

# **Questions and Answers**

Last Updated February 2014

# Looking for authoritative answers to your questions concerning food irradiation? This information may help.

These are relatively short answers to complex questions and more detailed information is available upon request.

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# CONTENTS

# 1) Consumer Benefits

- 1.1 Why is food irradiated?
- 1.2 Is irradiation used for non-food products?
- 1.3 Are irradiated foods being sold now?
- 1.4 How can I tell if food has been irradiated?
- 1.5 Does irradiated food cost more?
- 1.6 Are consumers buying irradiated food?
- 1.7 Who endorses the use of food irradiation?
- 1.8 Why not just cook food thoroughly to kill bacteria?
- 1.9 Does irradiated meat need to be cooked?
- 1.10 Why the emphasis on irradiating hamburger and not steak?
- 1.11 How does irradiation affect shelf-life?

# 2) Commercial Questions

- 2.1 What is the food irradiation process?
- 2.2 What equipment is employed to irradiate food?
- 2.3 At what step in the processing of food is irradiation used?
- 2.4 What other processes can control bacteria as alternatives to irradiation?
- 2.5 How does irradiation fit within HACCP?
- 2.6 How much radiation is used?
- 2.7 How does the irradiation process destroy bacteria?
- 2.8 What is the cost of a typical irradiation facility?

# 3) Nutrition & Taste

- 3.1 Are irradiated foods still nutritious?
- 3.2 How does irradiation affect the taste of food?

# 4) Safety of Irradiated Food

- 4.1 Does the irradiation process make food radioactive?
- 4.2 Is irradiated food safe?
- 4.3 Does eating irradiated food present long-term health risks?
- 4.4 Are the chemical changes in irradiated foods harmful?
- 4.5 Does irradiation create any unique chemical changes in the food?
- 4.6 Does irradiation create carcinogens like benzene in food?
- 4.7 Do the free radicals produced during irradiation affect the safety of food?
- 4.8 Does eating irradiated food cause genetic damage?
- 4.9 Are radiation pasteurized foods sterile?

# 5) Safety of Irradiation Process

- 5.1 Is there a risk of radiation exposure if you live next to an irradiation facility?
- 5.2 Do workers at irradiation facilities face dangers from radiation?
- 5.3 Is there a risk from the transportation of radioactive materials for irradiators?
- 5.4 Can an irradiation facility have a "melt down"?
- 5.5 What happens to the used cobalt-60 from a gamma irradiation facility?
- 5.6 Who makes sure irradiation facilities are operated safely?

5.7 Have there been fatal radiation accidents at irradiation facilities?

# 6) Labeling & Regulatory

- 6.1 What foods can be irradiated in the United States?
- 6.2 Do irradiated foods require special packaging in the United States?
- 6.3 Do irradiated foods require special labeling in the United States?

## 7) General

- 7.1 Do other countries irradiate food?
- 7.2 How should irradiated food be handled?
- 7.3 How can I find out more about food irradiation?

# 1) Consumer Benefits

### 1.1 Why is food irradiated?

Food is irradiated to destroy bacteria, fungi, or parasites that cause human disease or cause food to spoil. Irradiation destroys harmful bacteria such as *E. coli* O157:H7, *salmonella*, *listeria*, *campylobacter* and *vibrio* that are major contributors to the 5,000 deaths and 76 million food borne illnesses estimated by the US Centers for Disease Control (CDC) that occur every year in the United States. At the same time, parasites such as *cryptosporidium sp.*, *cyclospora sp.*, *toxoplasma gondii* and *trichinella* are eliminated. When used in this manner, irradiation is comparable to pasteurizing milk, in that the product is left fresh, but is much safer. Irradiation also extends the shelf-life of food by retarding maturation in some fruits and reducing spoilage organisms that can even grow under refrigeration. Irradiated strawberries and some other fruits can last weeks in the refrigerator without developing mold. Irradiation can also be used in place of fumigants and other quarantine procedures to allow fruits and vegetables to be imported or exported without risking the introduction of harmful insects to the receiving country.

### 1.2 Is irradiation used for non-food products?

Yes. Irradiation is used to sterilize approximately 40% of the single use sterile medical devices currently manufactured in the US including: bandages, blood plasma, burn ointments, catheters, eye ointment, hypodermic syringes, orthopedic implants, intravenous administration sets, surgical drapes, sponges, swabs, surgeons' gloves, procedure packs, trays and sutures. Irradiation is also used for commercial products including microbial reduction or sterilization of: aerosol saline solutions, baby bottle nipples, baby powder, bulk cotton bales, contact lens cleaning solutions, cosmetic ingredients, bar and liquid soap, detergents, polishes, shampoos and hair cream. Food packaging that often is irradiated to eliminate bacteria include: bulk food containers, cream cups and lids, dairy and juice cartons, plastic roll stock, heat shrinkable film and laminated foil bags. Irradiation is also used on pet treats and various animal foods including special diets for laboratory test animals. There are hundreds of other products that are irradiated that are not mentioned above.

