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Food Trade for Specific Health Use FOSHU through Patents in LATAM: Relevant Aspects in International Law

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Abstract: Food Trade for Specific Health Use FOSHU through Patents in LATAM: Relevant Aspects in International Law. Introduction: This article addresses the legal regulations for Foods for Specified Health Uses (FOSHU) in the main trade associations of Latin America (LATAM), based on the *Codex Alimentarius* system. **Objective:** The objective is to determine regulatory progress in the trade of FOSHU products. **Material and methods:** This study includes a review of the literature emanating from the databases from 2018 to 2022, according to the framework of three general food marketing regulations: food safety claims; inspection regulations, and food manufacturing and labeling. **Results:** The results reveal the absence of a specific legislation for FOSHU foods, as these are only mentioned in the area of nutrition. **Conclusions:** The legal framework in the trade of these products is based on *jus cogens*. Registration of industrial patents in the main member countries of LATAM trade associations can be facilitated through the Patent Prosecution Highway (PPH). **Arch Latinoam Nutr 2022; 72(3): 218-230.**

Keywords: functional foods, Pacific Alliance, MERCOSUR, SICA, comparative international laws.

Resumen: Comercio de Alimentos para Uso Específico de Salud FOSHU a través de Patentes en LATAM: Aspectos Relevantes en el Derecho Internacional. Introducción: El artículo aborda las regulaciones jurídicas en Alimentos para Uso Específico de Salud "FOSHU" en las principales asociaciones comerciales de América Latina (LATAM), basados en el sistema *Codex Alimentarius*. **Objetivo:** Determinar el avance regulatorio en la comercialización de productos FOSHU. **Materiales y métodos:** Se revisa la literatura emanada de las bases de datos desde el año 2018 al 2022, según el marco de tres regulaciones generales de comercialización de alimentos: las declaraciones de seguridad alimentaria; las regulaciones de inspecciones, las de manufacturas de alimentos y etiquetado. **Resultados:** Los resultados revelaron la ausencia de una legislación específica para alimentos FOSHU, siendo solo mencionados en el área de la nutrición. **Conclusiones:** El revestimiento jurídico en la comercialización de estos productos; se cimienta en el *ius cogens*. Las inscripciones de patentes industriales en los principales países miembros de las asociaciones comerciales en LATAM pueden facilitarse por la vía del *Patent Prosecution Highway* (PPH). **Arch Latinoam Nutr 2022; 72(3): 218-230.**

Palabras clave: alimentos funcionales, Alianza del Pacífico, MERCOSUR, SICA, derecho internacional comparado.

Introduction

Law evolves like language, slowly and imperceptibly, and the vast majority of times it lags behind political, social, cultural and material transformations. The pace of this evolution varies ostensibly, depending on the object of the regulation and whether the regulations are systematized or not. This work aims to be a contribution to an emerging topic: the regulation of the manufacture and trade of new food products, whose purpose is not only nutrition, but also specific health purposes, making use of the same biological processes of animals and vegetables to improve the quality of the final products. These are conceptualized as "foods

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that are characterized as having beneficial effects on human health due to their ingredients or because some characteristic harmful to health has been removed" and must be rigorously evaluated with scientific support in order to be marketed with this designation, i.e., they are nutritious foods that have a beneficial effect on health(1,2). These products, referred to in this article as FOSHU, their acronym in English, represent a very specific case both from an industrial and legal standpoint, and therefore this article will first analyze the industrial and legal assumptions surrounding this new phenomenon. The general objective of this work is to identify the regulatory progress of Foods for Specified Health Uses (FOSHU) in Latin America, considering the three main trade associations in the region: the Pacific Alliance (Chile, Colombia, Mexico and Peru); the Southern Common Market (MERCOSUR), considering only its founders Argentina, Uruguay, Paraguay and Brazil, and the Central American Integration System (SICA) integrated by Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama. There are two main specific objectives. The first is to identify the existence of the legal treatment of these products and the second is to determine the legal framework in their trade. This is in response to the growing needs of a global population in constant expansion and with an interest in consuming healthy food as a promise of better health and quality of life.

From an agro-industrial standpoint, food has undergone a large number of genetic modifications to improve its characteristics(3). Crops and food products are now physically and genetically modified through biotechnology(4). Biotechnology in its traditional or classical sense is understood as "a set of techniques for manipulating living beings or parts thereof for economic purposes" without direct genetic management, while in a modern sense it refers to a set of techniques that use direct genetic manipulation and transfer of DNA.

