods such as meat and poultry, could not be substantiated by modern methods of toxicity testing. Their claims were based on academic toxicity studies of extremely high concentrations of pure 2-ACBs. Such high concentrations are not found in any food. Furthermore, the assays used had not been validated as accurate or reliable. It should be remembered that many food constituents may have some toxic properties when they are tested in isolation and at high concentrations. Food contains hundreds of components, and every kind of processing—including irradiation—will induce some changes in these components. The bottom line is that treatment by irradiation or any other method must not impair the safety of the food.

The level of radiolytic products formed in an irradiated food depends on the dose of radiation used. Therefore, the findings of high-dose radiation studies can be extrapolated to lower-dose treatment of the same food. Proteins, fats, and carbohydrates respond similarly to irradiation regardless of the type of food in which they occur—the same kinds of radiolytic products are formed. It thus is not necessary to study every irradiated food in detail; information obtained about the safety of radiolytic products in one food can be applied to the evaluation of other, chemically similar foods. This principle of safety evaluation was dubbed "chemiclearance" by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food in 1976.

A question is sometimes raised about toxicity of "free radicals" in irradiated food. Free radicals are atoms or molecules that contain an unpaired electron. They are formed in irradiated food as well as in foods processed by baking, frying, or freeze-drying. Free radicals are very reactive and unstable—they continuously react with other substances to form stable products. Free radicals in foods disappear after they react with each other in the presence of liquids, such as saliva in the mouth. Consequently, their ingestion does not create any hazard. This was confirmed by a specially designed animal feeding study carried out in Germany in 1974 using high-dose (45 kGy) irradiated dry milk powder that contained large amounts of free radicals. Nine generations of rats were fed this irradiated product without any indication of toxic effects. A non-irradiated slice of toasted bread actually contains more free radicals than any irradiated food, and both are consumed without harm.

Toxicology
The most common procedure for evaluating the safety of foods or food ingredients is to feed them in various doses (including very high doses) to animals and then to observe their growth, development, and reproductive and general health. Many studies have been conducted in which animals' diets included large proportions of irradiated foods. Some foods were treated with doses as high as 59 kGy, and were fed to animals of several different species, often over several generations.

Animal feeding studies carried out with irradiated food have consistently failed to find evidence of a health hazard. Among the many extensive animal feeding studies of irradiated food, those conducted at the Raltech Laboratory during the 1970s are generally acknowledged to be among the best and most statistically powerful of all. These studies used chicken meat irradiated either by a cobalt-60 source or by an electron machine up to a dose of 59 kGy. Nearly 150 tons of chicken meat were used in multi-generation feeding studies of mice, rats, hamsters, and dogs, to compare the effects of high-dose irradiation with heat sterilization of chicken meat. No adverse effects from consuming chicken processed with high doses of radiation were reported. Indeed, there were no significant differences between animals eating chicken meat sterilized by either process. Similarly, a study in the Netherlands during the 1960s found no evidence of any toxicological hazard for humans who ate irradiation-sterilized ham.

Nutritional Studies
For details, please see the section "How Does Irradiation Affect the Nutrients in Food?" under Chapter IV, "Effects of Irradiation on Food."

Microbiological Studies
Some concern has been raised that the risk of food poisoning, especially of botulism, might be increased by radiation pasteurization of foods because spores of botulism bacteria could survive such doses and could later grow and produce their dangerous toxin in irradiated food. This concern is not unique to irradiation but is also relevant to any process, including heat pasteurization or chemical treatments, that partially destroy the microorganisms in a food. Any food processed by sub-sterilization treatments must be handled, packaged, and stored following good manufacturing practices (GMPs) that will prevent growth and toxin production by emerging spores of botulism bacteria. Generally, refrigeration and chemical additives capable of blocking spore germination are employed. Like the heat sterilization processes used for commercial canned foods, high-dose radiation sterilization can destroy all microorganisms, including spores of botulism bacteria.

Packaging Materials

Because some foods are in packages when they are irradiated, the effects of irradiation on food packaging materials has been evaluated. The irradiation treatment must neither impair package integrity, nor deposit toxic radiation reaction products on the irradiated food.

Extensive research has shown that almost all commonly used plastic packaging materials tested are suitable for use at any irradiation dose likely to be applied to food, including sterilization treatment. Glass is an exception because irradiation may affect its color. The FDA as well as food control authorities in Canada, India, and Poland have approved a variety of packaging materials for use in food irradiation.

It should be noted that many types of packaging materials are routinely sterilized by irradiation before being filled with foods. These include “bag-in-a-box” containers for tomato paste, fruit juices, and wines; dairy product packaging; single-serving containers (e.g., for cream); and wine bottle corks. Irradiation is also used to “cross-link” some food contact plastic materials to improve their strength, heat resistance, and other properties (e.g., heat-shrink wrap films).

Position of the World Health Organization (WHO)

The World Health Organization (WHO), the FAO, and the IAEA have been actively involved in the evaluation of the safety of irradiated foods since the early 1960s. WHO has stated on several occasions that it is satisfied with the safety of food irradiated with the doses specified in Table 1. It has endorsed the effectiveness of irradiation for ensuring microbiological safety of solid foods in the same manner as thermal pasteurization has been successfully employed to do so in liquid foods.

In 2001, a representative of the European Commission (EC) suggested that 2-alkylcyclobutones (2-ACBs), formed when fat-containing foods are irradiated, might be toxic. After reviewing the relevant data, both the EC and WHO concluded in 2003 that 2-ACBs thus formed would not pose a toxic hazard to humans.

SAFETY OF IRRADIATION FACILITIES

Would Irradiation Facilities Endanger Local Communities?

No. Food irradiation plants would not endanger a community. They are no different from the approximately 40 medical-products irradiation sterilization plants and the more than 1,000 hospital radiation-therapy units using cobalt-60 as radiation sources, as well as hundreds of industrial electron irradiation facilities, now operating in the United States. Worldwide, some 200 industrial gamma irradiation facilities currently operate for various purposes—including food irradiation. None of these facilities has been found to pose a danger to the surrounding community. Such facilities must be and are designed, constructed and operated properly, and are licensed by national or state authorities. Such facilities do not represent a new challenge as the necessary safety precautions are well understood, and have been practiced by industrial irradiation facilities for the past 50 years.

Could There Be a "Meltdown" in a Food Irradiation Facility?

No. It is impossible for a "meltdown" to occur in a food irradiation plant or for a radiation source to explode. The radioisotopic sources approved for food irradiation, cobalt-60 and cesium-137, cannot produce the neutrons that can make materials radioactive, so no "nuclear chain reaction" can occur at such facilities. Food irradiation plants contain shielded chambers within which the foods are exposed to a source of ionizing radiation. The radiation sources thus used cannot overheat, explode, leak, or release radioactivity into the environment. Machine sources of irradiation are non-radioactive themselves, and they produce no radiation when turned off.

Is It Safe to Transport Radioactive Materials to and from Irradiation Facilities?

