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NUTRACEUTICALS AND THEIR DEFINITION: A SCOPING REVIEW

Juliana Tomaz Pacheco Latini
Teacher, Institute of Pharmaceutical Sciences Multidisciplinary Center of the Federal University of Rio de Janeiro, UFRJ-Macaé
https://orcid.org/0000-0001-9528-1252

Rafaela Moreira Soares
Nutritionist, Institute of Pharmaceutical Sciences, Multidisciplinary Center of the Federal University of Rio de Janeiro, UFRJ-Macaé
https://orcid.org/0000-0001-7159-6719

Laiz Gomes da Silva Hortencio
Student, Institute of Pharmaceutical Sciences Multidisciplinary Center of the Federal University of Rio de Janeiro, UFRJ-Macaé
https://orcid.org/0009-0005-6292-4000

Aline Caceres Rodrigues
Pharmacist, Institute of Food and Nutrition Multidisciplinary Center of the Federal University of Rio de Janeiro, UFRJ-Macaé
https://orcid.org/0009-0009-6674-1593

Abstract: Over the years, concern about healthy eating habits has increased, given the relationship between food and health. This is how nutraceuticals emerge, capable of integrating food and medicine to promote health. However, these are confused with functional foods or present concepts that differ from their essence. This work aims to propose a new definition for nutraceuticals that allows it to be differentiated from functional foods. A scoping bibliographic review was carried out in the PubMed, Scielo and Scopus databases using the following keywords: nutraceutical, nutraceuticals, functional food and functional foods. Regulatory aspects were also researched on the electronic portals of ANVISA and the Official Gazette of the Union. Of the 15 articles analyzed, 60% of the authors designated nutraceuticals as substances present in food, and 40% as a product containing some bioactive compound with therapeutic activity, characterizing the need for standardization and regulation of this concept. Therefore, it is understood that nutraceuticals are pharmaceutical products containing quantities of bioactive compounds greater than those ingested in the normal diet and that they must be used under medical supervision to prevent diseases and/or as complementary therapy to medications.
Keywords: ANVISA, definition, functional foods and legislation.

INTRODUCTION

Over time, food has gained greater importance as a contributor to health and well-being. As a picture of this, changing eating habits and the search for healthier foods has become common (COSTA, 2010; PANDEY et al., 2010).

Amidst the emerging perception of global society with healthier lifestyle habits, the food industry is interested in developing products that meet this new consumer need. From then on, new products that offer health benefits emerge, such as functional foods and nutraceuticals (ESSA et al., 2021).

Functional foods originated from a Japanese government strategy in 1980 to reduce public health expenditures in view of the increase in life expectancy of the Japanese population (STRINGHETA, 2007). These foods were called "Foods for Specified Health Use" or Foods for Specified Health Use – FOSHU (STRINGHETA, 2007; MORAES and COLLA, 2006), and later became known worldwide as functional foods. They can be defined as foods that offer beneficial effects on health, both metabolically and/or physiologically, in addition to their nutritional functions (VIZOTTO, et al., 2010).

Following the spread of functional foods across several countries, to guarantee the consumption of safe food, several regulatory bodies, such as Codex Alimentarius and the Food and Drug Administration, began to regularize and standardize the claims of functional properties of these products. In Brazil, the legislation on these new foods was consolidated with the creation of the National Health Surveillance Agency (ANVISA) in 1999 by Law No. 9,782 (BRASIL, 1999e). According to the current Decree No. 3,571, of August 21, 2000, Anvisa's goods and products are subject to sanitary control and inspection: "food, including beverages, packaged water, their inputs, their packaging, food additives, limits of organic contaminants, residues of pesticides and veterinary medicines" (BRASIL, 2000).

ANVISA then began to regulate aspects regarding functional foods through the creation of ANVISA Resolutions No. 16/99, 17/99, 18/99 and 19/99 (MORAES and COLLA, 2006). Resolution Nº. 16/99 regulates the Procedures for Registration of Food and/or New Ingredients (BRASIL, 1999a). Resolution Nº. 17/99 which approves the Technical Regulation that establishes the Basic Guidelines for Risk Assessment and Food Safety (BRASIL, 1999b). Resolution Nº. 18/99 provides for the Technical Regulation that establishes the Basic Guidelines for the Analysis and Proof of Functional and/or Health Properties (BRA-

SIL, 1999c). And Resolution No. 19/99 brings the Technical Regulation of Procedures for Registration of Foods with Claims of Functional and/or Health Properties on their Labeling (BRASIL, 1999d).

