

# Scientific Opinion on the Standards and Regulations of Irradiated Food

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#### Abstract

Our markets and economies become more global and it is very much essential that food products must fulfill high standards of quality and safety to trade across borders. Food irradiation is one of them and it is a powerful food processing technology for controlling spoilage and reducing food-borne pathogens. International standards and regulations for food irradiation covering food safety and quality, labeling, plant protection and environment, packaging issue, dosimetry, facility management, nuclear safety and security, consumer behavior and so on established by the national and international organization in the world. International trade in irradiated foods increasing with wider acceptance of this technology by the consumer. Nowadays, more than 60 countries accepting and trading irradiated foods or food ingredients or food products. This paper focusing on irradiated food with consumer acceptance and standards and regulation of irradiated food as well as international trade issues.

**Keywords:** Food irradiation; Food safety; International food business; Nuclear safety; Consumer concern

# Introduction

Irradiation is a kind of energy. It is an exposure to radiant energy (heat, x-rays, etc.) for therapeutic or diagnostic purposes or food preservation. Bacteria and other life form which infect and infest food stuffs and medical products destroyed by irradiation. It kills the harmful bacteria and controls spoilage of certain foods including milk and milk products [1]. Food irradiation is the treatment of food by a certain kind of energy. The radiation energy passes through the food and it does not make food radioactive. Irradiated foods are nutritious. According to the FAO/IAEA, nutrient losses caused by irradiation are less than the same as losses caused by cooking and freezing. The process involves exposing the food, either packaged or in bulk, to carefully controlled amount of ionizing radiation for a specific time to achieve certain goals [2]. There are three different types of radiation are permitted for food irradiation such as Gamma rays, X-rays and electron beam radiation. Now-a-days, ionizing radiation processing of food has become a standard technology in the world [3]. There are different kinds of food irradiated, given in Table 1.

# **History of Food Irradiation**

In 1906, UK patent to use radioactive isotopes to irradiate particulate food in a flowing bed [4]. After that, in 1918, U.S. patent to use X-rays for the preservation of food. Next, in 1930, French first patent on food irradiation. In 1943 irradiated food first used for the U.S. Army. In 1958, world first commercial food irradiation (spices) started at Stuttgart in

Type of foods	Effect of irradiation	
Meat, poultry	Destroys pathogenic fish organisms, such as Salmonella, Clostridium Botulinum, and Trichinae	
Perishable foods	Delays spoilage; retards mold growth; reduces number of microorganisms	
Grain, fruit	Controls insect vegetables, infestation dehydrated fruit, spices and seasonings	
Onions, carrots, potatoes, garlic, ginger	Inhibits sprouting	
Bananas, mangos, papayas, guavas, other non-citrus fruits	Delays ripening avocados, natural juices	
Grain, fruit	Reduces rehydration time	

Table 1: There are different kinds of food and their effect of irradiation [40]

Germany. In 1970, Federal Research Centre for Food Preservation at Karlsruhe in Germany establishment of the International Food Irradiation Project (IFIP). After that in 1980, FAO/IAEA/WHO Joint Expert Committee on Food Irradiation recommends that the clearance generally up to 10 kGy «overall average dose». In 1983, Codex Alimentarius General Standard for Irradiated Foods revealed that on irradiation of any food at a maximum «overall average dose» of 10 kGy. In the year 1997, FAO/IAEA/WHO Joint Study Group on High-Dose Irradiation mentions lifting any upper dose limit on irradiation of food. In the year 1998, the European Union's Scientific Committee on Food (SCF) nominated on eight categories of food irradiation applications. 2003 Codex Alimentarius General Standard for Irradiated Foods said that no longer any upper dose limit and they had argument with SCF decision(s). After that in the year 2003, the SCF approves a revised opinion that recommends against the cancellation of the upper dose limit. But finally, in 2011 the successor to the SCF, the European Food Safety Authority (EFSA), reconsiders the SCF's grade and makes further recommendations for inclusion. Recently, almost sixty countries permit irradiation of one or more food or food products [5].

