Food Irradiation

Questions and Answers

Food Irradiation Processing Alliance

Benebion. S.A.

FOOD TECHnology Service Inc.

GRAY*STAR, Inc.

MDS Nordion

REVISS Services/Puridec

Sadex Corporation

Securefoods Inc.

Sterigenics - Food Safety

STERIS Isomedix Services,Inc.

FIPA is an affiliate of the International Irradiation Association

“Radura”

This document has been prepared to assist food industry representatives and other interested parties in answering questions on food irradiation. It is current as of September 2006 and is updated periodically.

It was prepared by representatives of FIPA and agreed to by the total consensus of the members of FIPA. For more in depth information on these issues and/or any other questions that you might have, please contact either the individual members of FIPA or the Chairman:

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The Q&A has two answers for each question:

The "a" answer is intended to be a short, easy to understand, "sound byte".
The "b" answer provides more complete and detailed information.

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1.1 Why is food irradiated?

a) Food is irradiated to destroy harmful bacteria and parasites that might be inadvertently present. This makes the food safer, and is comparable to pasteurizing milk. Irradiation at lower dose levels also extends shelf-life and can be used to control insects.

b) 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 estimated 5,000 deaths and 76 million food borne illnesses 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 vegetables and reducing spoilage organisms that can even grow under refrigeration. Irradiated strawberries 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?

a) Yes. Irradiation has been used to sterilize medical and personal hygiene products for more than 40 years. It is also used in the manufacture of plastic products.

b) 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?

a) Yes. Irradiated hamburger patties are being sold at over 2,500 retail outlets in 35 states and are available nationally from Schwan’s and Omaha Steaks. Irradiated fresh ground beef is available from Wegman’s. Irradiated chicken and tropical fruits are also being sold in some areas.

b) Irradiation has been approved in 40 countries for some 50 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. Irradiated chicken is sold at some retail stores and in restaurants in Florida. Irradiated hamburger patties and fresh ground meat are currently sold in over 2,500 retail stores such as Wegman's, Kroger's, and Lowe’s Foods. They are also available for home delivery by Schwan's and Omaha Steaks. Increasing amounts of tropical fruits are irradiated and

imported from Hawaii including papaya, lychee, rambutan and carambola. Soon other exotic fruits and vegetables will be imported into the US. Astronauts have eaten irradiated food on space missions for years.

1.4 How can I tell if food has been irradiated?

a) Irradiated foods destined for the retail store have a label or a sign indicating that they have been irradiated. This includes the internationally recognized symbol called the "radura".

b) 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?

a) Irradiation adds a few cents per pound to the cost of production.

b) 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 produces offsetting savings. 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 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?

a) Yes. Retailers such as Wegman's, Kroger's, Omaha Steaks and Schwan's are demonstrating acceptance of the process with their consumers in the market place.

b) 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?

a) Many prominent medical organizations, researchers and government organizations, including the American Medical Association, the American Dietetic Association and the Center for Disease Control and Prevention (CDC) endorse food irradiation.

b) 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?

a) 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.

b) 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?

a) Irradiated meat should be handled the same way as non-irradiated meat. Cooking times and temperatures are the same. While harmful bacteria are virtually eliminated by irradiation, care must be taken to ensure that the product is not re-contaminated after the package is opened before cooking.

b) Irradiation is a cold process that leaves meat virtually unchanged, so you cook it just as you would non-irradiated 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?

a) With a steak, bacteria are generally on the surface and are easily eliminated at the surface temperatures reached during cooking, which in itself is a form of pasteurization. When meat is ground into hamburger, bacteria can be carried into the center where the cooking temperature may not be high enough to destroy it. Radiation penetrates the hamburger and kills the bacteria in the center as well as the surface.

b) 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?

a) Irradiated food generally has a longer shelf-life because spoilage organisms are reduced. For example strawberries can last weeks in the refrigerator without becoming moldy.

b) Irradiation extends shelf-life of food in several ways. First, it reduces spoilage bacteria and molds that can grow under refrigeration. Irradiated strawberries 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 fruits and vegetables 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?

a) There are several processes that are collectively referred to as "**FOOD IRRADIATION**". Food is irradiated by placing it in, or moving it through, a field of ionizing energy consisting of electron beams or gamma rays or x-rays. Irradiation produces a wide range of beneficial effects on various foods including pathogen reduction, disinfestation of insects, growth inhibition, control of parasites and shelf-life extension.

