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An international regulatory review of food health-related claims in functional food products labeling☆

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ABSTRACT

Consumers are increasingly aware of the importance of diet in human health and they preferably choose functional food products. The present work is focused on describing the current status of the international regulatory framework for health-related claims in functional food products and the state of the art regarding these products market focusing on those with health-related claims. Specific regulation must control the use of these claims in the labeling of functional products. Although the European, American and Japanese claims are partly similar in nature, but the approval and use procedures and the regulatory framework are different. Consumers generally accept functional products with health-related claims, and most of them include more than one claim. This review could help consumers for making better-informed food decisions; food industry in marketing its products with a focus on international trade; and scientists in order to put in value their research work.

1. Introduction

The increasing awareness about the strong relation between diet and human health has considerably changed food preferences in developed societies that leads consumers to choose a concrete food product over another with view to obtaining some desirable health end-state (Bogue, Collins, & Troy, 2017; Pappalardo & Lusk, 2016). In this sense, functional products are excellent food options as they are aimed to improve life quality by preventing nutrition-related diseases (Domínguez Díaz, Fernández-Ruiz, & Cámara, 2019).

The messages or "claims" shown on the labeling of functional food products is highly important as it helps consumers to identify the specific health benefits provided by the consumption of these products as well as encourage consumers to make adequate food choices. According to the CLYMBOL Project (the first cross-country study funded by the European Commission for the purpose of assessing the role of health-related claims and symbols in consumers behavior and comparing the status-quo of claims on food and drink products in Europe), those functional foods bearing health-related claims are considered slightly healthier (e.g. lower saturated fatty acids and sodium contents, less calories) than others without any message (Hieke et al., 2016). In addition, health-related claims are considered an important issue for food industry as its use in food marketing is broadly widespread and promote the innovation and the competitiveness among food companies, which must ensure that every food product is adequately labeled before its commercialization (Tollin, Erz, & Vej, 2016).

In theory, a comprehensive and specific regulation should be applied to those health-related claims displayed in any food commercial communications (labeling, presentation, advertising and promotional campaings). However, there is a lack of a harmonized regulatory framework for these claims. The differences among food international regulation increase the difficulties of food industry on marketing functional food products as it has been expressed by Cámara and Fernández-Ruiz (2009) and Lalor and Wall (2011). The previous work of authors was aimed at clarifying the differences among functional food products' concepts and definitions in the frontier food-pharma including functional foods, food supplements and nutraceuticals (Domínguez Díaz et al., 2019). The present review is intended to provide a comprehensive analysis of three different but interconnected perspectives involved in the food health-related claims: regulation, consumers and food industry. As an increasing number of claims started to appear in the labeling of functional products, international regulation was required in order to (1) avoid misleading advertising and unfair competition in the food industry, (2) allow the free movement of functional products in the global market, and (3) ensure a high level of consumers protection by giving them all the information necessary to make adequate food choices with full knowledge. Thus, the objectives of the present review are focused on describing (1) the current status of

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the international regulatory framework for food health-related claims and (2) the state of the art regarding functional food products market, focusing on those with health-related claims.

The present work is focused on United States (US), Japan and Europe as the main representative countries with public and internationally available regulation of three continents (America, Asia and Europe). As it will be explained later, Japan was the first country in proposing the term "functional food", its classification and its regulation. In addition, it was the cradle of the functional food market. US and Europe are also considered important global powers in terms of functional food products with significantly different approaches regarding food and claims regulation (De Boer & Bast, 2015a). By including these three perspectives, authors aim to highlight those remarkable differences and provide a comprehensive overview of the main current regulation on functional food products and the state of the art of its market.

2. The international regulatory status of food claims

2.1. American regulation

The required information that must appear in the food and food supplements' package (e.g. data about the manufacturer and the distributor) as well as the nutrition labeling including health-related claims are under the Nutrition Labeling and Education Act (last amendment in 2016), codified in the Title 21 of the Code of Federal Regulations (21 CFR) (1967) (last amendment in 2018). Regarding health-related claims, there are three approved categories: "nutrient content claims", "structure/function claims" and "health claims" (United States Congress, 1990).

Nutrient content claims are those that express or imply the level of a nutrient in a food product (food and food supplements). Expressed claims directly inform about the level or range of the nutrient, for instance "low sodium" and "contains 100 calories". Implied claims can be those that suggest (1) the absence of the nutrient or its presence in a certain amount using terms like "free", "reduced/less" and "high" (e.g. "high in oat bran') or (2) the useful function that the food product may have in maintaining health dietary practices due to its nutrient content (e.g. "health, contains 3 g (g) of fat") (Food and Drug Administration (FDA), 2019a).

Structure/function claims are those that express the effect of a nutrient/ingredient on the structure or function of the organism without making a reference to a disease. These claims have historically appeared in the labeling of food, food supplements and even medicines. Regarding food and food supplements, there are four clear differences: (1) structure/function claims that appear in food supplements are focused on non-nutritive and nutritive effects of the nutrient/ingredient, whereas in food these claims are only focused on effects derived from nutritive value; (2) manufacturers must inform the FDA about the presence of these claims in any new food supplement within the first 30 days after its marketing to verify that the claimed effect is not related to a disease (this notification does not implied an assessment of the claim substantiation and it is not necessary for food with structure/function claims); (3) food supplements with structure/function claims must show in its labeling the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease" (it is not required in food with these claims); and (4) structure/function claims that appear in food supplements can state the role of the nutrient/ingredient intended to affect the normal structure of function of the organism (e.g. "calcium builds strong bones") as well as its mechanism necessary to maintain such structure or function (e.g. "fiber maintain bowel regularity"; "antioxidants maintain cell integrity"). There are other two types of structure/function claims that can appear in food supplements labeling: general well-being claims and nutrient deficiency disease claims. They are only allowed if the claim indicate how widespread the disease is in the US (Bagchi, 2019; FDA, 2019a).

Health claims are those that express a relation between a food component or a food supplement ingredient and a disease or health-related condition. The diseases mentioned in the claim must be those for which the American population or a specific population group (e.g. elderly people) is at risk, without including those caused by nutrient deficiencies (vitamin C – scurvy; vitamin D – rickets; vitamin B_2 – pellagra; iron – anemia). The relation component – disease must be well-described and based on a disease risk reduction and never on the cure, mitigation, treatment or prevention of a disease as a medicine does. For instance, a statement which describes a pain-relieving effect for the mitigation of the symptoms of the arthritis (chronic disease) cannot be a health claim because it suggests that the food product in question can be used as a drug. Only food products with an appropriate nutritional profile are able to include health claims in their labeling. In other words, food products must contain at least the 10% of the daily value for one or more of six key nutrients (proteins, fiber, calcium, vitamin D, etc.) per Reference Amount Customarily Consumed (RACC). This minimum nutrients contents must be fulfilled by the food product in question before any intentional nutrient addition. Moreover, health claims must be stated in a way which (1) shows the relative significance of that claimed health effect within the context of the total daily diet and (2) can be easily understood by consumers (Bagchi, 2019).

Regarding the types of health claims, there are two groups: "authorized health claims" and "qualified health claims".

Authorized health claims can suggest or imply that a food or food component may reduce the risk of a disease or a health-related condition. To be approved by the FDA as an authorized health claim, it must be based on Significant Scientific Agreement (SSA health claims) or on an authoritative statement from an appropriate scientific body of the US Government or the National Academy of Sciences or any of its subdivisions (FDMA health claims) (FDA, 2019a). The question regarding what means a Significant Scientific Agreement has always created a great debate. According to the FDA, a SSA is considered a strong and rigorous standard used among qualified experts that ensures a high level of confidence enough to confirm a relationship between a specific substance and a concrete disease; that is, the claim must be supported by the totality of publicly available scientific evidence for the above-mentioned relationship (FDA, 2018a). The SSA standard is applied to authorized health claims which appear in the labeling of both food and food supplements (Bagchi, 2019).