Like all potentially hazardous substances, radioactive materials must be transported in specially designed containers with appropriate safety precautions required by law. In the United States, the Nuclear Regulatory Commission (NRC) has jurisdiction over the safe storage and disposal of radioactive material and over the operation of irradiation facilities using radioisotopes. The Department of Transportation (DOT) has carrier requirements for the transport of hazardous materials, including radioactive materials. These substances have been transported to irradiation facilities and hospitals throughout the world for many years without incident. The containers used for the transport of radioactive cobalt are so well shielded and damage-resistant that the DOT permits them to be shipped by common carrier.

There is no transport problem if an irradiation facility uses machine-generated (electron or X-ray) radiation because no radioactive isotopes are involved.

Would the Health of Workers in a Food Irradiation Plant Be Endangered by Exposure to Hazardous Radiation?

No. Irradiation facilities, including those used for food irradiation, are designed with several levels of safety redundancy to detect any equipment malfunction and to protect personnel from accidental radiation exposure. All irradiation facilities must be licensed by national or state authorities to ensure their safety for workers and the environment. Regulations in all countries require such facilities to be inspected regularly to ensure compliance with the terms of the operating licenses. As a result of long experience in designing and operating similar types of irradiation facilities, the necessary precautions for worker safety in a food irradiation plant are in place. In the U.S., the Occupational Safety and Health Administration (OSHA) regulates worker protection from all sources of ionizing radiation. Food irradiation plants that use cobalt or cesium as their radiation source must be licensed by the NRC or an appropriate state agency. The NRC is responsible for the safety of workers in facilities it has licensed.

Plants in the U.S. that use machine-generated radiation are under the jurisdiction of state agencies that have established appropriate performance standards to ensure worker safety.

Is Irradiating Food a Means of Using Radioactive Wastes?

No. Spent fuel from nuclear reactors (radioactive waste) is not used in any food or industrial irradiation facilities. Of the four *possible* radiation sources for use in food irradiation, only one—cesium-137—is a by-product of nuclear fission. It is of limited commercial availability and is *not* used in any industrial irradiation facility. Cobalt-60, the most commonly used radioactive source for industrial radiation processing—including food irradiation—has to be manufactured specifically for this purpose; hence it is not a "nuclear waste" product. Cobalt-60 is produced by activating cobalt-59, a non-radioactive metal, in a nuclear reactor. Canada produces about 75% of the world's cobalt-60; the United States does not produce it. Cobalt-60 suppliers can in principle reactivate used cobalt-60 sources, if required, thus effectively recycling them.

Electron beam generators and X-ray machines, which use electricity as power sources, can be used for irradiating food—neither use radioactive materials.

How Can We Be Sure Foods are Properly Irradiated?

When specific applications of food irradiation are approved, the FDA and USDA issue guidelines requiring that food be irradiated in irradiation facilities licensed for this purpose. These facilities are legally required to use appropriate radiation doses, according to good manufacturing practices (GMPs), and as part of an overall Hazard Analysis and Critical Control Point (HACCP) system. HACCP guidelines emphasize that effective quality control systems must be established and closely monitored at critical control points at the irradiation facility. In all cases, only food of high quality should be accepted for irradiation.

ADVANTAGES OF FOOD IRRADIATION

Irradiation offers several advantages in food processing to improve the safety and quality of specific foods by meeting sanitary and phytosanitary (plant sanitation) requirements. These advantages include:

Improved Sanitation

For Raw Meat, Poultry, and Shellfish

Foodborne illnesses take a heavy toll on the economy and productivity of populations in most countries. Microorganisms such as *E. coli* O157:H7, *Campylobacter*, *Salmonella*, *Listeria*, *Vibrio*, and *Toxoplasma* are responsible for an estimated 1,500 deaths annually. Even low numbers of pathogenic bacteria such as *E. coli* O157:H7 and Listeria monocytogenes can cause illnesses and deaths, especially among immunocompromised individuals. The U.S. regulatory authorities therefore require "zero tolerance" of *E. coli* O157:H7 in ground beef and other non-intact meats, and of *L. monocytogenes* in ready-to-eat foods.

Destruction of pathogenic organisms in food and lowering the incidence of foodborne illnesses are the most important public health benefits of food irradiation. As with heat pasteurization of milk and juices irradiation improves sanitation of solid foods such as meat, poultry, shellfish, and fresh produce by significantly decreasing the number of microorganisms in foods without altering their sensory characteristics. It is the only technology that can do so effectively in raw and frozen foods.

Cooking to proper temperatures also kills pathogenic microorganisms, so properly cooked meat and poultry products are not hazardous even if they have not been irradiated. Contamination can occur during food preparation, and foods that are contaminated by pathogenic bacteria may in turn contaminate uncooked products such as fruits and vegetables, if strict sanitation control is not practiced. Irradiation of such foods prevents contamination from entering our homes or food preparation establishments.

Many illnesses and even deaths have occurred because of laxity in sanitation procedures during food preparation. For example, in 1993 an outbreak of *E. coli* O157:H7 food poisoning in a fast food restaurant resulted in the deaths of several children and hundreds of hospitalizations. Since as few as 10 cells of *E. coli* O157:H7 bacteria can cause illness and death in some people, very high levels of sanitation are needed. Another example was the contamination of deli poultry meat by *Listeria monocytogenes* in 2002 that resulted in 23 deaths and hundreds of illnesses.

For some products—such as hamburgers—the USDA Food Safety and Inspection Service (FSIS) recommends cooking to an internal temperature of 160o F to ensure destruction of pathogens such as *E. coli* O157:H7. Such a requirement significantly reduces the palatability of the product as the surface of the meat is overcooked. Irradiating ground beef allows a lower cooking temperature and thus can offer consumers the choice to have rare or medium-rare hamburgers without compromising microbiological safety, as dangerous pathogens such as *E. coli* O157:H7 will have already been destroyed.

Shellfish such as oysters and clams harvested from warm waters, which are often consumed raw, are naturally contaminated by pathogenic bacteria called *Vibrio* spp. Such bacteria cannot be removed by a commercial cleaning process called depuration. Each year, several deaths occur among immuno-compromised individuals in the U.S. from consuming raw oysters and clams contaminated by these bacteria, especially *V. vulnificus*. A moderate dose of irradiation (about 2 kGy) can kill this type of bacteria in raw, live oysters and clams without killing the shellfish.

For Spices and Dried Vegetable Seasonings

The traditional methods of production and processing of spices and dried vegetable seasonings lead to a high degree of contamination by spoilage and pathogenic bacteria. If such contaminated spices and seasonings are incorporated in a processed food such as sausages or canned meat, an excessive amount of heat would be needed to kill these bacteria and the processed products would no longer be palatable. Traditionally, spices and dried vegetable seasonings are fumigated by ethylene oxide/propylene oxide (EtO/PpO), a toxic gas that can be a health hazard to workers and can leave toxic residues in processed products. The European Union banned the use of EtO for fumigating food in 1991. EtO is still allowed in the U.S., as the FDA considers its risk to be minimal.

