CHAPTER 1

Legislation on Food Irradiation

European Union, United States, Canada, and Australia

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1.1 Introduction

Irradiation is a physical treatment in which food is exposed to a defined dose of ionizing radiation and is used on more than 60 food types in more than 40 countries worldwide. Irradiation of food can control insect infestation, reduce the numbers of pathogenic or spoilage microorganisms, and delay or eliminate natural biological processes such as ripening, germination, or sprouting in fresh food. Like all preservation methods, irradiation should supplement rather than replace good food hygiene, handling, and preparation practices (Food Safety Authority of Ireland [FSAI], 2005).

In 1986, 1992, and 1998, the Scientific Committee on Food (SCF) expressed favorable opinions on irradiation of fruit, vegetables, cereals, starchy tubers, spices and condiments, fish, shellfish, fresh meats, poultry, camembert from raw milk, frog legs, gum arabic, casein/caseinates, egg white, cereal flakes, rice flour, and blood products. The SCF emphasized that food irradiation must not be used to cover negligence in handling foodstuffs or to mask their unsuitability for use as food (European Union [EU], 2007).

Food irradiation is the exposure of food to a form of energy called ionizing radiation. The technique is used to reduce the losses of spoilage and to control microbes and other organisms in food (Confederation of British Industry, 2007). Radiation is an energy form traveling through space (radiant energy) in a wave pattern and can either be naturally occurring (e.g., from the sun or rocks) or produced by man-made objects (e.g., microwaves and television sets). The frequency or wavelength of the energy waves produced by different sources distinguishes the different types and functionality of radiation, with high-frequency radiation of UV, X-rays, and gamma-rays posing the most significant risk to human health (FSAI, 2005). In specific cases, irradiation of food is permitted. In the EU, this is regulated by EU Directives 1999/2/EC and 1999/3/EC (EU, 2007).

Irradiation of Food Commodities

Food irradiation in the United States is primarily regulated by the Food and Drug Administration (FDA, 1986) because it is considered a food additive. Other federal agencies that regulate aspects of food irradiation include the U.S. Department of Agriculture/Food Safety and Inspection Service (2006), which regulates meat and poultry products and fresh fruit; the Nuclear Regulatory Commission, which regulates safety of the processing facility; and the Department of Transportation, which regulates the safe transport of the radioactive sources. Each new food is approved separately with a guideline specifying a maximum dosage; in case of quarantine applications, the minimum dose is regulated. Packaging materials containing the food processed by irradiation must also undergo approval (Wikipedia, 2008).

1.2 EU Legislation

Directive 1999/2/EC (entry into force March 10, 1999) applies to the manufacture, marketing, and importation of foods and food ingredients, hereafter called "foodstuffs," treated with ionizing radiation. It does not apply to: (i) foodstuffs exposed to ionizing radiation generated by measuring or inspection devices, provided that the dose absorbed is not greater than 0.01 Gy for inspection devices that utilize neutrons and 0.5 Gy in other cases, at a maximum radiation energy level of 10 MeV in the case of X-rays, 14 MeV in the case of neutrons, and 5 MeV in other cases; and (ii) the irradiation of foodstuffs that are prepared for patients requiring sterile diets under medical supervision. Member States may maintain existing authorizations concerning the treatment of foodstuffs with ionizing radiation provided that: (i) the treatment of the foodstuff concerned has been subject to a favorable opinion of the SCF; (ii) the overall average absorbed radiation dose does not exceed the limit values recommended by the SCF; and (iii) ionizing radiation and placing on the market are effected in accordance with this directive. Foodstuffs may be treated only by the following sources of ionizing radiation: (i) gamma rays from radionuclides cobalt-60 (^{60}Co) or cesium-137 (^{137}Cs); (ii) X-rays generated from machine sources operated at or below a nominal energy (maximum quantum energy) level of 5 MeV; and (iii) electrons generated from machine sources operated at or below a nominal energy (maximum quantum energy) level of 10 MeV. Food irradiation may be used only for the following purposes: (i) to reduce the incidence of foodborne disease by destroying pathogenic organisms; (ii) to reduce spoilage of foodstuffs by retarding or arresting decay processes and destroying spoilage organisms; (iii) to reduce loss of foodstuffs by premature ripening, germination, or sprouting; and (iv) to get rid of foodstuffs of organisms harmful to plant or plant products. Member States shall inform the commission of the competent authority or authorities responsible for: (i) prior approval of irradiation facilities; (ii) the allocation of an official reference number for approved irradiation facilities; (iii) official control and inspection; and (iv) withdrawal or modification of approval. The labeling of foodstuffs treated with ionizing radiation shall be governed by the specific provisions. Such a foodstuff may not be imported from a third country unless it complies with the conditions that

apply to those foodstuffs, is accompanied by documents showing the name and address of the facility that carried out the irradiation treatment, and was treated in an irradiation facility approved by the Community.