Any food company interested in marketing its products with a new health claim describing or suggesting new health effects must make a request to the FDA as a pre-marketing approval is mandatory (De Boer & Bast, 2015a). Authorized health claims are only approved under an extensive review of the current scientific literature. Randomized and controlled clinical intervention trials are considered as the most reliable proofs (also called "the gold standard") to confirm the relationship between the specific component included in the food product, and the health. The number of clinical intervention trials needed for the approval of a new health claim varies in each case. For instance, five clinical trials were enough to support the approval of the health claim related to the barley soluble fiber and the coronary heart disease ("Soluble fiber from foods such as [name of food], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease"), whereas the approval of the health claim regarding the whole oat soluble fiber and the coronary heart disease ("Diets low in saturated fat and cholesterol that include soluble fiber from whole oats may reduce the risk of heart disease") was supported by thirty seven clinical trials. Those claims supported by scientific bodies of specific government authorities (U.S. Government or the National Academy of Sciences) meet the Significant Scientific Agreement as well and are subjected to be approved by the FDA. Before 120 days from the submission of the request, the FDA is required to notify the petitioner food company about its final decision, that is, the approval or refusal of the new proposed health claim. If the FDA does not refuse the claim within this

Table 1
List of authorized health claims based on Significant Scientific Agreement (SSA health claims) and those health claims based on authoritative statement from scientific bodies of the US Government, the National Academy of Sciences or any of its subdivisions (FDMA health claims) (FDA 2013, 2019b).

Component/ingredient – disease/health-related condition	Model claim statement(s)
SSA health claims	
Calcium and osteoporosis and calcium, vitamin D, and osteoporosis	"Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis" and "Adequate calcium and vitamin D, as part of a well-balanced diet, along with physical activity, may reduce the risk of osteoporosis".
Dietary fat and cancer	"Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers".
Sodium and hypertension	"Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors".
Dietary saturated fat and cholesterol and risk of coronary heart disease	"While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease".
Fiber-containing grain products, fruits, and vegetables and cancer	"Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors".
Fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease	"Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors".
Fruits and vegetables and cancer	"Low fat diets rich in fruits and vegetables (food that are low in fat and may contain dietary fiber, vitamin A, or vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors".
Folate and neural tube defects	"Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect".
Dietary non-cariogenic carbohydrate sweeteners and dental caries	"Frequent between-meal consumption of food high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay" and "Does not promote tooth decay".
Soluble fiber from certain food and risk of coronary heart disease.	"Soluble fiber from food such as [name of soluble fiber source and, if desired, name of food product], as part of a diet low in saturated fat and cholesterol, may reduce the risk heart disease. A serving of [name of food product] supplies _ grams of the [necessary daily dietary intake for the benefit] soluble fiber from [name of soluble fiber source] necessary per day to have this effect".
Soy protein and risk of coronary heart disease	"25 g of soy protein a day, as part of a low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies _ _ grams of soy protein", and "Diets low in saturated fat and cholesterol that include 25 g of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides _ _ grams of soy protein".
Plant sterol/stanol esters and risk of coronary heart disease	"Food containing at least 0.65 g per of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies _ _ grams of vegetable oil sterol esters", and "Diets low in saturated fat and cholesterol that include two servings of food that provide a daily total of at least 3.4 g of plant stanol esters in two meals may reduce the risk of heart disease. A serving of [name of food] supplies _ _ grams of plant stanol esters".
FDMA health claims	
Whole Grain Food and Risk of Heart Disease and Certain Cancers	"Diets rich in whole grain food and other plant food and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers".
Whole Grain Food with Moderate Fat Content and Risk of Heart Disease	"Diets rich in whole grain food and other plant food, and low in total fat, saturated fat, and cholesterol may help reduce the risk of heart disease".
Potassium and the Risk of High Blood Pressure and Stroke	"Diets containing food that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke".
Fluoridated Water and Reduced Risk of Dental Caries	"Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]".
Saturated Fat, Cholesterol, and Trans Fat, and Reduced Risk of Heart Disease	"Diets low in saturated fat and cholesterol, and as low as possible in trans fat, may reduce the risk of heart disease".
Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease	"Replacing saturated fat with similar amounts of unsaturated fats may reduce the risk of heart disease. To achieve this benefit, total daily calories should not increase".

period, the claim is able to be used in food products as it meets the statutory requirements (FDA, 2018b).

SSA health claims can be made on food and food supplements whereas FDMA health claims can only appeared on food (FDA, 2019a). As it is shown in Table 1, the FDA has approved 18 health claims.

Finally, *qualified health claims* are those supported by some scientific evidence which can appeared in the labeling of food and food supplements and must be accompanied by a disclaimer as they do not meet the Significant Scientific Agreement (FDA, 2019b). Below the SSA level (total agreement or consensus by the available scientific evidence), there is one level called "emerging agreement" in which the qualified health claims are based (Bagchi, 2019). At this level, a specific ranking system was established by the FDA in order to categorize the qualified health claims according to the relative weight of the scientific evidence which supports each claim. This classification includes three groups (B, C and D) that reflects the level of the scientific evidence (moderate/good, low and lowest, respectively). The qualified health claims must appear in the labeling of functional food products with a specific wording depending on the group in which they are categorized: (1) "although there is scientific evidence supporting the claim, the evidence is not conclusive…" (B or second level); (2) "Some scientific evidence suggests… however, FDA has determined that this evidence is limited and not conclusive" (C or third level); and (3) "Very limited and preliminary scientific research suggests… FDA concludes that there is little scientific evidence supporting this claim" (D or fourth level). The "A" group (first level) includes the authorized health claims which meet the SSA standard like the health claims approved in Japan and Europe (FDA, 2018c). An example of one qualified health claim is the following: "Scientific evidence suggests, but does not prove, that whole grains, as a part of a low saturated fat, low cholesterol diet, may reduce the risk of diabetes mellitus type 2". Table 2 shows an overview of the qualified health claims (FDA, 2019c).

2.2. Japanese regulation

Government of Japan. (1947) (1947) (latest amendment in 2018), Act on Standardization and Proper Labeling of Government of Japan. (1950) (1950) (latest amendment in 2009) and Government of Japan.

Table 2
Summary of qualified health claims in US (FDA, 2019c).

Atopic dermatitis
100% Whey-Protein Partially Hydrolyzed Infant Formula.
Cancer
Tomatoes and/or Tomato Sauce and Prostate, Ovarian, Gastric, and Pancreatic Cancers.
Calcium and Colon/Rectal Cancer and Calcium and Recurrent Colon/Rectal Polyps.
Green Tea and Cancer.
Selenium and Cancer.
Antioxidant Vitamins and Cancer.
Cardiovascular disease
Nuts and Heart Disease.
Walnuts and Heart Disease.
Omega-3 Fatty Acids and Coronary Heart Disease.
B Vitamins and Vascular Disease.
Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease.
Unsaturated Fatty Acids from Canola Oil and Coronary Heart Disease.
Corn Oil and Heart Disease.
Cognitive function
Phosphatidylserine and Cognitive Dysfunction and Dementia.
Diabetes
Psyllium Husk and Diabetes.
Chromium Picolinate and Diabetes.
Hypertension
Calcium and Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia.
Neural Tube Birth Defects
Folic Acid and Neural Tube Birth Defects.

(2002) (2002) (latest amendment in 2018) regulate the labeling on food and food supplements in Japan.

Unlike the US regulation, in Japan there are only four categories approved for the **nutrition claims**: "rich in" "source," "low," and "does not contain", with minimal and maximal limits of the nutrients in question. Food products with nutrition claims are required to include the nutrition composition in the labeling (Malla, Hobbs, & Sogah, 2013).

