GROCERY MANUFACTURERS ASSOCIATION
SCIENCE POLICY PAPER

Food Irradiation

A GUIDE FOR CONSUMERS, POLICYMAKERS AND THE MEDIA

GMA

The Association of Food, Beverage and Consumer Products Companies

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The **Grocery Manufacturers Association (GMA)** represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of chief executive officers from the Association's member companies. The $2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, and contributes over $1 trillion in added value to the nation's economy. For more information, visit the GMA website at **www.gmaonline.org**.

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List of Acronyms

APHIS — Animal Plant Health Inspection Service

CAC — Codex Alimentarius Commission

CDC — Centers for Disease Control and Prevention

EC — European Commission

FAO — Food and Agriculture Organization

FDA — Food and Drug Administration

FIPA — Food Irradiation Processing Alliance

FSIS — Food Safety and Inspection service

GAO — General Accounting Office

IAEA — International Atomic Energy Agency

ICGFI — International Consultative Group on Food Irradiation

NASA — National Aeronautics and Space Administration

NRC — Nuclear Regulatory Commission

USDA — United States Department of Agriculture

WHO — World Health Organization

FOREWORD

This paper addressing food irradiation is one in a series published by the Grocery Manufacturers Association (GMA) to evaluate and explore the science behind some of the most talked about food-related issues of importance to consumers and policymakers.

The Grocery Manufacturers Association represents the world's leading food, beverage and consumer products companies. The Association promotes sound public policy, champions initiatives that increase productivity and growth, and helps to protect the safety and security of the food supply through scientific excellence. One of the Association's goals is to ensure that the laws and regulations governing food marketing and production are feasible, practical and based on sound information.

Each of our science policy papers includes a review of key scientific peer-reviewed published articles, regulatory considerations, food and beverage applications and market insights. The Association's goal in publishing these white papers is to provide current, scientifically accurate resources to journalists, health professionals, policy makers, interested consumers and other stakeholders.

For more information, visit the Grocery Manufacturers Association website at **www.gmaonline.org/science/index.cfm**. ■

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EXECUTIVE SUMMARY

Food safety is a subject of critical importance to consumers. While the U.S. food supply is generally considered to be one of the safest in the world, foodborne illness continues to be a source of concern for consumers. Each year, millions of Americans become ill from foodborne infections and up to 5,000 people die. The United States Department of Agriculture (USDA) estimates that diseases caused by seven major foodborne pathogens could result in medical costs and productivity losses of between $6.6 billion and $37.1 billion annually. Furthermore, recalls of contaminated food—such as the massive recalls of thousands of pounds of ground beef contaminated with *Escherichia coli* O157:H7 have resulted in severe economic losses to the affected industry. There is no silver bullet on the horizon to eliminate foodborne illness.

Scientists, regulators and lawmakers, working to determine how best to combat foodborne illness, are encouraging the use of new technologies that can enhance the safety of the nation's food supply. Many food safety experts believe that irradiation can be a safe and effective tool in helping to control foodborne pathogens and should be incorporated as part of a comprehensive program to enhance food safety. Irradiation, which involves exposing food briefly to radiant energy (such as gamma rays, high-energy electrons or X-rays), can reduce or eliminate microorganisms that cause foodborne disease. Other benefits of food irradiation include extending the shelf life of certain foods, and controlling insect infestation in grain products, fruits and vegetables. The technology has been used routinely for more than 30 years to sterilize medical, dental and household products.

However, irradiation at the approved doses does not sterilize food nor does it make it shelf-stable (i.e., capable of being stored without refrigeration). Irradiation is not a substitute for proper food manufacturing and handling procedures.

Concerns on the part of food processors, retailers and others about consumer acceptance of irradiated foods have limited their efforts to introduce irradiated products. Consumer education will play a crucial role in promoting the acceptance of irradiated foods. Studies have shown that consumers are willing to buy irradiated food if the purpose of irradiation is clearly understood. They are also willing to pay a premium for a safer product.