Irradiation is the most effective method of ensuring the hygienic quality of spices and dried vegetable seasonings as it can treat these products in their final packaging, thereby avoiding the possibility of cross contamination during processing, storage, and distribution, without leaving residues. As a result, irradiation has been increasingly used in the U.S. to ensure hygienic quality of spices and dried vegetable seasonings. Such products are used mainly by the food industry. Globally, more than 260 million pounds (120,000 metric tons) of spices, herbs, and dried vegetable seasonings are irradiated annually.

For Ready-to-Eat Meat Products

Increasing consumer demand for convenience or ready-to-eat foods has spurred the development of a variety of chilled foods that are subject to minimal processing or precooking. This has been a new challenge for the food industry because it must produce such foods with enhanced shelf life at refrigeration temperature, but without pathogenic microorganisms.

Listeria monocytogenes, which can grow at refrigeration temperatures, may contaminate many types of ready-to-eat food products during production or post-production processing. Because such foods are typically eaten without further cooking, the potential for foodborne illness cannot be ignored. The FDA requires “zero tolerance” of *Listeria* in such foods because of the severity of the disease it can cause. Immune-compromised individuals, the elderly, children under 5 years of age, pregnant women, and organ-transplant recipients are especially vulnerable to *Listeria* infection.

In 1998/99, 21 deaths were caused by an outbreak of illness from consumption of *Listeria monocytogenes*-contaminated sausages. As a result, over 12,000 tons of sausages were recalled and destroyed. In October, 2002 one of the largest food recalls in the history of the U.S. occurred due to contamination of ready-to-eat poultry and turkey deli products with *L. monocytogenes* in several states. A total of 13,700 tons (over 12,000 metric tons) of these products were recalled. In both cases, class action lawsuits followed and the food industry had to absorb the extremely high cost of legal settlements and fees. Ultimately these costs are shared by the consumer.

In 1999, the U.S. National Food Processors Association (NFPA) petitioned the FDA to approve the use of irradiation for several types of ready-to-eat foods (such as hot dogs and deli meats, and fresh cut produce). Approval of this petition would likely greatly expand the use of irradiation. Indeed, the CDC has estimated that if half of the ground beef, pork, poultry, and processed luncheon meats in the United States were irradiated, there would be at least 880,000 fewer cases of foodborne illness, 8,500 fewer hospitalizations, 6,660 fewer catastrophic illnesses, and 352 lives saved *every year*. As of May 2007, the FDA has not yet acted on the petition to irradiate ready-to-eat foods.

<u>*For Fresh Produce*</u>

Consumption of fresh produce has increased significantly in the past decade. During this time, contaminated fresh produce as well as pre-cut fruits and vegetables have caused many incidences of foodborne illnesses and deaths—more outbreaks than have been caused by contaminated meat products. Several types of pathogenic bacteria and parasites including *Salmonella, Shigella, L. monocytogenes, E. coli* O157:H7, and *Cyclospora cayetanensis*, were responsible for these outbreaks. In some cases, the outbreaks caused a major disruption in trade. For example, in 1996 hundreds of illnesses and hospitalizations resulted from *Cyclospora cayetanensis* contamination of imported Guatemalan raspberries. These outbreaks interrupted import of this fruit for several years. An outbreak caused by consumption of Mexican cantaloupe contaminated by *Salmonella poona* resulted in an import ban of this fruit in 2003.

The outbreaks in 2006 from *E. coli* O157:H7-contaminated bagged fresh pre-cut lettuce and spinach in the U.S. resulted in hundreds of illnesses and several deaths plus nationwide recalls of these products. Mexico decided to temporarily halt import of fresh lettuce grown in California. Canada also banned import of fresh spinach from the U.S. As a result, sales of fresh produce—especially lettuce and spinach—decreased significantly. Some consumers lost confidence in the safety of these nutritious products and decided to shun them completely. According to the Western Growers Association and an agricultural economist at the University of California, the loss at the spinach farm and processor level alone could amount to $100 million.

The FDA first issued a safety guideline to produce growers in 1998, and sent them strong letters following outbreaks of illness from *E. coli*-contaminated lettuce in 2004. While good agricultural practice in the production of fresh produce can reduce environmental contamination, microbial contamination can come from various sources at different steps in the production chain. These can include bird and other animal droppings, manure, floodwater, irrigation, sewage, and even human handling, both before and after harvesting. Washing can reduce but not eliminate contamination of fresh produce.

The current system of centralized production and distribution of fresh produce makes it difficult for the industry to avoid contamination. Lettuce or spinach is collected from many fields and processed in a centralized facility using common vats for washing prior to bagging. Thus, contamination of produce harvested from one field can spread to those harvested from others at such facilities. Unfortunately for consumers, it takes less than 100 cells of some pathogens such as *E. coli* O157:H7 to cause illness and deaths. The situation is similar to the centralized production of ground beef, chicken, and spices, where contamination can be spread during processing.

Ample research data has demonstrated that irradiation is the most effective method to "pasteurize" fresh produce—including bagged lettuce and spinach—without significantly affecting quality. Irradiation of fresh produce, however, was given only limited approval by the FDA in 1986, for insect disinfestations and to delay physiological growth (such as sprouting of tubers, ripening of fruits, and cap-opening of mushrooms) with a maximum dose of 1 kGy.

For a "Killing Step" in HAACP Protocols

While comprehensive HACCP protocols play an important role in ensuring the safety and quality of food products, they do not eliminate all of the pathogens that may be present. There currently is no "killing step" for pathogens for which regulatory authorities have mandated "zero tolerance" such as *E. coli* O157:H7 in ground beef. Irradiation would uniquely provide such a step.

Increased Availability of Fresh Produce

As noted above, foods harboring certain insect species must be properly treated before they may enter countries with strict quarantine requirements such as Australia, Japan, New Zealand, and the United States. Fruits from tropical areas, even grown under good agricultural practices (GAP), may harbor fruit fly eggs and larvae inside the fruit. Different countries have approved several types of quarantine treatments to prevent the spread of these pests. Such treatments include fumigation by toxic gases, vapor heat treatment, hot water dip, cold treatment (maximum 2o C for a specific time), and irradiation.

Traditionally, national plant quarantine authorities approve methods for a specific pest/food commodity combination. For example, a fumigant schedule with ethylene dibromide (EDB) or methyl bromide (MB) for fumigating mangoes to kill a specific species of insect such as medfly cannot necessarily be used for papaya, or for other species of insects. Additional data must be obtained on the effectiveness of the same fumigant or other quarantine treatments against other insect species in other commodities. In addition, each quarantine treatment method must not significantly affect the quality of the treated fruits or it will not be marketable. Therefore, it may take years to conduct the necessary research and obtain regulatory approval before a specific quarantine treatment could be used for a specific commodity.

Traditional Quarantine Treatment Methods

Traditional methods such as fumigation by ethylene dibromide (EDB) or methyl bromide (MB), hot water dip, vapor heat treatment, and cold air have either limited technical applications or cause damage to the product quality, worker safety, or the environment. For example, EDB has been banned as a food fumigant in most countries due to its toxicity to workers and the environment. MB is a strong ozone depleter, and its production is being phased out globally. Hot water dip and vapor heat treatment are applicable to a few fruit cultivars such as mangoes and papaya that have thick peels. Cold air treatment (exposure to near-freezing temperatures for at least 10-14 days) is applicable only to a few fruit cultivars such as citrus, is expensive, and is not applicable for tropical fruit, since it would cause chill injury. A versatile, affordable treatment that is applicable to most types of fresh produce is urgently needed to meet international trade requirements.

