

Comparison of requirements for using health claims on foods in the European Union, the USA, Canada, and Australia/New Zealand

Anita Kušar¹  | Katja Žmitek^{1,2}  | Liisa Lähteenmäki³  | Monique M. Raats⁴ | Igor Pravst^{1,2,5} 

¹ Nutrition and Public Health Research Group, Nutrition Institute, Ljubljana, Slovenia

² VIST – Higher School of Applied Sciences, Ljubljana, Slovenia

³ MAPP Centre, Department of Management, Aarhus University, Aarhus V, Denmark

⁴ Food, Consumer Behaviour and Health Research Centre, University of Surrey, Guildford, Surrey, UK

⁵ Biotechnical Faculty, University of Ljubljana, Ljubljana, Slovenia

Correspondence

Igor Pravst, Nutrition Institute, Tržaška cesta 40, 1000 Ljubljana, Slovenia.
Email: igor.pravst@nutris.org

Funding information

Javna Agencija za Raziskovalno Dejavnost RS, Grant/Award Number: P3-0395; European Commission, Grant/Award Number: FP7-603036-REDICLAIM

Abstract

Nutrition is recognized as one of the leading factors influencing the growing incidence of noncommunicable diseases. Despite society experiencing a global rise in obesity, specific populations remain at risk of nutrient deficiencies. The food industry can use health claims to inform consumers about the health benefits of foods through labeling and the broader promotion of specific food products. As health claims are carefully regulated in many countries, their use is limited due to considerable investments required to fulfill the regulatory requirement. Although health claims represent a driving force for innovation in the food industry, the risk of misleading of consumers need to be avoided. The health claim scientific substantiation process must be efficient and transparent in order to meet the needs of companies in the global market, but should be based on strong scientific evidence and plausible mechanisms of actions, to ensure highest level of consumer protection. The objective of this review is to compare the possibilities for using health claims on foods in the European Union, the USA, Canada, and Australia and New Zealand. In particular, we focused on differences in the classification of claims, on the scientific substantiation processes and requirements for health claims use on foods in the selected regions. Reduction of disease risk (RDR) claims are associated with relatively similar procedures and conditions for use, whereas several notable differences were identified for other types of claims. In all cases, RDR claims must be approved prior their introduction to the market, and only a few such claims have been authorized. Much greater differences were observed concerning other types of claims.

KEYWORDS

food labeling, functional foods, health claims, regulation, substantiation

This is an open access article under the terms of the [Creative Commons Attribution](https://creativecommons.org/licenses/by/4.0/) License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.

© 2021 The Authors. *Comprehensive Reviews in Food Science and Food Safety* published by Wiley Periodicals LLC on behalf of Institute of Food Technologists

1 | INTRODUCTION

Nutrition is recognized as one of the leading factors influencing the growing incidence of noncommunicable diseases. The food industry uses health claims for both labeling and promoting foods that, when consumed, may have beneficial effects on health. Under certain conditions, such claims can play an important role in influencing the consumer's purchase and consumption decisions (Lahteenmaki, 2013; Miklavec, Pravst, Grunert, Klopčič, & Pohar, 2015; Nocella & Kennedy, 2012; Pothoulaki & Chrysoschoidis, 2009; Van Wezemael, Caputo, Nayga, Chrysoschoidis, & Verbeke, 2014; Wills, Storcksdieck genannt Bonsmann, Kolka, & Grunert, 2012). To ensure consumers are not given misleading information, many countries have regulated the use of health claims on foods (de Boer & Bast, 2015a). The use of such claims on food labeling is well documented in the European Union (EU) (Hieke et al., 2016; Kaur et al., 2016a; Kaur et al., 2016b; Lalor, Kennedy, Flynn, & Wall, 2010; López-Galán & De-Magistris, 2017; Pravst & Kušar, 2015; Storcksdieck genannt Bonsmann et al., 2010), Canada (Sacco, Sumanac, & Tarasuk, 2013; Schermel, Emrich, Arcand, Wong, & L'Abbe, 2013), the USA (Brecher, Bender, Wilkening, McCabe, & Anderson, 2000; Colby, Johnson, Scheett, & Hoverson, 2010), and Australia and New Zealand (Al-Ani, Devi, Eyles, Swinburn, & Vandevijvere, 2016; Devi et al., 2014; Hughes, Wellard, Lin, Suen, & Chapman, 2013; Ni Mhurchu et al., 2016; Walker, Woods, Rickard, & Wong, 2008; Wellard-Cole, Li, Tse, Watson, & Hughes, 2020; Williams et al., 2003, 2006).

