Global Harmonization Initiative (GHI)
Consensus Document
on
Food Irradiation

Discordant international regulations of food irradiation are a public health impediment and a barrier to global trade

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Working Group Food Preservation Technologies

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The authors studied the available scientific evidence of the application of irradiation of food on food safety. Following the consensus process published on the GHI website, the concept document has been sent for comments to all members of GHI, scientists involved in food safety and food security all over the world. Members of GHI do not represent their employers, governments or industries: Membership is individual and contributions to GHI are based on the scientific conscience of the members. After addressing comments received this GHI Consensus document has been produced.

Contents

Background and Objectives

History of use is a well-established fundamental principle of food safety. It is codified in the regulations of both the US and the EU. For example the notion of "prior sanction," a major tenet of US law governing the safety of food and food ingredients, is a prime exemplar of regulations predicated on the notion of history of use. Likewise, history of use is an essential element of the EU's Novel Foods regulations (EU 2015/2283).

Ionizing radiation has been studied and used in food processing operations, for public health and trade reasons, extensively since early 1900s. In 1920s researchers reported the use of X-Rays as a public health intervention for the elimination of Trichina spp from food. The first commercial food irradiation started in 1958 for spices in Germany. Spices, tubers, onions, frog legs and seafood were among the first irradiated foods sold at retail. (Ehrelmann, 2016; Eustice, 2018)

Scientists have studied ionizing radiation as a means of food preservation more comprehensively than any other food preservation technique. The scientific records confirm with a high degree of assurance that foods and food ingredients treated using this method are safe and fit for human consumption. The international toxicological, microbiological and nutritional safety assessments of foods treated with ionizing radiation are robust and supportive, providing harmonized, global standards and regulations to govern the use of this technology for the benefit of consumers globally.

Greater demands for food and growth of international trade are crucial in increased risk of foodborne illnesses worldwide (Quested et al., 2010). Other global issues, such as climate change, the emergence of new pathogenic microorganisms and toxicants, increased consumer preferences for minimally processed and fresh foods, and growing numbers of ageing consumers, are also impacting the availability of safe, nutritious food for everyone.

Food irradiation has the potential to answer global challenges in the way foods are processed and preserved, providing issues related to food safety and shelf-life can be overcome effectively. Currently, food irradiation is approved in more than 60 countries and there has been a notable growth in production and trade of irradiated foods since 2010 (Eustice, 2017).

According to a survey conducted in 2005 (Kume et al. 2009), 405,000 tonnes of food was treated with irradiation globally for commercial purposes. A more limited survey in 2010 indicated that approximately 400,000 tonnes of food was treated with ionizing radiation in the US, EU, and parts of Asia alone. The US has one of the most developed commercial food irradiation programmes in the world. In 2010, the total volume of US foods irradiated was 103,000 tonnes including 80,000 tonnes of spices, 15,000 tonnes of fruits and vegetables, and 8,000 tonnes of meat and poultry. (Kume and Todoriki, 2013)

In the EU, the amount of irradiated foods has been decreasing from approximately 15,000 tonnes in 2005 to 9,000 tonnes in 2010 and, in 2015, only 5,686 tonnes of products were irradiated within the 28 EU Member States. Of the treated foods, 80% were irradiated mainly in two EU Member States, namely Belgium (68.9%) and the Netherlands (11.1%). The two main commodities irradiated in the EU are frogs' legs (54.75%) and dried aromatic herbs, spices and vegetables seasoning (16.10%) (EC, 2016). While due the introduction of Directives in 1999 (EC, 1999) irradiated foods are decreasing in Europe, in 2010, China used irradiation of food, including spices, garlic, grain, and meat, more than any other country (over 200,000 tonnes). Treatment of spices and herbs continues to be the most widely used application of food irradiation with more than 100,000 tonnes treated across the USA, China and other Asian countries. (Roberts, 2016)According to Food Safety News, acceptance and use of food irradiation is growing and reached new levels in 2017 (Eustice, 2018). One of the reasons for this is access to international markets. The main applications include fruits and vegetables, and grain to prevent spoilage, retain quality and reduce risk of harmful pathogens. However, despite these successes and more than 80 years of technology development that has confirmed benefits of this processing for a broad variety of foods, there are still barriers that keep irradiation from wider commercial acceptance. One such barriers is that regulations governing food irradiation vary greatly among countries. Discordant regulations challenge the global trade in irradiated foodstuffs and hamper implementation of food irradiation as a method for food safety and security. In order for the commercial trade of irradiated foods to develop globally, it is critical that a framework of national regulations and international standards are agreed and implemented. Moreover, it is imperative that scientists and users of food irradiation technology tackle consumer acceptance. This report provides an overview and analysis of existing food irradiation regulations around the world, the history of safe use, updates on consumer acceptance and the position of the Global Harmonization Initiative (GHI) on the necessity for harmonization of internationally accepted irradiation regulations, dosimetry and labelling.

Defining ionizing radiation for food

Food irradiation is a process where foods and agricultural products are exposed to ionizing radiation. There are three sources of ionizing radiation that are used for treatment of food: gamma rays from Co-60 or Cesium-137 (137Cs) and X-rays at or below 5 MeV as well as electron beams (e-beam) or accelerated electrons at or below 10 MeV (CAC, 2003).