The development of new production techniques for more and better food is an absolute necessity. An aging population, higher life expectancies and an increase in the world population results in a growing demand for food. In the next 50 years, one of the main challenges for public policies will be to feed a population with a longer lifespan, who will suffer from the diseases of modernity, such as obesity, osteoporosis, cancer, diabetes, allergies and dental problems(5). Added to this, as a result of climate change and increased industrial development, there will be less availability of arable land, water and labor available for agriculture. The decrease in fresh water and available land means that we should expect a decrease in both the production of cereals in various parts of the world and in the productivity of other basic foods. Both factors require the development of technologies that make long-term food production sustainable. At the same time, increased purchasing power in several parts of the world will lead to an increase in the demand for meat and dairy products over the next two decades in developing countries(6).

Faced with these health and economic challenges, we are witnessing a shift in the paradigm of what is meant by food. The concept of "food" has surpassed the basic idea of satisfying primary needs, escalating to a new generation of food: Foods for Specified Health Uses or FOSHU. These seek to comply with three fundamental aspects that differ from each other: nutrition, sensory satisfaction and fortification. FOSHU foods contain beneficial substances for some functions of the human body, improving the health and well-being of those who eat them. They also have properties to reduce the risk of a disease or its scientifically proven symptoms.

Such scientific challenges are not new. Biotechnology has been in use for decades. However, there are two elements that have changed: the pressure for more and better food, imposed by the circumstances mentioned above, and the emergence of new production techniques within the biotechnology industry. There are different branches within this, depending on the object they work on. Foods for Specified Health Uses (FOSHU) have emerged in one of these, food biotechnology. Food biotechnology "uses the techniques and processes used by living organisms or their substances to produce or modify food, improve the plants or animals from which they originate, or develop microorganisms that intervene in their preparation. The use of these techniques has had positive effects in preventing some specific diseases.

As we hope to demonstrate in this work, the entire production process of the raw materials used in FOSHU foods is highly unregulated in the region. This raises the question of the existence of literature that proposes and systematizes this, progress in public policies and standards that try to provide a global legal framework to this type of food and regulate its trade, and implications for the biotechnological industry and environmental protection. This paradigm shift has opened a gap where little research exists regarding the differences between developed and developing countries in the marketing of these highly specialized products. While developed countries have implemented commercial and legal practices that aim to protect the production of FOSHU food, developing countries are still at a disadvantage in terms of the regulation of their food industry, generally following the *Codex Alimentarius*, which has been used around the world since 1963(7). Today, US and Japanese legislation includes a definition of these FOSHU foods, and this differentiation between countries makes their regulation difficult with respect to the less developed countries, where the main raw materials are produced rustically and with no added value.

Notwithstanding the above, the vision of international law allows us to encompass the trade of FOSHU products within the generic concept of food, given that their recognition through licensing in certain countries such as Japan adds a commercial value to these products. Accordingly, there is a legal tension between patent rights and freedom of trade, where the latter is covered by the protection of international free trade agreements in Latin America and the Caribbean. In this context, the following questions arise: Is there a regulatory framework for FOSHU products in Latin America and the Caribbean? Should there be a display of natural equity under international law between the interests of FOSHU food producers and the marketing needs of functional foods in Latin America? And finally, is it necessary to change the qualification matrix? This work addresses the existing knowledge gap based on the need to generate valid and reliable information on specific FOSHU foods and their marketing in Latin America.

Comparative food regulation

To protect consumers and safeguard the health of the population, in recent decades' different models have emerged to provide a general regulatory framework for the food industry. The European Union has opted for an optional labeling model, which has been marked by the heterogeneity of the regulations, highlighting the Nutri-Score, Multiple Traffic Lights, Healthy Choice and Keyhole systems. In contrast, Latin American legal systems have opted for a labeling alert system. However, there are differences within Latin American legal systems, which can be seen through two models: The Chilean and the Ecuadorian model(8).

