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Legislation and Regulations Regarding the Use of Ionizing Radiation in Phytotherapeutics in Brazil: A Documentary Analysis

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Abstract: This study aimed to conduct a documentary analysis of federal legislation and regulations in Brazil regarding the irradiation of phytotherapeutic products. The research was carried out between April and June 2024 through a review of official documents, including regulations, resolutions, constitutional amendments, and decrees published between 1983 and 2018. Although the analysis revealed the existence of specific norms and resolutions related to food irradiation, no direct regulation concerning the use of ionizing radiation in phytotherapeutics was identified in Brazil. National legislation addresses the use of ionizing radiation in food, particularly for radio-sterilization, with emphasis on RDC No. 21/2001, which may be indirectly applicable to medicinal plants. Normative Instruction No. 44/2014 provides the most relevant guidelines regarding the application of ionizing radiation in pharmaceuticals. In contrast, international legislation—such as that from the FDA (USA) and FSSAI (India)—explicitly regulates the radio-sterilization of medicinal herbs and plants. The documentary analysis highlights the need for the expansion, regulation, and harmonization of Brazilian standards and protocols to ensure the safe application of ionizing radiation in phytotherapeutics.

Keywords: Ionizing radiation, Regulation, ANVISA, Phytotherapeutics.

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Legislação e Normas relativas ao uso de radiações ionizantes em fitoterápicos no Brasil: Uma Análise Documental

Resumo: Este estudo teve como objetivo realizar uma análise documental da legislação e regulamentação federais no Brasil sobre a irradiação de produtos fitoterápicos. A pesquisa foi realizada entre abril e junho de 2024, por meio da revisão de documentos oficiais, incluindo regulamentos, resoluções, emendas constitucionais e decretos publicados entre 1983 e 2018. Embora a análise tenha revelado a existência de normas e resoluções específicas relacionadas à irradiação de alimentos, não foi identificada nenhuma regulamentação direta sobre o uso de radiação ionizante em fitoterápicos no Brasil. A legislação nacional trata do uso da radiação ionizante em alimentos, especialmente para radioesterilização, com destaque para a RDC nº 21/2001, que pode ser aplicada de forma indireta às plantas medicinais. A Instrução Normativa nº 44/2014 apresenta as diretrizes mais relevantes quanto à aplicação da radiação ionizante em medicamentos. Em contraste, legislações internacionais — como as da FDA (EUA) e da FSSAI (Índia) — regulam explicitamente a radioesterilização de ervas e plantas medicinais. A análise documental evidencia a necessidade de ampliação, regulamentação e harmonização das normas e protocolos brasileiros para garantir a aplicação segura da radiação ionizante em produtos fitoterápicos.

Palavras-chave: Radiações ionizantes, Regulamentação, ANVISA, Fitoterápicos.

1. INTRODUCTION

Traditional and integrative medicines are recognized by the World Health Organization (WHO) and are defined as "systems of knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, used in the maintenance of health and in the prevention, diagnosis, improvement or treatment of physical and mental illness." The WHO discusses and promotes the preservation and application of these systems through the joint efforts of communities, health professionals, and governments (WHO, 2019).

In the 1970s, the organization recommended "the formulation of national policies and regulations regarding the use of traditional medicines with proven efficacy and the exploration of possibilities for incorporating traditional knowledge holders into primary health care activities, providing them with appropriate training" (IAEA, 2015; WHO, 2019).

According to the WHO, traditional medical practices in primary health care are used by over 80% of the population in developing countries, and the use of plants and their derivatives accounts for about 85% of therapies employed in traditional medicine (WHO, 2019). In this context, it is important to understand how these practices are defined and regulated by modern health systems. The National Health Service (NHS, 2022) defines herbal medicines as those whose active ingredients are extracted from plant parts such as leaves, roots, or flowers, reflecting an attempt to align traditional knowledge with contemporary scientific and regulatory rigor.

Brazil has shown concern in establishing guidelines on the use of traditional medicines, especially regarding the use of herbal remedies. In 1991, the Federal Council of Medicine recognized the use of herbal medicines, and Ordinance MS/GM No. 971, issued in 2006, enabled their integration into the Unified Health System (SUS). The National

Policy on Medicinal Plants and Herbal Medicines (PNPMF) was established in 2006, and in 2008, the National Program on Medicinal Plants and Herbal Medicines was approved. The main objective of the PNPMF is "to ensure the Brazilian population safe access and rational use of medicinal plants and herbal medicines, promoting the sustainable use of biodiversity, the development of the production chain, and the national industry" (Brazil, 2008; Ministry of Health, 2016).

