IRRADIATED FOODS

Fifth Edition

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for the AMERICAN COUNCIL ON SCIENCE AND HEALTH

First Edition, October 1982 Second Edition (revised and updated), July 1985 Third Edition (revised and updated), December 1988 Fourth Edition (revised and updated), March 1996

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> > > May 2003

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ACSH GRATEFULLY ACKNOWLEDGES THE COMMENTS AND CONTRIBUTIONS OF THE FOLLOWING INDIVIDUALS, WHO REVIEWED THIS PUBLICATION.

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EXECUTIVE SUMMARY

- An overwhelming body of scientific data from around the world indicates that irradiated food is safe, nutritious and wholesome. Health authorities worldwide have based their approvals of food irradiation on the results of sound scientific research. When combined with proper hygienic practices in handling, processing, storage and distribution, irradiation increases the safety profile of a variety of foods.
- The safety of food irradiation has been studied more extensively than that of any other food preservation process, including canning, freezing, dehydration and chemical additives. As is true of other food processes, irradiation can lead to chemical changes in food. Compounds called radiolytic products (compounds formed because of action by radiation), are formed that are similar to thermolytic products in heat treatment of foods. None of these radiolytic products, in the amounts found in irradiated foods, has been demonstrated to be toxic by any modern toxicological methods.
- As of March 2003, food irradiation has been approved by more than 50 countries. This food preservation process has been applied successfully for several types of food in more than 30 countries, including such technologically advanced countries as Canada, France, Japan, The Netherlands, Belgium, South Africa and the United States.
- The U.S. FDA has approved the use of irradiation for a number of foods and purposes, including antimicrobial treatments for spices and dried vegetable seasonings (1983), destroying *Trichinella* in pork (1985), insect disinfestations and shelf-life extension of foods of plant origin (1986), and pathogenic bacteria control in poultry meat (1990), red meat (1997), shell eggs, and sprouting seeds (2000). The FDA is currently evaluating petitions for destroying harmful bacteria in ready-to-eat foods (e.g., deli meats) and seafood such as oysters and clams.
- Recent major food recalls have heightened awareness of the risks of food-borne pathogens and have highlighted the utility of irradiation as a sanitary treatment to ensure the microbiological safety of foods. It is increasingly accepted and applied in several countries. In the USA, irradiated ground beef was introduced into commercial channels in early 2000 following approval by the FDA in 1997 and the USDA Food Safety Inspection Service in 1999. The number of

supermarkets carrying this product has increased from 84 in May 2000 to over 7,000 in March 2003.

- Any irradiated food sold as such must be labeled with 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.
- Currently, several major meat processing companies have incorporated irradiation into their processing procedures to ensure the microbiological safety of their products. A major fast food restaurant chain and some other chain restaurants are beginning to offer irradiated meat on their menus. Irradiation provides an additional layer of product safety to protect the health of consumers.
- The United States Department of Agriculture estimates that the American consumer will receive approximately \$2 in benefits such as reduced spoilage and less illness for each \$1 spent on food irradiation.
- In 2000, electron beam and X-ray machines were introduced into the American food processing system. Previously, only cobalt-60 irradiators had been used for food irradiation.
- When electron beam or X-ray machines are used, no radioactive isotopes are involved. When a cobalt-60 source is used, food irradiation facilities and transport of radioactive source must meet stringent federal and state regulations. Such irradiators have been in use for many years for sterilization of a number of medical devices and consumer and other products. The industry has an excellent safety record.
- A unique characteristic of irradiation as a food process is that it can be used as a sanitary treatment to ensure microbiological safety of food and as a phytosanitary treatment to prevent the introduction of exotic pests in or on fresh produce before they enter the United States. The approval by Animal Plant Health Inspection Service (APHIS) of such phytosanitary irradiation should pave the way for a wide variety of tropical and sub-tropical fruits to enter the U.S. market, and will provide consumers with a wide variety of fresh and nutritious food.
- The American Council on Science and Health supports food irradiation as 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?

One reason is that the Centers for Disease Control and Prevention (CDC) estimate that some 5,000 deaths and 76 million illnesses a year in the U.S. occur due to food-borne illnesses—that toll could be sub-stantially reduced by irradiation.

Foods may be contaminated naturally during any stage of production 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 spoilage and destruction. Some foods are seasonal and highly perishable, while others are not allowed to enter the United States because they may har-

bor pests and diseases that cause damage to local agriculture or illness in humans.

For centuries, great effort has been devoted to finding ways of preserving food and protecting it from microorganisms, insects and other pests. Drying was The Centers for Disease Control and Prevention (CDC) estimate that some 5,000 deaths and 76 million illnesses a year in the U.S. occur due to food-borne illnesses that toll could be substantially reduced by irradiation.

most likely one of the first techniques developed. Heating, fermentation (acid or alcohol preservation), salting and smoking also have long histories of use in food preservation. Later techniques include the use of preservatives other than salt, heat pasteurization, canning, freezing, refrigeration, ultrahigh hydrostatic pressure, electrical conductivity heating, pulsed electrical fields and crop-protecting chemicals. All have played a role in improving the quality, quantity and safety of our food supply, protecting it against destruction, microbial contamination and spoilage.

Irradiation, a relatively new technology to enhance food safety, quality and trade, has joined this arsenal of food protection methods rather recently. Irradiation, being a cold process, can be used to inactivate spoilage and disease-causing (pathogenic) bacteria in solid foods such as meat, poultry, seafood, and spices. It can also kill insect eggs and larvae in fresh fruits and vegetables without changing the foods' quality or sensory attributes. 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.

The increasing awareness of food-borne disease outbreaks, as well as major food recalls to meet strict sanitary standards in the United States, has resulted in an increasing recognition and a wider use of irradiation as a sanitary treatment to destroy pathogenic bacteria such as *Escherichia coli* O157:H7 in ground beef. Its role as an insect control method to meet strict quarantine requirements in the U.S., especially for tropical fruits from Hawaii, is also growing. Irradiation has routinely been used to meet microbiological standards for spices and dried vegetable seasonings in the U.S. and many other countries in the past two decades.

To provide American consumers with information on the safety and benefits of food irradiation, the American Council on Science and Health (ACSH) has prepared this booklet to explain irradiation, and to answer some common questions about this relatively new food technology.

BACKGROUND

What Is Food Irradiation?

Food irradiation is the treatment of foods by exposing them to ionizing radiation, also called ionizing energy, to achieve certain technical objectives. For example, irradiation can kill harmful bacteria and other organisms in meat, poultry, and seafood, disinfest spices, extend shelflife of fresh fruits and vegetables, and control sprouting of tubers and bulbs such as potatoes and onions. It is a safe process that has been approved by the U.S. Food and Drug Administration (FDA) and over 50 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. 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 for other foods if consumers are to enjoy the benefit of this technology.

What Types of Radiation Energy Are Used for Treating Foods?

The radiation energy used to treat foods is called "ionizing radiation" because it produces 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 visible light, 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 produce gamma rays. The rays are directed onto the food being irradiated, but the food itself never comes into contact with the cobalt or cesium source. The second type of radiation source is a machine that produces either X-rays or high-energy electrons. 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.

Irradiation has a number of uses in food processing, most of which improve the safety and quality or prolong the useful life of foods.

What Can Irradiation Do?

Irradiation has a number of uses in food processing, most of which improve the safety and quality or prolong the useful life of foods. Different doses of radiation are used for different purposes, as is shown in Table 1 (page 10).

The major applications of irradiation are summarized below.

Radiation Pasteurization (Sanitary Treatment)

Food-borne illnesses take a heavy toll on the economy and productivity of populations in most countries. In the United States, the Centers for Disease Control and Prevention (CDC) estimates that food-borne diseases cause approximately 76 million illnesses; 325,000 hospitalizations and 5,000 deaths each year or approximately 100 deaths per week. Such microorganisms as *E. coli* O157:H7, *Campylobacter, Salmonella, Listeria, Vibrio* and *Toxoplasma* are responsible for 1,500 deaths annually.