All food product which meets the requirements and standards established by the Minister of Consumer Affairs Agency of the Government of Japan and that claims certain nutritional or health functions in its labeling can be labeled as **"food with health claims"**, which can be categorized in Food for Specified Health Use (FOSHU) and **"food with nutrient function claims"** (Government of Japan. (2002), 2002). Any claim about the efficacy and function made on these functional food products must be based on strong scientific evidence; that is, in vitro metabolic and biochemical studies, in vivo studies and, above all, randomized controlled trials carried out in Japanese individuals. Food products are not allowed to include claims related to the health maintenance and promotion which are eminently inconsistent with the above-mentioned scientific evidence. If any claim (1) could have a potential influence in the public health, (2) is not based in a strong scientific evidence and (3) appears in the labeling of any food product, the Minister of the MHLW or the General of the Regional Bureau of Health and Welfare recommend the corresponding food company to remove the claim. When the suggested measure is not taken, the recommendation becomes an order which could result in penalty charges if there is no compliance with it. It is prohibited the use of deceptive or misleading claims as well (Japanese Ministry of Health, Labour and Welfare (MHLW), 2019a,b; FOSHU system, 1991).

The FOSHU system was created by the MHLW as a regulatory system to approve statements related to the effects of food in the organism. In 1993, the first FOSHU products were approved. They contained hypoallergenic rice and low phosphorus milk for patients. These products were then transferred to another category called "food for illness" as they could not show medical claims including terms like "prevent", "cure" or "treat". In 2009, the FOSHU system fell under the jurisdiction of The Consumer Commission, Cabinet Office and since 2005, the FOSHU group has been classified as a special food group between medicines and regular food (Ohama, Ikeda, & Moriyama, 2014). Today, FOSHU are officially able to state health-related claims of physiological effects on the organism (Table 3).

The approval of a new FOSHU product requires an application by the food company interested in its commercialization to the Japanese (MHLW). With view to assessing the safety and effectiveness of the new FOSHU product before its commercialization, the MHLW performs two consultations to the Food Safety Commission and the Council on Pharmaceutical Affairs and Food Sanitation. Based on the data reported by both Institutions, the MHLW makes a final decision about its approval or refusal. For the approval and authorization, the FOSHU product must clearly demonstrate its effectiveness on the human organism based on strong scientific evidence (clinical studies) as well as the absence of any safety issue through (1) its historical consumption pattern data and (2) additional safety studies conducted in humans and animals (toxicity tests and confirmatory analyses). The new FOSHU must successfully overcome the strict quality controls such as the specifications of the ingredients. In addition, the FOSHU product must (1) ensure the compatibility with the product specifications by the time of consumption and (2) have an appropriate nutritional profile (no excessive salt, sugar or fat). Finally, an analytical determination of the functional compound responsible for the beneficial physiological effect claimed by the FOSHU product must be carried out. The claim included in the labeling must be approved by the MHLW as well (MHLW, 2019c).

There are four types of FOSHU: **"Regular/ordinary FOSHU"**, "Qualified FOSHU", "Standardized FOSHU" and "Reduction of disease risk FOSHU". Regular FOSHU contain nutrients which appear to possess a beneficial effect on the human organism. Before its commercialization, a complex and comprehensive assessment is performed by the Japanese Government in order to ensure the scientific validity of the specific health effect claimed on that FOSHU products as well as to provide the food manufacturer the required market approval. "Qualified FOSHU" and "Standardized FOSHU" categories were created in order to make the Regular FOSHU approvals easier for applicants.

Table 3
Approved FOSHU products (MHLW, 2019b).

Responsible ingredients for health functions	Specified health uses
Paratinose, maltitiose, erythritol, etc.	Food related to dental hygiene
Calcium citrated malate, casein phosphopeptide, hem iron, fracuto-oligosaccharide, etc.	Food related to mineral absorption
Soybeen isoflavone, Milk Basic Protein (MBP), etc.	Food related to osteogenesis
Indigestible dextrin, wheat albumin, guava tea polyphenol, L-arabiose, etc.	Food related to blood sugar levels
Lactotripeptide, casein dodecaneptide, tochu leaf glycoside (geniposidic acid), sardine peptide, etc.	Food related to blood pressure
Middle chain fatty acid, etc.	Food related to triacylglycerol
Chitosan, soybean protein, degraded sodium alginate	Food related to blood cholesterol level
Degraded sodium alginate, dietary fiber from psyllium seed husk, etc.	Cholesterol plus gastrointestinal conditions, triacylglycerol plus cholesterol
Oligosaccharides, lactose, bifidobacteria, lactic acid bacteria, dietary fiber 8 ingestible dextrin, polydextrol, guar gum, psyllium seed coat, etc.	Food to modify gastrointestinal conditions

"Qualified FOSHU" refer to food with a health function supported with insufficient scientific evidence or food with certain degree of effectiveness but without an established mechanism, whereas "Standardized FOSHU" is the name used for food with a health function supported with sufficient scientific evidence. Qualified FOSHU should include the following statement: "grounds for this effectiveness have not necessarily been established" (Malla et al., 2013; MHLW, 2019a,c). **"Reduction of disease risk FOSHU"** is the only type of FOSHU which is authorized to show reduction of disease risk claims in the labeling. This effect must be clinically and nutritionally established in a specific ingredient. Only two reduction of disease risk claims are authorized and are the following: "Intake of proper amount of calcium contained in healthy meals with appropriate exercise may support healthy bones of young women and reduce the risk of osteoporosis when aged" and "Intake of proper amount of folic acid contained in healthy meals may support women to bear healthy baby by reducing the risk of neural tube defect, such as spondyloschisis, during fetal development" (MHLW, 2019a,c).

Food with nutrient function claims contain concrete minerals and/or vitamins and are labeled with function claims of these nutritional ingredients. These specific nutrients are five minerals (zinc, calcium, iron, copper and magnesium) and twelve vitamins (niacin, panthotenic acid, biotin, vitamin A, vitamin B_1, vitamin B_2, vitamin B_6, vitamin B_9, vitamin B_{12}, vitamin C, vitamin D and vitamin E). Examples of nutrient function claims are the following: "Iron is necessary in the red blood cell formation" (in fruit drinks with iron) and "Vitamin E helps to protect fat in the body from being oxidized and to maintain the cell health" (in germ oil capsules). Unlike the FOSHU products (including the "Reduction of disease risk FOSHU"), food with nutrient function claims are not required to go through a pre-marketing approval by the MHLW (De Boer & Bast, 2015a; MHLW, 2019d).

Finally, food products approved by the Minister of Consumer Affairs Agency of the Government of Japan for specified dietary uses are labeled as **"food for special dietary uses"**. This group can state claims for a special dietary use and includes: formulas for pregnant or lactating women, infant formulas, food for elderly with mastication and swallowing problems, medical food and FOSHU (MHLW, 2019a).

2.3. European regulation

The first European country which approved rules and regulations on food related-claims was Sweden. It was called the "Code of Practice in the labeling of food with health claims" (Foundation, 2004). After that, Regulation (EC) 1924/2006 (last amendment in 2014) were the first legislative act related to food in EU and applies to "food", as defined in the Article 2 of Regulation 178/2002 (last amendment in 2018), and "food supplements" (mainly vitamins and minerals), as defined in Directive 2002/46/EC (last amendment in 2017) (European Parliament and Council of the European Union, 2002a,b). Functional foods and nutraceuticals do not have neither a specific regulatory framework, nor a statutory definition in Europe. However, the legal requirements applied to these functional products depends on the nature of each product as they can contain nutrients, bioactive compounds or other substances which are clearly regulated in the European market. Thus, functional foods and nutraceuticals with any nutrition and health claim related to vitamins, minerals and/or other substances in its labeling, presentation and/or advertising, have to meet the specific requirements established by the Regulation (EC) 1924/2006 (Domínguez Díaz et al., 2019).