### 1.3 Are irradiated foods being sold now?

Irradiation has been approved in over 40 countries for many food products. Each year about a billion pounds of food products and ingredients are irradiated worldwide. In the US, approximately 170 million pounds of spices are irradiated annually. Approximately 15 million pounds of irradiated hamburger patties and fresh ground meat are currently sold retail stores such as Wegman's and Safeway as well as by home delivery through Schwan's and Omaha Steaks. Irradiated live oysters in their shells are currently on the market. Increasing amounts of tropical fruits and vegetables are irradiated and imported from Hawaii, Thailand, Mexico, Vietnam, India and South Africa. Astronauts have eaten irradiated food on space missions for years.

### 1.4 How can I tell if food has been irradiated?

Although you cannot tell by the taste or appearance, federal regulations require that irradiated foods be labeled and carry the internationally recognized symbol called the "radura". Foods that contain irradiated ingredients or foods served in restaurants do not have to be identified as being irradiated.

#### 1.5 Does irradiated food cost more?

Any food process will add cost. Irradiation adds a few cents per pound to the cost of production.

However, food prices would not necessarily rise just because a product has been irradiated. In some cases, extended shelf-life offsets the extra cost. A study conducted by the USDA Economic Research Service and the University of Florida found that consumers are willing to pay more for a safer food product. In addition, the US Centers for Disease Control and Prevention (CDC) estimates that food irradiation on a large-scale basis could prevent nearly 900,000 cases of illness, 8,500 hospitalizations, over 6,000 catastrophic illnesses and 350 deaths each year in the US. This would also reduce the estimated \$5 billion to \$86 billion cost of medical treatment and lost productivity resulting from food borne illnesses in the US each year.

### **1.6 Are consumers buying irradiated food?**

Consumers are already buying irradiated foods. "When consumers are provided with factual information about food irradiation, they will choose irradiated food with confidence" was the conclusion reached by Dr. Christine Bruhn of the Center for Consumer Science, University of California, Davis, after she examined many different consumer surveys. Also, since Schwan's switched their ground beef to irradiated, its Vice President Michael Ziebel claims that "sales within Schwan's ground beef product line have increased more than 20%". Other retailers have reported similar results.

#### 1.7 Who endorses the use of food irradiation?

Endorsing organizations include: [Reference: Food Irradiation Research and Technology, Sommers & Fan, "Consumer Acceptance and Marketing of Irradiated Foods", Ronald F. Eustice and Christine M. Bruhn, IFT Press, Blackwell Publishing, 2006]

American Council on Science and Health American Dietetic Association American Farm Bureau Federation American Feed Industry Association American Meat Institute American Medical Association American Veterinary Medical Association Animal Health Institute **Apple Processors Association** Centers for Disease Control & Prevention **Chocolate Manufacturers Association** Codex Alimentarius Council for Agricultural Science and Technology Florida Fruit and Vegetable Association Food and Drug Administration Food Distributors International Food and Agriculture Organization Grocery Manufacturers of America Health Physics Society Institute of Food Science & Technology Institute of Food Technologists International Atomic Energy Agency International Food Information Council The Mayo Clinic Millers' National Federation National Confectioners' Association National Cattlemen's Beef Association

National Food Processors Association National Fisheries Institute National Meat Association National Turkey Federation National Pork Producers Council Northwest Horticulture Association Produce Marketing Association Scientific Committee of the European Union United Egg Association United Fresh Fruit & Vegetable Association United Egg Producers United Kingdom Institute of Food Science & Technology U.S. Department of Agriculture Western Growers Association World Health Organization

### 1.8 Why not just cook food thoroughly to kill bacteria?

Cross-contamination of cooking surfaces can lead to food borne illness. For example, *E. coli* left on a cutting board from contact with uncooked beef can then be transferred to lettuce being chopped on the same cutting board or *vice-versa*. Also, in many cases, food may not be cooked as thoroughly as intended. Some foods are not always cooked; such as sprouts, lettuce and shell eggs.