Health claims on food products offer a direct communication channel between food producers and consumers at the point of purchase to inform about the health-related benefits a product can offer. Health claims appear in the front of package in an easy-to-process format unlike the nutrition content table at the back of package, which requires knowledge on functions of different nutrients. To understand and process messages such as health claims, consumers need motivation and ability (Petty & Cacioppo, 1986). Health claims offer information in a form where consumers mainly need to make an assessment whether that information is relevant to them or not, while previous knowledge is not required. However, the claim formulation has an impact on the effort required to process the claims: many studies suggest that consumers like short claims that can be processed quickly (Lynam, McKevitt, & Gibney, 2011; van Trijp & van der Lans, 2007), but at the same time, simple claims also evoke more inferences that surpass what is promised by the claim (Miklavec et al., 2015; Stancu, Grunert, & Lähteenmäki, 2017). Furthermore, consumers pay little attention to qualifiers that express the level of certainty of the evidence behind the

claim (Lahteenmaki, 2013). This brings two major challenges: how to formulate claims in a manner that consumers can understand and find appealing, while fulfilling the regulatory requirements that safeguard the credibility of scientific evidence behind the claims. Having externally governed substantiation processes give claims credibility on the market, but different substantiation processes and rules for formulating claims in different legislations have an impact how attractive the use of claims is to food manufacturers in different markets.

Product with health claims, e.g., functional foods, provides food industry with the opportunity for innovation. However, such innovations are reliant on considerable investment as a result of the need to substantiate the claim. Although the health claim substantiation process should be based on strong scientific evidence and plausible mechanisms of actions to ensure highest level of consumer protection, it should also be efficient and transparent. Added complexity is introduced due to regional differences regarding regulations which can impact the efficient planning of research and the development of activities for global markets. To better understand the nature and implications of these differences, the European Commission-funded REDICLAIM project (Raats et al., 2015) sought to compare the opportunities for using health claims on foods in selected developed countries/jurisdictions, with a particular focus on the: (a) categorization of different health claims and (b) scientific substantiation processes and requirements for using health claims on foods. This work therefore presents an update of previous reviews on this area. For example, in 2013, the Canadian system was compared with the situation in other countries (Malla, Hobbs, & Kofi Sogah, 2013) for the Canadian Agricultural Innovation and Regulation Network (CAIRN), whereas in 2012 Food Standards Australia New Zealand (FSANZ) published a review report on nutrition, health and related claims, which also contained international comparison of regulatory requirements for nutrition content and health claims (FSANZ, 2012). Some international comparisons were also published in the scientific literature (Baldwin & Poon, 2014; de Boer & Bast, 2015a; Greene, Prior, & Frier, 2001; Lalor & Wall, 2011; Shimizu, 2003, 2015).

2 | DATA AND METHODOLOGIES

Territories with established health claim legislation and with well-documented use of nutrition and health claims on foods were selected for inclusion, namely, the EU, the USA, Canada, and Australia/New Zealand.

Considering that the use of health claims is regulated, points of our departure were interviews with key informants from the selected countries (from either

government institutions or research organizations, excluding food industry), rather than scientific literature. This approach was used because scientific papers might reflect an earlier regulatory situation, and not necessarily the current status. A questionnaire for interviews with key informants is provided in Supporting Information. Desk research, however, also included literature and official government pages review to establish the (a) categorization of different claims and (b) scientific substantiation processes and requirements for using health claims on foods. Regional documents were located through an open search, including the Internet, and by targeting the websites of relevant organizations, such as the responsible regulatory bodies (authorities), thus identifying relevant legislation, and recommendations, and lists of, where applicable, authorized health claims. A further literature search was performed using Web of Science and Scopus to identify relevant peer-reviewed literature. Key informants were identified from both the scientific literature (coauthors of relevant peer-reviewed papers on this topic) or provided by the authorities in the selected jurisdictions. Based on the available data extracted from the literature, including regulations and official recommendations, a questionnaire was prepared for the key informants, the main purpose being to ensure a complete interpretation of the regulation and recommendations in the selected jurisdictions. Key informants provided responses through telephone interviews and/or e-mail responses.