Electron beam irradiation does not involve radioactive sources and can be turned off anytime, meaning there is no hazard to workers or the environment. Electrons are accelerated in an electric field to a velocity close to the speed of light. Since electrons are particulate radiation, they do not penetrate the product beyond a few centimetres, depending on product density. The product is exposed to the beam of electrons as it moves along a conveyor belt. Single or double beams are used to solve issues of packaging thickness. (Eustice, 2014)

Gamma sources are produced by radioactive isotopes and specified in terms of their activity measured in becquerel (Bq). Traditionally, however, Curies (Ci) are used; 1 MCi (equal to 37 x 10^{15} Bq) is a moderate type source. Gamma rays are emitted continuously and penetrate products in all directions. (Eustice, 2014)

X-rays and electron beams are used as alternatives to radioactive materials and, typically, generatedin the range 25 to 50 kW for food applications. X-rays yield from reflecting a high-energy stream of electrons off a metal target on to the food. X-ray irradiators are scalable and have deep penetration comparable to electron beams. (Eustice, 2014)

The effect of irradiation on foods depends on the absorbed dose, expressed in Gray (Gy). One Gy equals 1 Joule/kg of product. Low doses (0.05 - 0.15 kGy) are enough for inhibition of potato sprouting, disinfection (insects and parasites) of fruits, and delay of ripening in fresh fruits and vegetables. A medium absorbed dose (1.0 - 10 kGy) is sufficient for prevention of foodborne diseases through destruction and control of pathogens such as Salmonella spp., *Campylobacter jejuni, Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Staphylococcus aureus*. Higher doses (10 - 50 kGy) are used for decontaminating food ingredients, like spices and herbs. Doses from 30 kGy to 50 kGy are applied for sterilization of foods for space and hospital diets at an industrial scale. (Ihsanullah and Azhar 2017)

International organizations, safety of irradiated foods, and consumer acceptance

Food processed by ionizing irradiation is subject to all relevant standards, codes and regulations applicable to non-irradiated counterparts including ISO (International Organization for Standardization). The standards, codes, and regulations establish uniform specifications, procedures or technical criteria. When developed through global consensus, such as Codex Standards, their aim is to remove barriers for international trade. ISO standards identify essential practices to be implemented in order to process foods in a manner that preserves quality and yields safe and suitable for human consumption. As an example, ISO standards articulate standard practices for dosimetry in facilities for food processing (ISO/ASTM 51204 and ISO/ASTM 51431), and selection and calibration of systems for radiation processing (ISO/ASTM 51261).

ISO 14470:2011 standard for Food irradiation sets the requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food. The standard suggests that food processors should include irradiation in food safety processes whenever applicable. The standard identifies food irradiation as a part of food safety management (ISO 22000) and as a critical control point in a HACCP programme, "*contributing to the minimization of risk from the transmission of pathogenic micro-organisms to consumers*".

A major landmark in the history of food irradiation took place in 1980 when The Joint FAO/IAEA/WHO Expert Committee on Food Irradiation (JECFI) concluded that:

1. "*The irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard; hence, toxicological testing of foods so treated is no longer required.*"
2. "*The irradiation of food up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems…*"

Based on these findings, in 1981, JECFI (1981) published a report reviewing the safety of food irradiation and concluded that irradiation up to a dose of 10 kGy presented no toxicological hazard and showed no specific nutritional losses or microbiological issues. In 1983, the Codex Alimentarius commission with the support from Food and Agriculture Organization (FAO) and the World Health Organization (WHO), published the Codex General Standard for Irradiated Foods (CAC, 1983). The standard referred to JECFI findings repeating the statement "*irradiation of foods up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems*".

In 1999, the FAO/IAEA/WHO Study Group on High Dose Irradiation concluded that foods treated with irradiation at any dose appropriate to achieve the intended technological effect was both safe to consume and nutritionally adequate (JSGHDI, 1999). This conclusion was reflected in a revision of the Codex General Standard for Irradiated Foods (CAC, 2003) and has been represented by other agencies, such as the European Food Safety Authority (2011) and US Food and Drug Administration (FDA, 2016). Today, the Codex standard has influenced international agreements and has shaped the basis for legislation in many countries by setting acceptable sources of ionizing radiation applied on food products, and providing guidelines for dose and energy limits.

Reviews of published data and deliberations of international regulatory committees provided scientific support that, when foods are treated with ionizing radiation for commercial applications, they are safe and nutritionally adequate because:

- There are no significant changes in the composition of the food or significant impairment in the nutritional quality of protein, lipid and carbohydrate constituents; and
- Irradiation is no more destructive to vitamins than other food preservation methods.