The most important public health benefit of food irradiation is its ability to destroy pathogenic (disease causing) organisms in food. Consumers are familiar with heat pasteurization of liquid foods like milk and juices, which effectively eliminates spoilage and pathogenic bacteria, inactivates spoilage enzymes, and extends shelf-life without

Purpose	Effective Dose Range (kGy*)	Products
Low Dose (up to 1 kGy)		
(a) Inhibition of sprouting	0.06-0.20	Potatoes, onions, garlic, gin- ger 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 vegeta- bles)
High Dose (above 10 kGy)		
(a) Industrial 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 prepara- tions, natural gum, gel, etc.

Table 1. USES OF VARIOUS DOSES OF IRRADIATIONFOR FOOD SAFETY AND PRESERVATION

* kGy (kilogray). For more information on the units used to measure radiation, see Appendix I.

significantly altering taste and nutritional value. Irradiation can perform the same protective functions for solid foods by decreasing significantly the number of microorganisms in foods without causing significant changes in their flavor and aroma. It is the only process that can do so effectively in raw and frozen foods.

It is important to note that irradiation cannot make up for mishandling or unsanitary food processing practices. Irradiated foods must be properly packaged to prevent re-contamination, kept at proper temperatures, and handled with care during food preparation to avoid cross contamination from other (unirradiated) foods or unsanitary utensils. Improved food handling alone could reduce but not prevent contamination by pathogenic bacteria. Irradiation gives us an additional, complementary tool to ensure food safety.

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. However, contamination can occur during food preparation, and foods such as meat, poultry and seafood-that often are contaminated by pathogenic bacteria-may in turn contaminate uncooked products such as fruits and vegetables, if strict sanitation control is not employed. Many illnesses and even deaths occurred in recent years 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 E. coli O157:H7 bacteria can cause illness and death in some people, very high levels of sanitation are needed. Another major benefit of irradiated meat, poultry and seafood is that such products do not carry pathogens into food preparation areas where contamination of other foods could occur.

Radiation Sterilization

Irradiation is used currently to sterilize—that is, kill—all microorganisms on more than 50% of disposable medical devices (including gauze, surgical gloves and supplies) used in the United States. The same technique can also be applied to foods, and extensive research has been conducted to demonstrate that a relatively high dose of irradiation (above 10 kGy), together with a mild heat treatment and proper packaging, can kill all microorganisms and allow foods to be kept for long periods at room temperature. This process is analogous to canning, which uses heat treatment to achieve the same preservation status. Meat, poultry, some types of fish and shellfish, some vegetables and entire meals are suitable for radiation sterilization. Radiation sterilization has been used in the U.S. to sterilize food for NASA's astronauts and for some patients with impaired immune systems. Radiation sterilization of food/meals could help outdoor enthusiasts (campers, mountain climbers, sailors, etc.) carry safe, nutritious and ready to eat food that requires no refrigerated storage.

Replacing Chemical Fumigation of Food

Irradiation can kill insects and microorganisms in cereals, legumes, spices and dried vegetable seasonings, as well as other stored foods. Irradiation could be used in place of chemical fumigation with ethylene dibromide (EDB, now banned in the U.S. and most other countries), ethylene oxide (banned in the European Union and Japan) and methyl bromide (MB).

Ethylene oxide (EtO) was widely used for fumigating spices and food ingredients to reduce microbial contamination. However, the toxicity of EtO and its derivatives—especially ethylene-chlorohydrin, a carcinogen—resulted in its being banned by the European Union in 1991. Irradiation provides an effective residue-free alternative to EtO fumigation that will also ensure the hygienic quality of food ingredients.

Currently MB, a widely used fumigant for insect control in fresh and dried fruits, is being phased out globally under an international environmental treaty called the Montreal Protocol, because of its strong ozone depletion potential. The U.S., along with other countries, is bound by this protocol and will phase out production of MB by 1 January 2005. Irradiation can provide a safe alternative to fumigation by MB to control insect infestation in fresh and dried horticultural produce.

Sprout Inhibition

Very-low-dose irradiation treatment inhibits the sprouting of vegetables such as potatoes, onions and garlic. Irradiation can replace the chemicals currently used for this purpose. The United States and many other nations have approved this use of irradiation for several types of roots, tubers, and bulbs. Currently, irradiation is used extensively to control sprouting of garlic and potatoes in China and Japan, respectively.

Enhancing Food Quality

Low-dose irradiation also delays ripening and therefore extends the shelf-life of some fruits, including bananas, mangoes, papayas, guavas and tomatoes. Medium doses can be used to control mold growth on strawberries, raspberries and blueberries, thereby extending their shelflife. Cap opening of mushrooms can also be delayed by relatively low dose irradiation and cool storage.

Irradiation can produce desirable physical changes in some foods. Bread made from irradiated wheat has greater loaf volume when certain dough formulations are used, irradiated dehydrated vegetables reconstitute more quickly than non-irradiated vegetables, and when fruits such as grapes are irradiated they yield more juice than non-irradiated ones.

Eliminating Certain Parasitic Hazards in Food

A low dose of radiation similar to that used to inhibit sprouting of roots and tubers or delay fruit ripening can eliminate the hazards of humans contracting trichinosis and toxoplasmosis from consumption of fresh foods such as pork without significantly affecting the flavor or texture of the meat. Irradiated pork cannot cause trichinosis or toxoplasmosis if it is undercooked or eaten raw. Irradiation treatment works by impairing the development of these parasites (*Trichinella spiralis, Toxoplasma gondii*) so that they cannot mature, complete their life cycles or cause human diseases.

The United States is one of the few technologically developed countries that does not inspect for *Trichinella spiralis* in commercial pork. Although *Trichinella* is uncommon in pork, it is a major problem in wild game. It can be serious and several cases occur in the United States each year. Some of the cases involve recent immigrants who have come

to the United States from areas where trichinosis is not a problem and so are unaware of the need to cook American pork thor-

Irradiation is a Versatile Process

oughly. Currently, many countries will not accept pork exported from the United States unless the meat is heat treated or frozen (freezing can kill the *Trichinella* parasite). Irradiation could play a major role in the U.S. pork industry's effort to develop a certified *Trichinella*-free pork supply, and it would make U.S. pork more acceptable in international commerce.

Irradiation is a Versatile Process

Irradiation causes a variety of changes in living cells. 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 bacteria and their spores in food. Food thus treated can be kept at room temperature when properly packaged to prevent recontamination.

Medium doses inactivate spoilage and pathogenic microorganisms in foods, and together with proper temperature control, provide a significant shelf-life extension. Low doses alter biochemical reactions in foods of plant origin in such a way that their sprouting or ripening processes can be significantly delayed. Low doses also interfere with cell division, thus preventing insects or parasites in foods from either reproducing or completing their life cycles.

Similar to other food processes, irradiation has technical and economic limitations that prevent its use on all foods under all circumstances. For example, irradiation cannot extend shelf-life of fresh food forever because enzymes in fresh foods, e.g., fruits and vegetables, fish, seafood, meat and poultry, etc., are still active and are resistant even to high-dose irradiation. Too high a dose of irradiation could induce loss of flavor in many foods—especially those that are high in fat. 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, e.g., milk and dairy products, are not suitable for irradiation as they would develop unpalatable flavors. Irradiation has an

Irradiation is not the same as cooking in a microwave oven. Irradiation does not make food radioactive.

economy of scale, i.e. a sufficient volume of food is required for processing to justify the investment.

EFFECTS OF IRRADIATION ON FOODS

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, e.g., killing pathogens, extending shelflife, controlling sprouting, replacing chemical fumigation, etc., without significantly increasing the temperature of 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, thus cooking them.