#### 1.9 Does irradiated meat need to be cooked?

Irradiation is a cold process that leaves meat virtually unchanged, so you cook it just as you would nonirradiated meat. While irradiation effectively eliminates harmful bacteria, the food is not made sterile. Proper sanitation procedures are still necessary for processors, retailers and consumers. Meat and poultry should be kept refrigerated. Contact surfaces, preparation implements and the cook's hands must be cleaned to help prevent cross contamination.

#### 1.10 Why the emphasis on irradiating hamburger and not steak?

Initially, bacteria are a surface contaminant on whole cuts of meat. When cuts of meat are cooked, this surface contamination is destroyed. However, when meat is ground to make hamburger, the surface bacteria is distributed throughout the hamburger where it may not be destroyed when cooked. Irradiation penetrates the hamburger and kills the bacteria in the center as well as the surface. While irradiation provides the greatest safety benefit for hamburger, it can also make whole meats safer by preventing cross contamination from surface bacteria.

### 1.11 How does irradiation affect shelf-life?

Irradiation extends shelf-life of food in several ways. First, it reduces spoilage bacteria and molds that can grow even under refrigeration. Irradiated strawberries and some other fruits can last weeks in the refrigerator without developing mold. The shelf-life of meat products is approximately doubled because they contain fewer spoilage bacteria. A second way irradiation extends shelf-life is by slowing the ripening process of some fruits and reducing mold. It can also keep potatoes, onions and garlic from sprouting and mushroom caps from opening.

# 2) Commercial Questions

### 2.1 What is the Food Irradiation process?

There are several processes that are collectively referred to as "**FOOD IRRADIATION**". The object of each process is to kill or impair the breeding capacity of unwanted living organisms or to affect the product morphology in a beneficial way that will extend shelf-life. Each process has an optimal dose of ionizing energy (radiation) dependent on the desired effect. The dose of radiation is measured in grays (Gy). A "gray" is a unit of energy equivalent to 1 joule per kilogram. This unit of measure is based on the metric system. Thus, 1 kilogray (kGy) is equal to 1,000 grays (Gy). All three forms of ionizing energy have the same effect, gray for gray. Some of the major processes are:

**Pasteurization** (**Pathogen Reduction**) – Irradiation is used to effectively eliminate disease causing organisms including bacteria and parasites. (e.g. Irradiating ground beef to make it safe from *E. coli* O157:H7. Irradiating live oysters to make them safe from *vibrio*.)

*Sterilization* – Irradiation is used at a very high dose to eliminate <u>all</u> organisms so that refrigeration is not required (shelf stable). (e.g. Certain foods are sterilized for NASA astronauts.)

*Sanitation* – Irradiation is widely used to reduce organisms for spices, herbs and other dried vegetable substances. (e.g. Irradiating spice blends that are added to meat for hot dogs and other "Ready to Eat" products that may not be cooked again.)

*Shelf-life Extension* – Shelf-life can be extended for certain foods using radiation by lowering the population of spoilage causing organisms, including bacteria and mold. On certain fruits and tubers, irradiation delays ripening and/or sprouting. (e.g. Irradiating berries to reduce mold. Irradiating fresh fruits to extend their market reach. Irradiating potatoes, onions and garlic to impair cell division and hence allow them to go through the "off" season without sprouting.)

*Disinfestation* – Irradiation is used to stop reproduction of both storage and quarantine insect pests. (e.g. Irradiating foreign produced mangoes to eliminate the seed weevil, which is a quarantined pest, for import to the US. Irradiating papaya to eliminate fruit flies, which are quarantined pests, for import from Hawaii or foreign countries into the US mainland.)

All three forms of irradiation are referred to as a "cold process". Although <u>all</u> of the radiation energy is converted to heat during treatment, the process typically increases the product temperature by about 1 degree Celsius.

### 2.2 What equipment is employed to irradiate food?

Food is irradiated in "irradiators" that use gamma rays or electron beams x-rays as their source of ionizing energy (radiation). All commercial irradiators have four primary components, a source of radiation, a method of product conveyance, "shields" to prevent exposure of personnel and the environment to radiation and safety systems. Ionizing radiation is penetrating energy and thus, products are usually irradiated after they are fully packaged. Below is a description of the four types of irradiators that are commercially available and in use today for food processing. The choice of which irradiator is most cost effective for a particular product depends on the type of product, how it is packaged, the product dose, dose uniformity requirements and, most important, logistics.