Despite the scientific evidence of benefits and safety, food irradiation lacks wider acceptance. The greatest barrier to application of food irradiation has been consumers' unwillingness and misconception. Studies to evaluate acceptance of irradiated food products (Bruhn & Schutz, 1989; Resurreccion et al., 1995) have indicated that consumers are concerned mainly that irradiated food is radioactive, i.e. fundamental misunderstanding of the difference between irradiated and radioactivity. These studies also suggested that, if consumers were educated about irradiation processes and given a chance to test irradiated food products, they might be more willing to accept this technology. The potential weakness of these studies is the reliance on consumer surveys that might underestimate the likelihood of consumers purchasing irradiated food products (Bruhn, 1995; Satin

1996). In the US, for example, irradiated food products, including hamburgers, sweet potatoes, and papaya, have been sold successfully for more than 10 years. Opposition to food irradiation limited mostly to initial complaints from food campaigners or special interest groups has been decreasing. (Roberts, 2014)

Even though a minority of consumers might avoid purchasing irradiated foods, there is strong evidence that consumers will buy irradiated foods based on purchasing observed in several countries (Roberts and Henon, 2015). In many cases, negative consumer opinions could be overcome when the perceived price and quality of the product is acceptable and supported by positive decision by authorities on product safety and suitability (Roberts, 2014).

Existing international irradiation regulations

One of the major challenges facing the global food sector in the use of irradiation is harmonization of regulations and equivalence of standards, dose and labelling. Legislation needs to be harmonized and updated continuously to facilitate the effectiveness of global food chains and trade, and respond to global food safety challenges. However, they can also add complexity and confusion if not harmonized globally (King et al., 2017).

Discordant applications

Foods that can be irradiated differ greatly between countries. The Codex Alimentarius General Standard (CAC, 2003) does not specify foods that may be treated with ionizing radiation. Instead, in most countries, approvals are issued for foods and food categories for a specified intended processing effect on a case-by-case basis. Currently, in the US, Canada, Australia and New Zealand, new approvals can only be obtained in response to a petition in order to amend the existing regulation. Any relevant agency can submit a petition but often this has been a food industry.

North America

In North America, Mexico follows the Codex Alimentarius Standards and allows irradiation of any food to achieve the technological purpose with a maximum dose of 10 kGy. However, the lists of foods authorised to be treated with irradiation in US and Canada differ greatly (Table 1 and 2). The US was the first country to establish a generic dose for fruit fly disinfestation on domestic exports from Hawaii and since then has led development of ionizing radiation for foods on commercial scale (Ihsanullah and Azhar, 2017). Today, the US allows 14 food categories to be treated with ionizing radiation (Table 1) whereas, in Canada, food irradiation is permitted for only six product categories (Table 2). Even though some food categories may be treated in both countries, the permitted dose allowances are not consistent, which creates hurdles in the trade of irradiated foodstuffs between Canada and the US.

Central and South America

In Central and South America, countries most of the countries have adopted the Codex Alimentarius standards on food irradiation. For example, Cuba (NC 38-02-03, 1986) and Chile (DTO.N° 977/96, D.OF. 13.0597) permit treatment of any food with irradiation at an overall average absorbed dose of 10 kGy. Brazil (ANVISA, 2001) and Mexico (Codex Stan 106, 1983, Rev.1-2003) allow any food to be treated for any purpose.

Table 1. Food irradiation legislation in the USA

Legislation	List of foods allowed to be treated	Maximum absorbed dose limitations
21 CFR 179	1) Pork carcasses	Min dose 0.3 kGy; max dose not to exceed 1 kGy
	2) For growth and maturation inhibition of fresh foods	Not to exceed 1 kGy
	3) For disinfestation of arthropod pests in food	Not to exceed 1 kGy
	4) Dry or dehydrated enzyme preparations (including immobilized enzymes)	Not to exceed 10 kGy
	5) Dry or dehydrated aromatic vegetable substances when used as ingredients in small amounts solely for flavoring or aroma: culinary herbs, seeds, spices, vegetable seasonings	Not to exceed 30 kGy
	6) Fresh (refrigerated or unrefrigerated) or frozen, uncooked poultry products	Not to exceed 4.5 kGy for non-frozen products; not to exceed 7.0 kGy for frozen products
	7) For the sterilization of frozen, packaged meats used solely in the National Aeronautics and Space Administration space flight programs	Min dose 44 kGy
	8) Refrigerated or frozen, uncooked products that are meat within the meaning of 9 CFR 301.2(rr), meat byproducts within the meaning of 9 CFR 301.2(tt), or meat food products within the meaning of 9 CFR 301.2(uu)	Not to exceed 4.5 kGy maximum for refrigerated products; not to exceed 7.0 kGy maximum for frozen products
	9) Fresh shell eggs	Not to exceed 3.0 kGy
	10) Seeds for sprouting.	Not to exceed 8.0 kGy
	11) Fresh or frozen molluscan shellfish	Not to exceed 5.5 kGy
	12) Fresh iceberg lettuce and fresh spinach	Not to exceed 4.0 kGy
	13) Unrefrigerated (as well as refrigerated) uncooked meat, meat byproducts, and certain meat food products	Not to exceed 4.5 kGy

Table 2. Food irradiation legislation in Canada

Legislation	List of foods allowed to be treated	Maximum absorbed dose limitations
Food and Drug Regulations Division 26. C.R.C., c. 870	1) Potatoes	0.15 kGy
	2) Onions	0.15 kGy
	3) Wheat, flour, whole wheat flour	0.75 kGy
	4) Whole or ground spices and dehydrated seasonings	10 kGy
	5) Fresh raw ground beef	min 1.0 kGy; max 4.5 kGy
	6) Frozen raw ground beef	min1.5 kGy; max 7 kGy

European Union

In EU, the list of foods allowed for irradiation treatment comprises only dried aromatic herbs, spices and vegetable seasonings (Table 3). National authorizations that existed prior to 1999 in seven EU Member States, which included other foodstuffs, are still in force, which means that while seven EU Member States can authorize and carry out irradiation of a number of foodstuffs, others may restrict or ban these foodstuffs because they are not on the harmonized list.