Nutraceuticals are defined as purified bioactive constituents of food, which can protect or treat diseases, and are generally sold as pharmaceutical forms, unlike functional foods which, although they have similar functionalities to nutraceuticals, are only foods rich in bioactive constituents. Both functional foods and nutraceuticals can be used as protective agents against diseases or as complements to medications that allow the dose of the medication to be reduced with a consequent reduction in its adverse effects (DIAZ et al., 2020), but they cannot and should not be prescribed as similar products.

In the case of nutraceuticals, they represent a different category from functional foods, being created in the United States by Stephen DeFelice, founder of the Foundation for Innovation in Medicine in 1989 (BARROS and STASI, 2012). DeFelice cites the term in the work "The nutraceutical revolution: Fueling a Powerful, New International Market" in 1989 (DEFELICE, 1989). Unlike functional foods, nutraceuticals are foods or parts of foods that have a medical appeal (MORAES and COLLA, 2006). In this way, nutraceuticals can be prescribed and present some advantages when used in the medical clinic, such as reducing the cost of therapeutic treatments (DAS et al., 2012) and reducing adverse events caused by medications in certain therapies (KALRA, 2003).

There is no clear demarcation between functional foods and nutraceuticals provided by regulatory authorities. Literature in recent years emphasizes the redefinition of the concept of nutraceuticals, taking into account the efficacy, safety and toxicity of these products (FERNANDES et al., 2019). Thus, there is a difficulty in standardizing the concept of nutraceuticals due to doubts about their meaning and confusion with functional foods, as both have health benefits. Due to these divergences, the prescription of nutraceuticals is still a somewhat confusing practice. Therefore, the present work aims to help elucidate these issues in order to facilitate their use by both lay society and health professionals.

MATERIALS AND METHODS

STUDY DESIGN

This work is a scope review (CORDEIRO and SOARES, 2016). The Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) (TRICCO et al. 2018) and the Methodology for JBI Scoping Reviews, contained in the Joanna Briggs Institute Reviewers Manual (PETERS et al. 2015) were employed. The purpose of the study was to answer the following question: "What is the definition of nutraceuticals and how do they differ from functional foods? "

The searches for articles were carried out in December 2022 and March 2023, through searches in the Scientific Electronic Library Online (SciELO), Scopus (ELSEVIER) and PubMed databases. The following keywords were used: nutraceuticals, nutraceutical, nutraceutical, nutraceuticals, functional foods and functional foods. The information made available on the electronic portal of the National Health Surveillance Agency (ANVISA), in the Food item, was also consulted.

All studies found based on the descriptors used and non-conventional literature were imported into the Parsifal software (https://parsif.al/), where data mapping was carried out.

ELIGIBILITY CRITERIA

Studies published in Portuguese and English were included, which addressed nutraceuticals and functional foods and their respective concepts, within a time limit of 2017 to 2023. Studies that did not fit the research concept were excluded, as some keywords used understood topics that were not of interest to the present study.

All studies found based on the descriptors used and non-conventional literature were imported into the Parsifal software (https://parsif.al/), where data mapping was carried out.

REVIEW AND SELECTION OF STUDIES

After selection by titles and abstracts, the publications were read in full and the most relevant ones constituted the final sample. Furthermore, to extract the elements from Parsifal, a spreadsheet was created, enabling data mapping: authors, year of publication and definition of the nutraceutical term.

The results found were analyzed using descriptive statistics, in order to evaluate the definition of the term nutraceutical and the main distinctions and similarities between these and functional foods, in order to construct a new definition with the aim of clarifying what a nutraceutical, thus facilitating its regulation and use in clinical practice.

RESULTS AND DISCUSSION

After the review, selection and exclusion process of duplicate studies, 224 studies were identified in the databases. However, only 17 addressed the topic of interest and, therefore, were included in the final sample. Figure 1 represents the selection stages of the studies that made up the research, following the PRISMA-ScR guidelines.