These last regulations have been positively evaluated in terms of health, but it does not regulate products as complex as FOSHU, for which the legislation on the sale of food products and their content is not as specific. Nor is it responsible for other relevant legal aspects such as intellectual property rights and biosafety regulations that have an international influence on the management of biological research and the trade of these products as food from the region(9). However, the above are the provisions of the moral conscience of international society or customary international law jus cogens. In the emergency resulting from a change of matrix in the trade of functional products due to the need to provide high quality food to the global population, this enables us to differentiate between the food product in itself and its protection covered by the patent. The question is whether the patent is legally protecting the discovery of the advantages and effects on health or the greater value of the food products covered by it. The occurrence of one of these at the exclusion of the other has substantive legal effects on an international level.

Regarding the routes of the definition of global food in the development of technological innovation, the growing demand for healthy food for humans can be met through the supply of products from the food and agriculture industry, providing an enormous business opportunity for FOSHU foods(10). This is with the understanding that this type of product is an "improved" food, or a sort of specialized food, but food, nonetheless(11). Examples of origin and use include the term functional foods. Although

the term was coined in the 1920s, there is no universally accepted definition, however they are generally understood as foods that give "the body the necessary amount of vitamins, fats, proteins, carbohydrates, etc., needed for their healthy survival" or can be defined as "foods that are characterized as having beneficial effects on human health due to their ingredients or because some characteristic harmful to health has been removed"(12). The history of functional foods dates back to 1000 BC. in China, which has a longstanding tradition of using certain foods and herbs with healing or therapeutic properties based on traditional medicine.

The term Medicinal Food was frequently used in the literature of the Eastern Han Dynasty, circa 100 BC. The term Special Foods is also mentioned in the literature of the Song Dynasty circa 1000 AD. In the West, Hippocrates, a Greek physician in the 5th-4th century B.C., already envisaged the importance of food with his famous phrase, "Let food be thy medicine and medicine be thy food,"(13) and in the 21st century this same philosophy applies to both functional foods in general and FOSHU foods in particular. In more modern times, iodized salt has been used in the United States since 1924 to fight goiter(14). In 1930, fermented milk was used in Japan to prevent intestinal diseases with the probiotic *Lactobacillus casei Shirota*, with the logic that the probiotic "provides specially cultivated live bacteria that remain active in the intestine," These foods are scientifically proven to strengthen the body's defenses, which results in the sale of probiotics estimated annual global sales market value of over US $ 3.7 billion in 2016, that is expected to rise to $ 17.4 billion by 2027 (15). However, there are still some gaps in information, and research is still being conducted as to their efficacy. Likewise, functional foods also include prebiotics, defined as "a selectively fermented ingredient, or a fiber that enables specific changes, both in the composition and in the activity of the gastrointestinal microflora, that bestow benefits to the well-being and health of the host," and synbiotics, which are the "combination of probiotics and prebiotics"(16). In the 1950s, the World Health Organization (WHO) (17) established fortified food programs to fight malnutrition, and eLENA (e-Library of Evidence for Nutrition Actions) provides guidelines based on scientific evidence on the growing number of global nutrition interventions. It was not until 1990 that Japan –pioneer in FOSHU food legislation– established an approval system for functional Foods, based on the results of health research, issuing a decree from its Ministry of Health and Welfare approving *Foods for Specified Health Uses* (FOSHU) in English, Tokuho in Japanese or *Alimentos para Uso Específico de Salud* in Spanish, given the rise in health costs and increase in life expectancy.

This new type of food category is the result of the scientific and legal application of an understanding of the function of the food item and its primary nutritional and regulatory function. Internationally, functional foods are recognized to have three functions: "nutritional" (survival); "sensory" (pleasant sensations due to the taste, smell, texture, among others) and "physiological" (producing a favorable effect on nutrition, biorhythm, the nervous system, the body's defense capacity, among others, of the consumer) the addition of calcium and folic acid can currently be claimed as reducing the risk of disease. In terms of the differentiation between Functional Foods and FOSHU, FOSHU foods are more advanced: they must be rigorously evaluated with scientific support in order to be marketed with the FOSHU designation. The Japanese approach to food indicates that the regulation is applied to the large segment of "healthy foods" with a total domestic market share of 65%, under two definitions for food: FOSHU (Foods for Specified Health Use) and FNFC (Foods with Nutrient Function Claims)(18).

In 1993, the first company authorized in Japan to sell physiologically functional food by the Japanese Ministry of Health, Labor and Nutrition was Shiseido, marketing a type of rice whose protein (globulin) had been extracted to make the rice apt for consumption by people allergic to this protein(19).

