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Brazilian and international legislation applied to food irradiation: a historical review

Félix[a, b *], B. S.; Calheiro[a, b], D. S.; Mesquita[a], A. Z.; Alonso[a], T. C.; Lopes[a], R. C.; Alonso[a], M. N.

[a] Centro de Desenvolvimento da Tecnologia Nuclear (CDTN), 31270-901, Belo Horizonte, MG, Brazil.
[b] Universidade Federal de Minas Gerais (UFMG), 30130-100, Belo Horizonte, MG, Brazil.

*Correspondence: biancasenario21@gmail.com

Abstract: Food irradiation is a physical process that subjects packaged or bulk foods to doses of ionizing radiation, which are energies high enough to displace electrons from atoms and molecules and convert them into electrically charged particles, known as ions. The standards that establish the requirements for approval of food irradiation process represent a technical set of rules for standardizing ideas. Although food irradiation technology is already approved and regulated by Brazilian Health Regulatory Agency (Anvisa), there are still many obstacles that prevent the complete commercialization of irradiated foods in Brazil, among which is the low consumer acceptance of this type of food. The commercial use of food irradiation technology is growing slowly due to misinterpretations by a large part of Brazilian consumers. Because of this lack of knowledge, laws, and experiments are important, as they define the limits of dose that can be employed in the irradiation process to guarantee the integrity of the product and the health of the consumer. In this work, the survey, analysis, and evolution of Brazilian, and international legislation related to ionizing irradiation practices in food will be carried out. A timeline of the evolution of legislation in Brazil will also be described, characterizing the importance of guidelines involving food irradiation. The irradiation of food favors the provision of food security and ensures the increase in the supply of food products of high biological and sanitary quality, contributing to the promotion of a privileged and sustainable nutritional status for all people.

Keywords: food irradiation, gamma irradiator, Brazilian and international legislation.

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Legislação nacional e internacional aplicada à irradiação de alimentos: uma revisão histórica

Resumo: A irradiação de alimentos é um processo físico que submete alimentos embalados ou a granel a doses de radiação ionizante, que são energias elevadas o suficiente para deslocar os elétrons dos átomos e moléculas e convertê-los em partículas eletricamente carregadas, conhecidas como íons. As normas que estabelecem os requisitos para a aprovação do processo de irradiação de alimentos representam um conjunto técnico de regras para padronizar ideias. Embora a tecnologia de irradiação de alimentos esteja aprovada e regulamentada pela Agência Nacional de Vigilância Sanitária (Anvisa), ainda existem muitos obstáculos que impedem a completa comercialização de alimentos irradiados no Brasil, entre eles está a baixa aceitação desse tipo de alimento pelo consumidor. O uso comercial da tecnologia de irradiação de alimentos está crescendo lentamente devido à má interpretação por grande parte dos consumidores brasileiros. Devido a essa falta de conhecimento, leis e experimentos são importantes, pois definem os limites de dose que podem ser empregados no processo de irradiação de forma a garantir a integridade do produto e a saúde do consumidor. Este trabalho tem como objetivo principal realizar o levantamento, a análise e a evolução da legislação brasileira e internacional relacionada às práticas de irradiação alimentos. Também será descrita uma linha do tempo da evolução da legislação no Brasil, caracterizando a importância das diretrizes que envolvam a irradiação de produtos alimentares. A irradiação de alimentos favorece a provisão de segurança alimentar e garante o aumento da oferta de produtos alimentares de elevada qualidade biológica e sanitária, contribuindo para a promoção de um estado nutricional privilegiado e sustentável para todas as pessoas.

Palavras-chave: irradiação de alimentos, irradiador gama, legislação nacional e internacional.

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1. INTRODUCTION

The constant loss of food due to its spoilage and contamination during transport and storage has led to the development of technologies capable of reducing waste rates during the process of exporting and importing food products [1]. The use of ionizing radiation in foods allows the prolongation of shelf life, by delaying the maturation time of some products and the inactivation of microorganisms, due to the inhibition of the cell division process of living cells, such as bacteria [2].

Food irradiation is a physical process that subjects packaged or bulk foods to doses of ionizing radiation, which are energies high enough to dislodge electrons from atoms and molecules and convert them into electrically charged particles, ions [3]. This technology has become viable for the food industry. It allowed the decontamination of several products after the packaging process without leaving residues [4].