Table 3. Food irradiation legislation in European Union

Legislation	List of foods allowed to be treated	Maximum absorbed dose limitations
Directive 1999/2/EC Directive 1999/3/EC	Dried aromatic herbs, spices and vegetable seasonings	Overall absorbed dose 10 kGy

Russia

Russia has adopted Codex Alimentarious International Standard for Irradiated foods in early 2016. In 2017 various irradiation standards became effective. Today Russia allows irradiation of several food categories, such as spices and herbs, meat products, and fresh agricultural products (IIA, 2017)

Oceania

Australia and New Zealand have harmonized their food irradiation legislation under Food Standards Australia New-Zealand (FSANZ Standard 1.5.3). The international export of irradiated fruit did not exist prior to 2004 when FSANZ established this standard for Australian mangoes. Today, the standard authorises irradiation treatment of 12 fruits, spices, herbs and herbal infusions for a phyto-sanitary purpose (Table 4).

Table 4. Food irradiation legislation in Australia and New Zealand

Legislation	List of foods allowed to be treated	Maximum absorbed dose limitation
FSANZ Standard 1.5.3	Herbs, spices and herbal infusions	Min 2 kGy - max 30 kGy
	Tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan), persimmons and tomatoes and capsicums	Min 0.15 kGy - max 1 kGy

Asia

In contrast to the EU, in Asia, the market for irradiated products has grown. The largest consumption of irradiated foods in the world is in China. In 2015 approximately 600 000 tonnes of food products were treated with irradiation (Eustice, 2017). However, it has been estimated that today around 1 million tonnes of food is treated annually. Most of the food products treated in China include garlic, chicken legs, spices, and dehydrated seasonings (Eustice, 2017). To the contrast, Japan limits the use of food irradiation to only gamma irradiation for inhibition of sprouting in potatoes, under "Food Sanitation Law", the plant protection regulation. Since 2001, there has been a Regional Cooperation Agreement (RCA) on food irradiation supported by FAO and the IAEA. Under this project, 10 countries have initiated collaboration on the harmonization of national regulations associated to food irradiation. Most countries in the region have already adopted the Codex General Standard and approval to irradiate foods is given by class or items. Numbers of approved irradiated food classes are India (7), China (10), Bangladesh (15), Indonesia (11), Pakistan (7), Vietnam (7), Korea (>6), Malaysia (7), Thailand (6) and Philippines (3). Ihsanullah and Azhar (2017) have collected lists of food categories allowed for irradiated and their dose allowances in several countries across Asia (Table 5). Other countries in this region, such as Mongolia, Nepal, Myanmar, Sri Lanka, are still deliberating the commercialization of food products treated using irradiation.

Table 5. Food irradiation legislations in Asia

Table 5a Bangladesh

Legislation	List of foods allowed to be treated	Absorbed dose limitations
Bangladesh Government 1983. Revised Codex General Standard for Irradiated Foods, Codex Stan 106, 1983	1) Chicken	Microbial control, 7 kGy
	2) Condiments	Disinfestation 1kGy; microbial control 10 kGy
	3) Fish	Microbial control max 2.2 kGy
	4) Dry fish	Disinfestation max 5 kGy
	5) Fish products	Microbial control, shelf-life extension max 7 kGy
	6) Frog legs	Max 1kGy
	7) Mango	Max 0.15 kGy
	8) Onions	Max 1 kGy
	9) Papaya	Max 0.15 kGy
	10) Potato	Max 1 kGy
	11) Pulses	Max 1kGy
	12) Rice	Disinfestation, quarantine 5 kGy
	13) Shrimp	Microbial control: Max 1 kGy
	14) Spices	Disinfestation: max 1 kGy; microbial control max 10 kGy
	15) Wheat/Wheat products	Disinfestation max 1 kGy; microbial control 8 kGy

Table 5b China

Legislation	List of foods allowed to be treated	Absorbed dose limitations
National standards for hygiene of irradiated foods, 1994	1) Poultry, livestock, cooked (pork, beef, chicken, duck)	Max 8 kGy
	2) Pollen (corn, buckwheat, sorghum, sesame, rape, sunflower, astragus)	Max 8 kGy
	3) Dried nuts, preserved fruits (peanut kernel, longan, hollow lotus, walnut, raw almonds, red dates, preserved fruit, peach, apricot, hawthorn, and others	Min 0.4 - 1 kGy
	4) Spices, dried (all)	Max 10 kGy
	5) Fruits, vegetables, fresh	Max 1.5 kGy
	6) Pork (fresh)	Max 0.65 kGy
	7) Poultry, livestock, frozen & packaged (pork, beef, chicken, duck, pre-packaged)	Max 2.5 kGy
	8) Beans and products	Max 0.2 kGy
	9) Cereals and products	Min 0.4 - max 0.6 kGy
	10) Sweet potato wine	Max 4 kGy