3 | TYPES AND DEFINITIONS OF HEALTH CLAIMS

3.1 | Codex alimentarius food standards

In 1963, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations published the Codex Alimentarius, a global collection of food codes, standards, and guidelines for consumers, food producers/processors, national food control agencies, and the international food trade (FAO, 2006). Today, Codex member countries cover 99% of the world's population. The code has influenced the protection of public health and fair practices in the food trade, as well as the international food trade (FAO, 2020). Codex Alimentarius content was compiled by the Codex Alimentarius Commission (CAC) and has played an important advisory role in establishing and developing national regulations and standards (Aggett et al., 2012; Grossklauss, 2009). Codex codes also provide the benchmarks against which national food measures and regulations are evaluated within the legal parameters of the World Trade Organization (WTO) agreements (FAO, 2006). The initial Codex guidelines in the field

of nutrition came into effect in 1997, and revised as the guidelines for use of nutrition and health claims in 2004 (last amended in 2013) (CAC, 2013).

The Codex guidelines define a *health claim* as “any representation that states, suggests, or implies that a relationship exists between a food or food constituent and health,” and distinguish three different categories of such claims (Table 1):

Nutrient function claims describe “the physiological role of the nutrient in growth, development, and normal functions of the body.”

Other function claims describe “specific beneficial effects of consuming a food or food constituent, within the context of the overall diet, for the body's normal functions or biological activities.” Such claims refer to a product's beneficial effect on health through either modification or preservation of fitness or to an improvement in function.

Reduction of disease risk (RDR) claims refer to “the consumption of a food or food constituent, within the context of the overall diet, to the reduced risk of developing a disease or health-related condition.” “Risk reduction” means significantly lowering one or more major risk factor(s) for a certain disease or health-related condition. The guidelines are clear that diseases have several risk factors and altering one of them may or may not have a desirable effect. Accordingly, when using RDR claims, food producers must assure that consumers do not misinterpret them as prevention claims (with the appropriate wording and reference to other risk factors).

3.2 | The European Union

The appropriate use of nutrition and health claims in the EU was determined by Regulation (EC) 1924/2006 on nutrition and health claims (NHCR), which states that only predefined, nonmisleading, and approved nutrition claims are allowed for use. Moreover, all health claims need to be supported by sufficient scientific evidence (EC, 2006). The NHCR requires the authorization of all health claims by the European Commission (EC) through the Comitology procedure, following the scientific assessment and verification of a claim by the European Food Safety Authority (EFSA) (Pravst, 2010; Verhagen & van Loveren, 2016).

A guidance document on implementing the NHCR is available (EC, 2007). Nevertheless, its implementation has involved a steep learning curve for different stakeholders, including authorities and the industry, and several suggestions have been made to improve it (Cappuccio & Pravst, 2011; de Boer & Bast, 2015b; de Boer, Urlings, & Bast, 2016; Kaur et al., 2016a; Khedkar, Broring, &

TABLE 1 Comparison of how health claims are categorized in different jurisdictions

WHO/Codex	EU	USA	Canada	Australia and New Zealand
Nutrient content claims	Nutrition claims	Nutrient content claims		Nutrition content claims
Health claims	Trade marks, brand names, fancy names (Art. 1.3) Generic descriptors (denominations) (Art. 1.4) General nonspecific health claims: reference to general, nonspecific benefits of the nutrient/food for overall good health or health-related well-being (Art. 10.4) (for example “healthy,” which can be used if accompanied by a specific authorized claim)		General health claims (for example, the term “healthy” would be only possible where food meets the recommendations of Canada’s Food Guide)	
Nutrient function claims	Function claims (Art. 13) Claims referring to children’s development and health (Art. 14.1.b)	Structure/function claims	Nutrient function claims	General-level health claims
Other function claims			Function claims	
Reduction of disease risk claims	Reduction of disease risk claims (Art. 14.1.a)	Significant scientific agreement (SSA) health claims FDA modernization act (FDAMA) health claims Qualified health claims	Therapeutic and disease risk reduction claims	High-level health claims

Notes: WHO: World Health Organization; Codex: Codex Alimentarius Commission; EU: European Union; USA: United States of America.