1.1. Irradiator

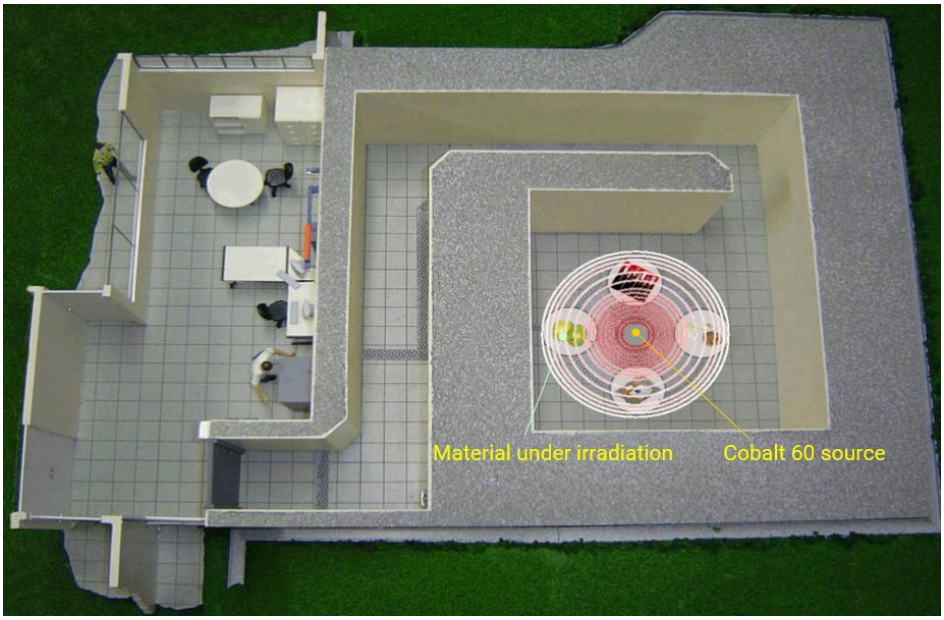
The food irradiation process must be carried out in specific establishments and in accordance with the requirements of the regulatory agencies present in the country. In Brazil, the licensing of facilities responsible for the radiation of food products is carried out by the Brazilian Nuclear Energy Commission (Cnen) [5].

According to Cnen, only isotopes emitting gamma radiation (cobalt-60 and cesium-137), X-rays emitted by generators of up to 5 MeV and electrons generated in machines that work with energy of up to 10 MeV are authorized to carry out the irradiation of food [5].

This work was developed at the Gamma Irradiation Laboratory (LIG) of the Center for the Development of Nuclear Technology (CDTN). It has a panoramic research irradiator with a cobalt-60 source. Figure 1 shows a gamma irradiator plant present in the LIG/CDTN.

Figure 2 shows the rotary tables where the samples to be irradiated are positioned. In the center of the image is the source that is suspended from the lower resting position when the irradiation process is started.

Figure 1: Panoramic irradiator with dry storage of LIG/CDTN.



Source: Ladeira (2015) [6].

Figure 2: Cobalt-60 supply position and turntables.

Source: Ladeira (2015) [6].

1.2. Dose Limit

Dose limits vary according to the purpose of irradiation and the type of food that will be subjected to ionizing radiation [4]. This variation in the dose value allows defining the irradiation processes of food in radurization, radicidation and radappertization.

Radurization refers to products subjected to low doses of radiation, usually less than 1 kGy, to inhibit sprouting, delay the maturation of some products, and extend the shelf life of the food by eliminating some species of fungi, bacteria, insects, and mites present [4, 7].

In the radicidation process, it uses slightly higher doses of radiation, between 1 kGy and 10 kGy. The main objective is to assist in the process of preserving fresh meat from the elimination of pathogens such as the *salmonella* genus [7].

Radappertization requires higher doses due to its main purpose which is to commercially sterilize seasonings, spices and processed products that may be contaminated with heat-resistant microorganisms, the doses used in this process are usually above 10 kGy [4, 7].

The study of food irradiation and, consequently, the legislation that provides for this process is important for the development and improvement of the technique. Because it allows the definition of a standard dose value for the type, quantity of product, and main purpose. The specification of absorbed dose and standardization are significant to seek wide use and, as a result, ensure food in safe conditions for consumption.

2. MATERIALS AND METHODS

For the development of the research project, a documentary and bibliographic review was carried out in the pertinent Brazilian and international legislation. Additionally, the

collection present in the Gamma Irradiation Laboratory of the Center for the Development of Nuclear Technology was consulted to complement and deepen the analysis.