Food treated by irradiation is generally as nutritious as, or better than, the same food treated by conventional processes such as cooking, drying or freezing. Irradiation has no significant effect on macronutrients, such as proteins, lipids and carbohydrates. Micronutrients, especially certain vitamins, may be reduced by irradiation, but generally these same vitamins are similarly reduced by the other commonly used food processing methods or by simple storage. Scientific studies have shown that irradiation of many foods according to a validated protocol does not significantly change food taste, texture or appearance. 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.

Several extensive reviews of toxicological data by regulatory and health organizations, including the U.S. Food and Drug Administration (FDA, 1986), Health Canada (2003), the Codex Alimentarius Commission (CAC, 1983), and the European Commission's Scientific Committee in Food (EC, 2003) have determined that food irradiated at doses below 10 kGy is safe. In fact, food is safer after being irradiated because the process destroys harmful bacteria that may be present. Food irradiation is endorsed by national and international food and public health organizations, such as the American Medical Association, the American Dietetic Association, the American Council on Diet and Health, the U.S. Public Health Service, the Mayo Clinic, the Center for Disease Control and Prevention and the World Health Organization.

There is no evidence of unusual amounts of toxic compounds formed in irradiated foods. Numerous studies have failed to produce evidence for the carcinogenicity and mutagenicity of irradiated foods, or for any other long-term adverse health effects associated with the consumption of irradiated foods.

Irradiated foods do not become radioactive. As the energy passes through the food, it only kills the bacteria, leaving no residue. Irradiation facilities are subject to strict federal and state regulations. In North America, in over four decades of transporting the types of radioactive isotopes used for irradiation, there has never been an accident resulting in the escape of radioactive materials into the environment.

The Food and Drug Administration has approved the irradiation of meat and poultry and allows its use for a variety of other foods, including fresh fruits and vegetables, and spices. More recently, the FDA has approved the irradiation of fresh spinach and iceberg lettuce for pathogen control and extension of shelf life. Food irradiation is approved in nearly 40 countries worldwide. The FDA currently requires that labels on irradiated foods contain an identifying symbol called a "radura" (pictured at left), surrounded by the words "treated with radiation" or "treated by irradiation".

Package symbol identifying irradiated foods.

Packaging materials irradiated in contact with food are subject to pre-market approval by the FDA and may be used only if they comply with the existing regulations. Testing and approving a wider array of packaging materials will be critical for the successful commercialization of irradiated foods. ■

PRINCIPLES OF FOOD IRRADIATION

Food irradiation is a process in which food products are exposed to a controlled amount of radiant energy to kill harmful bacteria such as *E. coli* O157:H7, *Campylobacter*, *Listeria* and *Salmonella*. The process can also control insects and parasites, reduce spoilage and inhibit ripening and sprouting.

Food is packed in containers and moved by conveyer belt into a shielded room. There the food is exposed briefly to a radiant energy source; the amount of energy depends on the type and amount of food. Energy waves passing through the food generate reactive ions, free radicals and excited molecules. These in turn chemically attack essential biomolecules, such as nucleic acids (DNA, RNA), membrane lipids, proteins, and carbohydrates of bacteria, other pathogens, and insects causing damage to them. As a result, these organisms die or, unable to reproduce, their numbers are held down. Food is left virtually unchanged, but harmful bacteria, parasites and fungi are greatly reduced in number or eliminated completely. Similar technology is used to sterilize medical devices so they can be used in surgery or implanted without risk of infection.

The dose of irradiation is usually measured in a unit called the Gray, abbreviated Gy. This is a measure of the amount of energy transferred to food, a microbe or other substance being irradiated (1 Gy = 1 Joule/kg). Parasites and insect pests, which have large amounts of DNA, are rapidly killed by extremely low doses of irradiation, with D-values* of 0.1 kGy (kiloGray) or less. It takes more irradiation to kill bacteria, because they have a somewhat smaller DNA, with D-values in the range of 0.3 to 0.7 kGy. Bacterial spores are more difficult to kill, with D-values on the order of 2.8 kGy. Viruses are the smallest pathogens that have nucleic acid, and they are in general resistant to irradiation at doses approved for foods. They may have D-values of 10 kGy or higher. Irradiation is not effective against prions, which are misfolded protein particles with no DNA (Satin, 1996; Molins, 2001).