Ciliberti, 2017; Kušar & Pravst, 2014; Lenssen, Bast, & de Boer, 2018; Martin, 2015; Pravst, 2011; Vero & Gasbarrini, 2012). It should be noted that the NHCR is still a subject of the EC's Regulatory Fitness and Performance program (REFIT) (EC, 2015a, 2017). REFIT is an ongoing program intended to keep European regulations fit for purpose, meaning that regulatory burdens are minimized and simplified. Considering this, various existing EU regulations are being evaluated in terms of their effectiveness, efficiency, coherence, relevance, and added value for the member states. Specifically, the NHCR has been evaluated regarding the need to establish nutrient profiles, and in terms of the use of health claims on plants (botanicals) because these two elements have not been implemented since the regulation was adopted in 2006 (EC, 2017). The evaluation report was published in May 2020 (EC, 2020b), indicating that currently the objectives of the NHCR are not fully attained and highlighting proposed future regulatory changes.

The NHCR defines a *health claim* as “any message or representation, which is not mandatory under EU or national legislation (including pictorial, graphic, or symbolic representation, in any form) which states, suggests, or implies that a relationship exists between a food category, a food or one of its constituents and health” (EC, 2006). In general, the NHCR distinguishes three types of specific health claims, which need to be supported by generally accepted scientific evidence and easily interpreted by an average consumer:

(a) “*health claims other than those referring to the reduction of disease risk and to children's development and health*” (also known as Art. 13 claims, hereinafter referred to as *function claims*); (b) “*claims referring to children's development and health*” (also known as Art. 14(1)b claims, hereinafter referred as *children's health claims*); and (c) “*reduction of disease risk (RDR) claims*” (also known as Art. 14(1)a claims). All authorized specific health claims are listed in the *EU Register of nutrition and health claims made on foods* (EC, 2020a), which includes health relationship, proposed wording and conditions of use, including possible limitations provided the population group. To achieve transparency and avoid repetitive applications for claims that have already been assessed, the EU Register also contains details of health claims applications that were not authorized. Although today all new health claims applications need to be submitted directly by the producer of the food or food constituent, the NHCR also provided a process for scientifically evaluating all function claims on the market before 2006, the year when this regulation was accepted.

The NHCR defines *function claims* as describing or referring to “(a) the role of a nutrient or other substance in

the growth, development, and functions of the body; (b) psychological and behavioral functions; or (c) slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to reduce the energy available from the diet.” As mentioned, all health claims on the market prior to 2006 were subject to scientific evaluation. Lists of claims currently in use were provided by EU member states with the help of industry, forming a consolidated list, which served as a base for the EFSA's evaluation. By 2009, it became clear that the procedure of evaluating all of the existing function claims was taking more time and efforts than initially expected (Pravst, 2010; Verhagen & van Loveren, 2016). Forty-four thousand claims supplied by the EU member states were included in a consolidated list, where similar claims were merged, forming a list of over 4,600 function claims which were submitted to the EFSA for their evaluation by the Panel on Nutrition, Novel Foods and Food Allergens (NDA). The majority of the claims were evaluated by 2011 using 341 published scientific opinions. Scientific opinion was provided for 2,758 general function health claims, with about 20% being approved (Pravst, 2012; Verhagen & van Loveren, 2016; Verhagen, Vos, Francl, Heinonen, & van Loveren, 2010). The EU Register currently includes 229 function claims authorized through this route. A majority of the approved function claims indeed originate from the described evaluation of claims, which were present on the market before 2006, but the EU Register also includes 12 function claims authorized on the basis of applications submitted by food companies (of which six for the protection of proprietary data were granted; status as in June 2017) (EC, 2020a).