Does Irradiation Make Food Radioactive?

No. Irradiation does not make food radioactive. The types of radiation sources approved for the treatment of foods have specific energy levels well below that which would cause any element in food to become radioactive. Food undergoing irradiation does not become any more radioactive than luggage passing through an airport X-ray scanner or teeth that have been X-rayed. It should be noted that everything in our environment, including food, contains natural trace amounts of radioactivity (background level). Irradiation of food at any dose will not result in an increased radioactivity beyond that of the background environment.

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. Basically, the same 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 dismantled, and the building used for other purposes.

When a machine source such as electron beam or X-ray generators, which use electricity as their power sources, is used for irradiating food, neither radioactivity nor radioactive materials is involved.

Effects on Microorganisms in Foods

Different types and species of microorganisms have different sensitivities to irradiation. Spoilage and disease-causing (pathogenic) bacteria of different species, the major causes of food spoilage and many common food-borne diseases, 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 off spoilage and pathogenic bacteria, to avoid growth and toxin production by spores of *Clostridium botulinum* bacteria (which causes botulism poisoning) that may be in some foods, and which can survive the treatment. This can be done through the use of good manufacturing practices, e.g., storing food products subject to radiation pasteurization at low temperature (below 4° C or 39° F) to prevent growth of *C. botulinum* spores. Yeasts and molds, which can spoil some food, are slightly more resistant to irradiation than are bacteria and require a dose of at least 3 kGy to inactivate them. Since viruses are highly resistant to radiation and require a dose of between 20 to 50 kGy to inactivate them, irradiation would not be a suitable means of dealing with viral contamination of foods.

There is a misconception that food irradiation produces harmful mutant strains of pathogenic microorganisms that might flourish in the absence of the bacteria killed by irradiation. Results of research carried out to examine this potential risk have been reassuring. Irradiation of food at doses required to inactivate spoilage and disease-causing bacteria results in major damage to their chromosomes—damage that is beyond repair. Thus, any surviving pathogenic bacteria in irradiated food are significantly injured and they are unable to reproduce. The food, on the other hand, that might be contaminated is not alive and thus is not damaged by irradiation.

Effects on Nutrients in Foods

A common consumer concern is whether irradiation adversely affects the nutritional value of food. The fact is that irradiation treatments do not change the nutritional quality of foods any more than do other methods of food processing such as cooking, freezing or canning.

Any changes in nutritional value caused by irradiation depend on a number of factors-radiation dose, the type of food, 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 thiamine in water lost 50% of the vitamin 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 even pork and beef treated by high-dose irradiation retain much more thiamine than canned meat, which is considered to be "commercially sterilized." Results of studies on the effects of irradiation on vitamin C in fruits and vegetables often are conflicting. Some studies reported an effect only on ascorbic acid, while others reported an effect

on total ascorbic acid, which is a mixture of ascorbic and dehydroascorbic acid, both of which provide vitamin C activity.

On the whole, however, the effects of irradiation on the nutritional value of foods are insignificant for low doses (up to 1 kGy); some losses may occur at medium doses (1-10 kGy) if food is irradiated in the presence of air; and high losses of sensitive vitamins such as thiamine may occur at high doses (above 10 kGy). As with other food processes, vitamin losses can be mitigated by protective actions, i.e. irradiation at low temperature and exclusion of air during processing and storage. Thus, the effects of irradiation on nutritional values in food in general are minimal and not greater than those in food processed by other methods for the same purposes. It should also be remembered that irradiated food will be consumed as part of a mixed diet, and that the process will have little impact on the total intake of specific nutrients.

Effects on Sensory Quality of Foods

Not all foods are suitable for processing by any one preservation method. Thus we need an array of food processing technologies to preserve or render food safe for consumption. Similar to other processes, irradiation causes certain chemical changes in food that may, under some circumstances, noticeably affect food quality.

Some foods react unfavorably even to low doses of irradiation. 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; thus milk and dairy products are generally not irradiated. Irradiation of some fresh fruits and vegetables may cause softening because of the breakdown of cell walls. High-dose irradiation sterilization could induce "off" flavors in many types of meat products if the process is not done properly.

Similar to food processed by other methods, food must be treated by irradiation under proper conditions, using the optimum dose for each food, for the food to benefit from the treatment. Too high a dose may affect the food's sensory qualities, while too low a dose will not achieve the intended sanitation, or other technical effect. Research by food scientists has determined the types of food that are suitable for irradiation, as well as the conditions that prevent damage or off-flavor. It is now generally recognized that roots and tubers, cereals and legumes, meat, poultry, fish and seafood, most fruits and vegetables, spices and seasonings, can be irradiated under proper conditions without causing noticeable changes in sensory quality. Some sensitive food products such as meat and fish should be irradiated under low temperature and in proper atmospheric packaging to avoid off-flavor.

SAFETY OF IRRADIATED FOODS

Are Irradiated Foods Safe to Eat?

Yes. The safety of food irradiation has been thoroughly studied and comprehensively evaluated for over 50 years, both in the United States

and elsewhere. No food technology has ever been as extensively studied and evaluated with respect to safety as has food irradia-

Irradiated foods are safe to eat.

tion. The studies involved many animal feeding tests including multigeneration tests in animals, e.g., rats, mice, dogs and monkeys, 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 as part of their daily diets. Data from these studies were systematically evaluated by panels of experts that included toxicologists, nutritionists, microbiologists, radiation chemists and radiobiologists, convened repeatedly by the Food and Agricultural Organization of the United Nations (FAO), International Atomic Energy Agency (IAEA) and World Health Organization (WHO) in 1964, 1969, 1976, 1980 and 1997, as data became available. 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.

Investigations since 1981 have continued to support the JECFI's conclusions about the safety of food irradiation. These investigations included a small human feeding trial in China in which 21 male and 22 female volunteers consumed 62 to 71% of their total caloric intake as irradiated foods for 15 weeks. Since 1980, there has been no credible scientific evidence, either from human feeding studies or from consumption of several types of irradiated foods available in commercial quantities in several countries that indicate such foods pose a toxic hazard.

In 1997, FAO, IAEA and WHO convened a Joint Study Group to evaluate data on wholesomeness studies of food irradiated with doses above 10 kGy. Based on scientific evidence supporting the safety of food irradiated with any dose, above or below 10 kGy, the Joint Study Group concluded that food irradiated with any dose to achieve technical objectives is 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. The studies took place in laboratories in several countries—Austria, Australia, Canada, France, Germany, Japan, Switzerland, the UK and the USA. No transmittable genetic defects teratogenic or oncogenic—have been observed that could be attributed to the consumption of irradiated diets.

Determining the Safety of Irradiated Foods

Establishing the safety of irradiated foods involves consideration of several allied scientific disciplines:

- Radiation Chemistry
- General Toxicology/Animal Testing
- Nutrition
- Microbiology
- 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 "thermolytic products" are produced by heat processing. Most of these radiolytic products have proved to be familiar substances that exist in nonirradiated 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 recent claim by a group of European scientists about the potential toxicity of 2-alkyl cyclobutanones, 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. Whenever food is irradiated, the same radiolytic products are formed, regardless of the radiation dose; only the amounts of the radiolytic products differ.

Accordingly, the results of an investigation carried out on the radiolytic products formed in a food irradiated at a high dose can generally be applied to lower-dose treatments of the same food. Also, similar food compounds (e.g., proteins, lipids, carbohydrates) have been shown to react to irradiation in similar ways regardless of the type of food; the same kinds of radiolytic products are formed in either case. 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 has been dubbed "chemiclearance."

