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EXISTING REGULATIONS ON DIFFERENT MARKETS REGARDING THE OBTAINING AND MARKETING OF FOODS WITH BENEFITS FOR HEALTH

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Abstract: *The issue of population health is a global problem, and because of that, the calling for food with health benefits has become a concern for many consumers, but also for various institutions that legislate or with interest in managing the health of population. The first researches in this field, applied as a national policy, were carried out in Japan, starting with 1984, the Japanese introduced "Foods for Specified Health Uses" (FOSHU) products, for which there are special labeling rules. Products have diversified, appearing, over time, alongside FOSHU, other categories of food with health benefits: foods with nutrient function claims (FNFC) and foods with function claims (FFC). To encourage the choice of healthy foods, but also to prevent the use of false messages, ambiguous or misleading, many countries have adopted legislation that ensures correct information and consumer safety. So, in the European Union (UE), were adopted and applies, Regulation (EC) No 1924/2006 on nutrition and health claims made on foods and Regulation (EU) No 1169/2011, on the provision of food information to consumers, also in the USA, FDA applies The Nutrition Labeling and Education Act of 1990 (NLEA), Dietary Supplement Health and Education Act of 1994 (DSHEA), Food and Drug Administration Modernization Act of 1997 (FDAMA).*

Keywords*: health claims; nutrition claims; FOSHU; FNFC; Regulation (EC) No 1924/2006; NLEA; DSHEA; FDAMA.*

1. Introduction

Foods with health benefits have become a concern for many consumers [1]. This was due to several converging factors, like: awareness of the deterioration of the population's health, increasing the number of people who "prescribe" their own medication [2], increased levels of information from health authorities and the mass media, on the link between diet and health, outstanding scientific advances in nutrition research, the competitive food market etc. [3], [4].

Foods with health benefits carry messages (claims) that convey, in a certain way, information that links product consumption to health or well-being. According to "Codex Alimentarius", a health claim represents „any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health" [5].

To be effective, developing food with health benefits must be based on appropriate regulations [6]. In countries where there is specific legislation on foods with health benefits, they are subject to a rigorous approval process before marketing [7]. The first country that paid special attention to the obtaining and marketing of these products was Japan. The products have been called "Foods for Specified Health Uses" (FOSHU), and at

international level, they have been called functional foods [8].

Functional foods can be identified on the market by two distinct elements: (i) the classical food form, not the pills; (ii) the presence on the packaging of a message that has to make a positive correlation between the food/food component and an improvement in a body function or a reduction in the risk of certain diseases [9], [10].

This messages (phrases or representations, including pictures, graphs, or symbolic representations, in any form) - the health claims - must have a solid scientific basis, not misleading to win and maintain consumer confidence) and be well understood by the average consumer [11]. A health claim, by definition, has two essential components: (1) a substance (either a food, a food component or a food supplement ingredient) and (2) a disease or condition related to health [12].

There are wide differences between the ways to regulate on the use of health claims in different countries and regions of the world [13]. So, some countries have an institution that regulates health claims (the Ministry of Health, Labor and Welfare – in Japan; the Food and Drug Administration - in the US; the State Food and Drug Administration (SFDA) - in China etc.), other countries regulates through private companies (UK and Sweden), and other have decided to cooperatively develop regulations on health and nutrition claims (European Union, Australia, New Zealand).

2. Japan

Japan is the country that recognizes foods with health benefits as a distinct category, and the Japanese market for these foods is the largest and most innovative in the world.

The food category, which appeared on the Japanese market in 1984 and was thought to have a beneficial impact on the health of consumers, was named "Foods for Specified Health Uses" (FOSHU).

According to the definition, FOSHU refers to foods containing ingredients with health functions and for which there are officially approved claims for physiological effects in the human body (health claims). FOSHU products are intended to be consumed to maintain / promote health or to be used by people who wish to control their health [14].

It is possible to delimit several categories of foods with health benefits on the Japanese market (Table 1); for each category there are clear indications of information (claims) that can be displayed on the packaging [15].