FOSHU foods affirm their functional properties in reference to the increase in the appearance of Lifestyle-Related Diseases (LSRD), known as lifestyle-related diseases. These include obesity, diabetes mellitus, high blood pressure, cerebrovascular diseases and cancer. In Japan, these foods are considered the only type of food product (not ingredients) that can legally carry health claims and that is composed of functional ingredients that affect the structure/

function (physiological functions) of the body. FOSHU products should be consumed by healthy people or those in the preliminary stage of a disease for the maintenance and/or promotion of health or special health uses, to control specific health conditions such as gastrointestinal issues and blood pressure(20). New changes in Japanese legislation to improve product positioning introduce new subsystems of FOSHU, such as (a) standardized FOSHU, (b) qualified FOSHU and (c) claims of reduced risk of disease for FOSHU. Japanese legislation on food uses the general designation term *Kenko-shokuhin* in Japanese, which includes foods recognized to have health properties; and the term *Keyno-sei-shokuhin* (for functional foods), and the legislation currently uses FOSHU foods and FNFC (Foods with Nutrient Function Claims) in English, Portuguese and Spanish (Alimentos con Declaraciones de Nutrientes Funcionales)(13,15). This leads to a difficulty in regulation in the international arena, in an attempt to issue regulatory documents, minutes and conferences on procedures to regulate the issue by specifically identifying the type of food.

If we consider FOSHU foods as improved or specialized, it allows us to conclude, based on the historical justification of international law *jus cogens*, recently presented, that they are regulated under the universal spectrum of foods. Their legal treatment in international trade should include the common requirements for "products," and their manufacturers should be free to market them as such food products regardless of whether they submit these to the fast-track patent examination program known as the Patent Prosecution Highway (PPH) used by member countries of the Pacific Alliance and MERCOSUR(21,22). Only SICA countries Guatemala and Honduras do not report information. In Latin America and the Caribbean, the only countries in the main trade associations that use PPHs in bilateral agreements are Argentina, Brazil, Uruguay, Paraguay, Mexico, Chile, Colombia, Costa Rica, El Salvador, Nicaragua, Panama and Peru, in the event that the food product has been industrially patented in its country of origin.

In conclusion, we can observe two legal ways for these products to enter the international market: the first is as common or general foods -which is the regular way that they are marketed- and the second is as inventions covered by internationally recognized industrial patents. We can see that the issue of recognition of FOSHU products does not prevent the entry of these products as such into the Pacific Alliance, MERCOSUR or SICA market. They either enter via patent from a country outside the associations or as new products generated and developed by producers from the trade bloc. This results in open and guaranteed competition based on the emergence of *jus cogens* when faced with eventual restrictions due to differentiations "by producer" but not by "product".

Methodology in the regulatory analysis of food regulations

The approach to the study object is added to the proposed methodology, which qualitatively approaches law with social science. This is based on the legislation on food health regulations and the intrinsic and extrinsic relationships to establish a relational framework for the research. This critical review of the literature integrates exploration and mapping through levels of synthesis in the review of the literature, distinguishing the characteristics that differentiate the system of food trends. A filter system is proposed to select works by title and with full content included for analysis. The approach involved a systematic review of articles on the subject in Spanish, English and Portuguese on legislation in Latin America, as well as international legislation on the concept of FOSHU foods in the three main trade associations in the region: Pacific Alliance (Chile, Colombia, Mexico and Peru), MERCOSUR (only Uruguay, Argentina, Paraguay and Brazil) and SICA (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama). A search for information was conducted in the online indexed databases of Scientific Electronic Library Online (Scielo) Journals, whose objective is to disseminate and draw attention to the science generated in Latin America, the Caribbean, Spain and Portugal. Google Scholar was also consulted. Google Scholar is not only a database and a reference manager, but also a powerful search engine that identifies indexed academic literature from different disciplines and different databases worldwide. This made it possible to combine and broaden searches for articles published in both databases from 2018 to 2022. The methodological proposal

addresses the issue of the interconnection between the social, legal and health fields by exploring articles published in Latin America and the Caribbean. The first criterion was that they exclusively contain progress on regulatory information relevant to FOSHU foods both in the title and in the full article by searching for: FOSHU foods and regulations. Therefore, the process was limited to publications generated by the aforementioned trade associations and the literature developed only in articles, adjusting the search to the use of one or all the terms and their relationship. It was necessary to integrate the search under three dimensions with variations of the term "FOSHU" and "regulations of claims," specifically: regulations of food safety claims and government policies; regulations of claims and inspections by product/market as raw materials; and regulations of claims that affect food manufacturing and labeling, as these are what this study seeks to address (23–26).