A question is often 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, freeze drying and oxidation processing. Free radicals are very reactive, unstable structures that continuously react with other substances to form stable products. Free radicals in foods would disappear after they reacted with each other in the presence of liquids, such as saliva in the mouth. Consequently, their ingestion does not create any toxicological or other harmful effects. This was confirmed by a specially designed animal feeding study carried out in Germany in1974 using high-dose (45 kGy) irradiated dry milk powder that contained large amounts of free radicals. Nine generations of rats were fed this irradiated diet without any indication of toxic effects. Similarly, a slice of toasted bread (non-irradiated) actually contains more free radicals than any irradiated food and can be expected to be harmless for consumption.

General Toxicology/Animal Testing

The most common procedure for evaluating the safety of foods or food ingredients is to feed them in excessive amounts to animals and then to observe the animals' growth, reproduction and general health. Many studies have been conducted in which large portions of irradiated foods were incorporated into animals' diets. Some foods were treated with doses as high as 59 kGy and were fed to several different animal species. Most such studies involved observations of several generations of animals.

Animal tests are used to demonstrate the safety of a food or food substance and are an effective way to detect potential toxicological hazards. Properly designed laboratory animal tests can also detect potential cancer hazards and reproductive problems. 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, USA, 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 electron machine up to a dose of 59 kGy. Some 134 metric tons of chicken meat were used in multi-generation feeding studies of mice, rats, hamsters and dogs, to compare 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 found no evidence of any toxicological hazard for humans who ate irradiation-sterilized ham.

Nutritional Studies

For details, please see "Effects on Nutrients in Foods" under the section "Effects of Irradiation," above.

Microbiological Studies

It is widely recognized by food control authorities that irradiation is an effective method of inactivating microorganisms and parasites in foods. High dose radiation sterilization can destroy all microorganisms, including spores of *C. botulinum* bacteria, with the same degree of efficacy as the heat treatment used to destroy these organisms in commercially canned foods.

There has been some concern that the risk of food poisoning, especially from botulism, might be increased by radiation doses in the pasteurization range as spores of *C. botulinum* bacteria could survive these doses and could later grow and produce toxin in irradiated food. This concern is not unique to irradiation; it also applies to other processes, including heat pasteurization and chemical treatments, that cause the partial destruction of microorganisms in a food. Any food to be processed using sub-sterilization doses must be handled, packaged, processed and stored following good manufacturing practices (GMPs), which are designed to prevent growth and toxin production by emerging spores of *C. botulinum* bacteria. Alternatively, sterilization processes either by heat or irradiation can be used to destroy any such spores present in the food.

Packaging Materials

Because some foods will already be packaged when they are irradi-

ated, the effects of irradiation on food packaging materials has been studied. The irradiation treatment must neither impair package integrity (potentially subjecting the packaged food to later contamination) nor deposit toxic radiation reaction products or additives on the food.

Results of extensive research have 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 and some other national 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 hermetically sealed "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 plastic materials that will be in contact with food in order to improve their strength, heat resistance and other properties (e.g., heat-shrink wrap films).

Safety of Food Irradiation Facilities

Would Food Irradiation Facilities Endanger Local Communities?

No. A food irradiation plant would not endanger a community. It would be 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 the hundreds of

industrial electron irradiation facilities used for different purposes, now operating in the United States. None of these facilities has been found to pose a danger to the surround-

Irradiation facilities are safe for local communities.

ing community. To be sure, a food irradiation facility must be designed, constructed and operated properly, as well as duly licensed by national or state authorities. This does not represent a new challenge, since the necessary safety precautions are well understood. They have long been applied in the design, construction and maintenance of similar types of irradiation facilities used for other purposes over the past 50 years.

<u>Could There Be a "Meltdown" in a Food Irradiation Facility?</u> 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, i.e., cobalt-60 and cesium-137, cannot produce the neutrons that can make materials radioactive, so no "nuclear chain reaction" can occur at such an irradiation facility. Food irradiation plants contain shielded chambers within which the foods are exposed to a source of ionizing radiation. The radiation sources used in food irradiation cannot overheat, explode, leak or release radioactivity into the environment.

Safety of Transporting 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 as well as over the operation of irradiation facilities using radioisotopes. The Department of Transportation (DOT) has carrier requirements for the transport of hazardous materials, including radioactive cobalt and cesium. These substances have been transported to irradiation facilities and hospitals throughout the world for many years without difficulty. 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 at all if an irradiation facility uses machine-generated (electron or X-ray) radiation, because no radioactive materials are involved.

<u>Would Workers in a Food Irradiation Plant Be Exposed to</u> <u>Hazardous Radiation?</u>

No. Irradiation facilities, including those used for food irradiation, are designed with several levels of safety redundancy to detect 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 the workers as well as for the environment. Regulations in all countries require such facilities to be inspected periodically 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 well understood. In the U.S., the Occupational Safety and Health Administration (OSHA) is responsible for regulating 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 United States that use machine-generated radiation are under the jurisdiction of state agencies, which have established appropriate performance standards to ensure worker safety.

See Appendix IV for diagrams of typical food irradiation facilities.

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—is a byproduct 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 pro-

duced by activating cobalt-59, a non-radioactive metal, in a nuclear reactor to absorb neutrons and change its characteristics to cobalt-60, which is

Food irradiation does not use radioactive wastes.

radioactive and generates gamma rays. Canada is the largest producer of cobalt-60, representing about 75% of world production. The remaining producers are in France, Argentina, Russia, China and India. Cobalt-60 suppliers can in principle reactivate used cobalt-60 sources, if required, thus effectively recycling them.

Electrically generated electron beam and X-ray machines have been designed and used for irradiating food in the United States, especially for ensuring microbiological safety of ground beef and meeting the quarantine requirements for tropical fruits. When such machines, which use electricity as power sources, are used for irradiating food, there is neither radioactivity nor radioactive materials involved.

How Can We Be Sure That Foods Are Properly Irradiated?

The effectiveness of a specific application of irradiation on food must be verified by FDA and USDA. When these agencies approve specific applications of food irradiation, they require that food be irradiated in facilities licensed for this purpose. These facilities also must use correct radiation doses as required by law, according to good manufacturing practices (GMPs) and as part of an overall HACCP plan. These guidelines emphasize that, as with all food technologies, effective quality control systems need to 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. As with other technologies, irradiation cannot be used as a substitute for poor hygienic practices or to reverse spoilage.

LEGAL AND REGULATORY ASPECTS OF FOOD IRRADIATION

International Standards and Agreements Governing Trade in Food and Agricultural Commodities

Trade in food and agricultural commodities has become increasingly global since the establishment of the World Trade Organization (WTO) in 1995. In the past, importing countries were essentially free to establish their own rules. Now, all governments that belong to the WTO will have to follow one set of rules and procedures. By accepting the Agreement that established the WTO, governments agreed to be bound by the rules of all of the multilateral trade agreements attached to it, including the SPS (Application of Sanitary and Phytosanitary Measures) and TBT (Technical Barriers to Trade) Agreements. These Agreements, which the WTO enforces, 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, which assist WTO in settling trade disputes with respect to these commodities. Especially relevant rules and rule-making bodies include:

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

International rules of particular significance for food irradiation are discussed below.

Codex General Standard for Irradiated Foods

The Codex Standard, promulgated in 1980, recognizes the safety and effectiveness of irradiation as a food process, regardless of the types of food or the purpose of irradiation, up to an overall average dose of 10 kGy. The Standard did *not* imply that food irradiated with doses above 10 kGy would be unsafe for consumption.

Because of this international standard, national authorities should implement regulations on food irradiation in a harmonized fashion. Unfortunately, many countries opted to allow irradiation on specific food items, instead of as a general food process such as heat processing. 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.

As of November 2002, the Codex General Standard is being revised based on the recommendations of the Joint FAO/IAEA/WHO study group on high dose irradiation of food, which examined newer safety data. Based on these data, they recommended removing the 10 kGy limit, since scientific studies did not support the idea that higher doses caused any adverse effect attributable to the consumption of irradiated foods.