# International Standards and Regulations for Food Irradiation

Recently, the consumers are accepted food irradiation and it is a well-established and very effective post-harvest treatment to reduce bacterial contamination, slow spoilage and keep food quality better [6]. The Codex Alimentarius Commission and International Atomic Energy Agency (IAEA) release the international standards and regulations for irradiation of food. The Codex Alimentarius and IAEA made their resolution(s) under the World Trade Organization (WTO) contract and

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agreement and they reveal that the member states are allowed to convert the standards into national regulations at their preference. According to the IAEA and the Codex Alimentarius Commission standards and regulations about food irradiation vary from country to country. There is a well-established structure of global standards and regulations about food irradiation and it covers food safety, labeling, human health, plant protection, labeling, quality assurance and so on [5].

#### Food safety

Food safety was a key issue early in the 20th century and it was one of the major concerns to the consumers. At that time just two methods were established and developed including retort canning and milk pasteurization. The two technologies were developed and promoted for prevention against foodborne illness [7]. However, at the beginning of the 21st century, foodborne illness/disease residues a major concern to public health but many of these concerns can be controlled by applying new methods and techniques and food irradiation technique is one of them [8]. For food safety issue, in USA, foodborne infections cause almost 76 million of people and more than 0.3 million people hospitalizations, over 4000 people deaths each year [9] and up to \$ 6.7 billion annually in patient-related costs for treatment of bacterial infections alone [10]. According to WHO, for food safety concern, almost 3.2 billion children aged > 5 are suffered from diarrhoea annually in South-East Asia and Africa and 1.15 million estimated deaths. For Global Food Supply matter, approximately 25% of worldwide food production lost after harvesting due to insects, bacteria and spoilage [11]. Codex Alimentarius Commission plays an important role relating to food and food production, food safety and consumer health. It is internationally recognized standards, codes of practice, guidelines. It's a body that was established in early November 1961 by FAO, was joined by the WHO in June 1962. Its main goals are to protect the health of consumers and ensure fair practices in the international food trade. According to Codex Alimentarius Commission in 2012, it consist of 186 Codex Members, 185 Member Countries, 1 Member Organization (EU), 215 Codex Observers - 49 IGOs, 150 NGOs, 16 UN. Recently, it works closely with the IAEA, Joint FAO/WHO Expert Committees on Food Additives (JECFA) [12]. In the year 2003, the Codex Alimentarius Commission established the dose limit for food irradiation and they have done it for food safety. The commission removed any upper dose limit for food irradiation as well as clearances for particular foods and they also revealed that all are safe to irradiate [13]. Some countries in the world have applied the Codex standards and regulations without any restriction. On the other hand, some other countries in the world have accepted the irradiation of fresh fruits for fruit fly seclusion purposes. All of the directions of Codex Alimentarius involved in processing food are applied to all foods before irradiated [14]. Worldwide the Public health agencies have assessed that the safety of food irradiation over the last 50 years and they established that it is safe. Approximately, 60 countries of the world and more than 40 food products are irradiated. In European countries, food irradiation has been in use for decades for food safety and most important thing is that food irradiation has received official endorsement from the American Medical Association, the World Health Organization, and the International Atomic Energy Agency [15]. Specifically, EU has standards and regulations on foods and food ingredients treated with ionizing radiation including-

Directive 1999/2/EC - general - approximating EU countries' laws

Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionizing radiation

Directive 1999/3/EC - implementing - EU list of irradiated food and food ingredients

Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionizing radiation Foods & food ingredients authorized for irradiation in the EU. Currently, these are:

- Fruit and vegetables including root veg.
- Cereals, cereal flakes, rice flour
- Spices, condiments
- Fish, shellfish
- Fresh meats, poultry, frog legs
- Raw milk camembert
- Gum Arabic, casein, egg white
- Blood products

List of Member States' authorisations of food and food ingredients which may be treated with ionizing radiation [16].

#### Labeling

According to the Medical Dictionary-2012, food label means the information provided on the food package specifying several nutrients, calories, additives, treatment process and so on present in the food [17] and much information about irradiated food must be available to the consumer and Product must be labeled «irradiated» [12]. U.S Environmental Protection Agency revealed that Irradiated food and containing any irradiated ingredients must be labeled. The agency also said that irradiated food has nothing to do with radioactive contamination of food. As a result, a fall or an accident does not happen. Agency said that Labels must contain the words «Treated with Radiation» or «Treated by Irradiation» and display the irradiated food. It comes from Italian word. It means clear or cleaning [18]. Here is the Radura symbol given below:



U.S Food and Drug Administration (FDA) clarify the requirement of labeling of packaged irradiated food sold at retail stores and it must be labeled. Irradiated whole foods sold including fruits and vegetables also must display the label. On the other hand, no label is needed for food products that have irradiated ingredients, such as spices, as long as the whole product has not been irradiated. FDA also said that about wholesale Foods matter, irradiated foods sold at the wholesale level similarly must be labeled as retail foods. And most important thing is that in shipping container and the invoice and bill of lading must show the statement «Do not irradiate again.» FDA also revealed that in restaurant foods do not require labeling of irradiates food when served in restaurants [19].