Within the search strategies, through the discussion of the terms and their contents, we made a strategic selection of keywords and their combinations that could give us a better scope of the complexity of the topic, divided into two equations. For this process, the first search equation was: (TITLE ("FOSHU Food*" OR "regulations")) OR (KEY("food safety" AND ("government policies") OR ("claims and inspections by product/market") AND ("raw materials") OR ("food manufacturing") AND ("labeling"). The new search equation was: (TITLE "FOSHU Foods*" OR "regulations")) OR (KEY("food safety" AND ("government policies") AND ("PA") OR ("MERCOSUR") OR ("SICA") OR ("claims and inspections by product/market") AND ("raw materials") AND ("PA") OR ("MERCOSUR") OR ("SICA") OR ("food manufacturing") AND ("labeling") AND ("PA") OR ("MERCOSUR") OR ("SICA") (See [Table 1]). The exploration undertaken aims to synthesize the main considerations in terms of epistemological influences through the diverse cultural contexts of the types of food, specifically FOSHU, with the understanding that a concern for cultural differences would not affect the research. In this conceptual framework proposed for the regulatory analysis of food in Latin America and the Caribbean, the basic regulations for the marketing of such food are recorded, determining the regulatory specifications and paying attention to each of them, their development by country and as a whole, acknowledging interactions. For verification purposes, this was complemented with specific regulatory documentation on food in each member country of the Pacific Alliance, MERCOSUR and SICA and the main international

Table 1: Search Equations for FOSHU Food.

DIMENSIONS	(TITLE("FOSHU Food*" OR "regulations")) OR (KEY("food safety" AND ("government policies") AND ("PA") OR ("MERCOSUR") OR ("SICA") OR ("claims and inspections by product/ market") AND ("raw materials") AND ("PA") OR ("MERCOSUR") OR ("SICA") OR ("food manufacturing) AND ("labeling") AND ("PA") OR ("MERCOSUR") OR ("SICA")	Keywords / and / or Spanish, English or Portuguese. Alimentos para Uso Específico de Salud. FOSHU Foods for Specified Health Uses. Foods for Specific Use for a Saúde.
FOOD REGULATION ASOC.COM.	-PACIFIC ALLIANCE (PA) -MERCOSUR -SICA	Foods for Specified Health Uses. FOSHU.
1	Regulations of food safety claims and government policies.	Foods for Specified Health Uses. FOSHU.
2	Regulations of claims and inspections by product/market as raw materials.	Foods for Specified Health Uses. FOSHU.
3	Regulations of claims that affect food manufacturing and labeling.	Foods for Specified Health Uses. FOSHU.

regulations. In order to maintain methodological consistency during the citation and management of the process, inclusion or exclusion criteria were not applied. However, an effort was made to ensure that the contributions on regulations were broad, reading not only the titles and abstracts but also the scope of the content of the articles. The methodological strategy used sought out a consistent food pattern. There was only one methodological option, which established a defined legal area that would facilitate the approach of the study and optimize the resources in the analysis of the literature. From the body of literature from Latin America and the Caribbean, we were able to find material on FOSHU Foods, focused on their conceptualization, innovation process and applications(27–34). The most significant information was narratively synthesized and characterized according to content. The research reviewers compiled the narrative synthesis and the material associated with the keywords, which included the articles found in the areas mentioned(35).

Results

One of the main results is that most of the literature on the subject focuses almost entirely on health -specifically on nutrition- and does not address the legal aspect. The reviews of articles on the subject in the area of social sciences and law have serious limitations in both Scielo and Google Scholar. First, they do not take a similar approach regarding the mention of the legislative aspect or its relationship with public policy on the type of food. In general, most of the material is focused on food in general or the area of food production, based on the general nutritional characteristics of the products in Latin America and the Caribbean that are primarily regulated by the *Codex Alimentarius*.