Irradiation as a Quarantine Treatment

Irradiation was first proposed as a quarantine treatment in the 1930s, when it was found to be effective against fruit flies endemic to Hawaii. However, since the FDA regulates irradiation as a food additive (rather than as a process), the safety of each treated food item would have to be demonstrated through long-term animal feeding tests before it could be used—a very cumbersome and expensive process. Also, irradiation could not compete financially with fumigation by ethylene dibromide (EDB), which was widely used at that time.

When EDB was banned by the EPA in the mid-1980s, irradiation emerged as an alternative to conventional quarantine treatment methods. However, even after the FDA approved irradiation of fresh fruits and vegetables for insect disinfestations and delay of physiological growth in 1986, no serious attempt was made to use it, since there was no commercial irradiator in Hawaii. There was also a concern that irradiation did not immediately kill the larvae in fruit, and therefore regulatory authorities would have difficulty regulating it in trade. In addition, research data demonstrating that irradiation could be used as a broad spectrum quarantine treatment was lacking.

The International Consultative Group on Food Irradiation (ICGFI), established under the aegis of FAO, IAEA, and WHO, evaluated the data on irradiation as a quarantine treatment in 1986 and recommended for the first time that it could be used as a quarantine treatment against the larvae of tephretid fruit flies for any fruit.

Research conducted in several countries confirmed the effectiveness of irradiation as a broad spectrum quarantine treatment against a large number of insect pests in different commodities. In 1987, APHIS approved irradiation as a quarantine treatment of papaya against three species of Hawaiian fruit flies. In 1995, APHIS added several other Hawaiian fruits to its approved list. As before, the approval required that the irradiation be carried out in Hawaii, where there was still no commercial irradiator. In 2002, additional research data and the limitations of conventional quarantine treatments prompted APHIS to extend the use of irradiation for eleven species of fruit flies and one species of weevil, for all fruits. APHIS again revised its ruling in January 2006 when it specified necessary radiation dosages for other insect species, for any fruits. Thus, irradiation is the only quarantine treatment method that can be used as a pest mitigation measure for all affected fruits.

LEGAL AND REGULATORY ASPECTS OF FOOD IRRADIATION

What Is the Legal Status of Food Irradiation in the United States?

FDA Approval
Food irradiation is regulated as a food additive (rather than as a process, like pasteurization or canning) by the FDA under the terms of the 1958 Food Additive Amendment to the Food, Drug, and Cosmetic Act. This law prohibits the use of a new food additive until its sponsor has established its safety and until the FDA has issued a regulation specifying conditions of safe use. The law specifically includes "any source of radiation" in its definition of "food additive." This legal definition created some problems in early studies of the safety of irradiation because it require that toxicological studies be carried out on individual irradiated foods such as cod, redfish, chicken, beef, papaya, and mangoes. Irradiated foods that have been approved for production and consumption by the FDA are listed in Table 2:

Table 2. **Irradiated Foods Approved by the FDA**

Food items	Purpose	Maximum dose	Date
Spices and dried vegetable seasonings	Insect and microbial control	10 kGy	1983
Pork	Control of *Trichinella*	1kGy	1985
Fresh fruits and vegetables	Insect disinfestations and growth control	1kGy	1986
Poultry meat	Inactivation of pathogens, e.g., *Salmonella*	3kGy	1990
Ground beef and other non-intact red meat	Inactivation of pathogens, e.g., *E. coli* O157:H7	7kGy	1997
Shell eggs	Inactivation of *Salmonella*	3kGy	2000
Sprouting seeds	Inactivation of pathogens, e.g., *Salmonella*	8kGy	2000
Mollusks	Inactivation of pathogens, e.g., *Vibrio*	2kGy	2005

(For a detailed list of approvals of irradiated foods in the U.S., Canada and Mexico, please see Appendix III.)

USDA Approvals

The USDA has jurisdiction over approval of quality control programs of processing of meat, poultry, and eggs, as well as of quarantine treatments of fresh fruits and vegetables that may harbor exotic pests. The maximum dose for any irradiated food must still follow the FDA-specified guidelines. The USDA may, however, require minimum absorbed doses to meet specific objectives—for example, a minimum of 0.40 kGy to control any insects in fresh produce.

The USDA approvals include the following foods:

Food Item	Purpose	Date
Fresh and frozen poultry Meat and meat products	Inactivation of pathogens	1992
Ground meat and other non-intact meat products	Inactivation of pathogens	2000
Fresh fruits and vegetables	Quarantine control	2006

How Have U.S. Health and Scientific Organizations Reacted to Food Irradiation?

Leading health and scientific organizations, including the American Medical Association (AMA), Centers for Disease Control and Prevention (CDC), the American Dietetic Association (ADA), the Council for Agricultural Science and Technology (CAST), and the Institute of Food Technologists (IFT), have long endorsed the safety and benefits of food irradiation. In 1993 the AMA's Council on Scientific Affairs called food irradiation a "safe and effective process that increases the safety of food when applied according to government regulations." Scientific summaries from ADA, CAST, and IFT are listed among this book's "Suggestions for Further Reading."

What Is the Legal Status of Food Irradiation Around the World?

About 60 countries have approved specific applications of irradiation, and irradiated foods are actually produced for commercial purposes in some 30 countries. Both the number of countries that have approved irradiation for food processing as well as the numbers of approved products/applications is increasing. Recently, the trend has been to approve irradiation of classes of food (e.g., fruits, vegetables, meat and poultry, seafood, roots and tubers, cereals and certain pod-bearing plants, spices and seasonings) rather than individual food items, per the recommendations of the International Consultative Group on Food Irradiation (ICGFI). Brazil has approved irradiation as a food process for any foods and doses, as recommended by ICGFI and the Codex General Standard for

Irradiated Foods.
The European Union (EU) as a bloc has been more restrictive in its approach to food irradiation. In 1999, it issued two Directives governing the use of food irradiation in all member countries of the EU (currently, 27 countries). Thus far, only irradiated spices, herbs, and dried vegetable seasonings are on the approved list for production and marketing in all EU member countries. Attempts by the European Commission to add more irradiated food products to this list have not been successful because of the political, emotional, and ideological stances of various member countries. EU member countries that had approved other irradiated food products prior to 1999 (Belgium, France, Italy, the Netherlands, Spain, and the UK) can maintain their national approvals, however.

The details of approval of irradiated foods in different countries may be obtained from the database maintained by the IAEA at: www.iaea.org/DataCenter/datasystems.html.