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

The effectiveness of irradiation as a sanitary treatment of fresh horticultural produce (phytosanitary treatment) has been demonstrated by decades of research as well as by recent commercial applications. Irradiation could facilitate international trade in fresh produce as well as provide a suitable alternative to fumigation by methyl bromide (which is being phased out globally). Currently, the Interim Commission on Phytosanitary Measures (ICPM), the standard-setting body of IPPC, is completing international guidelines on irradiation phytosanitary measures for fresh horticultural produce. Such guidelines should facilitate wide international trade in fresh produce.

Position of the World Health Organization (WHO)

The World Health Organization (WHO), the FAO and IAEA have been actively involved in the evaluation of food irradiation safety since the early 1960s. WHO has stated on several occasions that it is satisfied with the safety of food irradiated with any dose used for various applications, as stated in Table 1 in the section "What Can Irradiation Do?" above. WHO 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 such as milk.

In November 2002, WHO issued a draft position document regarding the safety of 2-alkylcyclobutanones (2-ACBs), which occur when fat-containing foods such as poultry meat and red meat are irradiated. The possibility that these compounds might be toxic was raised by representatives of the European Union in 2001. Following review of the relevant data, both the European Comission and WHO concluded that there were no sound scientific data to indicate that 2-ACBs as produced in irradiated foods would pose a toxic hazard to humans.

<u>How Have United States Health and Scientific Organizations</u> <u>Reacted to Food Irradiation?</u>

Leading health and scientific organizations, including the American Medical Association (AMA), 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." The reports of studies done by ADA, CAST and IFT are listed in the "Suggestions for Further Reading."

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

More than 50 countries have approved some applications of irradiation, and irradiated foods are now 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 are 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 pulses, spices and seasonings, etc.) rather than individual food items, per the recommendations of the ICGFI. In China, approximately 100,000 tons of various foods were irradiated and marketed in 2002. That same year, the U.S. produced close to 100,000 tons of irradiated ground beef, spices and vegetable seasonings, and tropical fruits from Hawaii. In Japan, 15,000 to 20,000 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 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 (as of this writing, 15 countries are members of the EU). Included was a list of irradiated food products that are allowed to be produced and marketed. However, the only group of irradiated food products on this list were spices, herbs and dried vegetable seasonings. Attempts by the European Commission to add more irradiated food products to this list have not been successful because of political, emotional and ideological stances of various member countries. EU countries that had approved other irradiated food products prior to 1999 can maintain their national approvals until such time as the EU completes its list of irradiated food products.

The estimated global quantity of irradiated food that entered commercial channels in 2002 was approximately 300,000 tons, of which about one-third were irradiated spices and dried vegetable seasonings. This quantity is expected to increase significantly in the next few years as irradiation is increasingly used as a sanitary and phytosanitary treatment in order to meet national and international trade requirements.

The details of approval of irradiated foods in different countries may be obtained from the database of the International Consultative Group on Food Irradiation (ICGFI), established under the aegis of FAO, IAEA and WHO in 1984, at <u>www.iaea.org/icgfi/database</u>.

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

Food irradiation is regulated as a food additive (rather than as a process, like 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. Improvements in safety-testing technology and in the scientific knowledge of radiation chemistry were needed before the safety of irradiated foods could be evaluated adequately. In 1986, the FDA published a rule in the *Federal Register* approving the use of irradiation for insect disinfestation and control of physiological processes in food of plant origin, up to a maximum dose of 1 kGy. The rule also mandated labeling requirements for irradiated foods. FDA has also approved the use of

irradiation to control insects and microorganisms in spices, herbs and plant-derived dehydrated foods (1983); to control *Trichinella* in pork (1985); to destroy pathogenic bacteria, e.g., *Salmonella* in poultry (1990); to destroy pathogenic bacteria in red meat (1997); to inactivate *Salmonella* in shell eggs (2000); and to control pathogens in sprouted seeds (2000). For a detailed list of approvals of irradiated foods in the U.S. as well as in Canada and Mexico, please see Appendix III.

CURRENT AND POTENTIAL APPLICATIONS

Sanitary Treatment

Irradiated Red Meat

In 1993, there was an outbreak of *E. coli* O157:H7 from undercooked hamburgers served at a chain restaurant on the West coast of the United States. This bacterial contamination caused hundreds of illnesses and the deaths of several children, and was widely publicized by the media. The American public became well aware of the possible risks from consuming such a common food product in their daily diets. In 1994 the USDA took steps to more strictly regulate *E. coli* O157:H7 in ground beef and other non-intact meat as an "adulterant." Since then, there have been several massive recalls of thousands of tons of ground beef, and both the food industry and consumers began to demand that an effective technology such as irradiation be used to combat such pathogenic contamination. In May 2000, ground beef irradiated by electron beam technology began to enter commercial distribution in the United States.

This product has been well received by consumers. The first food company to sell irradiated ground beef at the retail level was Huisken Meat, Inc., based in Sauk Rapids, Minnesota. In 2000, the company had projected 2 million pounds of irradiated beef patties would sell in its second and third quarters—but reported actually selling that amount in five weeks.

A number of supermarket chains, both regional and national, have since begun to market irradiated ground beef, some using their own brand names. In March 2003, over 7,000 American supermarkets and retail outlets carried irradiated ground beef on a routine basis. Several more supermarket chains plan to do so in the near future.

Irradiated Poultry Meat

Although the FDA approved irradiation of poultry meat in 1990, followed by the USDA's approval in 1992, little commercial production and marketing of irradiated poultry meat actually took place until recently. A food irradiation facility using cobalt-60 as the radiation source, called Food Technology Service (FTS), Inc. in Florida started marketing irradiated poultry meat in the mid-1990s under the Nation's Pride brand name but had only limited success. So far, sale of irradiated poultry meat remains somewhat limited, although a major supermarket chain in the Southeast, Publix, started marketing frozen irradiated 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 attributable to the fact that the USDA has not recognized Salmonella and other pathogenic bacteria such as Campylobacter jejuni in poultry meat as "adulterants" to be combated with irradiation. In fact, though, these bacteria cause many more illnesses and deaths than does E. coli O157:H7-contaminated red meat. The success in using irradiation to control E. coli O157:H7 in red meat may give rise to a demand by consumers that their poultry meat should also be irradiated to ensure safety from pathogenic bacteria.

Irradiated Fish and Seafoods

The FDA has not yet approved the use of irradiation for fish or seafood. There are two petitions pending with the FDA to approve irradiated mollusks and shrimp because of the high number of food-borne disease outbreaks caused by *Vibrio vulnificus* in raw mollusks such as oysters and clams and by *Salmonella* in shrimp. Scientific data support the effectiveness of irradiation to control *Salmonella* in fresh and frozen shrimp and *Vibrio* bacteria in live oysters and clams. Irradiated oysters and clams remain alive, although their longevity may be shortened.

Ready-to-Eat Food Products

Increasing consumer demand for convenience or ready-to-eat foods that are safe, high in quality, nutritionally superior, and easy to prepare has spurred the development of a variety of chilled foods that are subject to minimal processing or pre-cooking. This has been a new challenge for food safety, because the food industry must produce such foods with enhanced shelf-life at refrigeration temperature but without contamination by pathogenic microorganisms. Many types of ready-to-eat food products may be contaminated with *Listeria monocytogenes* during production or post-processing. This pathogenic type of bacteria can grow well in many ready-to-eat foods at refrigeration temperatures. Because such foods are typically eaten without further cooking, the potential for food-borne illness cannot be ignored. The FDA requires "zero tolerance" of *Listeria* in such foods because of the severity of the disease it can cause. There can also be a high death rate—especially among immune-compromised populations, including the elderly, children under 5 years of age and organ-transplant patients. *Listeria* can also cause miscarriage.