*Electron Beam Irradiator (employing a radiation chamber)* – The source of electron beams is an "accelerator". Accelerators generate and accelerate electrons very fast towards the food product being

irradiated. Because electrons have mass, they can only penetrate about 1.5 inches (3.8 cm) into a typical food product or about 3.5 inches (8.9 cm) if the food product is irradiated on both sides. Electrons also have an electric charge. This charge allows the stream of accelerated electrons to be scanned by magnets to track across the product. A commercial food, electron beam irradiator, accelerates electrons to an energy level of up to 10,000,000 electron volts (10 MeV). Electron beam irradiators typically use massive concrete, steel or lead shielding. Electron Beam accelerators can be turned on and off. Safety interlocks ensure that a person cannot enter the radiation chamber where the food is being irradiated when the accelerator is "on". Product is usually passed through the scanned "beam" on roller type conveyors.

*Gamma Irradiator (employing a radiation chamber)* – The source of photons in a gamma irradiator is cobalt-60. Unlike electron beams that are generated on site using electric power, cobalt-60 is produced off site in nuclear reactors and transported in special shipping containers ("casks") to the site. Cobalt-60 is a solid radioactive metal that is contained in two welded encapsulations of stainless steel creating a "sealed source". The sealed source contains the "radioactive" cobalt-60, but allows the photons ("radiation") to pass through the encapsulations and ultimately into the food product. Because Cobalt-60 photons have no mass they can penetrate more than 24 inches (60 cm) of food product if irradiated on both sides. Gamma irradiators that employ a radiation chamber typically have massive shields made out of concrete or steel. Cobalt-60 continuously emits radiation and cannot be turned "off". To allow personnel access to the chamber, the source is lowered into a storage pool of shielding water when it is not being used to irradiate product. The shielding water does not become radioactive. Safety interlocks are used to assure that a person cannot enter the chamber when the source is not in the stored position (at the bottom of the pool of water). Hanging carriers, totes and roller conveyors are typically employed to move the product through the chamber.

*Gamma Irradiator (underwater)* – Like the radiation chamber irradiator above, an underwater gamma irradiator uses cobalt-60. Unlike a radiation chamber irradiator, an underwater irradiator stores the cobalt-60 permanently at the bottom of a pool of water. Instead of raising the cobalt-60 into a shielded chamber, the product, placed in water free containers, is lowered to the bottom of the pool adjacent to the cobalt-60 to receive a dose of radiation. The water acts as the shield. The shielding water does not become radioactive. No above ground shielding or radiation chamber is present. There is no need for interlocks to prevent personnel from entering a radiation chamber when the cobalt-60 is present, because there is no radiation chamber. Typically, the product is loaded into water free containers and the containers are lowered/raised using a hoist mechanism.

*X-ray Irradiator (employing a radiation chamber)* – X-rays are photons and have similar properties to gamma rays emitted by cobalt-60. X-rays are generated by using an electron beam accelerator (above) and converting the electron beam (up to 7.5 MeV) to photons by accelerating the electrons into a high density material such as tungsten, steel or tantalum. The sudden deceleration of the electrons generates x-rays and waste heat. The shielding and product conveyance are similar to that of a chamber type gamma irradiator (above). The safety interlocks are similar to both electron beam and chamber type gamma irradiators. The advantages of x-rays over electron beams are that they have good product penetration (over 24 inches or 60 cm of food product if irradiated on both sides). The advantages of x-rays over both types of gamma irradiators are that they do not require a shielding storage pool. However, there is a substantial loss of energy during the conversion process. Thus, x-ray units suffer a severe cost disadvantage when compared to other types of irradiators for the same product volume throughput.

### 2.3 At what step in the processing of food is irradiation used?

One tremendous advantage of the irradiation process is that it can be performed on the product in its <u>final</u> retail package. The actual process can take place at the food processing facility, usually after packaging, or at an Irradiation Service Center. Irradiation Service Centers have been irradiating medical devices, household products, and some food products, for decades to control bacteria. In all cases, the process is conducted by qualified, licensed personnel who follow strict regulated procedures.

#### 2.4 What other processes can control bacteria as alternatives to irradiation?

High Pressure processing, and other emerging technologies, are being used, but none are as universally applicable and flexible as irradiation. Significant quality changes may occur with high pressure processing and some other technologies. The use of chemicals and even extraordinary sanitary measures at the food-processing site cannot guarantee food free of disease causing microorganisms. Fumigants such as propylene oxide and ethylene oxide are often used on spices and other dry materials. Heat processing is often used, but changes the nature of the product (e.g. canned foods). Irradiation can sometimes be combined with other techniques with synergistic results.

