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Regulation and supervision of food irradiation

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ABSTRACT

Food irradiation consists of a physical process that subjects food to doses of ionizing radiation, which are high enough energy to eliminate or neutralize harmful microbial contaminants without changing the taste or texture of food and without leaving residues. With this irradiation process we can prevent diseases transmitted by food, such as Salmonella and Escherichia coli, prolong the shelf life of foods, control pests that harm fruits by delaying germination and ripening, and finally sterilization, which allows their storage for years without refrigeration. The use of ionizing radiation for food preservation has been studied for several decades and is regulated in the USA by the Food and Drug Administration –FDA. In 1997, the World Health Organization - WHO released the use of the technique for all types of food. In Brazil, the first studies on food irradiation were carried out by the Center for Nuclear Energy in Agriculture - Cena, in the 50's. Currently, Brazilian legislation follows the international recommendations suggested by the Food and Agriculture Organization - FAO, the International Atomic Energy Agency - IAEA and Codex Alimentarius. The scope of this work is a survey, analysis and evolution of national and international legislation related to ionizing irradiation practices in food. For the preparation of this research, bibliographical reviews were carried out, consultations in Brazilian and international legislation, Internet sites, and in the documentation of the Gamma Irradiation Laboratory of the Nuclear Technology Development Center - CDTN.

Keywords: **Gamma Irradiators, Regulation and Supervision, Food irradiation validation.**

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1. INTRODUCTION

Food irradiation consists of a physical process that subjects packaged foods to doses of ionizing radiation, which are high enough energy to eliminate or neutralize harmful microbial contaminants without altering the taste or texture of the food and without leaving residues. With this irradiation process we can prevent diseases transmitted by food, such as Salmonella and Escherichia coli, prolong the shelf life of foods, control pests that harm fruits by delaying germination and ripening, and finally sterilization, which allows their storage for years without refrigeration [1]. There are many methods used in food processing and conservation, such as pasteurization, freezing, cooling, among others. Among these methods, food irradiation deserves special attention, which consists of submitting food to controlled doses of ionizing radiation. Ionizing radiation acts directly and/or indirectly on microorganisms, more precisely on DNA and RNA molecules, inhibiting their reproduction and growth. Added to this, ionizing radiation may be responsible for the destructive oxidation of the lipoprotein structures of cell membranes [2]. The effect of ionizing radiation and the efficiency of a given dose of radiation on microorganisms depend on the radioresistance of the microorganism.

The use of ionizing radiation for food preservation has been studied for several decades and is regulated in the USA by the Food and Drug Administration (FDA). As of 1997, the World Health Organization (WHO) released the use of the technique for all types of food, after studies proved that the technique is not harmful to health [3]. In Brazil, the first studies on food irradiation were carried out by the *Centro de Energia Nuclear na Agricultura* (Cena), in the 50s [4]. Currently, Brazilian legislation follows the international recommendations suggested by the Food and Agriculture Organization (FAO), the International Atomic Energy Agency (IAEA), and Codex Alimentarius [5, 6, 7].

For this industrial purpose there are two types of installations that irradiate food that are authorized by law. They are: irradiators by sources (cobalt 60 and cesium 137) and irradiators by radiation generating equipment (X-rays and electron beam) [8]. The ways of irradiating these foods are radurization, which is the method in which small doses of radiation are applied to the food to reduce the speed of fruit ripening, preventing sprouting. Radapertization or sterilization is the treatment of food with a dose of ionizing energy sufficient to prevent decomposition and microbial toxicity, whatever the time and storage conditions of the product. As long as it is not contaminated again. Radiopasteurization or rooting is the method in which an amount of radiation greater than that used in radurization and less than that used in radapertization is used to eliminate microorganisms on the surface of the food.

The scope of this work is the survey, analysis and evolution of national and international legislation related to ionizing irradiation practices in food. The Nuclear Technology Development Center (CDTN) (*Centro de Desenvolvimento da Tecnologia Nuclear* is one of the research units of the Brazilian Nuclear Energy Commission (Cnen), *Comissão Nacional de Energia Nuclear,* an autarchy linked to the Ministry of Science, Technology and Innovation (MCTIC), *Ministério da Ciência, Tecnologia e Inovação* It operates in research and development, teaching (postgraduate) and providing services in the nuclear area and in related areas, and has installed a panoramic research irradiator with a source of cobalt 60, the only one of this size in the State of Minas Gerais. Figure 1 shows the Gammabeam-127 cut-away. Figure 2 shows the source of cobalt-60 housed inside its biological shield.