This means that irradiation will work very well to eliminate parasites, insects and bacteria from food, but will not work to eliminate viruses. However, recent studies suggest that, depending on the food matrix, viruses can become sensitive to electron beam radiation (see below) at levels significantly lower than those produced with cobalt-60 irradiation (Pillai and Espinosa, 2003).

To measure the dose of irradiation of a product, a photographic film is exposed to the irradiation at the same time. The film fogs at a rate that is proportional to the irradiation level.

Three different irradiation technologies exist: gamma rays, electron beams and X-rays.

Gamma rays use the radiation given off by a radioactive substance (Cobalt-60 or Cesium-137), which can penetrate foods to a depth of several feet. These particular substances do not give off any neutrons, which mean that they do not make anything around them radioactive. Irradiation of food takes place in a chamber with massive concrete walls that keep any rays from escaping. This technology has been used routinely for more than 30 years to sterilize medical, dental and household products, and it is also used for radiation treatment of cancer.

Electron beams are streams of high energy electrons, propelled out of an electron gun. This electron gun apparatus is a larger version of the device in the back of a TV tube that propels electrons into the TV screen at the front of the tube, making it light up. This electron beam generator can be simply switched on or off. No radioactivity is involved. The electrons can penetrate food only to a depth of three centimeters, or a little over an inch, so the food to be treated must be no thicker than that to be treated all the way through. Two opposing beams can treat food that is twice as thick. Electron beam medical sterilizers have been in use for at least 15 years.

X-ray irradiation is the newest technology, and is still being developed. The X-ray machine is a more powerful version of the machines used in many hospitals and dental offices to take X-ray pictures. To produce the X-rays, a beam of electrons is directed at a thin plate of gold or other metal, producing a stream of X-rays coming out the other side. Like gamma rays, X-rays can pass through thick foods, and require heavy shielding for safety. No radioactive substances are involved. Several commercial X-ray irradiation units have been built in the world since 1996 (Molins, 2001; CDC, 2008).

BENEFITS OF FOOD IRRADIATION

Pathogen Reduction

According to numerous studies conducted worldwide over more than 50 years, irradiation, within approved dosages (typically 1–10 kGy), has been shown to destroy at least 99.9 percent of common foodborne organisms, including pathogens such as *Salmonella* (various species), *Campylobacter jejuni*, *Escherichia coli* O157:H7 and *Listeria monocytogenes*, which are associated with meat and poultry. It is also effective against *Vibrio* species

* Decimal reduction value or the dose of radiation which causes a 10-fold reduction in the numbers of a given microorganism.

associated with seafood and against parasites, such as *Toxoplasma gondii* (found in many animal species) and *Trichinella spiralis* (found in pork). Unfortunately, irradiation is not particularly effective against microbial toxins and toxins produced by molds (mycotoxins).

However, irradiation at the approved doses does not sterilize food nor does make it shelf stable (i.e., capable of being stored without refrigeration). The radiation doses used to treat meat and poultry typically achieve 10,000 to 1,000,000-fold reductions of the bacterial load, comparable to heat-pasteurization. Officials from the Food and Drug Administration (FDA) and others emphasize that irradiation does not replace proper food handling; irradiated food must still be properly refrigerated and cooked prior to consumption. Because of irradiation's effectiveness in controlling common foodborne pathogens and in treating packaged food (thereby minimizing the possibility of cross-contamination prior to consumer use), federal regulatory agencies and the Food Chemicals Codex at the National Academies Institute of Medicine view irradiation as an effective critical control point in a Hazard Analysis and Critical Control Points (HACCP) system. Appropriate radiation doses are well-known, and compliance can be monitored by accurately measuring the absorbed radiation dosage.