Therefore, reviews in both databases result in a lack of combined information on the three search criteria used in all cases, and there is a mix of information on the trade of functional foods, FOSHU and foods in general as raw materials without differentiation or added value in Latin America and the Caribbean. The literature reviews in both databases show that the member countries of the Pacific Alliance, MERCOSUR and SICA do not consider all the levels of comparative progress between similar products from member nations and do not share information on their legislative management and marketing. However, what they do share individually as a country and collectively as a trade association is the use of the *Codex Alimentarius*. We found a significant lack of material in the legislative area on this type of product both in Latin America and the Caribbean and on an international level in terms of agreements for control and trade. In contrast, there was a greater amount of material in the area of human nutrition, which is not the specific object of this study.

The general analysis was complemented with regulatory documentation on food on an international level. The markets that consume functional foods have the legislative assurance of a beneficial effect on the human body, beyond the usual nutritional effects, and that their consumption improves the health and well-being of those who eat them, as well as potentially reducing the risk of disease. In the United States, the International Life Sciences Institute (ILSI) includes modified and non-modified foods in its definition, in coordination with the FDA. As mentioned above, Japan has its own regulation, and in Europe, the Life Sciences Institute Europe (ILSE) works together with the European Food Safety Authority (EFSA). This differentiation in regulation between developed and developing countries hinders the classification and trade of these products, reducing the trade opportunities in the most attractive markets.

There was a subsequent review of the regulations of the members of the Pacific Alliance, MERCOSUR and SICA and the main international regulations followed by both the trade associations and the individual countries in Latin America and the Caribbean. In the first analysis of regulations of food safety claims and government policies, we can see that based on specific public policies and national regulations in the countries of the Pacific Alliance (Chile, Colombia, Mexico and Peru), these countries are better positioned on the subject, along with

MERCOSUR and SICA (with the exception of Guatemala and Honduras) (See [Table 2]). Based on a collective and individual search on the Pacific Alliance, MERCOSUR and SICA regarding the opening of markets and health policies, the general panorama observed is that in the countries with the largest number of peer-reviewed publications on FOSHU, these are in health (not the object of our study), in the area of nutrition, in both databases. A second regulatory review reports the results of the analysis of literature mentioned in the claims and inspections by product/market in connection to the country and the products marketed as raw material, considering that several goods are similar in Latin America and are sold to international markets with no added value. The third regulation criteria involve claims that affect food manufacturing and labeling, to determine whether there is any mention of this type of FOSHU food in Latin America. The results of the analysis in the Scielo database for the social sciences and legal areas are shown in [Table 3]. The regulations on the type of food addressed relate more to quality controls on the products and their production certifications for marketing them, such as ISO9000 or HCCP, rather than identifying them by their contents, nutrients or special or differentiating characteristics.

The previous procedure was repeated for the Google Scholar database. A search was carried out collectively and individually in the Pacific Alliance, MERCOSUR and SICA in terms of the three search criteria mentioned, and no information was found in peer-reviewed articles referring to legislative regulations on FOSHU products in any area of social sciences and law.

Table 2: Regulations on Food and Human Health on an International Level and in Latin America and the Caribbean

Organization/Country	Legislation	Government/Year
Organization of American States	The multinational biosafety project	Biosafety Regulations in Latin America and The Caribbean within the framework of the International Biosafety Protocol. 2002. Chile, Peru and Colombia.
Food and Agriculture Organization of the United Nations (FAO)	"Healthy Messages" or Health Claims. According to the *Codex Alimentarius* (FAO, 2020)	There are no Specific Regulations. Shared by Codex Alimentarius and WTO.
World Health Organization (WHO)	"Healthy Messages" or Health Claims.	There are no Specific Regulations Shared by Codex Alimentarius and WTO.
Japan	Law on improvements in nutrition, Law No. 248, July 31, 1952, amended by Law No. 101, May 24, 1995, and by the new law that regulates nutritional improvements pursuant to Ministerial Ordinance No. 41, July 1991, amended by Ministerial Ordinance No. 33. May 25, 1996). Kinousei Shokuhin Konwakai" or "Group to discuss functional foods".	Quick Guide to Food for Specified Health Use, published by Japan Health Food and Nutrition Food Association. Japanese Ministry of Health and Welfare, 2000. Standard that monitors the quality of the scientific testing that endorsed the effectiveness of the food. 2006.
United States	Claims of "disease-reducing" properties are allowed for certain foods. Authorization of claim of benefit is regulated by the FDA (Food and Drug Administration), provided that there is publicly available scientific evidence that demonstrates the validity of the relationship described in that claim. Nutraceuticals or Functional Foods	National Institutes of Health Centers for Disease Control and Prevention Standard that monitors the quality of the scientific tests that endorsed the effectiveness of the food. 2006. Offers marketing options: as fortified food (adds nutrients), enriched (adds nutrients lost in processing), or enhanced (adds nutrients through modification or indirect methods). They are not listed in the FDA.