Figure 1: *The Gammabeam-127 cut-away*

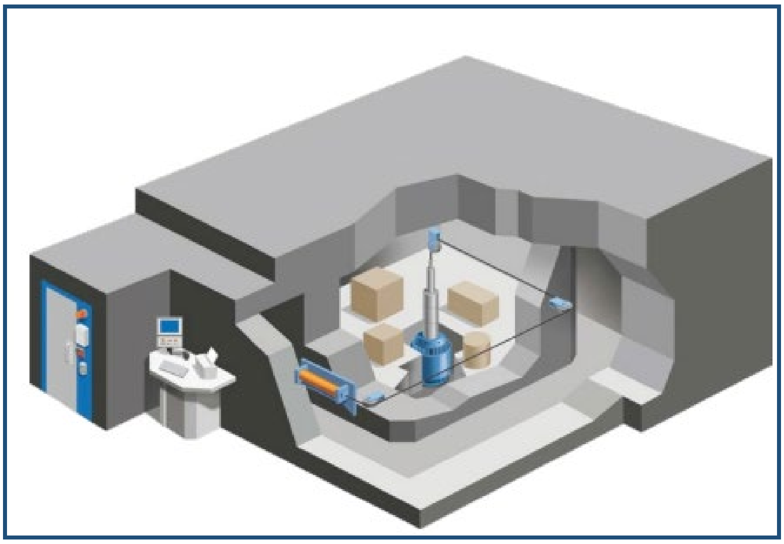

Figure 2: *Cobalt source inside your biological shield*

Source: Norton website [17]

The Gamma Irradiation Laboratory - LIG of the Nuclear Technology Development Center - CDTN is classified as a Category II Multipurpose Panoramic Irradiator, manufactured by MDS Nordion in Canada, Model/serial number IR-214 and type GB-127, equipped with a source of cobalt 60, dry stored with a maximum activity of 60,000 Ci. Among its attributions is the treatment of food, disinfestation of fruits and grains, conservation of works of art, sterilization of medical and pharmaceutical products. Its researches have been carried out through partnerships with universities and some projects from development agencies. The CDTN, in addition to research and development activities, includes the provision of specialized technical services and the generation of products, processes, technologies and patents in the nuclear area to serve customers and end users, whether national or international. Source characteristics of the Co 60 gamma irradiator, sealed, are linear rods arranged in one or more planar arrays, emits photons with energies of approximately 1.17 and 1.33 MeV in almost equal proportions. The half-life of radioactive decay has been regularly reviewed and updated. The most recent publication by the *Instituto Nacional de Padrões e Tecnologia* gave values of 1925.20 (60.25) days for Co 60.

2. MATERIALS AND METHODS

For the methodology of this research, bibliographical reviews were carried out, consultations in national and international legislation, research in books, internet sites and in the documentation available from a Gamma Irradiation Laboratory.

The literature is abundant in articles on the processing of food irradiation containing well-established guidelines and standards. Described by various organizations such as the International Atomic Energy Agency (IAEA) and the International Agency Commission on Radiation Units and Measurements (ICRU). And for its implementation a large number of standards have been published as ISO/ASTM standards, thus ensuring wider international acceptance.

An analysis of the evolution of the national and international legislation concerning the practices of ionizing irradiation and the control of the actions practiced in gamma irradiators was carried out, with emphasis on food irradiation. The regularization of a given procedure is established by the acceptable or objectionable conduct and actions of an individual, institution or company called the legal order. Through current legislation, it is possible to find those who benefit from food irradiation. Despite being a method used for a long time, it was proposed for the first time in 1905, according to English patent nº 1609 of January 26, 1905, requested by Appleby and Banks, [9].

3. RESULTS AND DISCUSSION

The present article is classified as exploratory in terms of purposes and is a work of a substantially bibliographical and documental nature. The evolution of legislation in Brazil was presented, characterizing the importance of guidelines involving food irradiation. The applicability of legislation was evaluated in facilities that irradiate food, considering the requirements of various government agencies. Remembering that the directives on food irradiation were adopted years ago in developed countries, not being changed significantly today, despite technological progress in the field of ionizing radiation. In 2002 a new and comprehensive legislative framework was adopted in the European Union for food safety and other significant developments such as the increasing globalization of food trade.