International Standards and Agreements Governing Trade in Food and Agricultural Commodities

Trade in food and agricultural commodities has become increasingly global following the establishment of the World Trade Organization (WTO) in 1995. Formerly, importing countries were essentially free to establish their own rules. Now, all member governments of the WTO will follow the same rules and procedures. They will be bound by the multilateral trade agreements attached to the WTO, which include the SPS (Application of Sanitary and Phytosanitary Measures) and TBT (Technical Barriers to Trade) Agreements. These Agreements are of particular relevance to international trade in food and agricultural commodities.

In particular, the SPS Agreement is designed to protect the health and life of humans, animals, and plants through trade in food and agricultural commodities. It recognizes standards, guidelines, and recommendations of relevant international organizations to assist the WTO in settling trade disputes with respect to these commodities: especially relevant are those of:

- Codex Alimentarius Commission (food safety)
- International Plant Protection Convention (plant protection and quarantine)
- International Office of Epizootics (animal health)

Because of such international standards, national authorities should implement regulations on food irradiation in a harmonized fashion. Unfortunately, many countries allow irradiation on specific food items, instead of as a general food process as is done for heat processing, for example. In some cases, different radiation doses were authorized for treating the same food products in different countries. Such differences have created obstacles to the introduction of irradiated foods into international trade.

The Codex General Standard was revised in 2003. The final version (www.codexalimentarius.net) recognized the safety of irradiated foods and recommended that no upper dose limit be imposed as long as the food is irradiated under current Good Manufacturing Practices (GMP) to achieve technological objectives.

International Guidelines on Irradiation Phytosanitary Measures of the International Plant Protection Convention (IPPC)

The effectiveness of irradiation as a phytosanitary treatment of fresh fruits and vegetables has been demonstrated by decades of research as well as by recent commercial applications. It has been endorsed by the International Plant Protection Convention through its International Guidelines on Irradiation Phytosanitary Measures adopted in 2003. Irradiation could facilitate international trade in fresh produce as well as provide a suitable alternative to fumigation by methyl bromide.

CONSUMER ACCEPTANCE OF IRRADIATED FOODS

Results of Market Trials

In the past few decades, a series of market tests of several types of irradiated food products have been conducted in the U.S., Argentina, Bangladesh, Chile, China, France, India, Indonesia, The Netherlands, Pakistan, the Philippines, South Africa, and Thailand. These tests showed consistently that consumers were not only willing to buy irradiated foods, but often preferred them to food treated by conventional means, once they were given truthful information about irradiation and its purpose. In a trial in Shanghai, China in 1991, over 90% of consumers were willing to purchase irradiated apples again once they realized the benefits of irradiation compared to chemical treatment. In 1986, market trials of irradiated fermented pork ("Nham") in Bangkok, Thailand, demonstrated that consumers purchased more irradiated than non-treated product in a ratio of 16:1.

Among the first irradiated foods entering the American market were strawberries, onions, and mushrooms that were treated in the first commercial food irradiator (Vindicator Co., Mulberry, Florida, later called Food Technology Service, Inc.) in 1992. The results of market trials of some irradiated foods conducted by a small grocer called Carrot Top in Northbrook, Illinois, starting in early 1992, found that consumers who were provided with accurate information preferred the irradiated products over their non-irradiated counterparts, which were also available at the same store.

The early success of marketing irradiated fruits, vegetables, and chicken by the Carrot Top grocery provided reassurance and an incentive to supermarket chains to follow suit. After the approval of irradiated red meats by the FDA and USDA, irradiated ground beef has been successfully marketed in several states. Similarly, the encouraging results of market trials have led to the successful introduction of irradiated foods both commercially and at the retail level in other countries—including Belgium, China, France, India, Japan, South Africa, and Thailand.

CURRENT AND POTENTIAL APPLICATIONS OF FOOD IRRADIATION

Sanitary Treatment

Irradiated Red Meat

Ground beef irradiated by electron beam technology began to enter commercial distribution in the United States in mid-2000 and was well received by consumers. Huisken Meat, Inc., based in Sauk Rapids, Minnesota, was the first company to sell irradiated ground beef at the retail level. In 2000, the company predicted that 2 million pounds of irradiated beef patties would sell in its second and third quarters—but instead reported selling that amount in five weeks. Since then, a number of supermarket chains, both regional and national, have begun to market irradiated ground beef, some using their own brand names. By late 2003, some 10,000 supermarkets and retail outlets in the U.S. routinely carried irradiated ground beef.

In 2004, sale of irradiated ground beef took an unexpected turn as the main irradiation service provider (SureBeam, Inc.) using electron beam technology went out of business because of accounting fraud. Consequently, many food companies no longer had access to irradiation facilities and suspended sale of irradiated ground beef (the few gamma irradiation facilities could not treat the same volume of ground beef). The production and sale of irradiated ground beef increased in 2006, though, when Sadex, Inc. acquired an electron beam irradiation facility and began offering the service to the food industry.

While it has been clearly proven that irradiation is the best method to ensure microbiological safety of fresh and frozen ground beef (and other foods), only a small fraction of this product is irradiated annually. Meanwhile, ground beef continues to be contaminated by pathogens such as *E. coli* O157:H7, the food industry continues to recall their contaminated product, occasionally consumers fall ill, and litigation continues to occur.

Irradiated Poultry Meat

Although the FDA approved irradiation of poultry meat in 1990, and the USDA approved it in 1992, little commercial production and marketing of irradiated poultry meat actually took place until several years later. A food irradiation facility using cobalt-60 as the radiation source, Food Technology Service (FTS), Inc., in Florida, started marketing irradiated poultry meat in the mid-1990s under the Nation's Pride brand name. So far, sale of irradiated poultry meat remains limited, although a major supermarket chain in the Southeast, Publix, started marketing irradiated frozen poultry breasts in all of its 725 stores in January 2003. Commercial quantities of irradiated poultry meat have been distributed to several restaurants and some hospitals in Florida. The reason for limited marketing of irradiated poultry meat was probably because the USDA (and consumers) had not recognized *Salmonella* and other pathogenic bacteria such as *Campylobacter jejeuni* in poultry meat as "adulterants." In fact, though, these bacteria cause many more illnesses and deaths than does *E. coli* O157:H7-contaminated red meat.

Irradiated Seafood
The FDA approved the use of irradiation for live mollusks (oysters and clams) in 2005. The purpose is to inactivate pathogens such as *Vibrio vulnificus*, which has caused several outbreaks of illness and occasional deaths from consumption of raw oysters and clams, especially by immune-compromised individuals. Irradiated mollusks have not entered the market to date, although irradiation remains the best method of ensuring their microbiological safety without significantly reducing their viability.

Spices, Herbs, and Dried Vegetable Seasonings
Irradiation has been widely used since the 1980s for ensuring the hygienic quality of spices, herbs, and dried vegetable seasonings. The volume of irradiated products increased significantly in Europe after EtO fumigation was banned in 1991. However, the imposition by the EU in 1999 of strict labeling requirements on irradiated spices, herbs, and vegetable seasonings in any other food (no matter how infinitesimal the quantities) has resulted in a lower production of irradiated products. Globally, some 260 million pounds (120,000 metric tons) of such products are produced in some 20 countries.