Table 2: Regulations on Food and Human Health on an International Level and in Latin America and the Caribbean. (cont.)

Organization/Country	Legislation	Government/Year
EU ILSE Europe International Life Science Institute Europe (ILSE) FUFOSE (Functional Food Science in Europe) Commission European Food Safety Authority (EFSA)	Regulation 1924/2006 on Nutrition, Functional and Health Claims made on food. European legislation on labeling prohibits attributing preventive, therapeutic or curative properties to foods, and the reference to such properties. EFSA, the European Food Safety Authority. Food-Based Dietary Guidelines, it is evident that in most EU member countries, the most frequent country-specific diet-related health problems are still cardiovascular diseases, overweight/obesity, dyslipidemia, hypertension, type 2 diabetes, osteoporosis and dental caries. www.efsa.europa.eu	Since 1999, FUFOSE has been working to establish a scientific approach to food. NUTRITION CLAIMS. Functionality: Suggests or implies that a food has particular nutritional properties due to its energy content or its nutrient composition. FUNCTIONAL CLAIMS: A functional claim will describe accepted and well-established roles of nutrients in development, growth, and normal physiological functions of the organism. HEALTH CLAIMS: They will describe the relationship between a food category, a specific food or one of its constituents and health. Created in 2002.
Pacific Alliance Chile	Food Sanitary Regulations (RSA), *Codex Alimentarius* relationship Technical standards on nutritional guidelines that indicate, for health claims of foods. Exempt Resolution No. 764/09. Published in the Official Gazette on October 05, 2009	Ministry of Health (MINSAL, 2009). Patent Prosecution Highway (PPT)
Pacific Alliance Colombia	Health claims and *Codex Alimentarius* Standards for food products INVIMA (Colombia)	Ministry of Health and Social Protection (INVIMA, 2019). Patent Prosecution Highway (PPT)
Pacific Alliance México	Production process – *Codex Alimentarius* Official Mexican Standards that control the production and safety of food are the official Mexican standard NOM-120-SSA1-1994: Goods and services, hygiene and sanitation practices for the processing of food, non-alcoholic and alcoholic beverages; and NOM-093-SSA1-1994: Hygiene and sanitation practices in the preparation of food offered in fixed establishments	Ministry of Health (DGIAAP, 2019). Patent Prosecution Highway (PPH).
Pacific Alliance Perú	*Codex Alimentarius* - reference regulation. Sanitary Food Regulations. Alimentarius.	Ministry of Health Sanitary Food Regulations, 2009. Patent Prosecution Highway (PPH).
MERCOSUR (Southern Common Market)	*Codex Alimentarius* reference regulation. Sanitary Food Regulations. Alimentarius.	Health Ministries. Sanitary Food Regulations. Argentina, Brazil, Uruguay and Paraguay (2010). Patent Prosecution Highway (PPH). PROSUR
SICA (Central American Integration System)	Ministry of Health. Costa Rica. WTO – Codex Alimentarius. Nutrients label: Energy value, Total Fat, Saturated Fat, Carbohydrates, Sodium, Protein. Preparation of food-based guidelines (GABAs) with recommendations from the FAO.	Health Ministries. Sanitary Food Regulations (2010). Patent Prosecution Highway (PPH). Only in: Costa Rica, El Salvador, Nicaragua and Panama

In attempting to analyze this through the regulatory system, internationally there is an inclination towards the management and certification of FOSHU foods, and no evidence is found in Latin America of specific characteristics in regulations to support valorization by content or special intrinsic characteristics of added value.