Regulation (EC) 1924/2006 defines claim as "any message or representation, which is not mandatory under community or national legislation, including pictoral, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics". Claims must be in accordance with good dietary practices and accepted principles of nutrition and health, without encouraging any excessive consumption of concrete products since a varied and balanced diet provides the adecuate amounts of nutrients that the organism requires.

The use of claims in any food commercial communication (labeling, presentation or advertising), will be authorized under strict conditions: (1) claims must refer to ready-to-eat food, (2) the nutrient or substance which has been previously shown to be absent or present (including in reduced content) in the product in question, possess a beneficial nutritional or physiological effect and must be assimilable by the organism and, most importantly, (3) the declared beneficial effects must be easily understood by the average consumer, "who is reasonably well-informed and reasonably observant and cautious, taking into account social, cultural and linguistic factors". Claims must be reliable, useful and clear in order to (1) protect consumers and avoid misunderstandings about the safety and/or nutritional adequacy of other food as well as (2) promote the innovation and the fair competition in the food industry (Cámara et al., 2019).

The article 2.2 of Regulation (EC) 1924/2006 establishes three categories of claims: "nutrition claims", "health claims" and "reduction of disease risk claims". All claims refer to the product as a food and/or food supplement. In any case they will suggest or imply that the product in question has preventive, therapeutic or curative properties of a human disease.

Nutrition claims are those that state, suggest or imply that a food has specific beneficial nutritional properties due to its caloric value, the nutrients or other substances, that it contains in a reduced or increased proportion, or directly that it does not have. For instance, "high in vitamins, fibre or proteins" or "low in calories, salt or sugar".

Health claims are considered those that affirm, suggest or imply that there is a relation between a food category, a food or one of its components, and health. As health claims could have a significant impact on the consumers dietary behaviour, important matters should be considered. Any claim which describes or suggests a new health-related benefit for the human organism is required to go through a pre-marketing approval (De Boer & Bast, 2015a).

The approval process of new health claims is complex as these claims must be based on a strong scientific evidence, which implies a harmonized evaluation by the European Food Safety Authority (EFSA) prior to their authorization. The highest weight of the scientific basis required for the substantiation of a health claim is provided by published human studies which addresses and confirm the relationship between the food or compound (to which the claim is referred) and the health effect. Thus, a comprehensive review about the above-mentioned human studies is indispensable and must be completely transparent as well as reflect all the scientific evidence currently available. Human studies which are yet unpublished can be considered as well; however, a detailed description about the process followed to identify these studies must be provided. Data from animal studies would never be enough to substantiate a claim on its own but can be useful as "supporting evidence" by proving the biological plausibility of the claim or clarifying the potential mechanism(s) by which the food or compound could possess the claimed effect. In any case, all studies selected for substantiating a specific health claim must be of high quality with regard to the methodology and reporting. One health claim will be finally authorized to be used in the labeling of food products as long as the available scientific evidence demonstrates that (1) there is a cause-effect relationship between the food or compound and its health effect, and (2) the food/compound with the claimed effect is completely defined and characterized and its amount and pattern of consumption necessary to obtain that effect are reasonably be achieved by following a balanced diet (EFSA, 2016).

The EU-funded REDICLAIM Project was created in order to help new applicants in the process of authorizing new health claims. This European Project includes guidance documents, analyses of EFSA Scientific Opinions made on new health claims and information given by experts involved in the application. The most important key points for the successful substantiation of new health claims are the following:

(1) consider the guidance documents published in the EFSA's webpage and other EU-funded Research Projects about the submission and substantiation of health claims; (2) the applicant should provide all the available scientific data in order to reduce the evaluation time by EFSA, above all when the substance subjected to the claim is considered novel; (3) the use conditions of the new health claim proposed by the applicant should reflect the conditions in which the studies that support the substantiation of the claim were performed. The REDICLAIM Project points out that a well-documented scientific substantiation of a health claim does not imply the final authorization of the new health claim (Pravst et al., 2018).

With regard to the requirements applied to the food industry, food companies must (1) justify the use of health claims, (2) meet the specific use conditions and (3) ensure a proper nutritional profile of those products with health claims. Nutrition labeling is mandatory in all food products, including those that contain claims. In addition, when a claim refers to a substance, which does not appear on the nutrition labeling, its quantity must be indicated in the same field of vision where the nutrition labeling appears. These will help consumers to make right food choices in order to follow a healthy diet (European Parliament and Council of the European Union, 2011). Food companies are generally interested in made health claims in the labeling of their food products whenever is possible; however; certain difficulties and barriers are reported. The strict requirements which food companies must meet in order to include these claims in the labeling of their products, the limited financial resources necessary to make new applications for approving new health claims, and the steady change in the food sector (product categories, list of ingredients allowed to be incorporated in new functional food products, etc.) are considered the major challenges to face by the food industry and could have a negative impact on the product innovation (Bröring, Khedkar, & Ciliberti, 2017; Khedkar, Bröring, & Ciliberti, 2016; Khedkar, Ciliberti, & Bröring, 2016).

The article 12 of Regulation (EC) 1924/2006, which establishes the restrictions on the use of health claims, affirms that those referring to recommendations of individual doctors or associations and/or the rate or amount of weight loss will not be authorized, as well as those suggesting that health could be affected if the product in question is not consumed. Finally, the article 10.2 of the Decision of 24 January 2013 informs about the obligation to show a statement (along with the health claim) which indicates that the product must be one more element in the context of a balanced and varied diet with view to preventing its excessive consumption.

The European Database "EU Register of nutrition and health claims made on foods" includes the positive list of the permitted health-related claims. As it was mentioned above, getting the approval of a new health claim is difficult. As an example, out of the 44.000 health-related claims which were sent to the European Commission in 2008, only 4637 were selected to be subjected to a scientific evaluation by the EFSA. 2758 claims were finally assessed by the EFSA and only the 8,1% (222 health claims) were authorized to be used in December 2012. In the case of health claims related to antioxidants (which were seen as a promising incentive to the functional foods' sector), only the 3,5% of the health claims sent to the European Commission were finally authorized (Lenssen, Bast, & De Boer, 2018). One of the main causes for rejecting new health claims is the type of scientific methods used by the applicants and provided to the EFSA in the scientific dossier. There are cases in which no consensus has been achieved with regard to the weight of evidence provided by specific scientific procedures for the substantiation and approval of health claims (De Boer & Bast, 2015b). Up to date, a total of 239 health-related claims has been approved: 10 claims for fat, 5 for carbohydrates, 14 for fiber, 3 for protein, 98 for minerals, 68 for vitamins, 24 for other substances, 12 for food and finally 5 related to food categories. Some examples are the following: "Vitamin C contributes to maintain the normal function of the immune system during and after intense physical exercise" or "Plant sterols/stanols contribute to the maintenance of normal blood colesterol in the development of a human disease" (European Commission, 2012, 2019). The European Commission updates the EU Register when required; that is after the adoption of EU decisions on applications for claims or on changes to use conditions as well as restrictions. Authorized and accepted wording of claims must be respected. However, certain flexibility is accepted whenever the meaning of the new wording is the same as the one authorized (European Parliament and Council of the European Union, 2006).

Reduction of disease risk claims are health claims that state, suggest or imply that the consumption of a food category, a food or one of its components, can significantly reduce a risk factor in the development of a human illness. Given that diet is an important risk factor in the development of chronic diseases, specific labeling requirements should be applied. Whenever one product shows these claims, it must appear on its label, in its presentation or advertising, a statement informing consumers that the disease which the claim is referring is influenced by other risk factors; thus, the modification of one of them may or not have a beneficial effect on the organism (European Parliament and Council of the European Union, 2006).

The process of authorization is different from the rest of claim categories. If a food company wants to use one reduction of disease risk claim that is not yet authorized, it has to request its use to the competent national authority, which will send all the information to the EFSA and this in turn to the European Commission and the rest of Member States. The Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) will assess the request in a maximum period of five months. Then, EFSA will make public its opinion, which can be favourable or not. The Commission will evaluate the claim authorization taking into account EFSA's opinion and inform the applicant food company about its decision. The claim in question will appear in the community list of accepted claims or rejected claims (European Parliament and Council of the European Union, 2006).