b) 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 effect 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?

a) Food is irradiated in "irradiators" that use electron beams or gamma rays or x-rays as their source of ionizing energy (radiation). Irradiators are designed to enable the irradiation of the food products to the desired dose and dose uniformity, without exposing workers or members of the public to radiation and without any effect on the environment.

b) Food is irradiated in "irradiators" that use electron beams or gamma rays or 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 or 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 the electrons to an energy 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 shields made out of massive 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 creating of the radiation is very similar to an electron beam irradiator

(above), including the ability to be turned on and off. 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 is that they do not require a shielding storage pool. However, there is a substantial loss of energy during the conversion process. Thus, it suffers 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?

a) Products are usually irradiated after packaging to minimize the risk of recontamination. This further assures the consumer of a safer product.

b) One tremendous advantage of the irradiation process is that it can be performed on the product in its final 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?

a) There is no process as flexible, as thorough, and as simple, as irradiation for reducing the microbial contamination on fresh food.

b) High Pressure processing, and other emerging technologies, are being used, but none are as universally applicable and flexible as irradiation. 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 and ethylene oxide are often used on spices and other dry materials. Heat processing is often used, but changes 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?

a) Irradiation, as an intervention technique, is an excellent critical control point within a HACCP system and is recognized as such by the USDA.

b) 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). Analysis 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?

a) The amount, or dose, of radiation used depends on the desired effects. Very small amounts are used to eliminate insect pests from fruit. Somewhat greater amounts are used on meat to kill harmful bacteria. Significantly higher amounts are required to fully sterilize food.

b) 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:	1.25 to 2.00 kGy
Spices and herbs to control bacteria:	5 to 10 kGy
Sterilized Diets For Astronauts	44 kGy

2.7 How does the irradiation process destroy bacteria?

a) Radiation breaks the DNA or damages other critical molecules in bacteria, either killing them or preventing them from reproducing.

b) 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?

a) Irradiation equipment used for commercial processing of food cost millions of dollars.

b) Commercial irradiators are capital intensive. Typically, the <u>total</u> capital cost can range from a couple of 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?

a) Yes. Irradiated foods are wholesome and nutritious.

b) 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. 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?

a) Food properly irradiated according to a validated protocol shows little if any change in taste. Most people can't detect any change.

b) 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?

a) Absolutely not, regardless of how high the radiation dose. As the energy passes through, it only kills the bacteria, leaving no residue.

b) 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. All of the radiation energy is converted to a very small amount of heat.

4.2 Is irradiated food safe?

a) Yes. In fact foods pasteurized by irradiation are safer, because the process destroys harmful bacteria that may be present. This is why such organizations as the American Medical Association and the World Health Organization endorse it.

b) 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 50 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?

a) No. Medical professionals, scientists and health organizations around the world have studied food irradiation for over 50 years and determined that it is perfectly safe and will save lives. There is no reproducible evidence that consumption of irradiated food poses any risk to long term health.

b) 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, multigeneration 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 claimed 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?

a) No. In fact the effect of irradiation is less than the changes that take place in food from cooking, canning or freezing.

b) 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?

a) After over 50 years of study, one potentially unique compound has been identified in irradiated food; 2-ACB. The FDA has concluded that there is no adverse effect from eating irradiated foods that may contain 2-ACB.

b) After over 50 years of study, one potentially unique compound has been identified in irradiated food; 2-alkylcyclobutanone (2-ACB). The irradiation of certain fats produce very small amounts of 2-ACB. Recently, tests have been performed on various non-irradiated foods to try to detect 2-ACB. So far, 2-ACB has only been detected in specific irradiated foods containing certain types of fat. The FDA has reviewed the data supporting the safety of irradiated foods and concluded that there is no adverse effect from eating irradiated foods that may contain 2-ACB in the quantities produced.