In 1998/99, 21 deaths were caused by an outbreak of illness related to consumption of sausages contaminated by *Listeria monocytogenes*. This product was produced by one of the top ten meat processing companies in the U.S. As a result, some 13,000 metric tons of sausages that had been distributed nationwide had to be recalled and destroyed. In October 2002, one of the largest food recalls in the history of the U.S. occurred. It involved ready-to-eat poultry and turkey deli products contaminated with *L. monocytogenes* in several states. There had been a series of outbreaks and death caused by this bacterium in several states. A total of 27.4 million pounds (over 12,000 metric tons) of such products were recalled by one of the largest poultry production and processing companies in the USA. In both cases, class action lawsuits followed.

In addition, there have been many incidences of food-borne illnesses and deaths caused by consumption of contaminated fresh, pre-cut fruits and vegetables. Several types of pathogenic bacteria and parasites including Salmonella poona, 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, hundreds of illnesses and hospitalizations caused by Cyclospora cayetanensis from imported Guatemalan raspberries in 1996 interrupted import of this fruit from Guatemala for several years. A recent outbreak caused by consumption of Mexican cantaloupe contaminated by Salmonella poona resulted in an import ban of this fuit. In recent years, many outbreaks have occurred from consumption of raw alfalfa and other sprouts. Pathogenic bacteria, such as Salmonella and E. coli O157:H7, were involved, and the FDA warned against the eating of such products-especially by immuno-compromised persons. Recent research data showed that irradiation could be used for inactivating pathogenic bacteria in several types of fresh, pre-cut fruits and vegetables.

Recognizing that irradiation can inactivate pathogenic bacteria such as *L. monocytogenes*, the U.S. National Food Processors Association

(NFPA) submitted a petition to the FDA in August 2000 to approve the use of irradiation for such products. Such an approval will likely greatly expand the use of irradiation, as there are many ready-to-eat food products (such as hot dogs and deli meats) whose safety could be enhanced by this technology. Indeed, the Centers for Disease Control and Prevention (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 over 880,000 fewer cases of food-borne illness, 8,500 fewer hospitalizations, 6,660 fewer catastrophic illnesses and 352 lives saved every year.

Spices, Herbs and Dried Vegetable Seasonings

Microorganisms, including pathogenic bacteria, often contaminate spices, herbs, and vegetable seasonings due to the traditional ways in which such products are produced and processed. Thus, they have to be treated either by fumigation with ethylene oxide (EtO) and propylene oxide, heated, or irradiated. In Europe, EtO fumigation is no longer allowed because of its toxicity to the workers as well as the possibly carcinogenic byproducts formed when food products are fumigated. In the United States, EtO fumigation is still allowed—both the FDA and the Environmental Protection Agency(EPA) consider the health risks from this process to be minimal.

Irradiation has been widely used for ensuring the hygienic quality of spices, herbs and dried vegetable seasonings since the 1980s. The volume of irradiated products increased significantly in Europe after EtO fumigation was banned in 1991. In the United States, the volume of irradiated spices, herbs and vegetable seasonings has also increased significantly to approximately 50,000 metric tons in 2001, making the U.S. the largest producer of such irradiated products in the world. Globally, some 100,000 metric tons of such products are produced in some 20 countries.

Future Trends

The use of irradiation as a sanitary treatment will continue to grow as consumers become more familiar with its benefits and with the risk of food-borne illness from foods contaminated by various pathogenic organisms. The food industry—especially in the U.S.—has already embraced the use of irradiation for this purpose. Irradiation is considered a "cold pasteurization" process to ensure the hygienic quality of solid foods in the same manner as thermal pasteurization has been successfully applied to ensure hygienic quality of liquid foods such as milk. The types and volume of irradiated food products treated for this purpose are expected to grow significantly in the near future. It should be noted that irradiation, similar to other food processing technologies, will be used only on foods for which it can enhance either technical or economic benefits. Not all food should or will be irradiated, just as not all foods should or will be fumigated, canned or frozen.

Phytosanitary Treatment

Tropical Fruits from Hawaii

Several species of tropical fruit flies are endemic to the Hawaiian islands, and can infest fruits grown there. These insects are quarantined from entering the U.S. mainland, which is free from such pests. Thus, the Animal Plant Health Inspection Service (APHIS) requires that Hawaiian fruits be treated to ensure that these pests are not introduced to the mainland United States, where they could wreak great damage on domestic crops. Until recently, fumigation by ethylene dibromide or methyl bromide, hot water dip or vapor heat treatments were used on Hawaiian fruits.

Because sugar cane and pineapple, once staples of Hawaiian exports, are no longer major crops, the Hawaiian Department of Agriculture has explored the use of irradiation for disinfestation of a variety of local fruits. Lychees, rambutan, carambola and cherimoya are examples of Hawaiian fruits that may be grown to replace sugar and pineapple as export crops. In early 1995, with special permission from the USDA's APHIS, fruits from Hawaii were flown to an irradiation facility near Chicago, IL. Hundreds of tons of tropical fruits from Hawaii were irradiated and marketed successfully in the Midwestern United States between 1995 and early 2000. It was the first time many Americans had tasted a variety of fresh, nutritious tropical fruits from Hawaii. The success of this market trial prompted the Hawaiian authorities to approve installation of a commercial X-ray machine for irradiating such fruits in Hilo, HI in July 2000. Thousands of tons of Hawaiian fruits have since been irradiated for marketing in the mainland U.S. Irradiation provides an added benefit to fruits such as papaya, since it allows them to be more completely tree-ripened before harvest and treatment, while other types of treatment have to be performed on essentially unripe fruit. Consumers therefore get an extra benefit of consuming irradiated papayas with fully developed natural flavor.

<u>Current APHIS Regulation on Irradiation Phytosanitary Treatment</u> <u>of Imported Fruits and Vegetables</u>

In October 2002, APHIS approved the use of irradiation against 11 major species of tropical and sub-tropical fruit fly and other pests, regardless of commodities and countries of origin. This rule should greatly facilitate trade in the tropical and sub-tropical fruits and vegetables that may harbor such pests.

Future Trends

With the increasing demand from the American public for fresh fruits and vegetables, irradiation will likely assume an active role in bringing fruits from tropical and sub-tropical countries into the USA. Because many tropical fruits that were not previously allowed entry into the U.S. market can now be treated by irradiation to control pests, American consumers will have more varieties and greater quantities of these fruits, some of which had not been available to them in domestic markets. In return, U.S. fruit growers and exporters could demand that markets in countries such as Australia, Japan and New Zealand, which have strict quarantine security regulations, will be opened for irradiated fruits exported from the United States.

The U.S. market for tropical and sub-tropical fruits could expand further when APHIS recognizes the effectiveness of irradiation as a method to meet quarantine requirements against even more insect pests in fresh fruits and vegetables. Research data have demonstrated that irradiation at specific minimum doses could provide even broader protection than is now allowed.

Quality Enhancement

Potatoes, Onions and Garlic

Japan was the first country to introduce irradiated food successfully into the market in 1973 when a commercial potato irradiation plant was built at Shihoro Agricultural Co-operative, Hokkaido. Some 15,000 metric tons of potatoes have been irradiated annually to control sprouting for off-season processing into various potato products. So far, Japan is the only country that uses irradiation to control sprouting of potatoes on a commercial scale.

Onions have been irradiated for sprout control and marketing during off-seasons in Argentina, Hungary, the Philippines and Thailand at various times over the past 20 years. The scale of production of these irradiated products remains small. China has become one of the largest producers of irradiated foods in recent years. They have irradiated up to 50,000 metric tons of garlic each year in the past few years.