Directive 1999/3/EC (entry into force March 10, 1999) laid down the establishment of a Community initial positive list of food and food ingredients, which may be treated with ionizing radiation, together with the maximum doses authorized for the intended purpose. Treatment of the products in question with ionizing radiation may be carried out only in accordance with the provisions of the framework directive. The foodstuffs that may be treated with ionizing radiation are dried aromatic herbs, spices, and vegetable seasonings. The maximum overall average absorbed radiation dose should be 10 kilogray (kGy).

Regulation (EEC) No. 3954/87 (entry into force January 2, 1988) laid down the procedure for determining the maximum permitted levels of radioactive contamination of foodstuffs and of feeding stuffs that may be placed on the market following a nuclear accident or any other case of radiological emergency that is likely to lead to or has led to significant radioactive contamination of foodstuffs and feeding stuffs. For the purposes of this regulation, "foodstuffs" means products that are intended for human consumption either immediately or after processing, and "feeding stuffs" means products that are intended only for animal nutrition. In the event of the Commission receiving official information on accidents or on any other case of radiological emergency, substantiating that the maximum permissible levels are likely to be reached or have been reached, it will immediately adopt, if the circumstances so require, a regulation rendering applicable those maximum permissible levels. The period of validity of any regulation shall be as short as possible and shall not exceed 3 months. The regulation applies to baby foods, dairy products, liquid foodstuffs, and feedstuffs. There are maximum permitted levels for isotopes of strontium, notably ^{90}Sr; isotopes of iodine, notably ^{131}I; alpha-emitting isotopes of plutonium and transplutonium elements, notably ^{239}Pu and ^{241}Am; and for all other nuclides with a half-life greater than 10 days, notably ^{134}Cs and ^{137}Cs.

In Regulation (EEC) No. 2219/89 (entry into force July 25, 1989) the conditions for exporting foodstuffs and feeding stuffs after a nuclear accident or any other radiological situation likely to lead to significant radioactive contamination of foodstuffs and feedstuffs are laid down. Foodstuffs and feed stuffs in which the level of radioactive contamination exceeds the relevant maximum permitted levels may not be exported. The Member States shall carry out checks to ensure that the maximum permitted levels are observed. Each Member State shall communicate to the Commission the fullest information on the application of this regulation, and in particular on any cases in which the maximum permitted levels have been exceeded. The Commission shall forward this information to the other Member States.

Regulation (EEC) No. 737/90 (entry into force April 1, 1990) applies to milk and dairy products. The accumulated maximum radioactive level in terms of ^{134}Cs and ^{137}Cs shall be: (i) 370 Bq/kg for milk and milk products and for foodstuffs intended for the special feeding of

infants during the first 4–6 months of life, which meet, in themselves, the nutritional requirements of this category of person and are put up for retail sale in packages that are clearly identified and labeled "food preparation for infants"; and (ii) 600 Bq/kg for all other products concerned. Member States shall check compliance with the maximum permitted levels set in this regulation, taking into account contamination levels in the country of origin. Checking may also include the presentation of export certificates. Depending on the results of the checks carried out, Member States shall take the measures required for regulation to apply, including the prohibition of release for free circulation, taking each case individually or generally for a given product. Each Member State shall provide the Commission with all information concerning the application of this regulation, notably cases of noncompliance with the maximum permitted levels. The Commission shall circulate such information to the other Member States. The Commission shall adopt measures that shall apply immediately. However, if these measures are not in accordance with the opinion of the committee, they shall be communicated by the Commission to the Council forthwith. In that event, (i) the Commission may defer application of the measures that it has decided for a period of not more than 1 month from the date of such communication and (ii) the Council, acting by a qualified majority, may take a different decision within the time limit referred to in the first indent.

Decision 87/600/EEC (entry into force March 21, 1988) shall apply to the notification and provision of information whenever a Member State decides to take measures of a widespread nature in order to protect the general public in case of a radiological emergency following: (a) an accident in its territory involving facilities or activities referred to in paragraph 2 from which a significant release of radioactive material occurs or is likely to occur; (b) the detection, within or outside its own territory, of abnormal levels of radioactivity that are likely to be detrimental to public health in that Member State; (c) accidents other than those specified in (a) involving facilities or activities from which a significant release of radioactive material occurs or is likely to occur; or (d) other accidents from which a significant release of radioactive material occurs or is likely to occur. The facilities or activities are the following: (a) any nuclear reactor, wherever located; (b) any other nuclear fuel cycle facility; (c) any radioactive waste management facility; (d) the transport and storage of nuclear fuels or radioactive wastes; (e) the manufacture, use, storage, disposal, and transport of radioisotopes for agricultural, industrial, medical, and related scientific and research purposes; and (f) the use of radioisotopes for power generation in space objects. The information shall include, as far as practicable and appropriate, the following: (a) the nature and time of the event, its exact location, and the facility or the activity involved; (b) the assumed or established cause and the foreseeable development of the accident relevant to the release of the radioactive materials; (c) the general characteristics of the radioactive release, including the nature, probable physical and chemical form, and the quantity, composition, and effective height of the radioactive release; (d) information on current and forecast meteorological and hydrological conditions, necessary for forecasting the dispersion of the radioactive release; (e) the results of environmental monitoring; (f) the results of