Table 3: Results of Search Databases Scielo and Google Scholar 2018-2022

No. of Search	No. of Articles Found 2018-2022	Database *Scielo Journals*	Main Area
1 2	0 0	There are no articles referring to FOSHU food legislation in Latin America and/or in main trade associations.	OBJECT OF STUDY: -Social Sciences -Legal NOT OBJECT OF STUDY: -Health (nutrition).
No. of Search	No. of Articles Found 2018-2022	Database *Google Scholar*	Main Area Identified
1 2	205 0	Health (food, diets, analysis of the properties of specific products, advertising and market research). There are no articles referring to FOSHU food legislation in Latin America and/or in main trade associations.	NOT OBJECT OF STUDY: -Health (nutrition). OBJECT OF STUDY: -Social Sciences -Legal

Most reviews concur that the Pacific Alliance, MERCOSUR and SICA only cover general food safety regulations and differentiated government policy. In the Scielo database consulted, no articles were identified that matched the search criteria on the regulations explored from the first search attempt with the term "FOSHU Food". The second attempt included a combination of words such as "regulations of food safety claims and government policies by trade association"; "regulations for claims and inspections by product/market as raw materials" and finally "regulations for claims that affect food manufacturing and labeling" but brought up no results, and then searched by country, with no results. In Google Scholar, the same search dynamic was followed, no papers were found in the legal area. Only 205 articles were shown, but in reference to health, specifically to nutrition (which is not the object of our study) focused only on diets, property analysis, advertising and market research (See [Table 3]).

Discussion

The interest of the consumer and the population in general in obtaining optimal diets to maintain good health throughout longer lifespans has led to an increase in the demand for natural foods, in which FOSHU-type foods take priority. The trade of "improved" or "specialized" foods is given a generic treatment under international law in consideration of the fact that its elements substantially constitute the same food products that have been known since ancient times. The granting or provision of industrial patents to certain food "products" protects these on the grounds of invention and industrial development as products from the area, paving the way to free competition in international markets, in accordance with the provisions of domestic law. The way for countries in Latin America and the Caribbean to develop as a significant food supplier lies in the development of legislation that integrates technological platforms to support the production and marketing of functional foods, using regulations and standards to evaluate and control these foods.

This will improve the supply of FOSHU foods with added value based on the needs and requirements of the end consumer, where the country can actively insert itself not only as an exporter of raw materials, but also with research into high-value premium products. We are witnessing a legal and commercial opening that will fast-track the circulation of improved food products through the Patent Prosecution Highway (PPH) in the Pacific Alliance, MERCOSUR and SICA in Latin America and the Caribbean. This

constitutes significant progress in this trade area for the free circulation of products and the recognition of differentiated products in what could be considered a food subspecies in the future. In other words, the reasoning is that the matrix used to determine the consideration of invention patents should be modified, gradually reducing the effect of novelty on the element of nature. This would lead to a reduction in the granting of patents for products that are considered as improved food products. This instigates a discussion on the differentiating measure between an invented product and a food. It is not the intention of this work to define this measure of differentiation between a food product and food with an invention patent.

Conclusions

The legal reviews of the analyzed material have severe limitations. First, the articles do not show a similar approach in terms of mentioning the legislative aspect or its relationship with public policy for the type of food. Most of the material analyzed is focused on food in general or on health based on the nutritional characteristics of Latin American products. Therefore, the revisions lead to data for which we do not have combined information in all cases, and the trade of functional foods and FOSHU is mixed with foods in general, such as raw materials with no differentiation or added value. Notwithstanding this, encompassing the issue in international law, the qualification of *jus cogens* supports the superimposition of the issue over the legal intricacies behind the internal legislation of each country and their constitutional charters. Production and industry therefore need to obtain a regulation that enables them to share the healthy properties of FOSHU products, facilitating the production and marketing of healthy, functional foods, integrating the adaptation of national legislation into international standards and promoting an increase of have more information on these products among consumers.

Most of the reviews agree that Latin American countries only cover the standardized Global Food Safety regulations and differentiated government policy. Likewise, there is no progress as a trade bloc -Pacific Alliance, MERCOSUR and SICA- in terms of differentiating trade and legislative policies that distinguish them from other producers of functional foods in domestic or foreign markets. There is no express regulation on the trade of FOSHU food after analyzing the different internal regulations of each country and those established in international conventions. However, the lack of regulation means that the law applicable to the trade of these products is supported and safeguarded by the *jus cogens* of international law. This operates as a subsidiary law in the face of this lack of express regulation, given the double meaning behind the trade of food products, the need for these by the human population and the protection of the commercial rights inherent in the very emergence of international law.

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Conflicts of interest

The authors have no conflicts of interest to disclose.

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