Table 5c India

Legislation		List of foods allowed to be treated	Absorbed dose limitations
Plant Quarantine Order, 2004, Food Safety and Standards Act 2006 and Atomic Energy Rules 2012	1)	Bulbs, stem and root tubers	Inhibit sprouting 0.02 - 0.2 kGy
	2)	Fresh fruits and vegetables	Delay ripening, insect disinfestation 0.2 -1.0 kGy; shelf-life extension 1.0 - 2.5 kGy
	3)	Cereals and pulses and their milled products, nuts oil seeds, dried fruits and their products	Insect disinfestation 0.25 -1.0 kGy; reduction of microbial load 1.5 - 5.0 kGy
	4)	Fish, aquaculture, seafood and their products (fresh/frozen)	Elimination of pathogens 1.0 -7.0kGy; shelf life extension 1.0 - 3.0 kGy; Control of human parasites 0.3 - 2.0 kGy
	5)	Dry vegetables, spices, condiments, dry herbs, tea, coffee, cocoa and plant products	Elimination of pathogens 6.0 -14.0kGy; Insect disinfestation 0.3-1.0kGy
	6)	Dried food animal origin	Insect disinfestation 0.3 -1.0kGy; Control of molds 1.0 - 3.0 kGy; Elimination of pathogens 2.0 - 7.0 kGy
	7)	Ethnic foods, military rations, space foods, TTC/RTE, minimally processed foods	Quarantine application min 0.25 - 1.0 kGy; Reduction of microorganisms 2.0-10 kGy; sterilization 5.0-25 kGy

Table 5d Indonesia

Legislation		List of foods allowed to be treated	Absorbed dose limitations
Government regulation, 1999 on food labelling and advertisement; Government regulation 2004 food safety, quality and nutrition; Food Act 18, 2012	1)	Bulb and tuber roots	Inhibit sprouting 0.15 kGy
	2)	Fresh fruit and vegetables	Delay maturation/insects disinfestation/quarantine treatment 1.0 kGy; Extend the shelf life 2.5 kGy
	3)	Processed vegetables and fruit products	Extend shelf-life 7.0 kGy
	4)	Mango	Extend shelf life 0.75 kGy
	5)	Mangosteen	Insects disinfestation/quarantine treatment 1.0 kGy
	6)	Cereals and products of penggilingannya, nuts, oil seeds	Insect disinfestation 1.0 kGy; reduce microbiota 5.0 kGy
	7)	Fish and sea food (fresh and frozen)	Reduce pathogenic microorganisms 5.0 kGy; extend shelf life 3.0 kGy; controlling infection 2.0 kGy
	8)	Processed fish products and sea food	Reduce pathogenic microorganisms 8.0 kGy; extend shelf life 10 kGy
	9)	Meat and poultry and processed products (fresh/frozen)	Reduce pathogenic organisms 7.0 kGy; extend shelf 3.0 kGy; controlling infection 2.0 kGy;
	10)	Dried vegetables, spices, herbs, dried herbs, herbal tea	Reduce pathogenic microorganisms 10 kGy; Insect disinfestation 1.0 kGy
	11)	Dried foods of animal origin, processed food of animal-based fast food	Insect disinfestation 1.0 kGy; eradicate microbes, fungi and yeast 5.0 kGy; sterilization and extend shelf life 6.5 kGy

Table 5e Malaysia

Legislation	List of foods allowed to be treated		Absorbed dose limitations
Food Irradiation Regulations 2011	1)	Bulbs, roots and tubers	Sprout inhibition 0.05 - 0.2 kGy
	2)	Fresh fruits and vegetables	Delay ripening 0.2 - 1.0 kGy; shelf life extension 1.0 - 2.5 kGy;
			quarantine control 0.15 - 1.0 kGy
	3)	Cereal and their milled products, nuts (including chestnut, coconut), oil seeds, pulses, dried fruits and their products	Insect disinfestation 0.25 - 1.0 kGy; reduction of microbial load 1.5 - 5.0 kGy; sprout inhibition (chestnut) 0.1 - 0.25 kGy
	4)	Fish and fish products an frog legs	Reduction of pathogens 1.0 - 7.0 kGy; shelf life extension 1.0 - 3.0 kGy; control of infection by parasites 0.1- 2.0 kGy; insect disinfestation 0.3 -1.0 kGy
	5)	Meat and meat products	Reduction of pathogens 1.0 - 7.0 kGy; shelf life extension 1.0 -3.0 kGy; control of infection by parasites 0.3- 2.0 kGy
	6)	Dried vegetables, spices, condiments, dry herbs, tea	Reduction of pathogens 2.0 - 10.0 kGy; insect disinfestation 0.3 - 1.0 kGy
	7)	Cocoa and cocoa products	Reduction of pathogens 2.0 - 5.0 kGy; reduction of microbial load 0.3 -1.0 kGy