4.6 Does irradiation create carcinogens like benzene in food?

a) Yes, but the levels produced are much less than those found naturally in many other non-irradiated food products. For example the amount of benzene in an ordinary egg is a thousand times higher than that found in an irradiated hamburger.

b) 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?

a) No. There is no evidence that "free radicals" produced in radiation processing affect the safety of food. You get more free radicals in a piece of toast than in a piece of irradiated food.

b) 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?

a) No. While some advocacy groups like to sensationalize a 1970's Indian study, it was found that the study's claims were based on flawed data. Scientists from India and elsewhere have tried, and failed, to replicate these studies.

b) 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 malnourished children. Polyploidy means a multiple set of chromosomes; it is naturally occurring and varies among individuals. 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?

a) No. Only a lower dose of irradiation is used to eliminate harmful bacteria in meat and poultry products, similar to pasteurizing milk. Because common spoilage bacteria are still present, irradiated food must still be stored and handled properly. Higher radiation doses are required for sterilization.

b) 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 non-irradiated 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. 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?

a) No. Commercial irradiators are equipped with safety systems designed to prevent radiation exposure to the public.

b) 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 40 years without exposure to the public.

5.2 Do workers at irradiation facilities face dangers from radiation?

a) Danger to the workers is minimal. Strict safety features and procedures prevent worker exposure and the workers wear monitors to verify the effectiveness of those safeguards.

b) 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?

a) No. In North America, in over 40 years of transporting radioactive isotopes in specially designed and rigorously tested shipping containers, there has never been an accident that caused a radiation exposure problem. E-beam and x-ray irradiators do not use radioactive material.

b) 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"?

a) No. As the source (cobalt-60) gives off radiation, it also produces heat. The heat generated is simply not sufficient to melt the source material. Electron beam and x-ray facilities contain no radioactive material.

b) 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?

a) When the cobalt-60 sources no longer have sufficient strength, they are returned to the manufacturer who either re-uses them or stores them until they are completely depleted.

b) 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?

a) In the United States, the Nuclear Regulatory Commission and their designated state authorities license gamma irradiators. The FDA and state authorities monitor electron beam and x-ray facilities. Other countries have similar regulatory authorities.

b) 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 oversee the regulation of these irradiators. Other countries have similar regulatory authorities.

5.7 Have there been fatal radiation accidents at irradiation facilities?

a) The industry has an excellent record with no fatalities caused by radiation exposure in North America in its 40 year history.

b) Irradiation facilities have been operating in the United States for over 40 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?

a) The FDA has approved irradiation of flour, potatoes, fruits, vegetables, herbs, spices, shell eggs, poultry, molluscan shellfish and meat as safe. Petitions are currently pending for "Ready-To-Eat" products and certain other seafood products.

b) Many foods can be irradiated effectively including meat, poultry, grains, shell eggs, spices, fruits and vegetables. The following table lists the safety approvals for irradiation by the US Food and Drug Administration:

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
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
- Dried Enzymes – 10 kGy Bacterial Reduction
1990 - Poultry < 3 kGy Bacterial Pathogen Reduction
1995 - NASA – Meat 4.4 kGy Sterilization
1997 - Fresh Meat < 4.5 kGy Bacterial Pathogen Reduction
2000 - Frozen Meat < 7kGy Bacterial Pathogen Reduction
2000 - Sprouts Bacterial Pathogen Reduction
2000 - Shell Eggs 3 kGy Bacterial Pathogen Reduction
2006 - Molluscan Shellfish < 5.5kGy Bacterial Pathogen Reduction

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

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

a) The FDA must approve packaging materials that are in contact with the food during the irradiation process. Many common materials such as polyethylene film, paper and cardboard have already been approved.

b) 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 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?

a) Yes. Irradiated foods destined for retail market shelves must contain an internationally recognized symbol called a "radura" and have the words: “treated with radiation” or “treated by irradiation”.

b) 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. The document is available from the resources section of the FIPA home page.

7) General

7.1 Do other countries irradiate food?

Over 40 countries allow irradiation of over 50 food types. It is estimated that over one billion pounds are irradiated annually. In addition to the US, other countries using irradiated food include Japan, Canada, France, Belgium, the Netherlands, Portugal, Israel, 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.

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

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

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

8 Quotations

"Irradiation should be our next step in food safety. Consumers must be educated not only of the safety of food irradiation, but also of the benefits it has for our food supply. Likewise it is the duty of the food industry to offer this extra food safety measure to the consumer. Irradiation of the ground beef would have been an additional safety measure that could have protected the consumer by controlling the bacteria in the product." - Dr. David A. Kessler, Dean, Yale School of Medicine, former FDA Commissioner.