Specialized Food Products

A number of specialized food products such as enzyme preparations, fermented pork sausages, honeys and shelf-stable meals have been irradiated in some countries (e.g., China, South Africa and Thailand) in the past decade. In South Africa in particular, shelf-stable meals such as beef curry, beef stroganoff, lasagna and sausages were produced by the South African Atomic Energy Commission and sold during the 1990s. These products were particularly useful for outdoor activities such as camping, hiking, safaris, and mountaineering. In Thailand, "Nham"-a traditional fermented pork sausage usually consumed raw-is often contaminated by pathogenic bacteria such as Salmonella or by parasites such as Trichinella spiralis. Nham has been irradiated for pathogen control and marketed widely in Bangkok since 1986. Irradiation not only ensures hygienic quality, but also extends the shelf-life of such products when they are marketed at non-refrigerated temperatures. In addition, research data have demonstrated that irradiation could be used not only to ensure microbiological safety, but also to extend the shelf-life of chilled, prepared meals, which are gaining popularity among consumers in western countries. When the petition for irradiation of ready-to-eat food is approved by the FDA, food manufacturers will be able to use this technology to enhance the safety and quality of a variety of chilled as well as frozen, prepared meals.

Future Trends

Irradiation will increase the availability of many types of fresh fruits, vegetables and specialized food products. As consumers come to appreciate some of these thus far unavailable products, it is reasonable to expect that the market for them will continue to grow.

CONSUMER ACCEPTANCE OF IRRADIATED FOODS

Results of Market Trials

Initially, food producers were concerned that consumers would be unwilling to accept irradiated foods; this was partly because some activist groups spread inaccurate and distorted statements about irradiation. However, when market trials of irradiated food products were carried out in many countries (e.g., Argentina, Bangladesh, Chile, China, France, India, Indonesia, the Netherlands, Pakistan, the Philippines, South Africa, Thailand and the U.S.), consumers were not only willing to buy irradiated foods but often preferred them over food treated by conventional means, once they were given truthful information about irradiation and its purpose. For example, market trials of irradiated vs. hot-water-treated papaya from Hawaii were conducted in California in 1987. Consumers chose irradiated papaya over hot-water-treated papaya at a ratio of 13:1. A 1991 trial in Shanghai, China, showed that more than 90% of consumers were willing to purchase irradiated apples again once they realized the benefits of irradiation as opposed to chemical treatment. In Bangkok, Thailand, market trials of irradiated fermented pork conducted in 1986 showed that consumers purchased more irradiated product compared to the non-treated version at a ratio of 16:1. In Northbrook, Illinois, market trials of irradiated strawberries carried out in 1992-93 showed that consumers purchased irradiated berries over non-irradiated ones at a ratio ranging from 10 to 20:1, depending on the time of year.

The results of such market trials have provided valuable information for introducing irradiated foods on a commercial scale. Consumers need factual and balanced information on the benefits of irradiation vs. those offered by other processes in order to make informed decisions about whether to buy irradiated foods. With proper information, consumers are empowered to view irradiation in a positive light and even prefer that some foods be irradiated to ensure their safety.

Endorsements of the safety and benefits of irradiation by respected national and international health authorities also played an important

role in increasing the confidence of consumers about irradiated foods.

The encouraging results of market trials have led to successful introduction of irradiated foods on a commercial scale in several countries. Irradiated Irradiation can increase the variety and quality of fruits and vegetables available to American consumers.

foods are now available at the retail levels in several countries including Belgium, China, France, Japan, South Africa, Thailand and the United States.

Availability of Irradiated Foods in the United States

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. A small grocer in Northbrook, Illinois—Carrot Top—pioneered the marketing of irradiated food in the United States in early 1992 to test consumer acceptance. The results were beyond expectation, as consumers who were provided with accurate

Table 2. AMERICAN STORES AND FOOD CHAINS SELLING IRRADIATED FOODS IN SOME LOCATIONS.

Supermarket Chain	Started Selling Irradiated Food
Correct Top (Northbrook, II.)	February 1992
Carrot Top (Northbrook, IL)	•
Supervalu stores (Eden Prairie, MN	· •
Rainbow Foods (Minneapolis, MN)	•
Cub Foods (Stillwater, MN)	May 2000
Nash Finch (Minneapolis, MN)	July 2000
Clemens (Philadelphia, PA)	June 2000
W.W. Johnson (Minneapolis, MN)	May 2001
Winn-Dixie (Jacksonville, FL)	November 2001
Wegman's (Rochester, NY)	May 2002
Kroger (Cincinnati, OH)	June 2002
Lowes Food (Winston-Salem, NC)	September 2002
D'Agostino (Westchester, NY)	September 2002
Pathmark (NY, NJ, Philadelphia)	October 2002
Price Chopper (Schenectady, NY)	October 2002
Hy-Vee (West Des Moines, IO)	October 2002
Farm Fresh (Hampton Roads, VA)	October 2002
Giant Food (Landover, MD)	November 2002
Jewel Osco (Boise, ID)	November 2002
Dominick (Pleasanton, CA)	November 2002
Pick 'n Save (Neemah, WI)	November 2002
Hannaford Bros. (Scarborough, ME) November 2002
Stop 'n Save (Quincy, MA)	November 2002
Publix (Lakeland, FL)	January 2003
Tops Markets (Amherst, NY)	January 2003
Giant Eagle, Inc. (Pittsburgh, PA)	January 2003
Schnuck Markets (St. Louis, MO)	January 2003
Safeway Eastern Division (Lanham	, MD) January 2003
Diersbergs Markets (St. Louis, MO)	January 2003
Weis Supermarket (Sunbury, PA)	February 2003

information preferred the irradiated products to their non-irradiated counterparts, which were available at the same store.

The early success of marketing irradiated food (fruits, vegetables and chicken) by the Carrot Top grocery has provided reassurance and an incentive to supermarket chains to follow suit. After the approval of irradiated red meats by the FDA in 1999 and USDA in 2000, irradiated ground beef has been successfully marketed in several states. Increasing numbers of supermarket chains and retail stores have introduced irradiated food, clearly labeled as such, at some or all of their stores as indicated in Table 2.

As of March, 2003, over 7,000 supermarkets and retail stores offered irradiated foods, mainly ground beef and Hawaiian fruits, in most states. Sales of such foods have been strong, and the majority of consumers are not reluctant to buy them. Several other supermarket chains plan to start offering irradiated foods to their customers in the near future.

Schwan, Inc., a nationwide food service company operating through home delivery, started marketing irradiated ground beef produced by Huisken Meat, Inc., in late 2000. The success in selling irradiated ground beef has led this company to market only irradiated ground beef since early 2002. Sysco Foodservice also started marketing irradiated ground beef at its distribution centers in 2002, followed by Associated Wholesale Incorporated and Performance Food Group, Inc., in January 2003.

Dairy Queen, a nationwide fast-food restaurant chain based in Edina, MN, began offering irradiated hamburgers at some of its stores in the Minneapolis-St. Paul area in early 2002. At the store, consumers are provided information about the irradiated ground beef through posters, trays, and napkins. Sale of irradiated hamburgers has increased steadily and Dairy Queen decided to offer irradiated hamburgers in all of its Minnesota stores on a voluntary basis in late 2002. It is possible that Dairy Queen will market irradiated hamburgers in its stores in other states in the future. Other restaurant chains including Shells, based in Florida, Champp, based in Milwaukee, and Embers American, based in Minnesota, are now offering some irradiated foods to their customers.

ISSUES AFFECTING TRADE IN IRRADIATED FOODS

Will Irradiation Increase the Cost of Food?

Any additional processing will add cost to the food. It will also "add value" to the treated food. Food processes such as canning, freezing, refrigeration, pasteurization, fumigation and irradiation all add cost to the product but will benefit consumers in terms of safety, quality, quantity, availability and convenience. These represent the "added value" of the food. The cost of low dose irradiation of food, e.g., for sprout or insect control, is on the order of \$20-\$50 per metric ton or about 1-2 cents per pound, while medium dose irradiation for pathogen control of meat products should add about 10-15 cents per pound, and 20-30 cents per pound for relatively high dose irradiation to ensure hygienic quality of spices and dried vegetable seasonings. In general, the cost of irradiation is competitive if not lower than that of other food processes that achieve the same purposes. For example, the cost of irradiation to meet quarantine requirements in the USA is approximately 10-20% of that of vapor heat treatment. Either one can be used to treat papaya to meet quarantine requirements.