measurements of foodstuffs, feeding stuffs, and drinking water; (g) the protective measures taken or planned; (h) the measures taken, or planned, to inform the public; and (i) the predicted behavior over time of the radioactive release.

The titles, main points, and comments of the directives, regulations, and decision about food irradiation are summarized in Table 1.1.

TABLE 1.1 EU Legislation Related to Food Irradiation

Directive/Regulation	Title	Main Points	Comments
Directive 1999/2/EC (entry into force March 10, 1999)	The approximation of the laws of the Member States concerning foods and food ingredients treated with ionizing radiation	Application to the manufacture, marketing, and importation of foodstuffs treated with ionizing radiation. No application to foodstuffs exposed to ionizing radiation generated by measuring or inspection devices under conditions. No application for the irradiation of foodstuffs that are prepared for patients. Specific limits of maximum dose of irradiation.	
Directive 1999/3/EC (entry into force March 10, 1999)	On the establishment of a Community list of foods and food ingredients treated with ionizing radiation	Establishment of a Community initial positive list of food and food ingredients that may be treated with ionizing radiation, together with the maximum doses authorized for the intended purpose.	
Regulation (EEC) No. 3954/87 (entry into force January 2, 1988)	Determination of maximum permitted levels of radioactive contamination of foodstuffs and of feedstuffs following a nuclear accident or any other case of radiological emergency	Maximum permitted levels of radioactive contamination of foodstuffs and of feedstuffs in case of nuclear accident. Any foodstuff or feedstuff that exceeds the maximum permitted levels is banned from the market disposal.	This regulation was amended by Regulation (EEC) No. 2218/89 (entry into force July 25, 1989).

(*Continued*)

Table 1.1 EU Legislation Related to Food Irradiation—cont'd

Directive/Regulation	Title	Main Points	Comments
Regulation (EEC) No. 2219/89 (entry into force July 25, 1989)	Special conditions for exporting foodstuffs and feedstuffs following a nuclear accident or any other case of radiological emergency	Conditions for exporting foodstuffs and feedstuffs after a nuclear accident. Any foodstuff or feedstuff that exceeds the maximum permitted levels is banned from exportation.	
Regulation (EEC) No. 737/90 (entry into force April 1, 1990)	Conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station	Application for products originating from third countries. Determination of maximum accumulated radioactivity of ^{134}Cs and ^{137}Cs. Control measures in case of noncompliance.	There are three regulations that amended this one. The last one is Regulation (EC) No. 806/2003 (entry into force June 5, 2003).
Decision 87/600/EC (entry into force March 21, 1988)	Community arrangements for the early exchange of information in the event of a radiological emergency	The Decision introduced the "Ecurie" system. Member States could provide information to the commission. The point of contact and the commission service designated to forward this information shall be available on a 24-h basis.	

Adapted from Arvanitoyannis et al. (2005) and Arvanitoyannis (2008).

1.3 U.S. Legislation

The use of ionizing radiation for food preservation began in the early 1920s. During the 1950s and 1960s, the U.S. Army conducted research on low-dose and high-dose irradiation of military rations. These experiments prompted similar studies in other countries, and the interest in food irradiation has grown ever since. With proper application, irradiation can be an effective means of eliminating and/or reducing microbial and insect infestations along with the foodborne diseases they induce, thereby improving the safety of many foods as well as extending shelf life (Diehl, 1995).

Another technological aspect is food irradiation. Food irradiation is one means of food preservation that may not be familiar to many, but it has been in development since the early 20th century. If properly applied, irradiation can be an effective way to treat a variety of problems in our food supply, such as insect infestation of grains, sprouting of potatoes, rapid ripening of fruits, and

bacterial growth. However, it has not yet obtained a significant place in the U.S. food industry (Andress et al., 2005). On December 2, 1997, the FDA approved irradiation of meat products for controlling disease-causing microorganisms. The approval applies to fresh and frozen meats such as beef, lamb, and pork. The FDA concluded that irradiation is safe in reducing disease-causing microbes in or on meats, and that it does not compromise the nutritional quality of treated products. Disease-causing microorganisms that can be controlled by irradiation include the *Escherichia coli* O157:H7 and *Salmonella* species (Whitmore, 1997).