### 2.5 How does irradiation fit within HACCP?

HACCP is a system that identifies the hazards associated with each food item and determines how each hazard can be reduced or eliminated at Critical Control Points (CCPs). Testing alone cannot prevent bacterial hazards from reaching the consumer; real intervention is required that actually kills the contaminating microorganisms. Irradiation is used as a recognized "kill step", or "hurdle", within HACCP plans. Irradiation is combined with other "hurdles" such as good sanitation and temperature control to maximize product safety.

#### 2.6 How much radiation is used?

The amount of radiation used, or "dose", is the minimum needed to achieve the desired effect. The radiation dose needed to enhance the safety or quality of any particular food product is carefully determined by testing and process validation. To make sure the good taste of the food is maintained and the processing costs are minimized, the amount of radiation delivered is kept as low as practical. The amount of radiation absorbed is measured in "kilograys" (kGy). Typical minimum doses for some foods to achieve the desired effect are:

Potatoes to prevent sprouting:	0.05 kGy
Fruit for quarantine:	0.15 to 0.40 kGy
Fresh meat to control pathogens:	1.0 to 2.0 kGy
Spices and herbs to control bacteria:	5 to 10 kGy
Sterilized Diets for Astronauts	44 kGy

It is interesting to note that the minimum dose for different food products may vary by a factor of 1,000.

#### 2.7 How does the irradiation process destroy bacteria?

Irradiation is a process that employs ionizing energy. Radiation energy ionizes a very small number of the molecules within the food product and any bacteria within the food product. When a molecule is ionized, it effectively breaks. If a DNA molecule of a bacterium is ionized, it is damaged or destroyed, preventing the bacteria from being able to reproduce. If a water molecule within a bacterium cell is ionized, it can form peroxide and act as a disinfectant within the bacterium itself. These molecular level

changes destroy the bacteria by preventing their reproduction. Only a very small fraction of the molecules within a living organism, such as a bacterium, need to be damaged to have this effect. Because only a small fraction of food product molecules are ionized, minimal adverse effects, such as changes in taste, occur.

### 2.8 What is the cost of a typical irradiation facility?

Commercial irradiators are capital intensive. Typically, the <u>total</u> capital cost can range from a few million dollars to several times that. Almost all of the expenses are fixed. Variable expenses are minimal (effectively there are no raw materials consumed). Therefore, irradiators are most cost effective if they are able to run around the clock. There are significant economies of scale. This creates a balance between having a large centralized facility that can benefit from scale, but might suffer from logistics costs, versus an in-house irradiator that does not have the benefit of scale, but saves on the costs of logistics.

# 3) Nutrition & Taste

# 3.1 Are irradiated foods still nutritious?

Food treated by irradiation is generally as nutritious as, or better than, the same food treated by the conventional familiar processes such as cooking, drying, or freezing. Numerous studies conclude that irradiation has no significant effect on the nutritional value of the macronutrients within foods (proteins, lipids, carbohydrates). Micronutrients, especially certain vitamins, can be reduced by irradiation, but generally these same vitamins are similarly reduced by the other commonly used food processing methods. Even simple storage can lead to major loss of certain vitamins. The significance of any loss of specific vitamins must be evaluated relative to the role of the irradiated food as a source of that particular vitamin in the diet of the consuming public. This consideration is heavily weighted by the regulatory agencies in their evaluation of petitions for clearance to irradiate any food. The FDA, World Health Organization and the American Dietetic Association have all considered the nutritional aspects of irradiated food and endorsed the process.

### **3.2 How does irradiation affect the taste of food?**

Unlike cooking, freezing, canning and other processes, irradiation applied at the right dose does not change the taste or texture of most foods. Food manufacturers obviously will not use any process that has a negative impact on the quality of the food to such an extent that it becomes unacceptable to consumers. There are many good examples of the excellent sensory quality of radiation processed foods, including the NASA menu items, which have been consumed by astronauts for many years. To best answer this question purchase irradiated hamburgers, which are nationally available, and try them for yourself.

# 4) Safety of Irradiated Food

### 4.1 Does the irradiation process make food radioactive?

Absolutely not, regardless of how high the radiation dose. As food is passed through the irradiation field, energy passes through the food much like a ray of light passes through a window. This energy destroys most of the bacteria that can cause disease, yet allows food to retain its high quality. Since the energy involved in irradiation is not powerful enough to affect the nucleus of the atoms within the food, the food cannot become radioactive. <u>All</u> of the radiation energy absorbed is instantaneously converted to a very small amount of heat. Nothing remains.