At present, 13 reduction of disease risk claims are authorized as long as food products respect the use conditions and wording (Table 4).

For a better understanding and after reviewing the international framework status of health-related claims, Fig. 1 provides a useful summary of the American, Japanese and European regulations.

3. The market of functional food products with health related-claims: state of the art

The prominent functional food products' market in developed societies reflects the **positive connotation** that consumers have of these products and their current tendency towards the adoption of healthy eating habits. The **promising future** of the functional food products market in developed countries is reflected in the value of more than $300 billion which is estimated to be invested in the next year, showing the current tendency towards innovation not only in the food industry but also in the pharmaceutical sector as its interest in the investment in functional food products is highly increasing in the last years. The huge costs of healthcare due to patients with chronic diseases, the shorter development times and the lower product development costs in comparison with the pharmaceutical ones are the main motivations of the pharmaceutical industry for promoting the development of functional foods products (Khedkar, Carraresi, & Bröring, 2017; Santeramo et al., 2018).

Market opportunities for functional food products with health-related claims could be linked to consumers acceptance, which depends on multiple factors classified in two main categories: consumers-related-characteristics group and product-related-characteristics group (Fig. 2). The first group are composed by personal factors as age, gender, health consciousness, familiarity, income and education; psychological factors as health motivation, consumers attitude and food neophobia; as well as cultural and social factors. For instance, the acceptance of functional food products increases with the presence of an ill member and children in the family and with doctors or dieticians as

Table 4
Reduction of disease risk claims authorized by EFSA (European Commission, 2019).

Nutrient, substance, food or food category	Model claim	EFSA opinion reference
Fat		
Monounsatured and/or polyunsatured fatty acids	"Replacing saturated fats with unsaturated fats in the diet has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease".	(EFSA, 2011a)
Plant stanol esters	"Plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease".	(EFSA 2008b, 2009a, 2012a,b)
Plant sterols / Plant stanol esters	"Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease".	(EFSA 2009a,b, 2012b)
Plant sterols: sterols extracted from plants, free or esterified with food grade fatty	"Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease".	(EFSA 2008a, 2009a, 2012b)
Sugars		
Barley beta-glucans	"Barley beta-glucans has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease".	(EFSA, 2011c,d)
Oat beta-glucan	"Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease".	(EFSA, 2010d)
Minerals		
Calcium	"Calcium helps to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures".	(EFSA 2009b, 2010a)
Minerals and vitamins		
Calcium and vitamin D	Calcium and vitamin D help to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures.	(EFSA 2009b, 2010a)
Vitamins		
Folic acid	"Supplemental folic acid intake increases maternal folate status. Low maternal folate status is a risk factor in the development of neural tube defects in the developing foetus".	(EFSA, 2013)
Vitamin D	"Vitamin D helps to reduce the risk of falling associated with postural instability and muscle weakness. Falling is a risk factor for bone fractures among men and women 60 years of age and older".	(EFSA, 2011b)
Other substances		
Chewing gum sweetened with 100% xylitol	"Chewing gum sweetened with 100% xylitol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries in children".	(EFSA, 2008c)
Sugar-free chewing gum	"Sugar-free chewing gum helps neutralise plaque acids. Plaque acids are a risk factor in the development of dental caries".	(EFSA, 2010c)
	"Sugar-free chewing gum helps reduce tooth demineralisation. Tooth demineralisation is a risk factor in the development of dental caries".	(EFSA, 2010b)

the source of information. The second group includes factors as price, taste, brand, package features and labeling. Among all these factors, **labeling**, **health motivation** and **consumers attitudes** towards functional food products are the ones which most influence consumers purchase decisions regarding these products. These three factors are partially interconnected as consumers who are motivated and committed to improve and/or maintain their health status, are more interested in the information shown on the labeling and more likely to have a positive attitude towards the purchase of functional food products. In fact, the more favourable information a functional food product shows, the more interest in buying it (Bimbo et al., 2017; Kaur & Singh, 2017; Santeramo et al., 2017).

Health-related claims included in the labeling and approved by official government agencies positively affect consumers food choices. In addition, they could create sensory and hedonic expectations which would influence the future experiences that consumers would have with the functional food product in question. In this sense, the European CLYMBOL Project concluded that the appearance of health-related claims in the labeling could have a high **influence in the consumers pucharse decisions** than the proper image on the package. Although design strategies of packages (e.g. images) can capture the consumera attention and help the functional food product in question to stand out from other food products, consumers tend to first look at the claim more often and for a longer time than the rest of the package features. In fact, the CLYMBOL Project results showed that package images were unable to encourage consumers to choose a functional food product with a health-related claim more often (Hieke et al., 2016).

On the one hand, the **consumers understanding** about the information provided by these claims is a remarkable factor to consider. It seems that the more consumers understanding and belief in the health effects claimed in the labeling of functional products, the more intention to buy it; however, it will not necessarily lead to make this final purchase. It should be noted that the impact of health claims in the purchase intention is significantly higher in those consumers who already tend to buy a specific type of product and with an interest in nutrition matters. Consumers without this intention are unlikely to finally buy a novel type of food product just due to the appearance of a health claim in its labeling (Williams, 2006). The CLYMBOL Project demonstrated that health-related claims referred to compounds or substances which are familiar to consumers (e.g. calcium and its effect in bones health) are considered more understable, truthful and confidence and leads consumers to believe more in the healthiness of the product in question and increase consumers purchase intention. Health-related claims must be easily understable as those including much information and complex scientific language are often not read and understood by consumers. However, those claims which resulted to be too familiar to consumers decrease their interest and those containing new information appear to gain consumers attention and prevent the 'wear-out' effect (Hieke et al., 2016). Several studies have reported that consumers prefer short or split claims (that is, with a short claim on the front label and the rest of information located elsewhere on the package) than the longer ones as the shortest claims create more positive connotations towards these functional products. The inclusion of qualifying words ("may", "reduce", etc.) in the wording of the claim could have a positive effect as the consumers see it more realistic and, at the same time, a negative effect because of the uncertainty of the meaning of that words, which can reduce the consumers confidence. The level of education could influence in the consumers understanding as well. The absence of a comprehensive knowledge in terms of nutrition may (1) limit the skills of consumers to understand and assess the