It should be noted that whereas some applications for health claim (that were present on the market before 2006) authorization were withdrawn, 2,078 proposed claims for plant substances (botanicals) were halted by the EC awaiting further advice on how to process them (Kušar & Pravst, 2014). Botanicals often raise issues on the borderline of food medicine, and their safety and efficiency assessment can be very challenging (Lapenna et al., 2015). These were among major reasons why substantiation of health claims on plants was selected as a topic of above-mentioned REFIT evaluation (EC, 2017). With huge delay, the EC is still conducting an evaluation of this topic, and until new decisions on this are accepted, the “on-hold” health claims for botanicals are still tolerated in the market of many EU countries, even though not officially authorized for use. A very recent REFIT evaluation report highlighted (EC, 2020b) that currently “consumers continue to be exposed to unsubstantiated health claims from the on-hold list and may believe that the beneficial effects communicated with the on-hold claims have been scientifically assessed and risk managed, whilst this is not the case.” On the other

hand, manufacturers benefited in this situation, because they are still able to continue to use health claims for botanicals without the need for clinical investigation to support health claims dossiers. The report also notes inconsistency between medicinal and food regulations regarding the possibility of using “traditional use” data for substantiation of claims. Such data are currently not considered relevant for the substantiation of health claims on foods, while contrary is the case with traditional herbal medicinal products. The evaluation also showed issues related with different lists of approved/banned plant substances, introduced in different EU member states. The final conclusion of the report is that EU harmonization of the use of botanicals in foods (including safety aspects) would support smoother functioning of the internal market, and that “it could be appropriate to explore the notion of ‘traditional use’ in the efficacy, quality and safety assessment of health claims on plants used in foods” (EC, 2020b).

Children's health claims have no further definition in the NHCR. Twelve of such claims are currently authorized (EC, 2020a); however, several favorable EFSA NDA Panel Opinions were published in the last few years for various vitamins and minerals (EFSA NDA Panel, 2015a, 2015b, 2015c, 2015d, 2016a, 2016d, 2016e, 2017b) so it is likely this list will be expanded considerably in the future. According to the Codex standards, children's health claims would be either nutrient function or other function claims for children as a specific target group. The categorization of function claims (not mentioning children's development or health in the wording of a claim) on products intended specifically for children remains controversial. Although in some EU member states health claims are regarded as *children's health claims* only when children are specifically mentioned in claims' wording, some member states' interpretation of *children's health claims* also include function claims, if those are used on products intended specifically for children.

RDR claims are defined as “claims that state, suggest, or imply that the consumption of a food (constituent/category) significantly reduces a risk factor in the development of a human disease.” The wording of RDR claims should always refer to the specific risk factor of a disease, and not to the disease specifically. The labeling or advertising of such claims must carry a note indicating the disease to which the claim is referring has several risk factors and that lowering one of these risk factors may or may not have a beneficial effect. The EU Register currently contains 14 authorized RDR claims (EC, 2020a) (Table 2; Supporting Information Table S1).

The use of *nonspecific health claims* is also possible. The NHCR distinguishes different types of such claims:

- *a trade mark, brand name, or fancy name* (Art. 1.3), “which may be construed as a nutrition or health claim may be used without undergoing the authorization procedures if accompanied by a related nutrition or health claim which complies with the provisions of the NHCR”;
- *generic descriptors* (denominations; Art. 1.4) “which have traditionally been used to indicate a particularity of a class of foods or beverages, which could imply an effect on human health are exempted from the NHCR.” The regulation also provides two examples of such descriptors, namely, “digestive” and “cough drops.” Generic descriptors need to be approved on the EU level and the EC has established rules for such applications (EC, 2013b);
- *Reference to general, nonspecific benefits of the nutrient or food for overall good health or health-related well-being* (Art. 10.3; hereinafter referred to as *general nonspecific health claims*). In practice, such claims can be very attractive consumer-friendly statements (like “healthy,” “for good health,” etc.), yet they can easily be misinterpreted by consumers, possibly leading to them imagining better health benefits of a food than actually exist. For this reason, such claims may only be made if accompanied by relevant specific authorized health claims, which need to be positioned “next to” or “following” the general nonspecific health claim (EC, 2013a). If challenged, food businesses are responsible for demonstrating the link between the general nonspecific claim and the accompanying, authorized health claim.