Ready-to-Eat Foods including Fresh Produce
A petition for irradiation to ensure microbiological safety of ready-to-eat food including fresh produce, submitted to the FDA in 1999, is still awaiting approval. Once approved, irradiation is likely to be applied widely, as it is currently the best method to sanitize such products. *E. coli* bacteria can grow inside plant tissues, and irradiation is likely to be uniquely effective for inactivating this pathogen in fresh produce without significantly impairing the food's quality.

Future Trends
The use of irradiation as a sanitary treatment is likely to increase as consumers become more familiar with the risk of illness from foods contaminated by various pathogenic organisms and the benefits that irradiation can bring. The food industry—especially in the U.S.—has already introduced the use of irradiation for this purpose. The types and volume of irradiated food products thus treated are expected to increase significantly in the near future, especially when the irradiation of ready-to-eat foods—including fresh produce—is approved. Irradiation, similar to other food processing technologies, will be used only when it can provide technical or economic benefits. Not all food should or ever will be irradiated, just as not all foods should or will be fumigated, canned, or frozen.

Phytosanitary Treatment
Commercial Development
The first market trial of Puerto Rican mangoes, irradiated to meet American quarantine requirements, was carried out in a supermarket in Florida in 1986. The trial proved that consumers would buy irradiated mangoes instead of those that were treated by hot water dips. It was followed by a market trial of irradiated papaya in California in 1987. The

results were highly successful, since consumers preferred irradiated papaya (with clear labeling) to hot water dipped ones by a ratio of 13:1. In 1995, the Hawaii Department of Plant Industry obtained special permission from APHIS to transport papaya from Hawaii by air to be irradiated at a commercial facility near Chicago, to test the market. The irradiated fruits were successfully sold in a few supermarkets in the Chicago area.

After several successful market trials of irradiated papaya between 1995 and 1999, the Hawaii Department of Plant Industry was convinced that irradiation offered the best prospect for commercialization of Hawaiian papaya. The first Hawaiian electron beam/X-ray commercial food irradiator was built in Hilo, Hawaii and began operation in mid-2000. Thousands of tons of papaya and other Hawaiian fruits have been irradiated per year at this facility since that time. Consumers have enjoyed the benefit of irradiation of tree-matured fruits with well-developed flavor as compared with less mature fruits subjected to other quarantine treatments.

Irradiation Phytosanitary Treatment and International Trade

The positive commercial developments in the U.S. and the regulatory framework described in the Final Rule of APHIS in January 2006 has begun to have a strong impact in international trade in fresh fruits and vegetables. Several countries—Brazil, Ghana, India, Mexico, Pakistan, the Philippines, and Thailand—have started planning to use irradiation as a phytosanitary treatment of their fruits and vegetables to allow their marketing in the United States. In April 2007, APHIS approved the use of irradiation to treat Indian mangoes to kill the mango seed weevil, and the importation of these fruits into the United States has begun.

Future Trends

With the increasing demand for fresh fruits and vegetables by the American public, irradiation will likely become widely used to bring fruits from tropical and sub-tropical countries into the U.S. American consumers will thus have more varieties and greater quantities of these fruits. In return, U.S. fruit growers and exporters could demand that markets in countries such as Australia and New Zealand, which have strict quarantine regulations and have already approved irradiation as a quarantine treatment, will be opened for irradiated fruits exported from the U.S.

Availability of Irradiated Foods in the United States

Irradiated spices and dried vegetable seasonings, mainly for use by the food industry, constitute the largest volume of irradiated food used in the U.S. market (about 70,000 tons per year). It is estimated that about 9,000 tons of irradiated ground beef and poultry are consumed annually. It is also estimated that some 4,000 tons of irradiated fruits and vegetables, mainly mango, papaya, and guava from Hawaii and Florida, are sold annually by U.S. retailers. Boniato sweet potatoes from Puerto Rico and purple sweet potatoes from Hawaii are also irradiated. Several supermarket chains—Supervalu, Wegmans, Publix, Safeway, and Giant—offer some of these irradiated foods. Schwan, Inc., a nation-wide food service company operating through home delivery, started marketing irradiated ground beef produced by Huisken Meat, Inc., in late 2000. Because sale of irradiated ground beef was so successful, Schwan, Inc. of Bloomingdale, MN chose to irradiate 100% of their uncooked ground beef offerings, as does Omaha Steaks. Similarly, Simeks, Inc. of St. Paul Park, MN uses only irradiated ground beef for various meals produced by its company.

Global Application of Food Irradiation

The estimated global quantity of irradiated food that entered commercial channels in 2005 was approximately 300,000 tons, of which about one-third were irradiated spices and dried vegetable seasonings. In China, approximately 120,000 tons of various foods were irradiated and marketed in 2005. That same year, the U.S. produced close to 100,000 tons of irradiated ground beef, spices, vegetable seasonings, and tropical fruits from Hawaii. In Japan, approximately 15,000 tons of potatoes are irradiated each year to prevent spoilage due to sprouting. A wide variety of irradiated foods has been approved in Belgium, France, the Netherlands, and South Africa, and each of these countries produces approximately 10,000 tons of irradiated food annually. The quantity of irradiated food produced globally is expected to increase significantly in the next few years.

ISSUES AFFECTING TRADE IN IRRADIATED FOODS

Will Irradiation Increase the Cost of Food?

Any additional processing of foods will tend to add to the immediate cost of production but allay other costs from coping with spoilage or paying settlements to customers made sick by pathogens. All food processes—canning, freezing, refrigeration, pasteurization, fumigation, and irradiation—benefit consumers because of improved safety, quality, quantity, availability, and convenience, all of this contributing to the "added value" of the food. The cost of irradiation depends on the dose required and the volume of food to be irradiated. In general, the cost of low dose irradiation of food, e.g., for sprout or insect control, is on the order of $60-$80 per ton, or about 3-4 cents per pound; medium dose irradiation for pathogen control in meat products should add about 5-10 cents per pound, and 30-40 cents per pound will be added for relatively high-dose irradiation of spices and dried vegetable seasonings. In general, the cost of irradiation is competitive if not lower than that of other food processes used for the same purposes. For example, the cost of irradiation to meet quarantine requirements for papaya in the U.S. is approximately half the cost of vapor heat treatment.

What about Labeling?

Most national authorities that approve the use of food irradiation require that food so treated be clearly labeled, and often require that the international food irradiation logo (the Radura—see Appendix I) also be on the label. Information from market trials indicates that consumers prefer that irradiated foods be labeled as such, as irradiated foods are less likely to serve as vehicles of foodborne pathogens. Labeling offers the opportunity to inform consumers of the reason why foods are or should be irradiated, as well as give them a choice.

Curently, the FDA requires that irradiated whole foods be labeled as such, and a mandatory green "Radura" logo was added to this labeling requirement in 1986. Labeling requirements could hamper the commercialization of some applications of irradiation even if consumers are willing to buy foods labeled "irradiated." In many cases irradiation will be competing with techniques that do not need to be declared on the label: heat processing, freezing, and fumigation. There is no *negative* health-related reason why irradiated foods must be labeled. There is no known population subgroup that needs to avoid these foods on health grounds. On the other hand, labeling irradiated foods provides the opportunity to inform consumers not only that the food has undergone irradiation treatment but also that the food is therefore a safer and better quality product. It also provides educational information for consumers.