Data collection occurred mainly through consultations on the websites of the following Brazilian institutions: the Brazilian Nuclear Energy Commission (Cnen), Brazilian Health Surveillance Agency (Anvisa), Brazilian Council of Radiology Technicians (Conter), Ministry of Agriculture, Livestock and Supply (Mapa). The following international bodies were also consulted: International Atomic Energy Agency (IAEA), International Organization for Standardization (ISO), Food and Agriculture Organization (FAO), Food and Drug Administration (FDA), and Food Standards Australia New Zealand (FSANZ).

From the information found, the main international regulations that provide for the use of ionizing radiation in the food industry were presented and a timeline regarding the legislation related to the practice of food irradiation in Brazil was developed for analysis.

3. RESULTS AND DISCUSSIONS

At the international level, organizations such as the FDA, IAEA, and ISO present some relevant regulations for the use of ionizing radiation in food. The Codex Alimentarius, for example, is a program created in 1963 by the Food and Drug Administration in conjunction with the World Health Organization (WHO) with the aim of describing and implementing international standards in the area of food, including the practice of food irradiation [8].

The Codex Committee on Food Hygiene (CCFH) presents irradiation as a method to reduce microbiological risk related to food hygiene [9]. The guidelines, norms, and recommendations adopted by the Codex Alimentarius do not have a direct link with the legislation of its member countries; however, they serve as a reference for updating and elaborating internal regulations [9].

The Code of Practice for Radiation Processing of Food (CXC 19-1979), implemented in 1979, presents the principles for carrying out the processing of food products with ionizing radiation and defines and specifies the practices necessary for effective processing while maintaining the quality and ensuring the safety of the products. This document follows the guidelines of the General Principles of Food Hygiene (CXC 1-1969) and, after revision in 2003, the General Standard of Irradiated Foods (CODEX-STAN 106-1983) developed by the Codex Alimentarius [10].

In 1983, CODEX-STAN 106-1083 presented the general requirements for the application of the irradiation process, among them are a description of the radiation sources that must be used for food hygiene and the minimum and maximum absorbed dose allowed, without discriminating specific dose values for each type of food [11].

The International Organization for Standardization, in 2011, through ISO 14470:2011, described the requirements necessary for the treatment of food from ionizing radiation, in addition to presenting the process of development, validation, and control of this process [12].

The label of products treated with the irradiation process is also defined by international standards; the identification of irradiated products must be made by means of the international symbol of irradiated food (Figure 3) or by words that describe that food or ingredients that compose it have been treated by ionizing radiation. The legislation regarding the labeling of irradiated foods may differ from country to country, but most use the Codex Alimentarius guidelines as the main reference [13].

In addition to international regulations, legal acts from different countries were found during the research. The main guidelines will be arranged below according to the continent of each country, except for Brazil, which will be detailed in a single topic.

Figure 3: Symbol indicating that a food product has been treated with ionizing radiation, Radura.

Source: World Health Organization (1988) [13].

3.1. North America

In the United States, the main regulation found was the Code of Federal Regulations (CFR), title 21, part 179: Irradiation in the production, processing, and handling of food (21 CFR Part 179). Unlike the legal acts presented above, this document presents the value of the maximum dose limit to achieve different purposes. In addition, it expands the types of fonts that can be used [14].

Canadian regulation of food irradiation is under the Food and Drugs Act and Regulations, Part B, Division B.26. The document specifies the food, the type, and source of ionizing radiation that can be used, the purpose of irradiation, and the minimum and maximum absorbed dose in kilo Gray (kGy) [15].

3.2. Europe

The European Union has two main directives, 1999/2/EC and 1999/3/EC, in 1999, the first deals with foods and food ingredients treated by the irradiation process [16]. The second relates to the establishment of a list specifying the foods and ingredients that have been subjected to ionizing radiation [17].

3.3. Asian

The National Food Safety Standards for Irradiated Food (GB 14891-2016) in China provides basic hygiene specifications for the food irradiation process, as well as management and registration [18].

3.4. Oceania

Food Standards Australia New Zealand, through standard 1.5.3 — Irradiation of Food, presents the requirements both for the prohibition of the practice of irradiation and the authorization and specifications for the use of ionizing radiation in food [19].

3.5. Brazil

The first legal act regarding the irradiation of food in Brazil was Decree-Law No. 986, of October 21, 1969. It establishes basic standards on food and defines irradiated food as any food that has been intentionally subjected to the action of ionizing radiation, for its preservation or for legal purposes, and provides for the indication on the label of the package [20].