(A) the FOSHU category, comprising:

1. "normal" FOSHU - refers to foods containing ingredients with health functions and for which there are officially approved health claims. FOSHU limits health claims to fourteen formulations, and requires extensive clinical trials [16], [3].
2. qualified FOSHU - are foods with a role in health that is not proven with scientific evidence at the same level as "normal" FOSHU, or foods with a certain effectiveness but without effective determination of the mechanism of action of the food components for the function concerned;
3. standardized FOSHU - are foods with sufficient approvals and that have accumulated sufficient scientific evidence, for which standards and specifications are established, according to the legislation specific to this group of foods;
4. reduction of disease risk FOSHU - are the foods for which the claim allowed when the disease risk reduction is

clinically and nutritionally determined for the target ingredient.

5. For the latter three subgroups, there are facilities for approval, for applicants [15].

(B) Foods with Nutrient Function Claims (FNFC) - can be manufactured and distributed without further authorization or notification from the Japanese government. For these, Standards and Specifications for Indicating Nutritional Functions [15] are established.

Standards and specifications refer to:

- the amount of nutrient in the products, which must be less than the values specified by the recommended daily intake;
- nutrient claims;
- warnings.

(C) Foods with Function Claims (FFC) - are introduced on the Japanese market in 2015 and allow for a more accessible and faster registration process than for FOSHU [17]. FFC monitoring is carried out by the governmental organization Consumer Affairs Agency (CAA), unlike the other categories, which are regulated by MHLW. For FFC, any health claim may be used. The new rules have made the claims environment less complex, widening the market at the same time and creating healthy competition.

In line with the FFC guidelines, manufacturers have to provide the CAA with scientific information on the safety and functional character of these products [18]. Manufacturers are also required to provide the health claim that will be included on the label [19].

Table 1

Categories of products with a beneficial effect on health, in Japan

Medicines	**FHC** (Food with Health Claims)			Another foods
	FOSHU (Food for Specified Health Uses)	**FNFC** (Foods with Nutrient Function Claims)	**FFC** (Foods with Functional Claims)	
	- individual approval system	- standard regulatory system	- notification	
	1991	**2001**	**2015**	

3. European Union (EU)

From the documents which govern health food and information on food labels on European markets can be listed:

a) Regulation (EU) No 1169/2011, on the provision of food information to consumers;

b) Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, including food supplements. The stated objective of this regulation is to ensure the effective functioning of the internal market in terms of the use of these two categories of claims, while providing a high level of consumer protection [20].

According to Regulation (REC) No 1924/2006, in the EU, are used on food: (I) nutrition claims, (II) health claims, (III) mentions on the reduction of disease risk, and (IV) children's development and health claims [21].

(I) Nutrition claims. REC No 1924/2006 defines the nutrition claim and stipulates that only the nutrition claims listed in the Regulation are allowed, provided that they comply with the established conditions of use [22].

(II) Health claims, under the REC, means any claim that states, suggests or implies that there is a relationship between a food

category, a food product or one of its constituents, and health.

Health claims are adopted by the European Council (EC) after consultation of the European Food Safety Authority (EFSA), according to Article 13 of the REC 1924/2006, and shall form the Consolidated List, which shall be completed continuously, in accordance with the procedure referred to in Article 25 (2) of that Regulation [21]. The consolidated list includes the wording of the claims and the conditions applicable to them, together with all restrictions [23].

The consolidated health claims database, according to article 13, contained 4637 mentions from EFSA, in 2011 [24].

From 2011 to August 2017, according to Article 13, paragraph 5 of REC 1924/2006, EFSA received 48 applications, 13 were withdrawn, 27 were adopted, the others being under review [25].

In order to support the preparation and submission of applications for authorization, EFSA initially prepared two guides: Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim [26] and General scientific guidance for stakeholders on health claim applications, followed by many others, in order to help the industry in substantiating health claims.

On the packaging of the food product that have on health claims must be specified: the quantity of food, the form of consumption, possible warnings, restrictions of use and instructions for use [26]. It is important that the consumer can consume enough food, as part of a balanced diet, to achieve the claimed effect [27].

EFSA established, based on evidence from different studies, conditions for the use of health claims for the main groups of functional compounds (in table 2 are presents the conditions for the use of health claims related to fat and fatty acids – according EFSA – [28]).