Table 5f Pakistan

Legislation	List of foods allowed to be treated		Absorbed dose limitations
	1)	Bulbs, roots and tubers	0.2 kGy sprouting inhibition; 1 kGy ripening delay; 1 kGy insect disinfestation; 2 kGy shelf life extension; 1 kGy quarantine treatment
	2)	Fresh fruit and vegetables	Ripening delay 1.0 kGy; Insect disinfestation 1.0 kGy; Shelf life extension 2.0 kGy; Quarantine treatment 1.0 kGy
	3)	Cereals/pulses, their products, dried vegetables/nuts/fruits	Insect disinfestation 1.0 kGy
	4)	Raw fish, seafood and their products (fresh/frozen)	Reducing pathogens 5.0 kGy; Shelf life extension 3.0 kGy
	5)	Raw poultry and meat and their products (fresh and frozen)	Reducing pathogens 5.0 kGy; Shelf life extension 3.0 kGy
	6)	Dried herbs, spices condiments	Reducing pathogens10.0 kGy; Insect disinfestation 1.0 kGy
	7)	Dried food animal origin	Insect disinfestation 1.0 kGy

Table 5g Philippines

Legislation		List of foods allowed to be treated	Absorbed dose limitations
Food and Drugs Administration (DOH AO 152) and Plant Quarantine Office (BPI AO 02) for sanitary and phytosanitary applications	1)	Mangoes for disinfestation	1 kGy
	2)	Onions for sprout inhibition	0.3 – 1 kGy
	3)	Garlic for disinfestation	0.3 – 1 kGy

Table 5h Republic of Korea

Legislation		List of foods allowed to be treated	Absorbed dose limitations
Food Sanitation Act (article 7, clause 1) and Radioactive Protection decree	1)	Potato, onion, garlic	≤ 0.15 kGy
	2)	Chestnut	≤ 0.25 kGy
	3)	Fresh or dried mushroom	≤ 1 kGy
	4)	Egg powder, cereals, legumes and their powder as ingredient of food products, starch as ingredient of food products	≤ 5 kGy
	5)	Dried meat and the powder of fish & shellfish as ingredient of food product, soybean paste powder, red pepper paste powder, soy sauce powder, dried vegetables as ingredient of food products, yeast & enzyme food, algae food, aloe powder, ginseng (including red ginseng) food	≤ 7 kGy
	6)	Dried spice; composite seasoning products, sauces, leaching tea, powdered tea, sterile meals for second pasteurization	≤ 10 kGy

Table 5i Thailand

Legislation		List of foods allowed to be treated	Absorbed dose limitations
Irradiated foods divided in 5 groups covering 225 foods	1)	Roots and tubers	max 1 kGy
	2)	Slow down ripening	max 2 kGy
	3)	Control insect disinfestation (fresh fruits)	max 2 kGy
	4)	Decrease the amount of parasite (meat products)	max 4 kGy
	5)	Extend shelf life	max 7 kGy
	6)	Reduce the amount of microorganisms and pathogens (herbs & spices; dried vegetables; dried/powder meat, poultry and seafood)	max 10 kGy

Table 5j Vietnam

Legislation	List of foods allowed to be treated	Absorbed dose limitations
Decision 3616/2004/QD-BYT for safety and sanitation of 7 foods by irradiation (Guidelines by Ministry of Health)	1) Agricultural products (bulbs, roots and tubes)	To inhibit sprouting during storage: 2 - 7.5 kGy
	2) Fresh fruits and vegetables	To delay ripening 0.3 -1.0 kGy; insect disinfestation 0.3 - 1.0 kGy; shelf-life extension1.0 - 2.5 kGy; quarantine control 0.2 - 1.0kGy
	3) Cereals, milled cereal products, nuts, oil seed, pulses, dried vegetables and dried fruits	Insect disinfestation 0.3 - 1.0 kGy; reduction of pathogens 1.5 - 5.0 kGy; delay ripening 0.1 - 0.25 kGy
	4) Aquatic food and its products including spineless, amphibian animals (fresh or frozen)	Reduction of pathogens 1.0 - 7.0 kGy; shelf-life extension 1.0 - 3.0kGy; control of infection by parasites 0.1 - 2.0 kGy
	5) Raw poultry and meat and their products (fresh and frozen)	Reduction of pathogens 1.0 - 7.0 kGy; shelf-life extension 1.0 -3.0 kGy; control of infection by parasites 0.5 - 2.0 kGy
	6) Dry vegetables, spices, and dry herbs	Reduction of pathogens 2.0 -10.0 kGy; control of infection by parasites 0.3 - 1.0 kGy; spices up to 12 kGy
	7) Dried food of animal origin	Control of infection by parasites 0.3 - 1.0 kGy Control molds and fungus 1.0 - 3.0 kGy Reduction of pathogens 2.0 - 7.0 kGy

Africa

South Africa has regulations that govern the irradiation of foods and a framework on equivalency with the US. Other countries, such as Algeria, Ghana and Zambia, are working to establish their irradiation programmes (Eustice, 2017).