According to the Codex Alimentarius Commission about labeling to irradiate foods, first generation products must be labeled «irradiated» as any product imitated directly from an irradiated raw material. The commission also said that the requirement for the ingredients is that even the last molecule of an irradiated food ingredient must be listed with the ingredients even in cases where an irradiated food ingredient does not appear on the label. The Codex Alimentarius reveals that the use of Radura symbol is not mandatory when many countries use a graphical version that varies from the Codex-version. The Codex Alimentarius published a guideline for labeling of irradiate food [20]. The commission also indicates that the Radura symbol must be used for all products that contain irradiated foods [21]. The European Union (EU) agrees with the Codex Alimentarius guidelines about the labeling of the irradiated food ingredients down to the final molecule of irradiated food.

#### Plant & environmental protection

The Environment and plant section of the IAEA/FAO joint program provide assistance, technical and other support to the member countries in their efforts to confirm and certify the safety of food, agricultural products, environmental protection and food security as well as at the same time helping international trade. Basically, the IAEA/FAO joint program helps on establishment of the member state capacities for the application of international standards on irradiation and capacity building in the control of food and environmental hazards as well as plant and environmental protection. The IAEA, together with the FAO, coordinated and comprehensive "farm to fork" approach to food production systems that ensure the application of good agricultural practices throughout the food chain. The IAEA and FAO jointly work together with the International Plant Protection Convention (IPPC) and the Codex Allimentarius Commission to harmonize irradiation standards worldwide [22].

#### Packaging

Most of the food scientists expose that it can be prevented postirradiation contamination by using food irradiation after packaging. But, the execution of irradiation on pre-packaged food still faces challenges on to considers the safety and quality of these packaging materials used during irradiation. It is known that irradiation make chemical changes to the food packaging materials. As a result, the formation of breakdown products named Radiolysis Products, it means irradiation might produce radiolysis products and it can be migrated into food affecting odor, taste, and possibly the safety of the food [23]. So, the safety of the food packaging material must be control to ensure safety of irradiated packaged food. The safety of food packaging materials has some technical challenges because of the sort of possible chemicals generated and migrated by ionizing radiation [24]. In US, Federal Drug and Administration (FDA) responsible for setting standards and regulation about the use of ionizing radiation on food and food packaging. This authority develops from the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The 1958 Food Additives Amendment also reveals that a food is adulterated if it has been irradiated, unless the irradiation is carried out in conformity with a regulation prescribing safe conditions of use [19]. The FDA also provides more specific standards, regulatory and scientific information about the irradiation of food and packaging for consumers, industry, stakeholders and so on. The U.S Federal Drug and Administration published the regulations in 21 Code of Federal Regulations Part 179, Subpart C-Packaging Materials for Irradiated Foods and it is the Code of Federal Regulation Title 21 [25]. According to the European Union Regulation reveals that about ionizing radiation on food ingredients and packaging to Article 4(6) of Directive 1999/2/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionizing radiation) [16].

#### Nuclear safety and security

Nuclear safety and security are one of the most important issues in food irradiation facilities. Radiation related accidents and injuries many times happened by operators or radiation worker in food irradiation facilities. The nuclear safety and security of irradiation facilities monitored and supervised by the different national Nuclear Regulatory Authority and regulated by the International Atomic Energy Agency (IAEA). In food irradiation facility, the nuclear safety and security concerns are different than other conventional occupational safety regulations which are monitored and supervised by the special authorities of each country [26].