Authorization of a health claim may be legally withheld if the health claim does not meet general or specific requirements of the NHCR, even if such claim is sufficiently substantiated (EU, 2012). Indeed, in the process of health claim authorization, some claims were not permitted due to public health reasons. For example, despite the well-established effect of sodium on the maintenance of normal muscle function, such a claim was not authorized. Use of such a claim would convey wrong message because it would encourage consumers to increase the intake of a micronutrient for which, on the basis of generally accepted scientific evidence for its negative health effects, public health authorities are trying to diminish its consumption. Therefore, a sodium claim would provide consumers with misleading information (EU, 2012). In some other cases, public health risks were addressed within the health claims' conditions of use (Cappuccio & Pravst, 2011; EU, 2012), whereas certain issues remained unresolved (Pravst, 2011; Ritz, Hahn, Ketteler, Kuhlmann, & Mann, 2012).

To limit the use of nutrition and health claims on foods with overall poor nutritional quality, the NHCR provided

TABLE 2 Comparison of authorized reduction of disease risk and related health claims in different jurisdictions

Food constituent [health relationship]	EU	USA	Canada	Australia and New Zealand
	Reduction of disease risk claims (Art. 14.1.a)(EC, 2017a)	Significant Scientific Agreement (SSA) health claims (US_FDA, 2017b) FDAMA claims (US_FDA, 2017a)	Reduction of disease risk (RDR) and therapeutic claims (HC, 2017b)	High-level health claims (FSANZ, 2017e)
CARDIOVASCULAR HEALTH				
Sodium (potassium) [blood pressure/CHD]	(√) (NOTE: function claim: maintenance of normal blood pressure)	√	√	√
Plant sterols/stanol esters [blood cholesterol/CHD]	√	√	√	√
Dietary fiber/specific fibers [blood cholesterol/CHD]	√ (barley/oat beta-glucans)	√ (soluble fiber)	√ (barley fiber/oat fiber/psyllium fiber/ground (whole) flaxseed) (PGX - Polysaccharide complex: glucomannan, xanthan gum, sodium alginate)	√ (beta-glucan)
Soy protein [blood cholesterol/CHD]	□	√ Note: claim under revision (US_FDA, 2016a)	√	□
Low saturated fat foods [blood cholesterol/CHD]	√ (replacing saturated fats with unsaturated fats)	√ (diets low in saturated fat and cholesterol, and as low as possible in trans fat); (replacing saturated fat with similar amounts of unsaturated fats)	√ (diet low in sat. and trans fats); (replacing sat. fats with polyunsat. and monounsat. fats)	√ (diet low in sat. fatty acids); (diet low in sat. and trans fatty acids)
EPA/DHA [triglyceride lowering]	(√) (NOTE: function claim)	□	√	□
Fruit and vegetables [CDH]	□	□	√	√

(Continues)

TABLE 2 (Continued)

Food constituent [health relationship]	EU	USA	Canada	Australia and New Zealand
CANCER				
Dietary fat, fruit, and vegetables [cancer]	□	√ (diet low in total fat); (low fat diets rich in: (a) fruits and vegetables; (b) fiber-containing grain products/fruits/vegetables)	√ (diet rich in a variety of vegetables and fruit)	□
GLYCEMIC RESPONSE				
Specific fibers [reduction of the blood glucose rise]	(√) (NOTE: function claim approved for a number of specific dietary fibers)	□	√ (PGX - Polysaccharide complex: glucomannan, xanthan gum, sodium alginate)	(□) (NOTE: nutrition content claims approved: high/low/medium glycemic index)
BONE AND TEETH HEALTH				
Calcium/vitamin D [bone mineral density/osteoporosis]	√	√	√	√
Dietary carbohydrate sweeteners, sugar-free products (chewing gum, hard candy or breath-freshening product, ...) [tooth health]	√	√	√ (chewing gum/hard candy/breath-freshening product); (sugar-free chewing gum)	□
Fluoridated water/fluoride [tooth health: dental caries/tooth decay]	(√) (NOTE: function claim: maintenance of tooth mineralization)	√	□	□
OTHER CLAIMS				
Folic acid [neural tube defects]	√	√	□	√
Vitamin D [risk of falling]	√	□	□	□