In U.S. Regulatory Requirements for Irradiating Foods (1986), Congress explicitly defined a source of radiation as a food additive. In a report accompanying the legislation, Congress explicitly stated, "Sources of radiation (including radioactive isotopes, particle accelerators, and X-ray machines) intended for use in processing food are included in the term 'food additive' as defined in this legislation." In early work on food irradiation, sources of sufficiently high energies to induce radioactivity in foods were sometimes used. As research continued, sources whose energies are too low to induce detectable radioactivity were adopted by the international community. Therefore, this issue is of no concern when currently approved sources of radiation are used, but it must be addressed if other sources are being considered. Toxicological safety of typical food additives has traditionally been assessed by feeding large amounts of purified substances to laboratory animals and applying a safety factor to the highest dose of a tested substance that causes no toxic effects in any species. Moreover, standards for the conduct of such studies have evolved over time. For substances such as irradiated whole foods, which may become a large proportion of the diet, application of a 100-fold safety factor is impossible; attempts to exaggerate the amount of irradiated food in the diet have produced adverse nutritional effects that have confounded the results of many feeding studies. It is recommended that foods irradiated at doses of less than 1 kGy, or foods representing a very small fraction of the diet, should be exempt from requirements for toxicological testing because the types and amounts of radiolytic products would not show any toxic effects in well-conducted tests and their presence in the diet did not justify such testing. For foods irradiated at higher doses that were consumed in significant amounts, the Committee recommended a testing regime. Under the general labeling requirements, the FDA has found it necessary to inform the consumer that an irradiated food has been processed because irradiation, like other forms of processing, can affect the characteristics of food. For situations in which the processing is not obvious, such as whole foods that have been irradiated, the FDA requires that the label bear the radura symbol and the phrase "treated with radiation" or "treated by irradiation." If irradiated ingredients are added to foods that have not been irradiated, no special labeling is required on retail packages because it is obvious that such foods have been processed. Special labeling is required for foods not yet in the retail market that may undergo further processing, however, to ensure that foods are not irradiated multiple times. In promulgating this regulation, the FDA advised that other truthful statements, such as the reason for irradiating the food, could be added to the label and encouraged food manufacturers to do so. Irradiation can cause chemical change in packaging,

as well as in food, and this can affect migration of the package components (or degradation products of those components) to food. Irradiation can cause cross-linking, which would likely reduce migration, but it can also cause decomposition to lower molecular weight entities with increased migration characteristics. Sometimes, irradiation has been used in the manufacture (or sterilization) of packaging before food is added. The FDA considers this use the same as any other manufacturing process, namely the final irradiated packaging must comply with the appropriate regulations and must not otherwise adulterate food.

In Poultry Irradiation to Control Foodborne Illness (USDA, 1990), the FDA approved as safe and effective the use of irradiation to control a major source of foodborne illness, the *Salmonella* and other illness-causing bacteria in chicken, turkey, and other fresh or frozen, uncooked poultry. Agency scientists described the process as the first approved process to "pasteurize" solid foods. As in the heat pasteurization of milk, the irradiation process greatly reduces but does not eliminate all bacteria. Thus, the processed poultry would be safe longer than unprocessed poultry but would still require refrigeration, just as pasteurized milk does. The agency emphasized that the process does not make the food radioactive and, as a result, does not expose consumers to radiation. In a notice published in the *Federal Register* (USDA, 1990), the FDA stated that it had determined that the use of gamma radiation, electron radiation, and X-ray to treat poultry or its parts, including mechanically deboned poultry, is safe at the levels being approved. The process could be used to control such foodborne pathogens as *Salmonella*, *Yersinia*, and *Campylobacter*, which are common in poultry and can cause human gastrointestinal illnesses through cross-contamination of other foods and via poultry when it is not thoroughly cooked. Approval limits the amount of radiation to be used to 3 kGy.

In Irradiation in the Production, Processing, and Handling of Food (1997), the FDA amended the food additive regulations to provide for the safe use of a source of radiation to treat refrigerated or frozen uncooked meat, meat byproducts, and certain meat food products to control foodborne pathogens and extend product shelf-life. Although proper handling practices and cooking to recommended internal temperatures are effective interventions in preventing foodborne illness associated with meat products, much effort has gone into the development of other interventions aimed at reducing microbial pathogens. Irradiation has been proposed as one such additional tool. The subject petition requests that the FDA amend the food additive regulations to authorize the use of ionizing radiation to "control microbial pathogens in raw, fresh-chilled, and frozen intact and comminuted edible tissue of the skeletal muscle and organ meat of domesticated mammalian food sources; with concomitant control of infectious parasites, and extension of acceptable edible/marketable life of chilled/refrigerated and defrosted meat through the reduction in levels of spoilage microorganisms." The petition also specifies that the proposed foods are to be "primarily from bovine, ovine, porcine, and equine sources." The petition requests that a maximum dose of 4.5 kGy be established for the irradiation of fresh (chilled, not frozen) meat, and that a maximum dose of 7.0 kGy be established for the irradiation of frozen meat. In addition, the FDA is establishing 4.5 kGy as the maximum permitted

dose for irradiation of refrigerated meat, meat by-products, and certain meat food products and 7.0 kGy as the maximum permitted dose for irradiation of frozen meat, meat byproducts, and certain meat food products.