# Dosimetry

Dosimetry is a very important and critical aspect of food irradiation process and dose measurement applied to food irradiation technology. Internationally, there are specific regulations and standards for dosimetry applied to food irradiation and these regulations and standards help and support to ensure traceability of ionizing radiation measurement [27]. In fact, the radiation absorbed dose is the sum of energy absorbed each unit of weight of the target food or food product or food ingredient. It is known that the SI unit for dose is Grays (Gy or Joule/kg) and the dose measurement equipment (dosimeter) is usually used to measure dose. Dosimetry involves exposing the target food or food product or food ingredient along with one or more dosimeters too. For determinations, regulation and standard of doses are allocated into three groups including low dose applications (up to 1 kGy), medium dose applications (1 kGy to 10 kGy) and high dose applications (above 10 kGy) [28].

## Specifics of dosimetry applying for food irradiation

Low dose applications (up to 1 kGy): It is used up to 1 kGy dose including sprout inhibition in bulbs and tubers 0.03-0.15 kGy, delay in fruit ripening 0.25-0.75 kGy and insect disinfestations of food borne parasites 0.07-1.00 kGy [29].

**Medium dose applications (1 kGy to 10 kGy):** It is used 1 kGy to 1 kGy dose including reduction of spoilage microbes to prolong shelf-life of meat, poultry and sea foods under refrigeration 1.50–3.00 kGy, Reduction of pathogenic microbes in fresh and frozen meat, poultry and sea foods 3.00–7.00 kGy and Reducing the number of microorganisms in spices to improve hygienic quality 10.00 kGy [29].

High dose applications (above 10 kGy): These doses are used to above 10 kGy. The U.S. Food Drug and Administration (FDA) announced and permitted that doses are above 10 kGy are used to commercial food items and other international regulators and authority around the globe permitted doses of 44 kGy sterilizing frozen meat for NASA astronauts as well as sterilization of packaged meat, poultry, and their products that are shelf stable without refrigeration 25.00-70.00 kGy [29].

#### Some approved foods in USA and around the world with doses

Codex alimentarius commission standards: In the year 1984,

the International Consultative Group on Food Irradiation (ICGFI), established under the regulation of the IAEA, WHO and FAO has deal with a number of standards and recommendations to strengthen control procedures in the operation of irradiation facilities with dosimetry and it is based on the principles of the Codex Alimentarius Standard [11]. On the basis of the Codex Alimentarius Standard and ICGFI, an ideal regulation on food irradiation for Asia and the Pacific, Africa, Latin America and the Middle East was developed by regulatory officials from this region [2]. The Codex Alimentarius general standard for irradiated food uses the model of overall average dose and 10 kGy as the maximum allowable value, which is based on toxicological findings (Tables 2-4) [30].

Food products	Purpose	Approval date	Max. dose (kGy)
Wheat & Flour	Control of mold	1963	0.5
Potatoes	Inhibit Sprouting	1964	0.15
Spices	Sterilization	1983	10
Pork	Kill Trichina parasite	1985	1
Fruits & Vegetables	Insect control, increase shelf-life	1986	1
Poultry	Bacterial pathogen reduction	1990 (FDA), 1992 (USDA)	3
Red meat (fresh)	Bacterial pathogen reduction	1991 (FDA), 1992 (USDA)	4.5
Red meat (frozen)	Bacterial pathogen reduction	1992 (FDA), 1992 (USDA)	7

Table 2: Some approved foods in usa and around the world with doses [39].

Food	Purpose	Dose
Fresh, non-heated processed pork	Control of Trichinella spiralis	0.3 kGy min. to 1 kGy max.
Fresh foods	Growth and maturation inhibition	1 kGy max.
Foods	Arthropod disinfection	1 kGy max.
Dry or dehydrated Enzyme preparations	Microbial disinfection	10 kGy max.
Dry or dehydrated spices/seasonings	Microbial disinfection	30 kGy max.
Fresh or frozen, uncooked poultry products	Pathogen control	3 kGy max.
Frozen packaged meats (solely NASA)	Sterilization	44 kGy min.
Refrigerated, uncooked meat products	Pathogen control	4.5 kGy max.
Frozen uncooked meat products	Pathogen control	7 kGy max.
Fresh shell eggs	Control of Salmonella	3.0 kGy max.
Seeds for sprouting	Control of microbial pathogens	8.0 kGy max.
Fresh or frozen molluscan shellfish	Control of Vibrio species and other foodborne pathogens	5.5 kGy max.