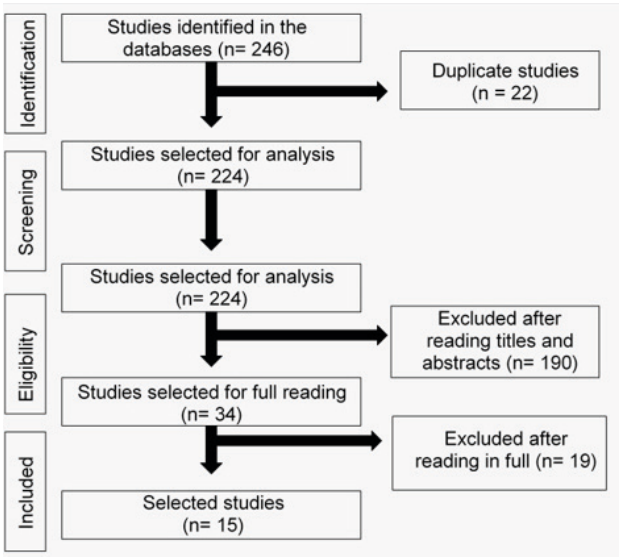

FIGURE 1

Regarding the language of the articles, 93.33% (14) were published in English and 6.67% (1) in Portuguese. As for the year of publication, it was observed that the highest frequency of publications was in 2020 (26.67%, 4) and 2021 (26.67%, 4), followed by 2017 (20%, 3) and 2018 (20%, 3) and the year with the lowest number of publications was 2022 (6.66%, 1). No publications of interest were found in the years 2019 and 2023.

Regarding the differentiation between nutraceuticals and functional foods, 10 (66.66%) studies did not make such a differentiation, encompassing the concept of functional foods in nutraceuticals, and only 5 (33.33%) differentiated such concepts.

Thus, different meanings were found for the term "nutraceutical (s)". In total, the definitions presented peculiar semantics, characterizing a diversification in the concept of nutraceuticals. It is inferred that this variation is common, both due to the close relationship between functional foods and nutraceuticals, and due to the evolution of the use of this term. This change in conceptualization over time can be explained by the elucidation of the pharmacodynamics of bioactive compounds, as well as by the development of new technologies to obtain new products containing these agents.

Analyzing the different meanings for nutraceuticals over time, it is observed that there are two basic conceptualization profiles: one defines nutraceuticals as a bioactive substance, and the other defines them as a product that contains bioactive compounds. Of the 15 articles selected, 9 (60%) referred to the concept of substance and 6 (40%) to the concept of product (Graph 1).

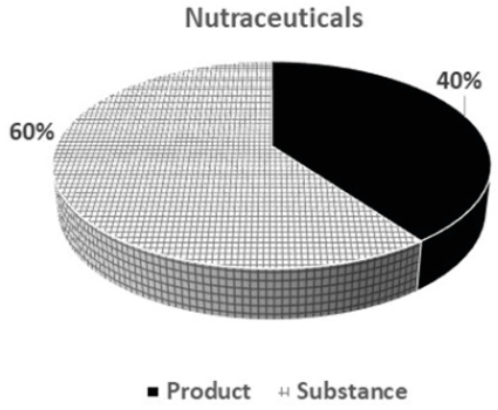

FIGURE 2

Considering the first definition created, DEFELICE (1995) initially states that a nutraceutical is a substance, although he refers to different types of products at the end of his explanation. Therefore, it was deduced that this meaning refers nutraceutical to a bioactive substance. This is in line with most of the studies found.

Based on the analysis of definitions found in the literature, the definition elucidated for nutraceuticals is that they are pharmaceutical products containing amounts of bioactive compounds that exceed those ingested in a normal diet, these compounds (nutrients or non- nutrients) coming from foods of plant or animal origin. , and which must be used under medical supervision to prevent diseases and/or as complementary therapy to drug treatments.

Regarding the unification between the concepts of nutraceuticals and functional foods, this was recurrent in several selected publications. However, some adversities between the terms were verified, reinforcing the uniqueness between them. Considering the first definition created, DEFELICE (1995) initially states that a nutraceutical is a substance, although he refers to different types of products at the end of his explanation. The similarities (Table 1) highlight the healthy characteristics of both functional foods and nutraceuticals, in addition to the shared bioactive substances, responsible for the benefits provided to the body.

Functional Foods	Nutraceuticals
Similarities	
Offer health benefits	
Can be of both animal and vegetable origin	
Present bioactive substances, that is, with specific metabolic or physiological action	
Groups of bioactive substances in common	
Must present biological activity scientifically	
Do not replace drug treatments	
It can't claim to cure diseases	

Table 1: Similarities between functional foods and nutraceuticals.

Despite the similarities between the two, it is possible to detect a greater number of differences (Table 2). Among the contrasts mentioned, it is clear that nutraceuticals are closer to medicines, while functional foods are similar to conventional foods. This relationship between nutraceutical and medicine is linked to the toxicological risk of inappropriate use of bioactive substances. GONZÁLEZ-SARRÍAS et al. (2013) supports the need for medical supervision regarding the intake of nutrients and micronutrients above the recommended daily intake (RDI), a situation relevant to nutraceuticals, which have high concentrations of nutrients or non-nutrients. However, unlike medicines, nutraceuticals cannot claim curative properties.