Table 2

Conditions for the use of health claims assessed by the EFSA, depending on the type of fat and composition in fatty acids

Fat type	Function	Usage conditions
Linoleic acid	cholesterol management	Ensuring at least 15% of the recommended daily intake, of 10 g linoleic acid/day;
alpha-lipoic acid (ALA)	cholesterol management	Ensuring at least 15% of the recommended daily intake, of 2g ALA/day;
Plant sterols	cholesterol management	0,8 g/zi;
Docosahexaenoic acid / Eicosapentaenoic acid (DHA / EPA)	blood triglycerides management	2 - 4g/day;
	blood pressure management	3 g/day;
	heart health	250 mg/day;
DHA	eyesight	250 mg/day;
	brain function	250 mg/day;

(III) Claims on reduction of disease risk. In accordance with Article 14 (1) (a), were been endorsed by 2009, three claims to the reduction of disease risk: plant sterols and heart disease; plant stanols and heart disease; chewing gum sweetened with 100% xylitol and dental caries or cavities [29].

Medical claims for foods (claims that express, imply or suggest that the product has properties to treat, prevent or cure diseases) are prohibited by European labeling rules [21]. In order for a product to be able to bear a medical claim, that product must be classified as a medicine.

c) EU Directive 2002/46 regulates nutritional supplements. These are, legally, considered foods - not medicines or an intermediate category [30], so all health and nutrition claims that can be used for food, can also be used for nutrition supplements [31].

4. USA

In the US, three categories of claim may be used under the law: (1) nutrition claims; (1) health claims and (3) claims related to a function-structure link [32]. The responsibility for these claims rests with: (i) the manufacturer; (ii) the Food and Drug Administration (FDA), the institution regulating the production and marketing of food, and medicines in the United States and (iii) the Federal Trade Commission, in the case of advertising [12].

In the USA are used:

1. Nutrition claims - are regulated by the Nutrition Labeling and Education Act (NLEA), in 1990.

2. Health claims. There are three ways the FDA exercises its oversight on the use of health claims on labels [33; 34]:

- *Authorized health claims,* according to NLEA and Dietary Supplement Health and Education Act (DSHEA), from 1994. These regulations characterize a relationship between a food, component of a food or ingredient of a food supplement, and the risk of a particular disease. The FDA authorizes these types of health claims based on an extensive analysis of the scientific literature, following the submission of a claim for a health claim [35].
- *Health Claims Based on Statements of Authorities*, according to Food and Drug Administration Modernization Act (FDAMA), issued in 1997. Under this law, a health claim can be approved for a food on the basis of an "authorized statement" of a scientific institution of USA, with official responsibility for the protection of public health or research, directly related to human nutrition, such as the National Institutes of Health, the National Academy of Sciences, the Center for Disease Control and Prevention [35].
- *Qualified Health Claims,* according "Consumer Health Information for Better Nutrition Initiative", of 2003, that allows the FDA to recognize these claims when there is a clear relationship between a food / component of the food or the food supplement and reducing the risk for a disease or for maintaining health status [36].

Authorizations for claims via NLEA or FDAMA require rigorous and time-consuming evidence, based on a number of rigid standards. The FDA has recognized the need for health claims based on less scientific evidence when they are not misleading consumers. As a result, the Agency has established intermediate procedures through which qualified health claims for conventional foods and supplements can be used.

3. Structure-function claims - are used on conventional food labels and on food supplements [37]. The structure-function claims may also describe a benefit in the context of disease due to the deficiency of a nutrient (such as vitamin C and scurvy). The manufacturer is responsible for ensuring the accuracy and authenticity of these claims; they are not pre-approved by the FDA, but must be truthful and not misleading. Manufacturers of dietary supplements using structure-function claims labels must submit a notification containing that claim to the FDA at least 30 days before the food supplement is marketed [38].

5. Conclusions

Foods with health benefits are primarily intended to improve the general health and

wellbeing of population. These foods bear messages (claims) that convey, in a certain way, information that links product consumption to health or well-being. Of particular interest in this direction was Japan, initially, through the introduction of FOSHU products (considered as a basis in the development of functional foods), but also the US and the EU, through the specific legislation adopted.

Communicating health claims has an important impact on consumers' attitudes, acceptance and acquisition.

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