Spoilage Reduction

Low doses of radiation (typically up to 1 kGy) can prolong the shelf life of many fruits and vegetables by reducing spoilage bacteria and mold, and by inhibiting sprouting and maturation. As a result, products can be harvested when fully ripened and can be transported and displayed for longer periods while maintaining desirable sensory qualities longer than non-irradiated products. For example, according to the Council for Agricultural Science and Technology, irradiating strawberries extends their refrigerated shelf-life to up to three weeks without decay or shrinkage, versus three to five days for untreated berries (Thayer et al., 1996).

Irradiation can also be used as an alternative to chemical sprout inhibitors for tubers, bulbs, and root crops. These inhibitors are considered by some to be harmful, and many countries have prohibited their use. The softening and browning associated with the ripening of certain fruits and vegetables, such as bananas, mangoes, and mushrooms, can be delayed with irradiation.

Insect and Microorganism Control

Irradiation is also an effective means to decontaminate certain food products. Spices, herbs and dry vegetable seasonings, which are among the most commonly irradiated food products in the United States, are frequently dried in the open air and become severely contaminated by air- and soil-borne microorganisms and insects. Food processors often fumigate these commodities with ethylene oxide to reduce or eliminate pathogens and sometimes treat with methyl bromide to reduce insects. An alternative to the use of chemical products would be to use irradiation.

Low doses of irradiation (up to 1 kGy) are effective against insects. Irradiation can be used as a pest control treatment on quarantined fruits and vegetables to prevent the importation of harmful pests, such as the Mediterranean fruit fly. To minimize this risk, the United States Department of Agriculture (USDA)'s Animal and Plant Health Inspection Service's (APHIS) quarantine procedures require the use of fumigation or heat (hot water or hot air) or cold treatment of fruit that is not ripe. Irradiation treatment is an effective alternative for many types of fresh produce because it can be used on riper fruit and on fruit that cannot tolerate heat treatment. Moreover, a number of past quarantine treatments have recently been prohibited, an example being fumigation with ethylene dibromide. In 1997, APHIS issued a final rule allowing the use of irradiation as a quarantine treatment for papayas, carambola and litchi coming from Hawaii to the U.S. mainland. In May 2000, APHIS proposed a rule to allow irradiation for use in killing fruit flies and mango seed weevils on fruits and vegetables imported into the United States. If approved, this rule will further expand the use of irradiation in pest control (ICGFI, 1999a; GAO, 2000; Tauxe, 2001; FIPA, 2006).

Higher doses of irradiation can also be used to greatly reduce the non-pathogenic microorganism and bacterial spore load of dried spices, herbs and dry vegetable seasonings. In the U.S., these products can be irradiated up to levels of 30 kGy for this purpose. In multi-ingredient foods, spoilage prevention and microorganism control is achieved more easily when spices are pre-treated by irradiation.

AVAILABILITY AND CONSUMER ACCEPTANCE OF IRRADIATED FOODS

To date, only limited amounts of irradiated foods have been sold in the United States. Concerns on the part of food processors, retailers and others about consumer acceptance of irradiated foods have contributed to their limited availability to date. Some wholesale and retail markets, primarily in Florida and several midwestern states have sold irradiated fruits and vegetables since the early 1990s. Irradiated poultry and ground beef is available in some grocery stores independent markets and on menus of a few restaurants. Irradiated frozen ground beef is marketed in several midwestern states and Florida and nationally by several retailers. American astronauts have eaten irradiated foods in space since the early 1970s.

Irradiated spices, herbs and dry vegetable seasonings constitute the largest category of irradiated food; about 175 million pounds of these products were irradiated in 2007, accounting for about 20 percent of their total consumption.

A major purchaser of irradiated foods are health care and food service establishments, which purchase them primarily to minimize the threat of foodborne illness. For example, nursing homes and hospitals serve irradiated poultry to patients with weakened immune systems to reduce the risk of contracting a foodborne illness that would further jeopardize their condition (ICGFI, 1999b).

Irradiated ground beef became an option for school lunches in January 2004. The product comes at a premium ($0.13–0.20/lb.), and the decision to use it resides with individual districts (USDA, 2003).