General

Spices, herbs and condiments are the only food category allowed to be irradiated in most countries, excluding Japan, and – therefore – the largest application and most traded irradiated commodity internationally. The spice trade makes wide use of spice mixtures from different origins as an ingredient in a diversity of processed foods. However, spices are not the only irradiated products to be traded internationally; irradiated fresh fruit and vegetables are also traded widely. While bilateral agreements have been established between many countries, the EU has been excluded due to its legislation. Also, while a market for meat and fresh produce treated with irradiation has been established in USA, Mexico, Australia, China and other Asian countries, the regulations require that some products are treated at different doses (Table 6).

Table 6. Comparison of permitted dose-applications in various regions

Country:	USA	Canada	EU	China	India	AU&NZ
Spices, dry herbs, seasonings						
Maximum permitted dose, kGy	30	10	10*	10	6 - 14	2 - 30
Fruits, vegetables, leafy produce for shelf-life extension						
Maximum permitted dose, kGy	4.0	-	1.0 - 2.0**	1.5	1- 2.5	0.15 - 1.0
Meat products						
Maximum permitted dose, kGy	4.5 (un)refrigerated uncooked products	1.0 - 4.5 Fresh raw ground beef	-	8 Poultry livestock, cooked meats	-	-

*EU maximum overall average absorbed dose, **in UK

Discordant doses allowances

The Codex General Standard for Irradiated Foods indicates that the dose should be such that the minimum absorbed dose is sufficient to achieve the technological intent and the maximum absorbed dose will not compromise consumer safety, wholesomeness, or adversely affect structural integrity, functional properties or sensory attributes (CAC, 2003). There are only a few countries that have regulations allowing irradiation treatment of any food product only to comply with the Codex Standard. For example, Brazil (ANVISA, 2001), Mexico (Codex 1983, Rev.1-2003) and Singapore (AFVAS, 2017) have stated that any food can be treated for any purpose.

Regulations regarding dose limitations for food irradiation vary greatly across countries. As shown in Table 6, the US permits 30 kGy maximum absorbed dose for spices (US FDA, 2017). In Australia and New Zealand, minimum and maximum absorbed dose for permitted spices varies between 2 kGy – 30 kGy, whereas in India doses from 6.0 kGy to 14.0 kGy are allowed for elimination of pathogens. In Canada, the EU and China, the maximum allowed dose is 10 kGy.

In the EU, regulations specify a *maximum overall absorbed dose* of 10 kGy for dried vegetable seasonings, spices and aromatic herbs (EU, 1999b) and the dose uniformity ratio should not exceed 3, meaning the lowest dose should not be more than three times less than the highest dose in the product lot. The concept of "*maximum overall absorbed dose*" is derived from the outdated Codex Standard from 1983 that stated the "*overall average dose absorbed by a food subjected to radiation processing should not exceed 10 kGy*" (CAC, 1983). It should be emphasized that the "*maximum overall average absorbed dose*" cannot be measured directly and needs to be calculated. Directly measurable parameters, such as minimum or maximum absorbed dose, are better for control and monitoring of irradiation. Codex updated this standard in 2003 to a concept of maximum absorbed dose. However, EU Directives 1999/2/EC and 1999/3/EC do not meet the existing Codex Alimentarius General Standard for Irradiated Foods (CODEX STAN 106-1983, REV.1-2003) or the Codex Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979 adopted 1979. Revision 2003. Editorial correction 2011).

Discordant dose limitations and approaches in dose measurements limit world-wide trade of irradiated foods. Countries that have allowed irradiation of more food categories are limited to national markets. Thus, the objective of the Codex to achieve a free movement of irradiated foodstuffs has not been attained and food irradiation applications globally are limited.

Discordant labelling of foods and food ingredients

The Codex General Standard recommends that foods treated with ionizing radiation should be labelled accordingly (CAC, 2003). However, interpretation and enforcement vary considerably regarding wording, use of logo(s), and an additional statement of benefit. Regulations also differ when it comes to the labelling of ingredients: according to Codex Alimentarius ingredients treated with irradiation should be labelled (CAC, 2010).

In the US, labelling of ingredients treated with irradiation is not required, as long as the whole food has not been treated with ionising radiation (FDA, 2018). Some countries require labelling of irradiated ingredients when these exceed a certain percentage of the food. As an example, Malaysia and Canada have decided that there is no need to label irradiated ingredient provided they make up less than 5% (total) and 10% (by weight) of the whole food product, respectively (MOHM, 2011; CFIA 2017).

The EU, and Australia and New Zealand constrain that every food and ingredient treated with irradiation must be labelled without any limit. Australia and New Zealand have suggested the wording for the label but its use is not compulsory and use of the Radura logo is optional (ANZFSC, 2016). In the EU, the label must include the phrase "*treated with ionizing radiation*" or "*irradiated*" (EU, 1999a).

The requirements regarding the labelling of irradiated foods are based on consumers' rights. However, many consumers do not associate such labelling with safe food products, i.e. the label for irradiated foods is often perceived as a warning rather than information about the process. Since confusion exists around irradiation and radioactivity, such labelling is misleading and lacks transparency. Some countries, such as Indonesia, have suggested a statement of benefit or purpose next to the label, but most offer not such guidance for consumers.