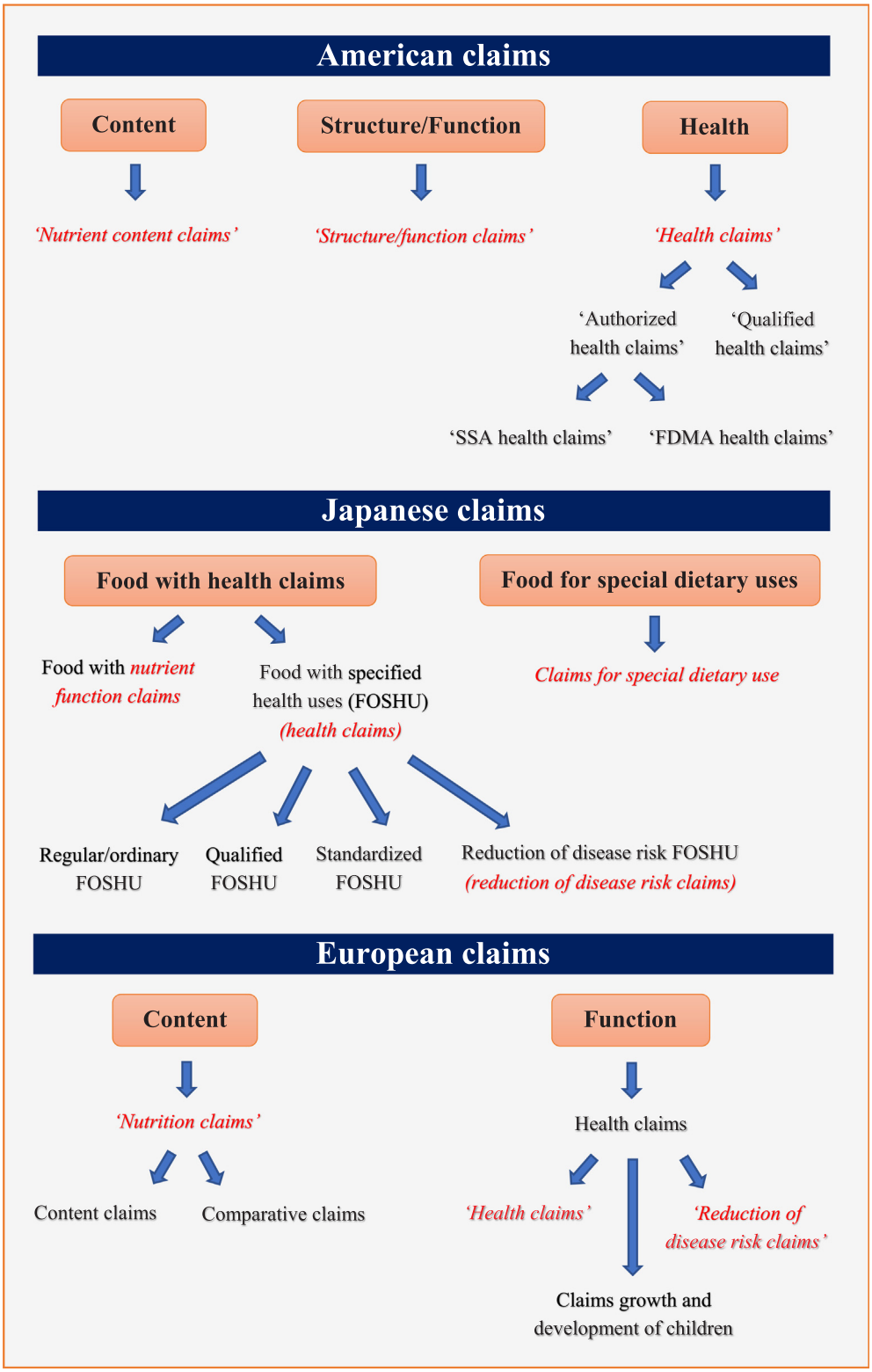

Fig. 1. Overview of health-related claims in US, Japan and Europe.

health effect claimed and (2) reduce significantly their credibility towards health claims (Williams, 2006). In the systematic review carried out by Mogendi, De Steur, Gellynck, and Makokha (2016), nineteen studies reported that this nutritional knowledge has a significant impact on the consumers acceptance and purchase intentions of those functional products with health-related claims (Mogendi et al., 2016).

On the other hand, the **health motivation** has also been recognized as a potential factor. Consumers with a specific health goal are more likely to choose a functional product with health-related claims (Küster-Boluda & Vidal-Capilla, 2017). In general, it seems that older and female consumers focused on enhancing their life quality through adopting a healthier diet pay more attention to the health claims included in the labeling than other consumers. The great majority of the consumers with a high health motivation would pay a higher price for

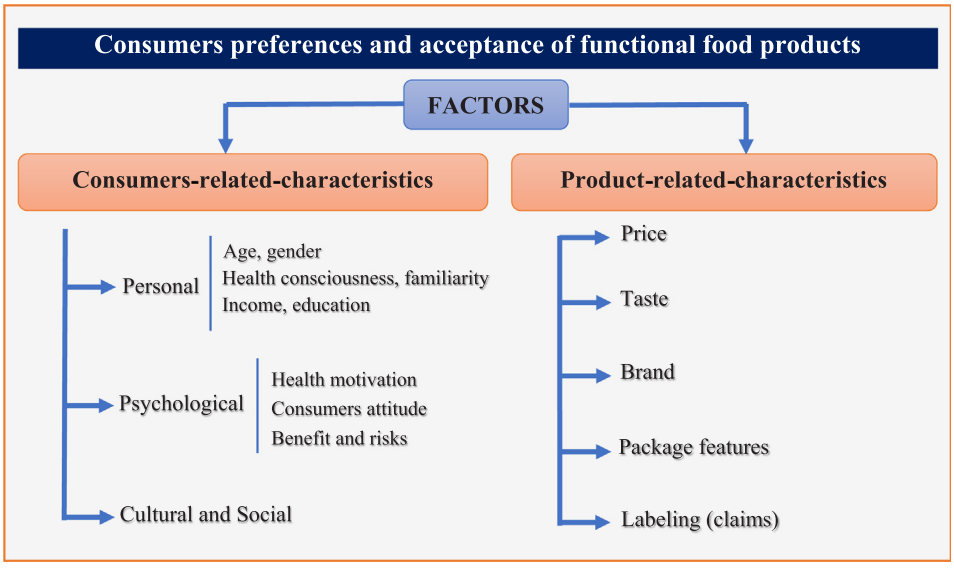

Fig. 2. General classification of factors affecting consumers preferences and functional products acceptance.

functional products with health-related claims; however, they would not be completely willing to compromise the taste for the health. The taste appears to be an important prerequisite for the acceptance of these products. In general, consumers would not have a positive connotation of healthy functional products if the taste is negatively affected (Mogendi et al., 2016).

In conclusion, health-related claims could (1) induce healthier consumption patterns and (2) enable better informed decisions by the consumers through informing them about the potential health effects provided by the consumption of functional products (Hieke et al., 2016). However, the consumers perception towards these products may not be highly predictable. Further studies in such complex area are required in order to accurately measure and evaluate the effect of health-related claims on the consumers behavior and attitudes towards functional food products with these claims (Khedkar et al., 2017).

Making a prediction about the potential success of the market of functional food products with health claims is complex; however, the assessment of the different **consumers attitudes** towards these products could be valuable as a good starting point (Khedkar et al., 2017; Mogendi et al., 2016). The twenty-three studies collected and analyzed in the systematic review of Mogendi et al. (2016) reported that the **socio-demographic factors** are as important as the above-mentioned ones. There are remarkable differences between cultures and countries (Stratton, Vella, Sheeshka, & Duncan, 2015). For instance, the **American and Japanese consumers** accept the concept of functional food products with health-related claims easier than the Europeans, and they are willing to incorporate these products in the daily diet (Tollin et al., 2016). **Europeans** from Finland, Sweden, The Netherlands, Poland and Cyprus are considered more open-minded than those consumers from other countries (Denmark, Italy and Belgium) as they are more interested in buying these products (Küster-Boluda & Vidal-Capilla, 2017). Taking the case of **Spain**, consumers are not highly familiar with the concept of functional food products. However, a great plethora of functional products showing health-related claims in its labeling are currently available in the market (Bosovsky, 2018).

3.1. A case-study: functional food products with health-related claims marketed in Spain

Firstly, an updated **review of the health claims approved in the European Union** was conducted using the public information available on the European Commission website, concretely, on the European Register of nutrition and health claims made on food and food supplements (last retrieve 3rd November 2019): https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home.

Secondly, a thorough **search strategy** of the functional products (food and food supplements) commercialized with any of the approved health claims in the Spanish market were established and performed. No differences in the approval process of food claims and the positive list of health claims between the Spanish and the European markets exist. As it was explained in the first section (international regulation), all the Member States of the European Union must meet the requirements established by the Regulation (EC) N° 1924/2006, which (1) harmonizes the provisions laid down by law, regulation or administrative action in Member States with regard to nutrition and health claims and (2) guarantees an efficient functioning of the internal market (European Parliament and Council of the European Union, 2006).