### 4.2 Is irradiated food safe?

Yes. In fact food pasteurized by irradiation is safer, because the process destroys harmful bacteria and parasites that may be present. It has been studied more than any other food process over the last 60 years, and is already approved in more than 40 countries. The Food and Drug Administration has thoroughly examined the process from nutritional, microbiological and toxicological perspectives, as have international bodies under the auspices of the United Nations. All peer reviewed scientific studies have found irradiation to be safe and wholesome. This is why it is endorsed by a multitude of organizations, including the American Medical Association, the American Dietetic Association, the Centers for Disease Control and Prevention and the World Health Organization.

### 4.3 Does eating irradiated food present long-term health risks?

No. The safety and effectiveness of food irradiation has been demonstrated in hundreds of studies and experiments. There is a consensus of opinion by federal regulatory agencies and national and international food and public health organizations that food irradiation is safe. The FDA has examined numerous studies on the chemistry of irradiated food, the impact of irradiation on the nutrient content of foods, potential toxicity concerns and effects on microorganisms in or on irradiated products. Many hundreds of research studies tried to identify problems from eating irradiated foods but failed to discover any long-term health risks. Several of these studies were long-term, multi-generation feeding studies, involving several species of test animals whose health and vitality were carefully monitored. An international committee of independent experts representing a broad cross-section of scientific disciplines and institutions (United Nations) reviewed the studies that <u>claimed</u> various possible health risks and determined that these studies either were lacking the proper scientific procedures to insure their results or could not be duplicated by other scientists. A very complete review of scientific studies on the effects of irradiation on food is available in a report titled "High Dose Irradiation: Wholesomeness of Food Irradiated with Doses Above 10 kGy" released by the World Health Organization in 1999.

### 4.4 Are the chemical changes in irradiated foods harmful?

The irradiation of food causes chemical changes producing so called "radiolytic products". Evaluations of approximately 100 substances showed that they do not pose long-term health risks. For example, most of the radiolytically (produced by radiation) generated compounds are present naturally in other (non-irradiated) foods at levels that are many times greater than the levels generated by irradiation. This conclusion of wholesomeness is reinforced by comparison of the chemical effects of irradiation with those of thermal processing. With few exceptions the chemical identities of the radiolytic products are identical to those generated "thermolytically" (produced by heat), while their levels are generally much lower than is found in thermally processed foods. Thermally processed foods are safe; so are irradiated foods. Finally, in a different but complementary approach based on function rather than chemistry, irradiated foods have been applied to various biological test systems, such as the Ames test for mutagens, or feeding the foods to test animals. Such tests have consistently failed to reveal the presence of mutagenic or other toxic principles in irradiated foods, strengthening the conclusion of safety.

#### 4.5 Does irradiation create any unique chemical changes in the food?

After over 60 years of study, no unique compound has been identified in irradiated food. There have been instances when previously unknown compounds have been found in irradiated food. However, subsequent testing identified those same compounds in non-irradiated food.

### 4.6 Does irradiation create carcinogens like benzene in food?

Radiolytically produced benzene in irradiated foods is present at much lower levels than is found naturally in a variety of common foods, such as eggs or dairy products. Numerous carcinogenicity bioassay studies have been performed. These studies have not demonstrated any short term or long term toxicity related to the irradiation of food. Indeed, in the RALTECH study (the largest toxicology study ever conducted on irradiation or any other food processing method) the lowest incidence of cancer was found in the test groups that were fed the irradiated diets. This study was initiated by US Office of the Surgeon General, and the findings reviewed by the FDA and the National Toxicology Program's Board of Scientific Counselors who agreed that the evidence did not show any carcinogenicity. The FDA has also reviewed data demonstrating that very low concentrations of benzene are produced by high dose radiation sterilization of beef at doses 35 times higher than permitted by regulation. Analysis by expert scientists conclude that such low concentrations are of no health concern, and that foods irradiated at lower doses would present even less reason for concern.

### 4.7 Do the "free radicals" produced during irradiation affect the safety of food?

No. Free radicals can be formed when food is irradiated, as with other food processing methods, and even the normal oxidation process in food. For instance, toasted bread (non-irradiated) contains more free radicals than even very dry irradiated foods. A long-term study in which animals were fed dry milk powder irradiated at more than four times the maximum approved dose failed to disclose any toxic effects over nine generations.

### 4.8 Does eating irradiated food cause genetic damage?

The claim of abnormal chromosomes resulting from eating irradiated food has been sensationalized as a result of a very small study done in the 1970's in India. The study reported increases in the frequency of polyploid cells in animals and four malnourished children. Polyploidy means a multiple set of chromosomes; it is naturally occurring and varies among individuals. Attempts to replicate the India study were unsuccessful. In the early 1980's eight studies with several irradiated food items were conducted in China. More than 400 people consumed irradiated foods for 7 to 15 weeks. No significant differences in chromosomal abnormalities were seen between the test and control groups.