In this context of seeking safety and quality in the use of plant-based products, the Brazilian Ministry of Health establishes quality requirements to ensure the safety of herbal materials (ANVISA, 2018). One well-established method of sterilization is the use of ethylene oxide. However, according to Satomi et al. (2005), its use poses risks associated with toxic residues, requiring a minimum of 14 days of forced aeration for complete removal of these residues. Another method is radio-sterilization, which, although more commonly associated with food preservation, has been successfully applied to plant materials, contributing to the microbiological stability and safety of herbal medicines (Santos et al., 2011; Lemos et al., 2013; Costa et al., 2013; Santos, Amaral & Silva, 2018; Maia-Neto et al., 2020; Araújo et al., 2022; Soares et al., 2024a; Soares et al., 2024b; Freitas et al., 2025).

The first international guidelines for the use of ionizing radiation (IR) in food and plant-based products were established in the 1980s through the Codex Alimentarius, developed by FAO and WHO. In Brazil, these guidelines were later incorporated into national legislation, expanding the possibilities for the safe, sustainable, and technically qualified use of plant biodiversity, particularly in relation to the preservation and sterilization of raw materials intended to produce herbal medicines (Brazil, 2001; Santos, 2008; IAEA, 2015).

The regulation of food radio-sterilization was established by Resolution RDC No. 21 of January 26, 2001, which does not define a maximum dose but states that the dose must be such that it does not compromise the characteristics of the material (ANVISA, 2018). However, the literature indicates that ionizing radiation can alter the phytochemical profile

of plant products, possibly causing changes in their phytochemical composition, which may result in the suppression or enhancement of their pharmacological activities (Krishnan et al., 2018; Pereira et al., 2018; Khawory et al., 2020; Neto et al., 2020; Anjali et al., 2023). For these reasons, the appropriate selection of both the technique and the radiation source is essential, as well as adherence to the regulations regarding specific doses and intervals for each product, taking into account the intended objective (Levy et al, 2020).

The first commercial irradiator in Brazil was implemented in the 1980s, with the food industry being one of its main areas of application. However, despite scientific and technological advances in this field, the industrial use of radiation is still considered insufficient, especially when the country's territorial size and productive potential are taken into account. (Levy et al., 2020).

Given this context, the objective of this study is to evaluate and discuss the current state of legislation regarding the use of ionizing radiation in herbal products through a documental analysis.

2. MATERIAL E METHODS

A documental analysis was conducted between April and June 2024, during which official documents related to regulations and legislation at the federal level of the Federative Republic of Brazil were selected.

The documents were cataloged according to their year of publication (Table 1). For this research, government databases and websites were consulted, as well as indexers such as PubMed and SciELO. The keywords used were: "legislation on ionizing radiation in Brazil (legislação acerca de radiações ionizantes no Brasil)", "public policies on herbal medicines (políticas públicas sobre fitoterápicos)", "radio-sterilization in Brazil (radioesterilização no Brasil)", "use of ionizing radiation in food in Brazil (uso de radiações ionizantes em alimentos

no Brasil)", "use of ionizing radiation in medicines in Brazil (uso de radiações ionizantes em remédios no Brasil)", and "regulation of ionizing radiation in Brazil (regulamentação das radiações ionizantes no Brasil)".

After the research, the following documents were selected and analyzed:

- CODEX STAN 106-1983, REV.1-2003 (FAO/OMS);
- RDC nº 21, dated January 26, 2001 (ANVISA);
- Constitutional Amendment No. 49, dated February 8, 2006;
- Decree No. 5,813, dated June 22, 2006 (PNPMF);
- Normative Instruction No. 4, dated June 18, 2014 (ANVISA);
- RDC No. 26, dated May 13, 2014 (ANVISA);
- Normative Instruction No. 44, dated August 21, 2019 (ANVISA);
- Consolidated Standards for Registration and Notification of Phytotherapeutic Products (2018).

3. RESULTS AND DISCUSSION

The documental analysis made it possible to identify and systematize the main legal and regulatory milestones that directly or indirectly govern the use of ionizing radiation in phytotherapeutic products in Brazil. The results were organized based on thematic categories, covering sanitary legislation, international guidelines, national public policies, and specific technical regulations, and are presented in Table 1.

The discussion of the findings is structured to highlight the historical and institutional evolution of these regulations, emphasizing the progress made, existing gaps, and ongoing challenges in consolidating the safe and regulated use of ionizing radiation in

the context of production, quality control, and research involving medicinal plants and phytotherapeutic products.

International guidelines on the use of ionizing radiation (IR) in food were established in the 1980s through the Codex Alimentarius, coordinated by the FAO/WHO. These standards served as the foundation for the safe and standardized application of technologies such as gamma radiation, particularly focused on sterilization processes and the control of biological contaminants. According to the Codex, the authorized radiation sources include gamma rays from radioactive isotopes of Cobalt-60 (Co-60) or Cesium-137 (Cs-137); X-rays generated by equipment with energy equal to or below 5 MeV; and electron beams with energy equal to or below 10 MeV (FAO/WHO, 2003; Alves, 2007).