The search strategy was divided into two steps: (1) first, an **online preliminary search** of the above-mentioned functional products was carried by means of (a) the online purchasing applications and/or platforms used by the most common supermarkets in Spain and (b) the trendiest e-commerce companies as AMAZON; (2) second, a **physical search in 10 national supermarkets** characterized by a high market share were performed. Both steps (the online and physical searches) provided the authors an integrated and detailed approach about the use of health claims in the labeling of these functional products in Spain.

The **inclusion criteria** selected in this case-study were the following: functional products (concretely, functional foods and food supplements) with health claims included in the positive list of the European Regulation and commercialized in the Spanish market through both the online and traditional purchasing vias. The **exclusion criteria** considered (1) medicines, nutraceuticals and other products different from functional foods and food supplements, and (2) those functional products with health claims or any statement that state, suggest or imply any health benefit not included in the above-mentioned positive list.

A total of **725 health-related claims** were found in the labeling, presentation and/or advertising of functional foods and food supplements in the Spanish market. **The 89,7% (650 declarations out of 725)** were present in 153 functional foods and 44 food supplements; that is a total of 197 functional products. The great majority of these 197 products showed more than one health claim in its labeling, explaining the higher number of health-related claims in comparison with the number of products found in the Spanish market. These preliminary

results are in accordance with the CLYMBOL Project, which selected over 2000 food and drink products from five European countries (Germany, the Netherlands, Slovenia, Spain and United Kingdom) and concluded that most of the food products with health-related claims in its commercial presentation had more than one declaration (Hieke et al., 2016).

Almost half of the 650 health-related claims are referred to vitamins (317 declarations out of 650; that means a 48,8%), followed by minerals (221/650; 34%), lipids (67/650; 10,3%), other compounds or food products as chewing gum (25/650; 3,8%), fiber (11/650; 1,7%) and proteins (9/650; 1,4%). This finding can be explained as the great majority of the authorized health claims are predominantly related to vitamins and minerals.

Regarding the health-related claims focused on **vitamins**, vitamin D, vitamin B9 (folic acid) and vitamin C are the most often compounds found in the labeling of functional food products with a total of 79, 54 and 42 health-related claims respectively. With less frequency are used those referred to vitamin B6 (30/317), vitamin A (22/317), vitamin E (18/317) and vitamin B12 (19/317). Finally, the present Spanish study market showed that claims supporting the health effects provided by the rest of B-group vitamins (B1, B2, B3, B5, B7) are the most difficult declarations to be found in the labeling of functional food products. Only 15 health-related claims referred to vitamin B1, 13 to vitamin B2, 9 to vitamins B3 and B5, and 7 to vitamin B7 were found.

The next principal group of compounds in which health-related claims are focused on corresponds to the **minerals**. With 83 declarations, calcium is the mineral which appeared the most in the labeling of these products, followed by zinc (42/221), iron (25/221), magnesium (24/221) and selenium (13/221). Health-related claims regarding other minerals as iodine (7/221), phosphorus (6/221), sodium (5/221) as well as potassium and chromium (3/221 both) were less common to be found. Sodium claims inform consumers about the positive health benefits provided by the reduction of the consumption of sodium. Only functional foods with a low or reduced content of sodium are able to show this type of claims in its labeling.

After vitamins and minerals, **lipids** is the third group of compounds with the greatest number of health-related claims in the labeling of functional food products. Omega-3 fatty acids as alpha-linolenic acid (ALA), docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) were the principal representative compounds of the lipid group with 28 declarations. Other fatty acids as the monounsaturated and/or polyunsaturated ones as well as the linoleic acid (omega-6) were found in 17 and 6 health-related claims respectively. Finally, 16 declarations regarding the health benefits provided by the consumption of a low content of saturated fatty acids were included in the labeling of several functional foods.

According to Regulation (EC) No 178/2002, which lays down the general principles and requirements of food law, establishes EFSA and lays down procedures in matters of food safety, the chewing gum must be considered as a “food” as it meets the food requirements and it is included in the food definition. 25 health-related claims focused on this food category, specifically the **sugar-free chewing gum**, were found in the labeling of these products.

The last two groups of compounds with the fewest number of health-related claims in the labeling of functional food products corresponds to the **fiber** and **proteins**, with 11 and 9 declarations out of 648, respectively. In the case of the fiber, it was found that the 54,5% of the health-related claims are referred to the wheat bran fibre, followed by the beta-glucans from oats (36,4%) and chicory inulin (9,1%).

All the above-mentioned results suggest that a great number of the health claims approved in Europe appear not to be used in the labelling of functional products in the Spanish market.

For a better understanding, Table 5 summarizes all the functional food products including health-related claims found in the Spanish market. In order to make it easier, functional products were classified in groups according to the food classification and description system FoodEx 2 (EFSA, 2011d).

The other **10,3% (75 declarations out of 725) corresponded to reduction of disease risk claims**. These 75 reduction of disease risk claims were found in 38 functional foods and 37 food supplements (75 functional products in total), and are referred above all to vitamins and minerals as vitamin B9, vitamin D and calcium (49,4%); fats as stanols and/or sterols (37,3%) and fiber, specifically oat beta-glucans (13,3%). Table 6 summarizes all the functional food products with reduction of diseases risk claims found in the Spanish market. Functional products were also classified according to the food classification and description system FoodEx 2 (EFSA, 2011d).

4. Conclusions

The labeling of functional food products can display health-related claims, an important vehicle that informs consumers about diet-health relationships. As these claims appear to influence consumers food choices, specific regulation must control it. Although the European, American and Japanese claims are partly similar in nature, the approval and use procedures as well as the regulatory framework are quite different. The European approval process for claims could be considered more bureaucratic than the American one. On the one hand, the EU process counts with two different entities (EFSA and European Commission) for the scientific assessment of claims and for making final decisions about its approval and refusal. This working procedure follows the same structure than the one applied to all EU regulation. For instance, in the EU risk (and benefit) regulation, the risk assessment and risk management are separated as well. EFSA conducts the risk (or benefit) evaluation, whereas the European Commission is in charge of the risk management. In US, the FDA has all the decision power as it assesses health-related claims and makes the final decisions. On the other hand, all the European claims need to be subjected to the complete regulatory process, whereas in the US a great number of claims do not (notification is sufficient). Regarding the types of health-related claims, the American regulation only allows the authorization of nutrient deficiency claims. In US, there is not a defined category for “reduction of disease risk claims” as in Europe and Japan, where this type of claims is authorized and use in the labeling of specific functional food products. However, the American health claims category includes approved statements that in Europe and Japan could be confused with reduction of diseases risk claims. Furthermore, new health-related claims for which there is not yet solid scientific evidence (qualified health claims) can be used in US and Japan, whereas in Europe that claims are not permitted. All the EU claims must be based on strong scientific evidence, which means a harmonized assessment by the EFSA prior to their authorization. An international harmonization in some of these regulatory points could lead to an improved commercialization conditions in the global market and ensure a similar level of the health-related information provided to the consumers through the labeling of functional food products.

The labeling, health motivation and consumers attitudes towards functional food products could have an influence in consumers purchase decisions. Understable claims ensure a high level of consumers protection by allowing them to make better informed food choices. The consumers behavior towards functional food products depends on multiple factors and it differs between countries as the acceptance of those products in the American and Japanese societies is generally easier than in Europe. Further research is needed in order to completely understand the effect of health-related claims on the consumers behavior and attitudes towards functional food products with these claims.

The investment in the functional food products market has been increasing since the last years and seems to hold a promising future. Results from the market study carried out by the authors showed that most of the functional food products with health-related claims tent to include more than one declaration on its labeling, matching up with the CLYMBOL Project. The great majority of these health-related claims are

Table 5
Summary of the functional products with health related-claims found in the Spanish market. Functional products classified according to the food classification and description system FoodEx 2 (EFSA, 2011d)[a].