In 1973, Presidential Decree No. 72,718 legitimized the use of the irradiation technique through the establishment of regulatory guidelines for the preparation, storage, transportation, distribution, import, export, and sale or delivery for consumption of irradiated food [21]. Seven years after the publication of this decree, the Brazilian Nuclear Energy Commission established the conditions for the operation of the facilities used for food irradiation through Resolution No. 5 [22].

The characterization of the types of food, dose values, and general conditions for the use of the irradiation technique were specified by Ordinance No. 9, approved in 1985. This ordinance was responsible for specifying the requirements for the use of ionizing radiation to comply with the limits established to ensure the food security of the population [23]. On October 18, 2000, Anvisa carried out a Public Consultation No. 83 to approve the Technical

Regulation for Food Irradiation, aimed at regulating packaged, or bulk foods submitted to radiation doses within the established limit and complementing the guidelines related to licensed establishments [23].

In 2001, Anvisa's RDC No. 21 specified the main concepts related to irradiation, the techniques, the processes for operating the equipment used for the irradiation of food, the sources of radiation allowed for use, packaging specifications, and instructions to industries [5]. In the same year, the Brazilian Council of Radiology Technicians (Conter) presented, through Resolution No. 9, the necessary training and radiological safety and the exclusive attributions of Conter, respectively [23].

The Ministry of Agriculture, Livestock, and Supply, through Ordinance No. 28, of April 14, 2004, regulates the use of ionizing radiation to carry out quarantine phytosanitary treatments and describes the values of specific doses for each type of pest [24].

The most recent standard published is Normative Instruction No. 9 of 2011, also from the Ministry of Agriculture, Livestock, and Supply, which is based on international guidelines to establish the requirements for the use of ionizing radiation in the prevention and dissemination of pests [25].

Currently, only RDC No. 21 and Normative Instruction No. 9 remain in force, and Decree-Law No. 986/PR and Decree No. 72,718 do not have express repeal. As established by the legal acts in force, the minimum, and maximum dose values are defined as sufficient to achieve the intended purpose and lower than that which compromises the properties of the food, respectively. Thus, there is no regulation that specifies the doses used for each application of ionizing radiation in foods for sale and consumption.

Table 1 summarizes all the legal acts found in Brazil during the development of this research.

Table 1: Legal acts related to the irradiation of food in Brazil.

	LEGAL ACTS	YEAR
1	Decree-Law No. 986/PR	1969
2	Presidential Decree No. 72.718	1973
3	Resolution No. 5/Cnen	1980
4	Ordinance No. 9/SVS	1985
5	Public Consultation No. 83/Anvisa	2000
6	Anvisa RDC No. 21	2001
7	Resolution No. 9/Conter	2001
8	Ordinance No. 28/DAS	2004
9	Normative Instruction No. 9	2011

The analysis of the legislation of the different countries mentioned revealed legal acts published more than a decade ago, such as in Brazil. However, some older international guidelines presented specific dose values for certain food products, unlike the current Brazilian legislation that defines the minimum and maximum value of absorbed dose as necessary to achieve the proposed objective and sufficient to ensure food safety without altering the sensory characteristics of the product, respectively.

The influence of the guidelines published by the Codex Alimentarius for the development of existing legislation in the world today was also noted.

4. CONCLUSIONS

In Brazil, industrialized foods that have been subjected to the irradiation process or that have ingredients that have been treated by this means must indicate on their label that they have been treated with ionizing radiation, as exemplified by Figure 4.

Figure 4: Label of a product containing information of food treated by irradiation process.

Source: Author's personal archive.

Although this information is available on package labels, many Brazilians do not have knowledge about the use of ionizing radiation for the treatment of food products. The lack of information makes the acceptance of this practice a challenge in Brazil.

The publication and wide dissemination of research and standards on food irradiation are fundamental for the dissemination of reliable information to the population. In addition to allowing the definition of safe doses for human health. However, many advances regarding the safe practice of ionizing radiation are overshadowed by news reports and tragedies.

Works, such as those carried out from this project, are relevant to develop knowledge and critical sense, as well as to stimulate the participation of students, professors, and researchers in bills and updates of current standards related to the use of ionizing radiation for food preservation.

Based on the literature review carried out for the preparation of this work, it is possible to affirm that food irradiation is a clean and safe preservation method that guarantees the increase in the supply of products with biological, sanitary, and nutritional quality, favoring the supply of food and food and nutritional security.

However, the current legislation in Brazil regarding this practice needs significant updates to reflect recent scientific progress. This legislative gap negatively impacts the spread of the use of ionizing radiation in food products, making it necessary to review and update existing regulations to promote food irradiation and ensure the safety of the population and the environment.

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CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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