A survey of legislation on high-dose dosimetry and on all steps involving product validation was carried out. As a result of this study, it can be said that the entire validation process requires strict monitoring of the tests, considering the quality assurance part of the applicant and the Gamma Irradiation Laboratory.

The Brazilian Resolution, issuing body Brazilian Health Surveillance Agency - Anvisa (*Agência Nacional de Vigilância Sanitária*) RDC nº 21, of January 26, 2001, aims to establish the general requirements for the use of food irradiation with a view to the sanitary quality of the final product, applied to all foods treated by irradiation. The acts related to this resolution are Law No. 6437, of August 20, 1977, Decree No. 72718, of August 29, 1973, Law No. 7394, of October 29, 1985 and Ordinance No. 326, of October 30 July 1997. And the general standards for irradiated foods, they are Codex Alimentarius, CAC/RCP 19-1979, Rev. 1-2003, the International Code of Practice, Report No. 890 of the World Health Organization (OMS), Report Series High Dose Irradiation: healthiness of irradiated foods with doses above 10 kGy, Geneva, 1999, and the draft ICGFI, International Consultative Group on Food Irradiation, Standard for Good Practices on Food Irradiation. Based on these documents, the safety of the installation and equipment operators is guaranteed, which are licensed by municipal and federal bodies, competent state or municipal authority or the Federal District upon issuance of a Sanitary Permit, after authorization from the Brazilian Nuclear Energy Commission - Cnen has been granted. Nuclear and registration with the competent body of the Ministry of Health [10].

The Standard Guide for Absorbed-Dose Mapping in Radiation Processing Facilities ISO/ASTM 52303:2015(E), provides guidance for determining absorbed dose distributions (mapping) in irradiated products, materials or substances. This guide is part of a set of standards that present the recommendations for the correct implementation of dosimetry in radiation processing, it is part of the set of ISO/ASTM 52628. The control of obtaining a quantitative dosimetric record is mandatory. Validation protocols are required for all irradiated products. Foods to be treated by irradiation follow the minimum absorbed dose conditions, which must be sufficient to achieve the intended purpose, and the maximum absorbed dose, which must be lower than that which could compromise the functional properties of the food. Dosimetry is an element of total quality assurance of the installation system. Other controls are needed for specific applications of food preservation irradiation. For food irradiation and product irradiation sterilization, ISO and ISO/ASTM standards are specific. ISO/ASTM 51431, 51608, 51649, 51702 and 51818 and ISO 11137-1 practices must be verified [11].

ISO 51900/2009 is the Standard Guide for Dosimetry in Radiation Research on Food and Agricultural Products, this document presents the minimum dosimetry requirements to perform analyzes on the effect of irradiation on food. It establishes the quantitative relationship between dose and the effects caused in the products. The Codex Alimentarius Commission presents the General International Standard and a Code of Practice that emphasizes the importance of dosimetry in guaranteeing the applied doses. Together with ISO/ASTM 52701:2013 (Reapproved 2020)(E) it defines the Standard Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing, is part of the quality assurance control in the irradiation routine, where the user is directed to the implementation of the ISO/ASTM 52628 Practice. Mathematical methods described in the standard guide for selection and use of methods for calculating absorbed dose in irradiation processing - Designation: E2232 – 21, detail the methods of Monte Carlo, punctual kernel, discrete ordinate, semi-empirical and empirical methods. This guide is limited to the use of general purpose software packages for calculating the transport of charged or uncharged particles and photons, or both, from various types of ionizing radiation sources. This guide allows the user to select which technique is appropriate for calculating absorbed dose.

Standard Guide for Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing are described to identify, evaluate and estimate measurement uncertainty components associated with the use of dosimetry systems and to calculate the combined standard measurement uncertainty and the expanded (general) uncertainty of dose measurements based on the Guide to the Expression of Uncertainty in Measurement - GUM and is intended to be read in conjunction with ISO/ASTM 52628, ISO/ASTM 51261 and ISO/ASTM 52701 [11].