Food group	Food subgroup	FoodEx 2 Code	Nutrient with health-related claim	Number of products
Vitamins				
Biscuits (sweet and semi-sweet). Biscuits, sweet, plain	Biscuits, sweet, wheat wholemeal	A00AA	B_9	1
	Biscuits, oat meal	A00AB	B_9	1
Breakfast cereals	Oat based breakfast cereals	A00DG	B_1, B_2, B_3, B_5, B_6, D	11
Cocoa ingredients	Cocoa powder	A03HG	B_1, D	4
Fruit juices	Mixed fruit juice	A03AN	B_1, B_6, B_7, B_{12}, C	11
Functional drinks	Energy drinks	A03GA	B_5, B_6, B_{12}, C, E	8
Milk	Cow milk	A02LV	A, B_9, B_{12}, D, E	24
	Goat milk	A02MB	B_9	1
Milk-based drinks	NA	A06BJ	A, B_1, B_6, B_9, B_{12}, D, E	33
Milk imitates	Almond drink	A03TK	D, E	2
	Oats drink	A03TL	D, E	6
	Soya drink	A03TJ	A, D	4
Oilseeds	Linseed	A015G	D, E	2
	Sunflower seed oil, edible	A037D	E	1
Products for non-standard diets, food imitates and food supplements or fortifying agents. Food supplements or fortifying agents	Vitamin and mineral supplements	A03SK	A, B_1, B_2, B_3, B_5, B_6, B_7, B_9, B_{12}, C, D, E	200
	Miscellaneous supplements or fortifying agents. Bee-produced supplements or fortifying agents	A03SQ	C	1
Vegetable fats and oils, edible	Spreadable vegetable fat	A04PH	B_1, E	6
Yoghurt	Yoghurt drinks, sweetened and/or flavoured	A02NQ	B_9	1
Minerals				
Biscuits (sweet and semi-sweet).	Biscuits, sweet, plain. Butter biscuits	A009Y	Ca, Fe, K	5
	Biscuits, chocolate	A009Z	Ca, Fe	2
Breakfast cereals	Oat based breakfast cereals	A00DG	Ca, Mg	2
Cereal and cereal-like grains	Quinoa grain	A000R	P	1
Cocoa ingredients	Cocoa powder	A03HG	Fe, Zn	3
Fruit juices	Mixed fruit juice	A03AN	Mg, Se, Zn	3
Functional drinks	Energy drinks	A03GA	Zn	1
Milk	Cow milk	A02LV	Ca, P, K, Se	26
	Goat milk	A02MB	Ca	1
Milk imitates	Almond drink	A03TK	Ca, Na[a]	2
	Oats drink	A03TL	Ca, Na[a]	5
	Rice drink	A03TM	Na[a]	1
	Soya drink	A03TJ	Ca	3
Muesli and similar	Muesli mixed	A00EL	Na[a]	2
Oilseeds	Linseed	A015G	Fe, Mg, Zn	4
	Pumpkin seeds	A015X	Fe, Mg	2
Processed and mixed breakfast cereals	Processed oat-based flakes	A00DN	Ca	3
Products for non-standard diets, food imitates and food supplements or fortifying agents. Food supplements or fortifying agents	Vitamin and mineral supplements	A03SK	Ca, Cr, I, Fe, Mg, P, K, Se, Zn	152
Lipids				
Biscuits (sweet and semi-sweet). Biscuits, sweet, plain	Butter biscuits	A009Y	Saturated fatty acids[2]	1
	Biscuits, oat meal	A00AB	Monounsaturated and/ or polyunsaturated fatty acids	2
	Biscuits, sweet, wheat wholemeal	A00AA	Monounsaturated and/ or polyunsaturated fatty acids, saturated fatty acids[2]	4
Milk	Cow milk	A02LV	Saturated fatty acids[2]	1
Milk-based drinks	NA	A06BJ	DHA, EPA, monounsaturated and/ or polyunsaturated fatty acids, saturated fatty acids[2]	18
Milk imitates	Almond drink	A03TK	Monounsaturated and/ or polyunsaturated fatty acids	1
	Oats drink	A03TL	Monounsaturated and/ or polyunsaturated fatty acids, saturated fatty acids[2]	2
	Rice drink	A03TM	ALA, saturated fatty acids[2]	3
	Soya drink	A03TJ	Saturated fatty acids[2]	3
Miscellaneous dairy imitates	Soya yoghurt	A03TV	Saturated fatty acids[2]	1
Products for non-standard diets, food imitates and food supplements or fortifying agents. Food supplements or fortifying agents. Miscellaneous supplements or fortifying agents.	Other common supplements or fortifying agents. Supplements or fortifying agents containing special fatty acids	A03SX	ALA, DHA, EPA, linoleic acid, monounsaturated and/ or polyunsaturated fatty acids	13
Oilseeds	Linseed	A015G	ALA	3
	Pumpkin seeds	A015X	Monounsaturated and/ or polyunsaturated fatty acids	1
	Other minor oilseeds	A04MK	ALA	1
Other bread and bread products	Rusk, wholemeal	A006P	Saturated fatty acids[2]	1

(*continued on next page*)

Table 5 (*continued*)

Food group	Food subgroup	FoodEx 2 Code	Nutrient with health-related claim	Number of products
Vegetable fats and oils, edible	Spreadable vegetable fat	A04PH	ALA, linoleic acid	11
Fiber				
Biscuits (sweet and semi-sweet). Biscuits, sweet, plain	Biscuits, oat meal	A00AB	Beta-glucans from oats	1
	Biscuits, sweet, wheat wholemeal	A00AA	Wheat bran fibre	1
Breakfast cereals	Wheat based breakfast cereals	A00DZ	Wheat bran fibre	3
Cereal and cereal-like derivatives	Oat bran	A003B	Beta-glucans from oats	2
Milk-based drinks	NA	A06BJ	Chicory inulin	1
Milk imitates	Oats drink	A03TL	Beta-glucans from oats	1
Other bread and bread products	Rusk, wholemeal	A006P	Wheat bran fibre	1
Single grain bread and rolls	Wheat bread and rolls, brown or wholemeal	A005E	Wheat bran fibre	1

[a] Foods with a low or reduced content of sodium; [2] Foods with a low or reduced content of saturated fatty acids; NA = non applicable.

Table 6
Summary of the functional products with reduction of disease risk claims found in the Spanish market. Functional products classified according to the food classification and description system FoodEx 2 (EFSA, 2011d).

Food group	FoodEx 2 Code	Reduction of disease risk claim	Number of products
Biscuits (sweet and semi-sweet) - Biscuits, sweet, plain			
Biscuits, oat meal	A00AB	"Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"	5
Grains and grain-based products			
Bread and similar products	A004V	"Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"	1
Breakfast cereals			
Oat based breakfast cereals	A00DG	"Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"	1
Grains and grain-based products - cereal and cereal-like grains			
Oat grains	A000F	"Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"	2
Milk and dairy products - fermented milk or cream			
Yoghurt	A02NE	"Calcium helps to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures"	1
Vegetable fats and oils, edible			
Spreadable vegetable fat	A04PH	"Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"	28
Products for non-standard diets, food imitates and food supplements or fortifying agents - Food supplements or fortifying agents			
Miscellaneous supplements or fortifying agents	A03SP	"Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"	1
Vitamin and mineral supplements	A03SK	"Calcium helps to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures" "Calcium and vitamin D help to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures" "Supplemental folic acid intake increases maternal folate status. Low maternal folate status is a risk factor in the development of neural tube defects in the developing foetus" "Vitamin D helps to reduce the risk of falling associated with postural instability and muscle weakness. Falling is a risk factor for bone fractures among men and women 60 years of age and older"	36

related to compounds which are familiar to the consumers (vitamins and minerals). This comprehensive review could be used as an useful tool for helping to (1) consumers for making better-informed purchasing decisions about functional products, (2) food industry in marketing its products with a focus on international trade, and (3) scientists in order to put in value their daily research work.

Ethics Statement

None.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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