### 4.9 Are radiation pasteurized foods sterile?

No. Irradiation pasteurizes food by using energy, similar to pasteurizing milk using heat. In this process harmful bacteria will be destroyed thus making our food safer, but not sterile. The amount of radiation used does not kill certain spoilage organisms providing a further protection for consumers. As with nonirradiated foods, spoilage bacteria will multiply if the food is not properly handled. This spoilage, (smell), alerts consumers not to use this particular food product. Food can be sterilized at higher irradiation doses, but they are not commercially available in the United States at the present time. Irradiated food eaten by astronauts has been treated at higher doses to make it sterile so that refrigeration is not required. Not all foods are suitable for radiation sterilization.

# 5) Safety of Irradiation Process

# 5.1 Is there a risk of radiation exposure if you live next to an irradiation facility?

No. Commercial irradiators are equipped with safety systems designed to prevent radiation exposure to the public. Public safety is inherent in the design of irradiators augmented by multiple safety systems. Irradiators have been operating in the United States for over 50 years without exposure to the public.

### 5.2 Do workers at irradiation facilities face dangers from radiation?

Danger to the workers is minimal. At all times, the radiation source is shielded either by water, concrete or metal. Irradiators are designed with several layers of overlapping protection to detect equipment malfunctions and to protect personnel from accidental radiation exposure. Potentially hazardous areas are monitored and a system of interlocks prevents unauthorized entry into the radiation chamber when the source is exposed. Some irradiators that do not use a radiation chamber are "inherently safe" for the workers and their safety does not rely on interlocks or operator training. All irradiation facilities using radioactive materials must be licensed. Regulations require periodic inspections of facilities to insure compliance with the terms of the operating license. Non-compliance will result in severe penalties for the workers and the owners of the facilities.

### 5.3 Is there a risk from transportation of radioactive materials for irradiators?

Cobalt-60 required for gamma irradiators is transported in casks that prevent the release of radiation and/or radioactive material. The casks are designed to meet national and international standards modeled on the Regulations for Safe Transport of Radioactive Materials of the International Atomic Energy Act. The shipping cask must pass extensive tests before it can be used to ship radioactive material. These tests simulate accidents much worse than any cask would experience during transportation. Large quantities of radioactive materials are safely shipped all over the world. For example, during a 35 year period, there were 870 shipments of cobalt-60 from the Canadian supplier without any release of radioactive material. Over the same period, there were more than one million shipments of radioactive material in North America without a release of radiation and/or radioactive material. The excellent safety record of this industry exceeds that of any other industry involved in shipping hazardous materials such as toxic chemicals, crude oil or gasoline. E-beam and x-ray irradiators do not use radioactive material.

### 5.4 Can an irradiation facility have a "melt down"?

No. It is impossible for a "melt down" to occur in a gamma irradiator. The radiation source (cobalt-60) gives off radiation and decay heat. Under any and all conditions, the heat generated is not sufficient to melt the source material. It is a passive system. Electron beam and x-ray facilities contain no radioactive material.

### 5.5 What happens to the used cobalt-60 from a gamma irradiation facility?

The radiation sources (cobalt-60) decay over time into nickel-60, a non-radioactive material. Generally, when the energy from the radioactive source falls to a low level, (usually about 20 years), the source is returned to the supplier who will either re-encapsulate it and sell it to an irradiation company with a lower energy requirement, mix the old cobalt-60 with new cobalt-60 (recycle) or store it until it is harmless. The amount of non-productive cobalt-60 is minimal. It has been estimated that all of the cobalt-60 made in the last twenty years could be stored in a space of a small office cubicle. The same process takes place when a facility closes. The sources are returned to the supplier, sent to another irradiation facility, or stored. The machinery is dismantled and the building can be used for any purpose since no radioactivity or radiation remains. Electron beam and x-ray facilities do not use radioactive material.

#### 5.6 Who makes sure irradiation facilities are operated safely?

In the United States, facilities using radioactive sources must be licensed by the Nuclear Regulatory Commission (NRC) or through state regulatory agencies that they designate. To be licensed, the facility

operator must demonstrate extensive and well-documented safety design, procedures and training, which will prevent the accidental exposure of workers or the public to radiation. The licensee must also demonstrate that their operations will have no adverse effect on the environment. The Department of Transportation regulates the safe transport of radioactive sources. The NRC does not monitor e-beam or x-ray irradiators. Rather, the FDA, in conjunction with state authorities, oversees the regulation of these irradiators. Other countries have similar regulatory authorities.