Standard Practice for Blood Irradiation Dosimetry, this document describes the gamma irradiator facility qualification program and the dosimetric procedures to be followed during operational qualification and performance qualification. Describes routine procedures for products such as blood and its blood components. The absorbed dose range for irradiation of blood is typically 15 Gy to 50 Gy, intended to be followed in conjunction with ISO/ASTM Practice 52628 [12].

ISO/ASTM 51261:2013 (Reapproved 2020)(E) is the Standard Practice for Calibration of Routine Dosimetry Systems for Radiation. The dosimeter calibration system must be rigorous, following well-defined standards, including the establishment of measurement traceability and estimation of the associated uncertainty. It is intended to be read in conjunction with ASTM E2628 and the relevant ASTM or ISO/ASTM standard practice for the dosimetry system being calibrated. ISO/ASTM 51276:2012(E) is the practice that indicates the use of polymethylmethacrylate (PMMA) in dosimetry systems to measure the absorbed dose in materials irradiated by photons or electrons in terms of absorbed dose to water. The PMMA dosimetry system is classified as a routine dosimetry system. The PMMA dosimeter is classified as a Type II dosimeter based on the complex effect of influence quantities (see ASTM E2628). This document is intended to be read in conjunction with ASTM E2628 (Practice for Dosimetry in Radiation Processing), [13,14].

ISO/ASTM 51026:2015 – This document covers the procedures for using the high dose dosimetry system by the Fricke dosimeter. Fricke dosimeters constitute a well-characterized system, simple to prepare, easy to handle and used as absolute dosimeters. Among the various dosimetric systems employed in the determination of high doses, this dosimeter is based on ferrous sulfate solutions in sulfuric medium, as a solution to measure the absorbed dose of water when exposed to ionizing radiation [15]. The method of preparing Fricke solutions for dosimetry purposes was standardized by the American Society for Testing and Materials (ASTM) and establishes the conditions for preparation, irradiation and reading of this type of dosimeter. This practice forms part of a set of standards that provide recommendations for correct dosimetry in radiation processing, and describes a means of achieving compliance with the requirements of ISO/ASTM 52628 practice for the Fricke dosimetry system [16].

The Standard Guides, ISO 11137-1 (2006), Sterilization of health care products – Radiation; Requirements for development, validation and routine control of a sterilization process for medical devices. ISO 11137-2 (2012), Sterilization of health care products – Radiation; Establishing the sterilization dose. ISO 11137-3 (2006), Sterilization of health care products – Radiation; Guidance on dosimetric aspects, establish the guidelines used for the validation of the sterilization dose by the gamma irradiation process, applied methodologies and acceptance criteria with the respective required analyzes.

The guidelines to be considered for validation must be carried out whenever a new irradiator is installed, when there is any change that compromises the irradiation process; when there is a change in the product or packaging to be irradiated, or the inclusion of a new product. A new study evaluating the different irradiation doses, whose weight or form may result in different results of the radiation distribution in the product, must be carried out. Samples of each product must be tested to guarantee the irradiation dose value for the new product. The irradiation process is defined as a critical step, and its purpose is to guarantee the sterilization of the products. Therefore, the products to be used in the validation process are defined, the maximum and minimum acceptable doses that must be applied to the products are defined, with the objective of safeguarding their original characteristics. After receiving the products submitted to irradiation, the person in charge sends them to the sterilization test, with the aim of verifying whether the applied dose corresponds to the established dose and complies with the expected final result.

4. CONCLUSION

The technical regulation establishes that the purpose of using food irradiation for the final quality of the product, defines that the process subjects the food to controlled doses of ionizing radiation for sanitary, phytosanitary and/or technological purposes.

Most foods do not have their nutritional properties altered, as long as they comply with the radiation doses recommended for each type of food. The technology of introducing food irradiation in Brazil occurs since the end of the 60s. During the following decades, there was an evolution along with the appeal of this technology in the world.

The technology used for food irradiation favors the provision of food and nutritional security. In addition to being a clean and safe food processing method, it ensures an increase in the supply of high biological, sanitary and nutritional quality foods. Brazilian legislation complies with international standards.

As for the validation and control of the irradiation process, the ISO 11137/1994 standard - Sterilization of Health Care Products lists the necessary steps to adequately guarantee the activities carried out in the sterilization process by irradiation. These activities comprise documented and designed work programs with the objective of demonstrating that the process is operated within the intended limits.

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