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 V) 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 food-borne pathogens. Labeling offers the opportunity to inform consumers of the reason why foods are or should be irradiated, as well as

giving them a choice.

The FDA is one of the authorities that requires that irradiated whole foods be labeled as such. In 1986 a mandatory green

"Radura" logo was added

ACSH supports *informational* not warning—labeling requirements for irradiated food as approved by the FDA.

to this labeling requirement. 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 bet-

ter 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.

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 safety" and "irradiated to greatly reduce harmful bacteria" on irradiated food packages. With the recently passed U.S. Farm Bill, it is likely that labeling of irradiated food could be more liberal, and a statement such as "cold pasteurization" may be permitted instead of irradiation in the future. Labeling is currently not required in restaurants or other food service milieus.

Are Irradiated Foods Being Traded Internationally?

Some irradiated food such as spices, herbs and dried vegetable seasonings, and food 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 are mainly used in domestic markets to meet local food demands.

With the recent approval by APHIS of irradiation for imported fruits and vegetables, international trade in irradiated food is likely to increase significantly in the near future. Irradiation will also likely be used to meet strict hygienic standards for several food products that enter international trade.

Are There Scientific Methods to Determine Whether Foods Have Been Irradiated?

Yes. Scientific research carried out in the past two decades has resulted in several methods that can be used to determine whether foods have been irradiated or not. Unfortunately, there is no single method that works for all foods. The Codex Alimentarius Commission endorses the following five methods for analyzing irradiated foods:

- Irradiated food containing fat—gas chromotagraphic (GC) analysis of hydrocarbons
- Irradiated food containing fat—GC/mass spectrometric analysis of cyclobutanones
- Irradiated food containing bone—electron spin resonance spectroscopy

- Irradiated food containing cellulose—electron spin resonance spectroscopy
- Irradiated food from which silicate materials can be isolated—thermoluminescence analysis.

CONCLUSIONS

The safety and effectiveness of irradiation as a food process have been clearly established, and this food technology is increasingly accepted by regulatory authorities all over the world. Irradiation provides an added layer of safety to many food products including meat, poultry, seafood and spices that are susceptible to contamination by pathogenic microorganisms. It can ensure their microbiological safety at the market place and prevent consumers from bringing contaminated products into their homes. Faced with liability from selling contaminated products, the food industry will have to weigh the cost of using irradiation against the cost of product recalls, lawsuits, loss of brand equity or even bankruptcy as a result of illnesses and deaths caused by such contaminated products. Irradiation may provide a cheaper and more effective option for the food industry to ensure the safety of its products. Recent trends indicate that irradiation is likely to play the same role for solid foods as heat pasteurization has played for liquid foods. Consumers now have the option of purchasing either irradiated foods without such contamination or non-irradiated products that may be contaminated by various pathogenic organisms.

The unique characteristics of irradiation as an effective sanitary and phytosanitary treatment for food and agricultural commodities will create a strong demand for its use by the food industry. It will provide U.S. consumers with a wide 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 USA to its trading partners. Thus, irradiation will likely expand trade in many types of food products on a global basis.

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 methods. While the introduction of irradiated foods into the U.S. market has been slow, this trend is likely to accelerate because of increasing consumer acceptance of and demand for improved safety and quality characteristics. Irradiation is therefore providing consumers in the U.S. and some other countries with another choice for safety-enhanced foods.

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Appendix I. SOME TERMS FREQUENTLY USED IN DISCUSSIONS OF FOOD IRRADIATION*

- **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.
- **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."
- **Kilogray (kGy); Gray (Gy):** A Gray (Gy) is the unit (or level) of ionizing energy absorbed by 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 spores of 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.

^{*} Adapted from Radiation Preservation of Foods, Institute of Food Technologists, Chicago, 1983.

Appendix II. FOOD IRRADIATION: SOME MAJOR MILESTONES

- 1895: Wilhelm Konrad von 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 pass-

es 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 UN bodies and their member governments.
- 1988: FAO, IAEA, WHO and ITC/UNCTAD/GATT convened an international conference, which adopted an agreement on provisions to accept, control and trade irradiated foods on a global scale.
- 1992: The first commercial food irradiator in the USA (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 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.

- 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, either 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 starts 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 fruits to meet quarantine requirements for export to the U.S. mainland.
- 2002: Many supermarket chains start offering irradiated foods, mainly ground beef and fresh fruits from Hawaii, in some 4,000 stores in most states of the USA. 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.

Appendix III. **PADURA: INTERNATIONAL SYMBOL FOR** IRRADIATION.

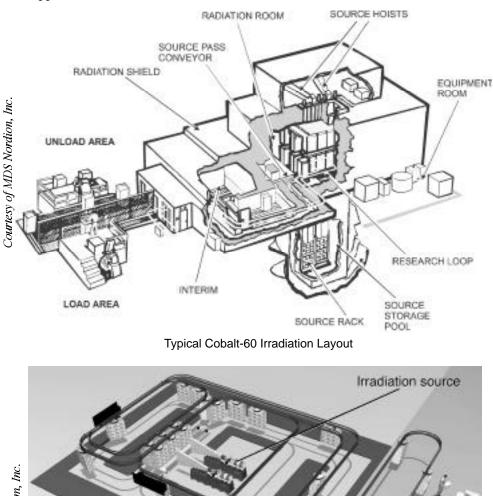


Year	Canada	Mexico	USA
1960	Potatoes (sprout inhibition, 0.15 kGy max.)		
1963			Wheat & wheat prod- ucts (insect disinfesta- tion, 0.5 kGy max.)
1964			Potatoes (sprout inhibi- tion, 0.15 max.)
1965	Onions (sprout inhibition, 0.15 kGy max.)		
1969	Wheat and wheat products (insect control, 0.75 kGy max.)		
1983			Spices and dried veg- etable seasonings (microbial control, up to a max dose of 10 kGy)
1984	Spices and dried vegetable season- ings (microbial control, 10 kGy max.)		
1985			Dry and dehydrated enzyme preparations (microbial control, 10 kGy max.)

Appendix IV. FOOD IRPADIATION: MAJOR REGULATORY APPROVALS IN NORTH AMERICA

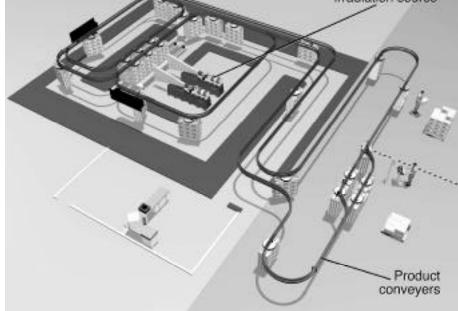
Appendix IV. FOOD IRRADIATION: MAJOR REGULATORY APPROVALS IN NORTH AMERICA (continued)

Year	Canada	Mexico	USA
1985			Pork (trichinosis con- trol, 1 kGy max.)
1986			Fresh foods for insect control and delay of physiological growth, 1 kGy max.)
1990			Spices and dried veg- etable seasonings (max. dose 30 kGy)
1995		Roots, tubers, fruits, vegetables, meat, fish, spices, season- ings, 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.)
2000			Seeds for sprouting (pathogen control, 8 kGy max.)



Appendix V. DIAGRAMS OF IRRADIATION FACILITIES

Courtesy of SureBeam, Inc.



Typical Electron Beam Irradiator

Elizabeth M. Whelan, Sc.D., M.P.H. President

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