Studies show that consumers are becoming more interested in irradiated foods. For example, the University of Georgia created a mock supermarket setting that explained irradiation and found that 84 percent of participating consumers said irradiation is “somewhat necessary” or “very necessary”. Consumer research conducted by a variety of groups, including the American Meat Institute, the International Food Information Council, the Food Marketing Institute and the Grocery Manufacturers Association has found that between 45 percent and 90 percent of the consumers polled would buy irradiated foods. The acceptance of irradiated foods is greatly increased if the purpose of the irradiation is clearly indicated (Fox, 2002).

The slightly increased cost of production of irradiated foods is offset in some cases by the savings resulting from an extended shelf life. 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. According to Nayga et al. (2004), consumers are willing to pay premiums ranging from $0.05 to $0.50/lb. depending on their level of concern and awareness and the provision of sufficient background information.

Nutritional Value of Irradiated Foods

Food treated by irradiation is generally as nutritious as, or better than, the same food treated by the conventional processes such as cooking, drying or freezing. Irradiation has no significant effect on macronutrients, such as proteins, lipids and carbohydrates. Micronutrients, especially certain vitamins (e.g. thiamine, ascorbic acid, retinol and α-tocopherol), can be reduced by irradiation, but generally these same vitamins are similarly reduced by the other commonly used food processing methods or by simple storage. The use of vacuum packaging can reduce the loss of retinol and α-tocopherol upon irradiation. Irradiation at cold temperatures also diminishes vitamin losses. 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, and relative to the natural variation of the level of that particular vitamin in that particular type of food (WHO, 1994; Smith and Pillai, 2004).

In a recent study (Fan, 2005), three varieties of irradiated lettuce contained higher levels of antioxidants and phenols (desirable micronutrients) than controls, i.e. irradiation in this case improved the nutritional quality of the food (even though it caused enhanced browning, probably due to the increased phenolic content).

The U.S. Food and Drug Administration, the World Health Organization and the American Dietetic Association have all considered the nutritional value of irradiated foods and have endorsed the process.

Sensory Quality of Irradiated Foods

Scientific studies have shown that irradiation of many foods according to a validated protocol does not significantly change food taste, texture or appearance. Most consumers can’t detect any change in sensory properties upon irradiation. 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. The sensory properties of ground beef have not been affected by irradiation at doses up to 3 kGy (Murano et al., 1998; Vickers and Wang, 2002). Similarly, no significant sensory changes have been noticed in irradiated boneless pork chops at doses up to 2.5 kGy (Luchsinger et al., 1996). Celery irradiated at 1 kGy was judged by a sensory panel to be superior in sensory quality to celery preserved by other methods (blanching, acidification and chlorination), and to untreated celery (Prakash et al., 2000).

Some foods treated by irradiation may taste slightly different, just as pasteurized milk tastes slightly different from unpasteurized milk. Poultry and pork can be sensitive to flavor and color (pinking) changes (Houser et al., 2003; Nam and Ahn, 2002); however in at least one instance, consumers have shown preference for the pink color (Lee at al., 2003). Processing techniques, such as packaging and the use of antioxidants could potentially improve these meat characteristics.

Sensory effects of irradiation on fruits, vegetables and juices are likely to be highly variety-specific (Niemira, 2003). Certain foods (e.g., eggs, milk, diary products, and some fruits and vegetables) are considered unsuitable for irradiation due to the strong off-flavors they develop upon radiation processing (WHO, 1999).

Safety of Irradiated Foods

Several extensive reviews of toxicological data by regulatory and health organizations, including the U.S. Food and Drug Administration (FDA, 1986), Health Canada (2003), the Codex Alimentarius Commission (CAC, 1983), and the European Commission's Scientific Committee on Food (EC, 2003) have determined that food irradiated at doses below 10 kGy is safe. In fact food is safer after being irradiated because the process destroys harmful bacteria that may be present. Food irradiation is endorsed by national and international food and public health organizations, such as the American Medical Association, the American Dietetic Association, the American Council on Diet and Health, the U.S. Public Health Service, the Mayo Clinic, the Center for Disease Control and Prevention and the World Health Organization.