 Table 3: Foods allowed to be irradiated under FDA's standards and regulations [25].

Classes of food	Purpose	Maximum dose (kGy)	ICGFI document No.
Class 1: Bulbs, roots and tubers	To inhibit sprouting during storage	0.2	8
Class 2: Fresh fruits and vegetables (other than Class 1)	To delay ripening Insect disinfestation Shelf life extension Quarantine control	1.0 1.0 2.5	6 3, 7, 17 6
Class 3: Cereals and their milled products, nuts, oil seeds, pulses, dried fruits	Insect disinfestation Reduction of microbial load	1.0 1.0 5.0	7, 13, 17 3, 20 3, 20
Class 4: Fish, seafood and their products (fresh or frozen)	Reduction of certain pathogenic micro-organisms Shelf life extension Control of infection by parasites	5.0 3.0 2.0	10 10 10
Class 5: Raw poultry and meat and their products (fresh and frozen)	Reduction of pathogenic micro-organisms Shelf life extension Control of infection by parasites	7.0 3.0 2.0	4 4 4
Class 6: Dry vegetables, spices, condiments, animal feed, dry herbs and herbal teas	Reduction of certain pathogenic micro-organisms	10.0 1.0	5, 19 5, 19
Class 7: Dried food of animal origin	Disinfestation Control of moulds	1.0 3.0	9 9
Class 8: Miscellaneous foods, including, but not limited to, honey, space foods, hospital foods, military rations, spices, liquid egg, thickeners	Reduction of micro- organisms Sterilization Quarantine control	>10 >10 >10	

Table 4: ICGFI recommended Dose Limits for irradiation [2].

# International Trade in Irradiated Food

It is known that food irradiation is a recognized process by the World Trade Organization (WTO) for trading internationally [12]. According to Japan Radioisotope Association, as of 2010 internationally irradiated food supply in Asia, the European Union and the United States were 285,200, 9,300 tons. Some countries use tests that can identify the irradiation of food items to apply labeling standards and to strengthen consumer acceptance. Usually, there are three types of foods irradiated to the mainland United States and the most were spices which are 77.7%, fruits and vegetables are 14.6% and meat and poultry are 7.77% and according to Japan Radioisotope Association, almost 17953 tons of irradiated fruits and vegetables from India, Vietnam, Thailand, Mexico are exported to the mainland United States [31]. In the year 2013, more than 6875 tons of food and food products were irradiated in European Union countries including Belgium (49.4%), the Netherlands (24.4%), Spain (12.7%) and France (10.0%) and most of the food products were frozen foods and dried herbs and spices [32]. Over all, the general guidelines for trading irradiated foods are some regulations and standards internationally including SPS Agreement with World Trade Organization. It is a scientifically based and justification to impose standards stricter than international food safety authority. Codex Alimumentarius Commission has Codex General Standard for trading irradiated foods as well as International Plant Protection Convention (IPPC), Office of Epizootics (OIE) have specific standards for irradiated food trading [33].

#### **Consumer Concerns on Irradiated Food**

Consumer acceptance is most important on food irradiation and it is based on a difficult decision making process considering the risks and benefits of food irradiation [34]. Actually, the consumer acceptance is depends on not only their kind of requirements, beliefs and their attitudes but also their nature of the economic, political and social environment of the consumer [35]. Although, consumer awareness, scientific documents, scientific information of safety and benefits of irradiated foods are limited. Basically, consumers deny food irradiation due to their lack of knowledge of food irradiation and ionizing radiation [36]. Another concern is that the formation of breakdown products named Radiolysis Products; irradiation might produce radiolysis products. It means irradiated food contains free radicals and radiolytic products [37]. Scientific opinion recommended that food irradiation related authority could take a vital role in educating the consumer about the benefits and restrictions of food irradiation. Actually, consumer education has resulted in increase of the advantages of irradiated food. Although the consumer acceptance differ among countries of irradiated foods [38]. Recently, consumer awareness has increased significantly on food irradiation and if the consumer is made awareness of the benefits of food irradiation they are willing to pay a quality price for the irradiated products [39]. The scientific opinion concludes that when this includes GAP, GHP, GMP and HACCP, and depending on the dose applied, food irradiation can contribute to improved consumer safety by reducing food-borne pathogens.

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