Food irradiation is a technology for controlling spoilage and eliminating foodborne pathogens, such as *Salmonella* (Food Irradiation, 1999). The result is similar to conventional pasteurization and is often called "cold pasteurization" or "irradiation pasteurization." Like pasteurization, irradiation kills bacteria and other pathogens that could otherwise result in spoilage or food poisoning. The fundamental difference between the two methods is the source of the energy they rely on to destroy the microbes. Whereas conventional pasteurization relies on heat, irradiation relies on the energy of ionizing radiation. The FDA emphasizes that no preservation method is a substitute for safe food handling procedures. The food irradiation process uses three types of ionizing radiation sources: ^{60}Co gamma sources, electron beam generators, and X-ray generators. ^{60}Co emits ionizing radiation in the form of intense gamma rays. "Gamma facilities" store it in stainless-steel capsules in underwater tanks. ^{60}Co has several advantages: (i) up to 95% of its emitted energy is available for use; (ii) it penetrates deeply; (iii) it yields substantial uniformity of the dose in the food product; (iv) it decays to nonradioactive nickel; and (v) it is considered to pose a low risk to the environment. However, its 5.3-year half-life offers disadvantages: ^{60}Co "pencils" require frequent replenishment, and treatment of the food is relatively slow. ^{137}Cs is a gamma source that is also used for irradiation. ^{137}Cs has a less penetrating gamma beam and a longer half-life, making it more suitable in certain circumstances. Electron beam facilities generate electron beams with an electron beam linear accelerator. (It works on the same principle as a television tube.) The electrons are concentrated and accelerated to 99% of the speed of light and energies of up to 10 MeV. Because electron beams are generated electrically, they offer certain advantages: (i) they can be turned on only as needed; (ii) they do not require replenishment of the source as does ^{60}Co; and (iii) there is no radioactive waste.

In Irradiation in the Production, Processing and Handling of Food (2000), the FDA amended the food additive regulations to provide for the safe use of ionizing radiation for the reduction of *Salmonella* in fresh shell eggs. The FDA reviewed the relevant data and information submitted in the petition regarding the radiation chemistry of fresh shell eggs and data available in the agency's files. Fresh whole eggs are composed mainly of water (75.3%), protein (12.5%), and lipid (10.0%). The radiation chemistry associated with these types of compounds is well-known. The FDA concluded that the concentrations and types of radiolysis products formed by the irradiation of eggs will be comparable to those products produced by the irradiation of other foods of similar composition, such as meat. In addition, the petitioner's data support the conclusion that there is little change in the levels of individual fatty acids, or in the structure, digestibility, or biological value of protein, when shell eggs are treated with ionizing radiation up to 3 kGy. Most of the radiolysis products are either the same as or structurally similar to compounds found in foods that have not been irradiated, and they are formed in very small

amounts. In summary, an absorbed dose of 3 kGy for the irradiation of fresh shell eggs will result in only minimal changes in the macronutrients (protein, lipid, or carbohydrate), and the chemical composition of eggs will not differ in any significant manner from that of eggs that have not been irradiated. Included in the information considered by the FDA in the review of this petition are three studies conducted specifically on irradiated eggs. In the first such study, rats were fed a biscuit diet containing whole eggs irradiated at 5 kGy at a dietary level of 25% on a dry weight basis for 3 years (two generations). No adverse effects were observed compared to the control group fed a diet containing non-irradiated eggs. In the second study, mice and rats were fed a diet containing dried eggs irradiated at 93 kGy and irradiated pork brain. No effects were observed that were attributed to the irradiated food. In the third study, rats were fed canned eggs irradiated at 5 kGy in their diet for two generations. No effects were observed that were attributed to the irradiated diet. Based on the totality of evidence from all evaluated data and studies, the FDA concluded that the petitioned use of irradiation on fresh shell eggs raises no toxicity concerns.