Table 1 – Legal documents analyzed on the use of ionizing radiation in phytotherapeutics in brazil.

Authors	Title	Year
ANVISA	RESOLUÇÃO-RDC Nº 21	2001
FAO/OMS	REVISED CODEX GENERAL STANDARD FOR IRRADIATED FOODS	2003
Presidency of the Republic/Civil House	Constitutional Amendment No. 49	2006
Presidency of the Republic/Civil House	Decree Nº 5.813 (PNPMF)	2006
ANVISA	Normative Instruction Nº 4	2014
ANVISA	RDC RESOLUTION No. 26	2014
ANVISA	Consolidated Standards for Registration and Notification of Phytotherapeutic Products	2018

Source: Prepared by the authors based on the documents analyzed in the study (ANVISA, 2001, 2014a, 2014b, 2018; FAO/WHO, 2003; Presidency of the Republic/Civil House, 2006a, 2006b).

The Codex also defines parameters for the absorbed radiation dose, specifying that the minimum dose must be sufficient to achieve the intended technological objective, while the maximum dose must not compromise consumer safety or negatively affect the structural,

functional, or sensory integrity of the food. The generally accepted maximum dose is up to 10 kGy, unless specific technological situations justify higher levels (FAO/WHO, 2003).

Although these guidelines were originally developed for food, they have served as a reference for other applications in plant materials, including phytotherapeutics, particularly regarding sterilization. In exceptional cases, such as specific sterilizations, doses may reach up to 70 kGy, with Cobalt-60 being the most used source (Brazil, 2001; Santos, 2008; Carvalho and Oliveira, 2017). It is important to emphasize that the use of ionizing radiation does not replace good hygiene or quality practices, as highlighted by the Codex, being recommended only as a supplement to ensure the sanitary safety of the products.

Unlike Brazil, other countries already have consolidated regulatory frameworks regarding the irradiation (Table 2) of phytotherapeutic products. The U.S. Food and Drug Administration (FDA), for example, allows the irradiation of dried herbs, provided specific conditions regarding the applied dose are met. The FDA's actions are based on the Amendment on Food Additives to the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1958, which defines irradiated food as a food additive. In this way, the FD&C Act sets the control criteria and conditions necessary for the authorization of radiation use in food (Pauli & Tarantino, 1956; FDA, 2018).

In the European context, experts from the European Food Safety Authority (EFSA) issued a technical opinion in 2011, considering the use of ionizing radiation for radio-sterilization purposes to be safe. The Directive 1999/3/EC of the European Parliament defines the specifications for the application of this technology, although only one food category is explicitly authorized: dried aromatic herbs, spices, and plant seasonings. According to the EFSA opinion, the doses applied should not be restricted to the categories currently regulated, requiring consideration of contemporary food diversity, microorganism load and type, as well as the physicochemical aspects of the products.

In turn, the Food Safety and Standards Authority of India (FSSAI) clearly regulates the radio-sterilization processes applicable to herbal products, including phytotherapeutics. This regulation is based on the Atomic Energy Act of 1962, whose normative implementation was consolidated in 2012, with the promulgation of specific rules for the radiation processing of food and related products.

Table 2 – Radiation doses used in herbs/plants in the USA, European Union, and India.

Regulatory agency	Specific legislation/year	Dose
FDA	*Federal Food, Drug, and Cosmetic Act* – FD&C Act/1958	Up to 30 kGy[a]
EFSA	DIRECTIVE 1999/2/EC	Up to 10 kGy[b]
FSSAI	Atomic Energy Radiation Processing of food and allied products rules/2012	Up to 25 kGy[c]
ANVISA	RDC nº 21, dated January 26, 2001	Establishes that the maximum dose should be such that it does not compromise the functional and sensory characteristics of the material.

[a]The law covers various food categories, and the dose described refers to herbal supplements. [b]The law only mentions dried aromatic herbs, spices, and plant seasonings. [c] The law covers various food categories, and the described dose refers to the maximum dose for medicinal herbs and phytotherapeutics.
Source: (FDA, 1958; EFSA, 1990; ANVISA, 2001; FSSAI, 2012).

In the national context, the Constitutional Amendment No. 49 of 2006 represented an important milestone by allowing, under a permit regime, the commercialization and use of radioisotopes for medical, agricultural, industrial, and research purposes. This amendment filled a legal gap that was previously exclusive to the Union, allowing, for example, the use of radiopharmaceuticals and the development of nuclear medicine centers (Brazil, 2006). The amendment also authorized the production and use of short-lived radioisotopes (up to two hours), contributed to the decentralization of nuclear activities, reaffirmed objective civil liability for nuclear damage, and regulated the exploration and commercialization of minerals and nuclear derivatives.