Experience with retail sale of irradiated foods indicates that informed consumers are willing to buy irradiated foods, even at a higher cost. In addition, comments submitted to the FDA suggest that many people want to know when foods have been irradiated. This desire to know is also a strong argument in favor of labeling for informational—not warning—purposes.

Indeed, FDA officials have stated that the purpose of any label should be informative only. The FDA and USDA have allowed truthful statements such as "irradiated for food safety," "irradiated for your safety," or "irradiated to greatly reduce harmful bacteria" on irradiated food packages. In April 2007, the FDA proposed that labeling would be required only for irradiated food that is "materially changed" because of the treatment. The FDA is willing to consider a petition to allow the use of other descriptive terms, such as "cold pasteurization" on irradiated foods.

The FDA does not require labeling of irradiated ingredients that are incorporated in other foods, such as irradiated pepper in sausages. It also does not require labeling of irradiated foods served in food service establishments.

In contrast, all European Union member countries require labeling not only on whole food sold as such, e.g., chicken and shrimp, but also on irradiated ingredients that are incorporated into other food, regardless of quantities or proportions. Thus, any irradiated ingredients, no matter how infinitesimal the quantity, have to be labeled if they are incorporated into other foods. If the food is further processed, labeling of irradiated ingredients continues to be required. This unique labeling requirement has become a barrier not only to the use of food irradiation in Europe but also to international food trade. As a result, the quantity of irradiated spices, herbs, and vegetable seasonings produced in Europe has declined significantly since 1999, when these labeling requirements went into effect.

Are Irradiated Foods Traded Internationally?

Some irradiated foods, such as spices, herbs, and dried vegetable seasonings, and ingredients such as mechanically-deboned poultry meat, have entered international markets for use by the food processing industry. Many types of irradiated spices and seasonings in processed food also have entered international commerce. Other irradiated foods, e.g., ground beef, chicken, and fruits, are mainly used in domestic markets to meet local food demands. Starting in April 2007, irradiated mangoes from India entered the U.S. for the first time, paving the way for international trade in fresh produce using irradiation.

With the recent generic approval by APHIS of irradiation for imported fruits and vegetables, international trade in irradiated food is likely to increase significantly in the near future.

Are There Methods to Determine If Foods Have Been Irradiated?

Yes. There are several methods that can be used to determine whether foods have been irradiated or not. There is no single method that works for all foods, however. The Codex Alimentarius Commission has recognized different analytic methods for irradiated foods containing fat, bone, cellulose, or silicate materials, for example.

CONCLUSIONS

The safety and effectiveness of irradiation as a food process have been clearly established, and this food technology is increasingly approved by regulatory authorities all over the world. Irradiation provides an added layer of safety to many food products that are susceptible to contamination by pathogenic microorganisms. Irradiation ensures the microbiological safety of food at the market place and prevents consumers from bringing contaminated products into their homes. As a "cold pasteurization" process, irradiation offers unique advantages to ensure microbiological safety of raw, frozen, and ready-to-eat foods, including fresh produce.

Faced with liability from selling contaminated products, the food industry will weigh the low cost of using irradiation against the high cost of product recalls, lawsuits, loss of brand equity, or even bankruptcy as a result of illnesses and deaths caused by contaminated products. The onus is now on the food industry to use every safe and effective food technology to ensure the safety of its products. Irradiation can play the same role to ensure microbiological safety of many types of solid foods as heat pasteurization has for liquid foods. As irradiation is more widely used, consumers will have the option of purchasing irradiated foods without such contamination.

Irradiation complements the globalization of the food trade, since it is an effective sanitary and phytosanitary treatment and is widely applicable to most food and agricultural commodities. Once the food industry decides to implement the broad use of food irradiation, it will provide U.S. consumers with safer food and a wider choice of fresh fruits and vegetables from overseas, especially those from tropical countries that have limited access to the U.S. market because of strict quarantine regulations. It will enhance the export of fruits and vegetables from the U.S. to its trading partners.

The ultimate success of any food technology or product is in the marketplace. It is the consumer who will decide whether to buy irradiated foods or to buy food processed by other appropriate methods. While the introduction of irradiated foods into the U.S. market and elsewhere has been slow, this trend is likely to change because of increased consumer demand for improved safety and availability of many food products. Irradiation therefore can provide consumers with another choice for safety-enhanced foods. However, consumers can exercise their choice only when the food industry changes its stance on irradiation from “low profile” to “high profit” and offers irradiated foods widely in the market place.

SUGGESTIONS FOR FURTHER READING

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Appendix I. Some Terms Frequently Used in Discussions of Food Irradiation

Dosimetry: A system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

High-energy electrons: Streams or beams of electrons accelerated by a machine to energies of up to 10 million electron volts (MeV). Electrons are also emitted by some radioactive materials; in this case they are called "beta rays."

Gamma rays: Electromagnetic radiation of very short wavelength, similar to high-energy X-rays. Gamma rays are emitted by radioactive isotopes of cobalt-60 and cesium-137 as these isotopes spontaneously disintegrate.

HACCP: Hazard Analysis and Critical Control Point (HACCP), science-based and systematic, identifies specific hazards in food processing systems and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing.

Inactivation: Rendering microorganisms incapable of development.

Kilogray (kGy); Gray (Gy): A Gray (Gy) is the unit (or level) of ionizing energy absorbed by a food during irradiation. One Gy is equivalent to energy of 1 joule absorbed by one kilogram of matter, e.g., food; 1000 Gy = 1 kilogray (kGy). (An older unit of absorbed radiation dose is the rad. One Gy =100 rad.)

Phytosanitary treatment: Any treatment designed to protect plant health by preventing the introduction and/or spread of pests, or to ensure their official control.

Radiation pasteurization: Treatment of food with doses of radiation large enough to kill or render harmless all disease-causing organisms except viruses and spore-forming bacteria. Processed foods usually must be stored under refrigeration.

Radiation sterilization: Treatment of food with doses of radiation large enough to kill or render harmless all disease-causing and spoilage organisms. The resulting processed food can be stored at room temperature in the same way as thermally sterilized (canned) foods—that is, packaged to prevent recontamination.

Radura: A symbol or logo developed in the Netherlands and recognized internationally by the World Health Organization and the International Consulting Group on Food Irradiation as the official symbol that indicates a product has been subjected to irradiation.

X-rays: Ionizing electromagnetic radiation of a wide variety of short wavelengths. They are usually produced by a machine in which a beam of fast electrons in a high vacuum bombards a metallic target and is converted to X-rays.

Appendix II. Food Irradiation: Some Major Milestones

1895: Wilhelm Konrad Roentgen, German physicist, discovers X-rays.

1896: Antoine Henri Becquerel, French physicist, discovers emission of radiation from naturally occurring radioactive materials. Minsch publishes proposal to use ionizing radiation to preserve food by destroying spoilage microorganisms.