The Federal Food, Drug and Cosmetic Act (2005) claims that the Director of the Center shall: (a) conduct postmarket risk assessment of drugs approved under this Act and of biological products licensed under the Public Health Service Act; (b) conduct and improve postmarket surveillance of approved drugs and licensed biological products using postmarket surveillance programs and activities, risk–benefit analyses, adverse event reports, the scientific literature, any clinical or observational studies, and any other resources that the Director of the Center determines appropriate; (c) determine whether a study is required under this subsection and consult with the sponsors of drugs and biological products to ensure that such studies are completed by the date, and according to the terms, specified by the Director of the Center; (d) contract, or require the sponsor of an application or the holder of an approved application or license to contract, with the holders of domestic and international surveillance databases to conduct epidemiologic and other observational studies; (e) determine, based on postmarket surveillance programs and activities, risk–benefit analyses, adverse event reports, the scientific literature, and any clinical or observational studies and any other resources that the Director of the Center determines appropriate, whether a drug or biological product may present an unreasonable risk to the health of patients or the general public, and take corrective action if such an unreasonable risk may exist; (f) make information about the safety and effectiveness of approved drugs and licensed biological products available to the public and health care providers in a timely manner; and (g) conduct other activities as the Director of the Center determines appropriate to ensure the safety and effectiveness of all drugs approved under this section and all biological products licensed under the Public Health Service Act. No later than 90 days after the date of enactment of the Food and Drug Administration Safety Act of 2005, the Director of the Center shall (I) review and publish a list in the *Federal Register* of any postmarketing studies outstanding on the date of enactment of the Food and Drug Administration Safety Act of 2005, and (II) as the Director determines appropriate,

require the sponsor of a study described in subparagraph (I) to conduct such study under this subsection.

Governmental regulation of irradiation of food varies considerably from country to country. Where irradiation is permitted, regulations are needed to license the plant, radioactive materials, or process; to ensure radiation safety, environmental security, and general health and safety during plant operation; and to provide for safe disposal of any hazardous materials at the end of the operation. Each country has adopted its own unique approach to the introduction, approval, and regulation of the technology for food production. Although there is an agreement among international committee experts that food is safe and wholesome for consumption after irradiation up to a dose of 10 kGy, there is no approval for irradiation of all foods up to this limit in any country. Most countries approve food irradiation on a case-by-case basis (Morehouse and Komolprasert, 2004).

The main points of U.S. legislation focused on food irradiation are summarized in Table 1.2.

1.4 Canadian Legislation

The Canadian Food Inspection Agency (CFIA) is responsible for the enforcement of the regulations relating to the labeling of irradiated food products under the Food and Drug Act. The CFIA establishes inspection and testing programs to verify compliance by both domestic producers and importers. Irradiated foods that have not been approved for sale in Canada are not permitted entry, and the CFIA takes appropriate action if such products are illegally imported. Prepackaged foods that have been wholly irradiated display the international radiation symbol, along with a statement that the product has been irradiated. Food that is not prepackaged must have a sign with this information displayed beside the food (CFIA, 2002).

In the Food and Drug Act (2008), the symbol of the label of irradiated food required shall appear in close proximity on the principal display panel or on the sign to one of the following statements or a written statement that has the same meaning: “treated with radiation,” “treated by irradiation,” or “irradiated.” The symbol that indicates irradiated food shall: (i) have an outer diameter equal to or greater than the height of the numerical quantity and the declaration of net quantity of the package; and (ii) be not less than 5 cm. If an ingredient or component of a prepackaged product has been irradiated it shall, if the food constitutes 10% or more of the prepackaged product, be included in the list of ingredients and preceded by the statement “irradiated.” The label attached to a shipping container that contains any food referred to in the Act that has been subjected to the maximum permitted absorbed dose shall have the statement “Do not irradiate again.” Any advertising of an irradiated food referred to this Act shall identify the food as having been irradiated. No person shall sell milk, skim milk, partly skimmed milk, (naming the flavor) milk, (naming the flavor) skim milk, (naming the flavor) partly skimmed milk, skim milk with added milk solids, partly skimmed milk with

TABLE 1.2 U.S. Legislation Related to Food Irradiation

Act	Entry into Force	Main Points	Comments
U.S. Regulatory Requirements for Irradiating Foods	1986	Legal requirements Safety issues (radiological, toxicological, microbiological, nutritional adequacy) Labeling of irradiating foods Packaging of irradiating foods.	There are two amendments (Federal Register 62(1997) and 64(1999)) for these requirements.
Poultry Irradiation to Control Food-Borne Illness	1990	The FDA approved as safe and effective the use of irradiation to control a major source of foodborne illness, the *Salmonella* and other illness-causing bacteria in chicken, turkey and other fresh or frozen, uncooked poultry.	
Irradiation in the Production, Processing and Handling of Food	1997	The petition requests that a maximum dose of 4.5 kGy be established for the irradiation of fresh (chilled, not frozen) meat. A maximum dose of 7.0 kGy can be established for the irradiation of frozen meat.	
Food Irradiation	1999	Food irradiation is the process of exposing food to ionizing radiation. Food irradiation is a technology for controlling spoilage and eliminating foodborne pathogens, such as *Salmonella*. FDA approved irradiation for the control of pathogenic microorganisms in red meats.	
Irradiation in the Production, Processing and Handling of Food	2000	The safe use of ionizing radiation for the reduction of *Salmonella* in fresh shell eggs An absorbed dose of 3 kGy for the irradiation of fresh shell eggs will result in only minimal changes in the macronutrients.	
Federal Food, Drug and Cosmetic Act	2005	Duties of the center for postmarket drug evaluation and research Publication of progress reports and completed studies Amount of penalties.	