However, it is noted that both the amendment and the resulting regulations focus on the medical field, not directly addressing the use of ionizing radiation (IR) in phytotherapeutic products. RDC No. 21 of 2001 addresses food irradiation and defines the process as a physical treatment that exposes packaged or bulk food to controlled doses of radiation for sanitary, phytosanitary, and technological purposes. Despite its broad scope and direct influence from the Codex Alimentarius, this regulation does not explicitly mention phytotherapeutics.

It is also important to highlight that since the creation of the National Nuclear Safety Authority (ANSN) by Law No. 14.222/2021, responsibility for the regulation, licensing, and oversight of activities involving ionizing radiation has been shared with this new regulatory agency, particularly concerning irradiator facilities and the physical and operational safety of these systems.

The ANSN became a federal agency after the disbandment of the National Commission for Nuclear Energy (CNEN), created in 1956, under the Ministry of Science, Technology, and Innovation (MCTI) and linked to the National Council for Scientific and Technological Development (CNPq). Later, through Law No. 4.118/1962, CNEN was also transformed into a federal agency. CNEN's institutional mission is: "To ensure the safe and peaceful use of nuclear energy; to develop and make available nuclear and related technologies, aiming at the well-being of the population." With the enactment of the decree that established the National Nuclear Safety Authority (ANSN), it was foreseen, among other changes, that the regulatory and oversight functions of the nuclear sector, which were previously concentrated within the National Nuclear Energy Commission (CNEN), would be transferred to the newly created authority. CNEN would then be responsible for maintaining and promoting nuclear activities, with an emphasis on research and development (CNEN, 2021).

However, due to budgetary, organizational, and human resource risks identified by the Federal Court of Accounts (TCU) during the 2024–2025 biennium, the ANSN has not yet been fully implemented. The TCU requested the development of an action plan to ensure the proper establishment of the authority. Considering this scenario, CNEN continues to perform its original regulatory functions and responsibilities (TCU, 2025).

The absence of specific regulations is also evident in Decree No. 5.813/2006, which established the National Policy on Medicinal Plants and Phytotherapeutics (PNPMF). Although the decree promotes safe access and rational use of phytotherapeutics, the sustainable development of the production chain, and the incorporation of these products into the SUS, there is no mention of the use of ionizing radiation in its processes.

The Interministerial Ordinance No. 2,960 of 2009, which created the National Program for Medicinal Plants and Phytotherapeutics, reinforces the principles of PNPMF and encourages the creation of standards and strategies for technological and scientific development and quality control. Still, the use of ionizing radiation is not addressed in the document.

RDC No. 26/2014 advances by establishing requirements for the registration and renewal of phytotherapeutic medicines, including imported products, packaging, and criteria for efficacy and safety. However, it also does not include irradiation in its provisions.

Instructional Norm No. 44/2014 is, to date, the document closest to regulating the use of ionizing radiation in the pharmaceutical field. Focused on good manufacturing practices, it authorizes the use of gamma radiation and electron beams for the sterilization of medicines, including inputs and packaging, and defines dosimetric criteria, requirements for installations, and radiological safety measures. Although it does not directly address phytotherapeutics, its guidelines could serve as a basis for future regulation.

Additionally, the Consolidation of Registration and Notification Standards for Phytotherapeutics, derived from Instructional Norm No. 4, briefly addresses ionizing

radiation as sanitizing agents but does not delve into the topic or provide specific guidelines for its use in plant extracts.

Currently, there is no exclusive regulation addressing the irradiation of phytotherapeutics in Brazil. The existing regulations are primarily directed at food irradiation or the sterilization of synthetic medicines, indicating the need for regulatory advancements to include the application of ionizing radiation in phytotherapeutic products, respecting the safety and efficacy parameters already established for other sectors.

4. CONCLUSION

The use of ionizing radiation represents a well-established technology in the food sector and a promising approach for other areas, such as the pharmaceutical industry and herbal products. In Brazil, although there are robust regulations for irradiated foods and medicines in general, the absence of a specific regulation covering herbal medicines creates a regulatory gap that limits progress and innovation in the sector. Given the growing demand for safe and effective natural products, it becomes urgent to revise and update the current legal framework, explicitly including plant extracts and herbal medicines eligible for ionizing radiation treatment. This incorporation would enhance the microbiological safety, stability, and standardization of such products, in accordance with the principles of the National Policy on Medicinal Plants and Herbal Medicines (PNPMF). Moreover, the adoption of regulations based on scientific evidence and aligned with international guidelines, such as the Codex Alimentarius, could stimulate technological development and improve the competitiveness of the national herbal medicine industry, without compromising public health or the environment. Therefore, it is recommended that a specific regulation be formulated to expand and harmonize Brazilian guidelines, aiming to regulate the application of ionizing radiation in herbal medicines, ensuring their safety and efficacy.

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