Functional Foods	Nutraceuticals
Differences	
Emerged through a strategic policy of the Japanese government in the 1980s	Emerged through an initiative by the scientist Stephen L DeFelice in 1989 in search of investments for the development of research in the area
It comes in the form of a conventional food	It does not come in the form of a conventional food, but can be in pharmaceutical forms (capsules, freeze-dried powders, etc...)
Interest of the Food Industry	Interest of the Pharmaceutical Industry
They contain bioactive substances in quantities normally ingested in a common diet	They present bioactive substances in quantities exceeding those ingested in a common diet
Reduce the risk of developing some chronic diseases	They can reduce the risk of developing chronic diseases and can be prescribed as a complementary treatment to medication
They are part of a common diet	They are indicated in specific cases
They can be consumed without medical advice	They must be prescribed and their use guided by health professionals
They should not present toxicity in large quantities	They have recommended use, in determined doses and controled intake
Do not allow medical appeal claims	They allow medical appeal claims

Table 2: Differences between functional foods and nutraceuticals.

Regarding legislative aspects, among the legislation proposed by ANVISA, none presented a specific regulation that defines nutraceuticals or guides their use in clinical practice. Resolution nº 16/99 (BRASIL, 1999a) and RDC nº 2/02 (BRASIL, 2002) present regulations on aspects that refer to nutraceuticals. Resolution Nº. 16/99 (BRASIL, 1999a) deals with the registration of new foods and ingredients, which can be presented in a pharmaceutical form, such as capsules and tablets, as well as nutraceuticals. And RDC nº 2/02 (BRASIL, 2002) regulates regulatory aspects regarding categories of bioactive substances that may be present in nutraceuticals. However, these regulations refer to foods consumed in a common diet, excluding products with therapeutic or medicinal purposes, which are not suitable for nutraceuticals. Therefore, nutraceuticals are not applied to legislation pertinent to the food area, so they do not come in the form of conventional foods and have a pharmacological nature.

The health claims recommended by the Codex Alimentarius and the definition of food- medicine by the FDA are also close to nutraceuticals (MORAES and COLLA, 2006), but just like the regulations provided by ANVISA, these two concepts refer to foods. The similarity between them and nutraceuticals involves the requirement of medical supervision. However, the recognition of health claims, both by Codex Alimentarius and ANVISA, and the food-drug regulation by the FDA, represent tools for the process of standardizing nutraceuticals.

The present literature review on nutraceuticals revealed major challenges for their conceptualization. Among the reasons identified, confusion with functional foods stands out due to characteristics shared by both.

In addition to this recurring mistake, the non-standardization of nutraceuticals and the lack of investment in studies, especially clinical studies, make it difficult to guarantee the quality and safety of these products, in addition to hindering their potentially advantageous therapeutic use in the treatment of chronic diseases.

Despite these obstacles, some publications advocate defining and recognizing the importance of nutraceuticals for preventive and therapeutic purposes. However, different meanings were detected, which presented two profiles regarding the scope of the term. Most claim that nutraceuticals are products that contain bioactive substances that provide health benefits, as long as they are scientifically proven. Part of the definitions alluded to nutraceuticals as substances with pharmacological activities.

CONCLUSION

Regarding the confusion between nutraceuticals and functional foods, it is concluded that the divergences between the concepts are evident, especially regarding the risk associated with nutraceuticals, which is not associated with functional foods. The possible toxicity of nutraceuticals is due to the high concentrations of bioactive compounds contained in their formulations, which highlights the indispensable professional advice when using these products. The presentation of nutraceuticals in pharmaceutical forms is another contrast observed, a characteristic that stimulates the pharmaceutical industry's interest in them.

Based on the specificities pertinent to nutraceuticals, it is suggested that they can be defined as: pharmaceutical products containing quantities of bioactive compounds that exceed those ingested in a normal diet, with these compounds (nutrients or non-nutrients) coming from foods of plant or animal origin, and which must be used under medical supervision to prevent diseases and/or as complementary therapy to drug treatments.

Therefore, nutraceuticals compete in the interests of the pharmacist, as well as other professionals in the field, in the role of health promotion and recovery. This fact highlights the need to encourage the proper standardization of these products at the level of definition, registration and technical regulation, in order to guarantee quality and safety in their use in clinical practice.

DISCLOSURE STATMENT

The authors report there are no competing interests to declare.

DECLARATION OF GENERATIVE AI AND AIASSISTED TECHNOLOGIES IN THE WRITING PROCESS

The authors report there is no use of generative AI and AI-assisted technologies in the writing process

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