Numerous published research studies have tried to identify problems resulting from eating irradiated foods but failed to disclose 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 reviewed the studies that claimed various possible health risks and determined that these studies either were lacking the proper scientific protocols or could not be duplicated by other scientists (Diehl, 1995). A comprehensive review of scientific studies on the effects of irradiation on food was released by the World Health Organization in 1999 (WHO, 1999).

Chemical Changes in Irradiated Foods

Irradiation can produce changes in food, similar to changes caused by cooking, but in smaller amounts. With few exceptions, the chemical identities of the radiolytic products (hydrocarbons, aldehydes and ketones) are identical to those generated 'thermolytically' by heating food, while their levels are generally much lower. Alkylcyclobutanones (ACBs) appear to be unique radiolytic products since they have not been found in raw or heat-processed foods as yet (Smith and Pillai, 2004). Despite several studies, the purported genotoxicity of ACBs has not been demonstrated (EC, 2003; Health Canada, 2003).

Very low concentrations of benzene (a known carcinogen at high doses) 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. 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. Scientific studies have conclusively demonstrated that irradiated foods do not cause cancer (Chinn, 1979).

Recent studies have indicated that irradiation of fresh fruits and vegetables and apple cider generates small amounts of furan (a known rodent carcinogen at high doses). Amounts of furan formed by irradiation of produce are less than amounts formed when foods are processed by heat, or even the background levels which are formed during refrigerated storage (Fan and Geveke, 2007; Fan and Sokorai, 2008).

Mutagenicity of Irradiated Foods

There is no evidence that free radicals produced in radiation processing affect the safety of food. There are more free radicals in a piece of toast than in a piece of irradiated food (FIPA, 2006).

Studies have failed to bring forth evidence for the mutagenicity of irradiated foods in the Ames test or in feeding trials to test animals. There is no evidence or reason to expect that irradiation produces more virulent pathogens among those that survive irradiation treatment (Diehl, 1995).

Do Irradiated Foods Become Radioactive?

Irradiated foods do not become radioactive. As the energy passes through, it only kills the bacteria, leaving no residue. 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, and leaves the food virtually unchanged. Since the energy involved in irradiation is not strong enough to cause changes at the atomic level, and since the food is never in contact with a radioactive source, the food can not become radioactive (FIPA, 2006).

Worker and Environmental Safety

Worker and environmental safety issues, particularly with respect to the use of cobalt-60 (a source of gamma rays) in food irradiation, have also raised concerns. However, irradiation facilities are subject to strict federal and state regulations. Facilities using radioactive sources are regulated by the Nuclear Regulatory Commission (NRC). Electron beam and X-ray sources are monitored by the part of the FDA that regulates medical X-ray devices. Worldwide, over the past 30 years, while several accidents have injured or killed workers because of radiation exposure, all of these accidents occurred because safety systems and control procedures had been bypassed. Furthermore, in North America, in over four decades of transporting the types of radioactive isotopes used for irradiation, there has never been an accident resulting in the escape of radioactive materials into the environment (Diehl, 1995; FIPA, 2006).

Identification and Detection of Irradiated Foods

Several detection methods for irradiated foods are available. Electron spin resonance (ESR) measures the concentration of free radicals in irradiated matter (e.g., foods containing bones, shells or other particles). Thermoluminescence (TL) measures light emission by excited molecules upon heating material and is suitable for foods containing mineral dust particles. Chemical methods (gas- and liquid chromatography) measure volatile radiolytic products such as alkanes, alkenes and 2-alkylcyclobutanones, or non-volatile compounds such as 6-ketocholesterol and o-tyrosine (especially in fatty foods). A number of DNA-based and biological screening methods are also available (Molins, 2001).

Irradiation and Food Packaging

Packaging materials irradiated in contact with food are subject to pre-market approval by the FDA and may be used only if they comply with the existing regulations. Packaging materials approved for use during irradiation of prepackaged foods are listed in Table 1. These packaging materials do not generally meet today's needs as do newer materials that may be more desirable to the food industry. However, many of these newer packaging materials have not yet been evaluated by FDA. Testing and approving a wider array of packaging materials will be critical for the successful commercialization of irradiated foods.