Adapted from Arvanitoyannis et al. (2006).

added milk solids, (naming the flavor) skim milk with added milk solids, (naming the flavor) partly skimmed milk with added milk solids, condensed milk, evaporated milk, evaporated skim milk, evaporated partly skimmed milk, milk powder, or skim milk powder in which the vitamin content has been increased by either irradiation or addition unless: (i) in the case of the addition of vitamin D, the menstrum containing the vitamin D contributes not more than 0.01% fat foreign to milk; and (ii) in cases in which the vitamin D content is increased by irradiation, the principal display panel of the label carries the statement "Vitamin D Increased" immediately preceding or following the name of the food, without intervening written, printed, or graphic matter. A manufacturer who sells a food that has been irradiated shall keep on his or her premises, for at least 2 years after the date of the irradiation, a record containing the following information: (i) the food irradiated and the quantity and lot numbers of the food; (ii) the purpose of the irradiation; (iii) the date of the irradiation; (iv) the dose of ionizing radiation absorbed by the food; (v) the source of the ionizing radiation; and (vi) a statement indicating whether the food was irradiated prior to the irradiation by the manufacturer and, if so, the information referred to in paragraphs (i)–(v) in respect of that prior irradiation. Every person who imports a food that is intended for sale in Canada that has been irradiated shall keep on his or her premises a record of the information referred to this Act for at least 2 years after the date of importation. A request that a food be added or a change made to the table to this Division shall be accompanied by a submission to the Director containing the following information: (i) the purpose and details of the proposed irradiation, including the source of ionizing radiation and the proposed frequency of and minimum and maximum dose of ionizing radiation; (ii) data indicating that the minimum dose of ionizing radiation proposed to be used accomplishes the intended purpose of the irradiation and the maximum dose of ionizing radiation proposed does not exceed the amount required to accomplish the purpose of the irradiation; (iii) information on the nature of the dosimeter used, the frequency of the dosimetry on the food, and data pertaining to the dosimetry and phantoms used to ensure that the dosimetry readings reflect the dose absorbed by the food during irradiation; (iv) data indicating the effects, if any, on the nutritional quality of the food, raw and ready-to-serve, under the proposed conditions of irradiation and any other processes that are combined with the irradiation; (v) data establishing that the irradiated food has not been significantly altered in chemical, physical, or microbiological characteristics to render the food unfit for human consumption; (vi) where the Director so requests, data establishing that the proposed irradiation is safe under the conditions proposed for the irradiation; (vii) the recommended conditions of storage and shipment of the irradiated food, including the time, temperature, and packaging, and a comparison of the recommended conditions for the same food that has not been irradiated; (viii) details of any other processes to be applied to the food prior to or after the proposed irradiation; and (ix) such other data as the Director may require to establish that consumers and purchasers of the irradiated food will not be deceived or misled as to the character, value, composition, merit, or safety of the irradiated food. The main points of this Act are given in Table 1.3.

TABLE 1.3 Canadian Legislation Related to Food Irradiation

Act	Entry into Force	Main Points
Food and Drug Act	2008	Labeling of irradiating foods. No person shall sell a number of products in which the vitamin content has been increased by either irradiation or addition. Every person who imports a food that is intended for sale in Canada that has been irradiated shall keep on his or her premises a record of the information.

1.5 Australian Legislation

Food irradiation is a food preservation process and a quarantine measure (Food Irradiation, 2003). Food processors use it to kill bacteria that cause food decomposition and food poisoning. Those bacteria include the parasites, moulds, and yeasts that spoil food and also salmonella and campylobacter that cause illness. Food can only be irradiated if there is no other safe method available. Any irradiated food must go through a strict safety assessment by Food Standards Australia New Zealand (FSANZ) and, if approved, must be labeled as having been treated by radiation. To date, in Australia and New Zealand, only herbs and spices, herbal teas, and some tropical fruits have been approved to be irradiated. Under the Food Standard covering the irradiation of food in Australia and New Zealand, this energy can be in the form of gamma rays from ^{60}Co, machine-generated X-rays, or an electrically generated electron beam. All food preservation methods, such as canning and freezing, change the composition of the food in some way. Some change the taste, appearance, texture, and nutritional value of the food more than others do. When food is cooked or preserved in any way, its composition changes and new compounds form. Irradiation causes minimal changes to the chemical composition of the food, although many of the composition changes that do occur are similar to those formed when food is cooked or preserved in more traditional ways. However, with irradiation, different doses have different effects. At low doses, irradiation lengthens the shelf life of fruits such as strawberries by destroying moulds, and it inhibits sprouting in vegetables such as potatoes. At higher doses, irradiation helps to kill the bacteria and pathogens that cause food poisoning. More than 40 countries allow the use of irradiation for food safety reasons. Most of the frogs legs sold in France, for example, are irradiated. Most of the herbs and spices sold in South Africa have been irradiated, whereas in Thailand there is growing demand for irradiated Nham, a fermented pork sausage that is usually eaten raw.