Conclusions

There is a substantial amount of high quality scientific data from the reputed international research organisations that attests to the safety of foods and foodstuffs subjected to ionizing radiation. Legislation should not impede technological innovations that can provide solutions for food safety and security, while also contributing to sustainability of food chain, reducing consumption of resources (e.g. energy) and generation of waste. Harmonizing global regulations would help with the adoption and implementation of food processing technologies such as irradiation to ensure global food safety and food security for consumers.

The World Health Organization (WHO), Food and Agriculture Organization (FAO), International Atomic Energy Agency (IAEA), Codex Alimentarius Commission, and European Food Safety Authority (EFSA) and the US Food and Drug Administration (FA) and Department of Agriculture (USDA) have promoted treatment of foods with irradiation as a food safety measure globally since 1980. At that time, JECFI concluded that the use of ionizing radiation at an average overall dose of 10kGy did not adversely impact the safety of the treated foods. Similarly, in 1983, FAO/WHO echoed the findings of JECFI regarding the safe use of this technology in food production in their document "*The Codex GeneralStandard for Irradiated Foods*" (CAC, 1983).

Although scientific support for food irradiation are exhaustive and compelling, future growth in the treatment of foods with irradiation depends partly on evidencing to the food industry and retailers that not only is this technology beneficial and cost-effective, but also accepted by consumers. Achieving these objectives can be bolstered by harmonization of labelling regulations and treatment legislation. Existing legislation should be revised in accordance with international standards and codes of practice that are up-to-date and were established to facilitate trade and ensure consumer protection. For example, in the EU, the 1999 Directives have not been revised since their entry into force, despite anabundance of scientific and technological developments. Due to the current state of EU legislation, no widespread implementation of food irradiation exists in Europe, even though irradiation is seen as an effective and versatile technique for microbial decontamination of food and foodstuffs with little or no changes in quality.

It is clear from the literature and widespread safe use that ionizing radiation is a beneficial and necessary technology for control of food infestation and prevention of foodborne pathogens. Since 1980, the international community of scientists working in this area have confirmed a dose of 10 kGy as safe (nutritional and toxicological) for treating foods or foodstuffs that are intended for human consumption. Annually, 26 nations produce more than 500,000 of tonnes of spices, root crops, wheat, ground meat, fruits and vegetables that have been treated successfully by using ionizing radiation without reports of morbidity resulting from exposure to the treated foods.

Food irradiation improves food safety and pathogen control. Several years of research have resulted in regulatory approvals for the technology use in a growing number of countries. Retailers offering food products treated with irradiation for sale have experienced positive consumer responses. There is no other food processing method that has been studied more than food irradiation. Organizations, such as the World Health Organization and the Food and Agriculture Organization, recognize food irradiation as an important tool for pathogen control and food spoilage prevention. These preeminent international organizations also recognize the importance of framing use of ionizing radiation on the scaffolding of a comprehensive, integrated food safety system. That system must include Good Agricultural Practices (GAPs), Good Hygienic Practices (GHPs), Good Manufacturing Practices (GMPs), Quality Assurance Programmes (QAPs), Regulatory Compliance Programmes (RCPs), and

HACCP. Consumers and food industry stand to benefit immensely from increased use of ionizing radiation as a tool for supporting the mass production of safe, high quality, nutritious food products. Ionizing radiation can also help reduce spoilage and, therefore, improve food security and reduce food waste globally.

The Global Harmonization Initiative (GHI) is an impartial organization of individual conscientious scientists, not representing industries or governments, working towards harmonization of food safety legislation and regulations worldwide, and recommends that international regulatory bodies recognize and accept the finding of the Joint FAO/IAEA/WHO Expert Committee on Food Irradiation (JECFI) first published in 1981 (JECFI, 1981) and, subsequently, adopted by FAO/IAEA/WHO Joint Study Group High-Dose Irradiation in 1999 (JSGHDI, 1999) namely:

1. *"The Study Group concluded that food irradiated to any dose appropriate to achieve the intended technological objective is both safe to consume and nutritionally adequate" and "does not result in any toxicological hazard."*
2. *"Doses applied to eliminate the biological hazards would be below those doses that might compromise sensory quality, the Study Group concluded that no upper dose limit need be imposed."*

These findings are reflected in the revision of Codex General Standard for Irradiated Foods (CODEX STAN 106-1983, REV.1-2003):

"*For the irradiation of any food, the minimum absorbed dose should be sufficient to achieve the technological purpose and the maximum absorbed dose should be less than that which would compromise consumer safety, wholesomeness or would adversely affect structural integrity, functional properties, or sensory attributes. The maximum absorbed dose delivered to a food should not exceed 10kGy, except when necessary to achieve a legitimate technological purpose*." (CAC, 2003)

GHI also supports international recommendations for comprehensive integrated food safety programmes, as foundations for allowing and supporting the use of ionizing radiation in food processing operations. Current labelling of irradiated foods is incorrectly but frequently seen as a safety warning. Due to the consumer misperceptions, the current label is seen as misleading and lacks transparency. Based on the long history of use, global geography of irradiated foods (both labelled and unlabelled) and the needs of international trade, GHI recommends that all foods treated below the doses that will not compromise sensory quality and are deemed wholesome, should bear no mandatory label or a label that will be educative rather than misleading, encouraging consumer purchase of safe and wholesome foods.

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