1904: Prescott publishes studies at Massachusetts Institute of Technology (MIT) on the bactericidal effects of ionizing radiation.

1905: U.S. and British patents issued for the use of ionizing radiation to kill bacteria in foods.

1905–1920: Significant basic research is conducted on the physical, chemical, and biological effects of ionizing radiation.

1921: USDA researcher Schwartz publishes studies on the lethal effect of X-rays on *Trichinella spiralis* in raw pork.

1923: First published results of animal feeding studies to evaluate the wholesomeness of irradiated foods.

1930: French patent issued for the use of ionizing radiation to preserve foods.

1943: MIT group, under U.S. Army contract, demonstrates the feasibility of preserving ground beef by use of X-rays.

Late 1940s and early 1950s: Beginning of era of food irradiation development by U.S. Government, Atomic Energy Commission, industry, universities, and private institutions, including long-term animal feeding studies by the U.S. Army and by Swift and Company (an American meat processing company).

1950: Beginning of food irradiation program by Great Britain and numerous other countries.

1958: The Food, Drug, and Cosmetic Act is amended, directing that food irradiation be evaluated as a food additive, not as a physical process. All new food additives, including irradiation, must be approved by FDA before they can be used. The U.S. Congress passes legislation to this effect, which President Eisenhower signs in 1958. This legislation is still the law of the land.

1973: The first successful commercial potato irradiator started operating at Shihoro Agricultural Co-operative, Hokkaido, Japan. The irradiator continues to operate even today.

1976: The Joint Expert Committee on the Wholesomeness of Irradiated Foods (JECFI), convened by Food and Agricultural Organization of the United Nations (FAO), International Atomic Energy Agency (IAEA), and World Health Organization (WHO), declares that food irradiation is a physical process comparable to heating and freezing preservation of food.

1980: The JECFI concluded that irradiation of any food commodity up to an overall average dose of 10 kGy causes no toxicological hazard; hence, toxicological testing of food so treated is no longer required. The JECFI also stated that irradiation of food up to an overall average dose of 10 kGy introduces no special microbiological and nutritional problems in food.

1983: Codex Alimentarius Commission of the FAO/WHO Food Standards Program, representing 130 countries, adopts worldwide standards for the application of irradiation to foods with doses up to an overall average of 10 kGy.

1984: An International Consultative Group on Food Irradiation (ICGFI) was established under the aegis of FAO, IAEA, and WHO to evaluate global developments on food irradiation and provide a focal point of advice to the three U.N. bodies and their member governments.

1988: FAO, IAEA, WHO, and ITC/UNCTAD/GATT convened an international conference that adopted an agreement on provisions to accept, control, and trade irradiated foods on a global scale.

1992: The first commercial food irradiator in the U.S. (Vindicator, Inc., Mulberry, Florida) starts operation and offers service to the food industry. A small grocer based in Northbrook, Illinois, pioneered sale of irradiated food at the retail level.

1995: Irradiation is commercially applied in the United States to preserve poultry, strawberries, tomatoes, mushrooms, onions, and citrus products and to kill insects and parasites in herbs and spices. Irradiated fruits from Hawaii debuted in the U.S. market.

1997: A Joint Study Group on High-Dose Irradiation of Food was convened by FAO, IAEA, and WHO to evaluate wholesomeness data of food treated above 10 kGy. The Group concluded that irradiation of food at any dose, whether below or above 10 kGy, causes no toxicological hazards and is nutritionally adequate. No upper dose limit need be imposed on food irradiation as a food process.

2000: The first commercial electron beam machines of Surebeam, Inc., for food irradiation start operation in Sioux City, Iowa, to provide service to the food industry. Irradiated ground beef produced by Huisken Meat, Inc. of Minnesota starts entering the market. Sale of irradiated ground beef expands rapidly.

2000: The first commercial X-ray machine for food irradiation (produced by Surebeam, Inc.) starts operating in Hilo, Hawaii, for treating fruit to meet quarantine requirements for export to the U.S. mainland.

2003: Many supermarket chains start offering irradiated foods, mainly ground beef and fresh fruits from Hawaii, in some 10,000 stores in most states of the U.S. A fast-food restaurant chain, Dairy Queen, starts offering irradiated hamburgers at their stores in Minnesota. Several restaurant chains start offering irradiated ground beef on their menus.

2003: The First World Congress on Food Irradiation, organized by the National Food Safety and Toxicology Center, Michigan State University, was held under the co-sponsorship of FMI, GMA, NFPA, IFT, and IUFoST and held during the FMI Convention, Chicago, May 3-5, 2003.

2003: The Codex Alimentarius Commission of FAO/WHO Food Standards Program adopted the final version of the Codex General Standard for Irradiated Foods that recognizes the safety of food irradiated with any dose and recommends no upper dose limit be imposed on food irradiated under Good Manufacturing Practices (GMPs).

2003: The International Plant Protection Commission (IPPC) issued an International Guideline on Irradiation Phytosanitary Measures that recognizes irradiation as an effective quarantine treatment of fresh produce in international trade.

2004: The International Consultative Group on Food Irradiation, established under the aegis of FAO, IAEA, and WHO in 1984, completed its mandate and was terminated.

2004: SureBeam, Inc., the major electron beam (EB) food irradiation service provider, went out of business.

2006: SADEX, Inc. started operating by providing irradiation services to the food industry using an EB machine in Sioux City, Iowa.

2006: USDA/APHIS issued a Final Rule on Irradiation Phytoasanitary Treatment for Imported Fruits and Vegetables that allows irradiation to be used as a mitigation measure for any insect pests and commodities.

Appendix III: Food Irradiation: Major Regulatory Approvals in North America

Year	Canada	Mexico	USA
1960	Potatoes (sprout inhibition, 0.15 kGy max.)		
1963			Wheat and wheat products (insect disinfestation, 0.5 kGy max.)
1964			Potatoes (sprout inhibition, 0.15 max.)
1965	Onions (sprout inhibition, 0.15 kGy max.)		
1969	Wheat and wheat products (insect control, 0.75 kGy max.)		
1983			Spices and dried vegetable seasonings (microbial control, up to a max. dose of 10 kGy)
1984	Spices and dried vegetable seasonings (microbial control, 10 kGy max.)		
1985			Dry and dehydrated enzyme preparations (microbial control, 10 kGy max.)
1985			Pork (trichinosis control, 1 kGy max.)
1986			Fresh foods for insect control and delay of physio logical growth, 1 kGy max.)

1990			Spices and dried veg- etable seasonings (max. dose 30 kGy)
1995		Roots, tubers, fruits, veg etables, meat, fish,spices, seasonings, grains, legumes (for various purposes and difference max. doses)	Fresh and frozen poul try (pathogen control, 3 kGy max.)
1997			Raw and frozen red meat (pathogen control, 7 kGy max.)
2000			Fresh shell eggs (Salmonella control, 3 kGy max.) Seeds for sprouting (pathogen control, 8 kGy max.)
2005			Molluscan shellfish (pathogen control, 5 kGy max.)