According to Irradiation of Tropical Fruit (2003), FSANZ has approved an application seeking permissions to irradiate a range of tropical fruits (breadfruit, carambola, custard apple, litchi, longan, mango, mangosteen, papaya, and rambutan) as a phytosanitary measure. The safety of irradiating tropical fruits has been examined by FSANZ. The available studies

on fruits indicate that there are no safety concerns. There are no changes to the composition of the fruits following irradiation that are likely to cause public health and safety concerns. Irradiation of tropical fruits up to a maximum of 1 kGy employing good manufacturing/irradiation practices is considered safe for Australian and New Zealand consumers. When the nutritional changes induced by irradiation are considered in conjunction with the FSANZ analysis of dietary intake of nutrients, the irradiation of tropical fruits is found not to have a significant nutritional effect on the diet of the Australian and New Zealand populations. The tropical fruits being considered for irradiation are not significant sources of certain vitamins, including beta-carotene, folate, vitamin C, and vitamin B_1, within the context of the total dietary intake.

The Food Additives Guide (2005) makes clear that food additives are an important component of our food supply. By using food additives, we can enjoy a wide variety of foods throughout the year. They also have an important role in ensuring that our food lasts longer and is easier to use. There are good reasons for the use of food additives. They can be used to improve the keeping quality or stability of a food. For example, sorbitol, humectant (E420), may be added to mix dried fruit to maintain the moisture level and softness of the fruit preserve food when this is the most practical way of extending its storage life. Sulfur dioxide, preservative (E220), is added to some meat products such as sausage meat to prevent the bugs that cause food poisoning from growing and to improve the taste or appearance of a processed food. Lecithin, emulsifier (E322), may be added to margarine to help maintain texture. Additives are used in processed foods in relatively small quantities. Many substances used as additives also occur naturally, such as vitamin C or ascorbic acid (E300) in fruit and lecithin (E322) in eggs or soybeans. Some food additives have more than one use. Food additives are listed according to their functional or class names: (i) colorings add or restore color to foods; (ii) color retention agents retain or intensify the color of a food; (iii) preservatives help protect against deterioration caused by microorganisms; (iv) artificial sweetening substances impart a sweet taste for fewer kilojoules/calories than sugar; (v) flavor enhancers improve the flavor and/or aroma of food; (vi) flavorings restore taste losses due to processing, maintain uniformity, and make food more palatable; (vii) anti-caking agents keep powdered products such as salt flowing freely when poured; (viii) emulsifiers help to prevent oil and water mixtures separating into layers; (ix) food acids help maintain a constant level of sourness in food; (x) humectants prevent foods such as dried fruits from drying out; (xi) mineral salts improve the texture of foods, such as processed meats; (xii) thickeners and vegetable gums improve texture and maintain uniform consistency; (xiii) stabilizers maintain the uniform dispersion of substances in a food; (xiv) flour treatment agents are substances added to flour to improve baking quality or appearance; (xv) glazing agents impart a shiny appearance or provide a protective coating to a food; and (xvi) propellants are gases that help propel food from a container. The main points of Australian legislation are shown in Table 1.4.

TABLE 1.4 Australian Legislation Related to Food Irradiation

Act	Entry into Force	Main Points
Food Irradiation	2003	Irradiation of food in Australia and New Zealand, this energy can be in the form of gamma rays from ^{60}Co, machine-generated X-rays, or an electrically generated electron beam. At low doses, irradiation lengthens the shelf life of fruits such as strawberries by destroying moulds and inhibits sprouting in vegetables such as potatoes. At higher doses, irradiation helps to kill the bacteria and pathogens that cause food poisoning.
Irradiation of Tropical Fruit	2003	The tropical fruits that are irradiated are breadfruit, carambola, custard apple, litchi, longan, mango, mangosteen, papaya, and rambutan. Irradiation of tropical fruits up to a maximum of 1 kGy employing good manufacturing/irradiation practices is considered safe for Australian and New Zealand consumers.
Food Additives Guide	2005	Use of food additives. Food additives are listed according to their functional or class names. Intolerance and food additives. Food additive safety.

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