Most food packaging materials are composed of polymers that may be susceptible to chemical changes induced by ionizing radiation that are the result of two competing reactions, cross-linking (polymerization) and chain scission (degradation). Radiation-induced cross-linking of polymers dominates under vacuum or an inert atmosphere. Chain scission dominates during irradiation of polymers in the presence of oxygen or air and can results in the presence of polymer fragments (oligomers) in the irradiated food (FDA, 2007b).

TABLE 1. Packaging materials approved for use during irradiation of prepackaged foods

Packaging Material	Max Dose [kGy]
Nitrocellulose-coated cellophane	10
Glassine paper	10
Wax-coated paperboard	10
Polyolefin film	10
Kraft paper	0.5
Polyethylene terephthalate film (basic polymer)	10
Polystyrene film	10
Rubber hydrochloride film	10
Vinylidene chloride-vinyl chloride copolymer film	10
Nylon 11 [polyamide-11]	10
Ethylene-vinyl acetate copolymer	30
Vegetable parchment	60
Polyethylene film (basic polymer)	60
Polyethylene terephthalate film	60
Nylon 6 [polyamide-6]	60
Vinyl chloride-vinyl acetate copolymer film	60

In addition to the base polymers, additives such as antioxidants, stabilizers, plasticizers and colorants are prone to degradation during polymer processing and, especially during irradiation, as they degrade preferentially over the polymer and could result in radiolytic products migrating into food. Absorbent pads (widely used for refrigerated, uncooked meat, poultry, pork and seafood products) can also generate radiolytic products upon irradiation. Radiolytic products are typically low molecular weight alcohols, aldehydes, ketones, acids and hydrocarbons. These radiolytic products can potentially affect the organoleptic properties of the food or raise safety concerns (FDA, 2007b). The dietary exposures to most radiolytic products formed in several irradiated polymers were determined to be < 0.5 µg/kg in the daily diet, less than the threshold of regulation concern level (Paquette, 2004).

The migration of both base polymers and additives, as well as migration of their radiolytic products must be evaluated in the pre-market safety assessment of a packaging material in contact with food during irradiation.

REGULATORY STATUS OF FOOD IRRADIATION

Food irradiation has already gained approval in more than 37 countries worldwide.

In the United States, the Food and Drug Administration (FDA) has primary regulatory responsibility for ensuring the safe use of irradiation on all foods. At the same time, the United Stated Department of Agriculture (USDA)'s Food Safety and Inspection Service (FSIS) is responsible for the lawful processing of meat, poultry and some egg products. Hence the two agencies have overlapping responsibilities for ensuring the safety of certain irradiated foods. To date, irradiation has been approved by the FDA (and the USDA, where applicable) for use on uncooked meat and poultry and fresh shell eggs, as well as a variety of other foods, including spices and fresh fruits and vegetables (Table 2). Final approval for the irradiation of meat (including ground beef) took effect in February 2000. Ground beef poses particular food safety concerns because the grinding process can spread pathogens present on the meat's surface throughout the product. This action has heightened interest in using irradiation to reduce food-borne pathogens (FDA, 2001; USDA, 2001).

A petition seeking approval of irradiation for enhancing the safety of several ready–to-eat foods was submitted to the FDA by an industry coalition and notice published in 2000. This coalition was organized by the National Food Processors Association (now the Grocery Manufacturers Association—GMA). In the wake of the 2006 *E. coli* outbreak from spinach, which killed three people and sickened nearly 200, plus a list of lettuce recalls, GMA worked with the FDA to narrow the scope of the petition to rule on the leafy greens first. As a result, effective Aug. 22, 2008, the FDA approved the irradiation of fresh spinach and iceberg lettuce for pathogen control and extension of shelf-life at doses up to 4.0 kGy, a key safety move amid increasing outbreaks from raw produce (FDA, 2008). GMA is pursuing approvals for irradiation of additional ready-to-eat foods through further consultations with FDA.

TABLE 2. Overview of the regulatory approval of irradiation on various foods in the United States (FDA, 2007a).