> ***"If food irradiation had been widely used since its early approval by scientists, millions of food borne illnesses would have been prevented as well as thousands of deaths."*** - Dr. James H. Steele, D.V.M., M.P.H., Assistant Surgeon General, USPHS, Retired.

"A lot of foods harbor harmful bacteria which can be taken care of by irradiation. The recent hamburger poisonings would have been avoided had the meat been irradiated." - Julia Child, Deceased.

> ***"Food irradiation could prevent hundreds of deaths and millions of illnesses each year."*** - Richard Lechowich, Director, The National Center for Food Safety and Technology.

"If you have a choice, select fresh or frozen poultry treated with ionizing irradiation." - World Health Organization.

> ***"Despite these alarming figures, the good news is that the United States, even without widespread use of irradiation has the safest food supply in the world. The bad news, though, is that more than 1.8 million pounds of ground beef contaminated with E Coli 0157.H7 and more than 36.5 million pounds of hot dogs and various luncheon meats contaminated with Listeria Monocytogones were recalled in 1998."*** *(In response to CDC figures of 76 million illnesses, 325,000 hospitalizations and 5,000 deaths associated with known food borne pathogens each year in the United States.)* - Dr. Donald Thayer, Department of Agriculture - Agriculture Research Service, Retired.

"Consumers should be demanding that irradiation be added to the arsenal of techniques routinely used to safeguard our food supply." - Dr. Elizabeth Whelan, President, American Council on Science and Health.

> ***"Irradiation, like pasteurization, could be one of the most important public health technologies, preventing globally millions of episodes of food borne illness and tens of thousands of deaths."-*** Dr. Fritz Kaferstein, Distinguished Visiting Scientist, Joint Institute for Food Safety and Applied Nutrition.

"Irradiation is the only safe, proven, non-thermal treatment to 'eliminate' the risk posed by pathogenic bacteria and parasites in raw foods of animal origin." - Ricardo Molins, Food Chemicals Codex, The National Academies Institute of Medicine.

> ***"High dose irradiated foods are indeed as safe as food materials sterilized by thermal processing, which humans have been eating for over a century ... food irradiated to any dose to achieve the intended technological objective is both safe to consume and nutritionally adequate..."*** - Joint FAO/IAEA/WHO Study Group on High Dose Irradiation.

"Most of the safety legislation this far for the meat industry includes closing down plants, but we want to discuss if irradiation of food, specifically of meat, might be more effective. People are going to be unhappy about something. I'm more unhappy about E. coli and its effect on people." *(Referring to those who have opposed irradiation of meat)* - Sen. Richard Lugar, Chairman, Senate Agriculture Committee.

> ***"Given these reassuring conclusions, the World Health Organization hopes that food irradiation will now become more acceptable as a means for the improvement of food safety."*** - Fernando Antezana, WHO Assistant Director General.

"I think it's just a matter of time before the food industry realized the public health risk of having these kind of E. coli outbreaks is greater than the risk of some consumers and activist groups boycotting their products. In the St. Paul Pioneer Press. Not a single credible science organization in the world that has looked at this has not endorsed it." - Dr. Michael T. Osterholm, former Minnesota State Epidemiologist; Mayo Health Oasis.

> ***"You can't erase decades of scientific substantiation. From the American Medical Association to the World Health Organization, the mainstream scientific and medical community around the globe has attested to the safety of irradiation."*** - Dr. Lester Crawford, Former Commissioner, Food and Drug Administration (FDA) and former Director of the Georgetown Center for Food and Nutrition Policy, former Administrator at the USDA's Food Safety and Inspection Service and former Director of FDA's Center for Veterinary Medicine.

"The bottom line is that food irradiation can help save lives. Acceptance of pasteurization was long delayed because of fear mongering and misinformation. We should not let that happen with food irradiation." - Lisa Katic, a registered dietician and GMA Director, Scientific and Nutrition Policy.

> ***"NFPA and the food industry support food irradiation as a safe and effective technology that benefits consumers by enhancing the safety of the U.S. food supply."*** - Dr. Jeffrey Barach, VP Special Projects, National Food Processors Association.