### 5.7 Have there been fatal radiation accidents at irradiation facilities?

Irradiation facilities have been operating in the United States for over 50 years without a single fatal radiation accident. There have been a small number of fatal incidents in other countries where workers ignored or intentionally bypassed safety systems and procedures and were exposed to the radiation source.

# 6) Labeling & Regulatory

### 6.1 What foods can be irradiated in the United States?

Many foods can be irradiated effectively including meat, poultry, grains, shell eggs, spices, fruits and vegetables. The following table lists the <u>safety</u> approvals for irradiation by the US Food and Drug Administration and the US Department of Agriculture:

### **Approval Year Food Dose Purpose**

- 1963 Wheat Flour 0.2 0.5 kGy Control of Mold
- 1964 White Potatoes  $0.05-0.15\ kGy$  Inhibit Sprouting
- 1985 Dried Enzymes 10 kGy Bacterial Reduction
- 1986 Pork 0.3 1.0 kGy Kill Trichina Parasites
- 1986 Fruits & Vegetables < 1.0 kGy Insect Control, Extend Shelf-Life
- 1986 Herbs & Spices (Flavoring Materials) < 30 kGy Sanitization
- 1992 Poultry 1.5 3.0 kGy Bacterial Pathogen Reduction
- 1995 NASA Meat 4.4 kGy Sterilization
- 1999 Fresh Meat and Poultry < 4.5 kGy Bacterial Pathogen Reduction
- 1999 Frozen Meat and Poultry < 7.0 kGy Bacterial Pathogen Reduction
- 2000 Sprouts <8.0 kGy Bacterial Pathogen Reduction
- 2000 Shell Eggs <3 kGy Bacterial Pathogen Reduction
- 2005 Molluscan Shellfish < 5.5 kGy Bacterial Pathogen Reduction
- 2008 Fresh Spinach and Iceberg Lettuce < 4.0 kGy Bacterial Pathogen Reduction

[For specifics and up to date regulations see: 21CFR179.]

#### 6.2 Do irradiated foods require special packaging in the United States?

Generally irradiated products do not require any special packaging, from a physical point of view. However, packaging that is in contact with the food during irradiation must be approved by the FDA. Current packaging materials that are approved include paper, polyethylene and polypropylene film (including containers made from the film), white polystyrene trays, certain nylons and PET. Packaging producers are working with their customers and the FDA to obtain approval for other materials in the near future.

### 6.3 Do irradiated foods require special labeling in the United States?

All irradiated foods must be labeled and carry a symbol called the "Radura". Federal regulations require that irradiated foods be labeled and carry an internationally recognized symbol called the "Radura" and contain the words: "treated with radiation" or "treated by irradiation". Foods that contain irradiated ingredients or foods served in restaurants, (food service), do not have to be identified as being irradiated. Alternate verbiage may be used if approved by the FDA on a case to case basis.

### 6.4 Proposed FDA rules on labeling requirements for irradiated food:

On April 04, 2007 the USDA proposed relaxing rules concerning the labeling of irradiated foods.

# 7) General

### 7.1 Do other countries irradiate food?

Over 40 countries allow irradiation of many food types. It is estimated that over one billion pounds are irradiated annually and that number is increasing. In addition to the US, other countries using irradiated food include Japan, Canada, France, Belgium, the Netherlands, Portugal, Israel, India, Thailand, Russia, China, South Africa and Brazil.

### 7.2 How should irradiated food be handled?

Like other food processes irradiation is not intended as a substitute for good hygienic practice. Consumers, stores and restaurants should follow the same careful handling and preparation procedures whether the food is irradiated or not.

### 7.3 How can I find out more about food irradiation?

Documents on the safety and efficiency of food irradiation:

- "Food Irradiation Available Research Indicates That Benefits Outweigh Risks"; United States General Accounting Office, (GAO/RCED-00-217), August 2000.

- "Irradiated Foods"; Richard A. Greenberg; American Council on Science and Health, NY, NY, 1995.

- "High-dose Irradiation: Wholesomeness of Food Irradiated with Doses Above 10 kGy". WHO technical report series 890; World Health Organization, Geneva, 1999.

- <u>Food Irradiation Research and Technology</u>; Christopher H. Sommers, Xuetong Fan; IFT Press, Blackwell Publishing, 2006.

- Food Irradiation A Guidebook; Morton Satin; Technomic Publishing, Lancaster, PA, 1996.

- <u>Safety of Irradiated Foods</u>; J.F. Diehl; Marcel Decker Inc., New York, NY, 1990.