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	Control of *Trichinella spiralis* parasites
1986	Fruit and Vegetables	1.0 kGy	Insect control, extend shelf-life
1986	Herbs and Spices	30 kGy	Sterilization
1990—FDA	Poultry	3 kGy	Bacterial pathogen reduction
1992—USDA	Poultry	1.5-3.0 kGy	Bacterial pathogen reduction
1997—FDA 2000—USDA	Meat (frozen)	4.5 kGy (7.0 kGy)	Bacterial pathogen reduction
2000—FDA	Shell eggs	3 kGy	Bacterial pathogen reduction
2000—FDA	Seeds for sprouting	8 kGy	Bacterial pathogen reduction
2001—FDA	Packaging equivalency for electron beam and X-ray	Levels as used for gamma sources	Allow gamma approved packages for other sources
2005—FDA	Molluscan shellfish	5.5 kGy	Bacterial pathogen reduction
2008—FDA	Fresh iceberg lettuce and spinach	4.0 kGy	Bacterial pathogen reduction and shelf-life extension

Since the sensory qualities of fresh produce in general are easily affected by irradiation, the most promising approaches combine low-dose irradiation (achieving a 100 to 10,000-fold reduction in bacterial load) with other anti-bacterial treatments. The best combinations of measures are likely to be highly specific for food variety and pathogen to be controlled. While much work has been done already, it is important to prioritize future studies and products that need to be evaluated by their implication in outbreaks and/or volume of consumption. Another issue is related to some of the packaging materials used for produce today, which have not been tested from a chemical migration standpoint. (Groth, 2007; Fan et al., 2008).

Most major U.S. food-related consumer groups cautiously support or are neutral on the use of food irradiation, particularly for vulnerable populations. However, a few groups, such as Public Citizen and Food and Water Watch, oppose its use because they believe that the FDA has not sufficiently proven that irradiation can safely be used on food and that more long-term research on the effects of consuming irradiated food is needed. A common concern often stated by those who oppose food irradiation is that it would be used as an alternative to proper food processing plant sanitation and cleanliness practices (Smith and Pillai, 2004; Fan et al., 2008).

LABELING OF IRRADIATED FOODS

FDA Labeling Requirements

The FDA currently requires that labels on irradiated foods contain an identifying symbol called a "radura" (pictured below), surrounded by the words "treated with radiation" or "treated by irradiation". A number of labeling statements about the purpose of radiation processing have been authorized for use on labeling in conjunction with the radura in addition to or instead of "Treated with radiation" or "Treated by irradiation". Examples are: "Irradiated for food safety" and "Treated with irradiation for food safety".

Foods that contain irradiated spices or foods served in restaurants do not have to be identified as being irradiated (FDA, 2001).

If finalized, a proposed rule by FDA would allow companies to label irradiated food with the word "pasteurization". In addition, if an irradiated product displayed no "material change" due to processing, labeling may not be required at all.

USDA Labeling Requirements

Irradiated beef can be listed in the ingredients statement either as "Irradiated beef," or "Beef, treated by irradiation." An irradiated meat or poultry component used in a multi-ingredient product needs to be labeled as "irradiated" in the ingredients statement of the multi-ingredient product, even if the finished product is also irradiated.

Irradiated, single ingredient meat or poultry can be labeled "all," "pure", or "100%". An irradiated product can not be labeled as "natural" since irradiation is considered to be more than minimal processing. Nor can irradiated products be labeled "certified Organic by (a certifying entity)" (USDA, 2003).

Summary

1. Irradiation is an effective way to enhance the safety of the nation's food supply. It can help prevent food-borne illness, control insect infestation and extend product shelf life.
2. Irradiated foods are safe, wholesome and nutritious. Irradiation is endorsed by federal regulatory agencies and numerous national and international health organizations.
3. The Food and Drug Administration (FDA) has approved the irradiation of meat and poultry, and recently fresh spinach and iceberg lettuce, and allows its use for a variety of other foods, including fresh fruits and vegetables and spices.
4. Consumer education is needed to enhance the acceptance of irradiated foods by the public.

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