Notes: WHO: World Health Organization; Codex: Codex Alimentarius Commission; EU: European Union; USA: United States of America; EC: European Commission; FDA: the U.S. Food and Drug Administration; FSANZ: Food Standards Australia New Zealand; CHD: coronary heart disease. See also Supporting Information Table S1 for details of the wording of health claims.

Sources: (EC, 2020a; FSANZ, 2013b; HC, 2020b; US FDA, 2020a, 2020b).

for the establishing of nutrient profiles, including exemptions that food or certain categories of food must comply with in order to carry the claims (EC, 2006). The scientific criteria for establishing nutrient profiles were prepared by the EFSA in 2008 (EFSA NDA Panel, 2008), although this segment of the legislation has yet to take effect (Cappuccio & Pravst, 2011) and was subject to the above-mentioned REFIT evaluation. The REFIT evaluation report highlights that implementation of nutrient profiles is in line with the wider EU policy to improve nutrition and public health, and to prevent diet-related NCDs, and that with growing use of front-of-pack nutrition labeling schemes and existing food reformulation initiatives, the concept of nutrient profiles could now be more acceptable than ten years ago (EC, 2020b), when the implementation was stopped due to lack of the support of the EU member states and the industry. The report therefore indicates an ambition of the EC to continue with the implementation of nutrient profiles, even though the time delay gave an impression that nutrient profiles will be eventually removed from the NHCR. Until a final decision is made on this topic, there are no general nutritional criteria for foods labeled with health claims. However, certain criteria are included in the conditions for use of some health claims.

3.3 | The United States

A key legalization milestone in regulating food labeling in the USA was the Nutrition Labeling and Education Act of 1990 (NLEA) (US, 1990), which gave the U.S. Food and Drug Administration (FDA) the authority to require that claims on foods be consistent with FDA regulations; legislation is codified in the Federal Food, Drug, and Cosmetic Act (US, 2010). In the regulation (US, 2014b), a *health claim* is defined as “any claim made on the label or in the labelling of a food, including a dietary supplement, that expressly or by implication, including *third party* references, written statements (e.g., a brand name including a term such as *heart*), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition.” Implied health claims include those “statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition” (US, 2014b). Such a claim may appear on a food label only if there is a specific regulation, where the wording and conditions of use of such claims are defined, and if food is below disqualifying levels of cholesterol, sodium, fat, and unsaturated fat for nutrient content claims (US, 2014a). It should be noted

that the advertising of foods is addressed by different legislation and falls under the authority of the US Federal Trade Commission, and not the FDA.

We can distinguish three types of health claims:

- (a) **Significant scientific agreement (SSA) health claims** where the nutrient/disease relationship is scientifically well established and has passed the FDA’s extensive review of scientific literature as provided in the NLEA (US FDA, 2020b). It should be emphasized that the health claim regarding soy protein in relation to coronary heart disease, which was authorized in 1999, was subject to additional FDA review, concluding lack of scientific agreement. Proposal rule to revoke this claim was announced by the FDA in 2017 (US FDA, 2017), but the final decision has not yet been implemented (Petersen, 2019). Additionally, in response to an application submitted by the American Heart Association, the conditions for use of health claim regarding dietary saturated fat and cholesterol and risk of coronary heart disease were changed in December 2016 (US FDA, 2016a), thereby expanding use of this health claim to certain fruits and vegetables previously ineligible for the health claim (due to their failure to comply with the “low fat” definition and/or the minimum content of specific nutrients).
- (b) **FDA Modernization Act (FDAMA) claims** were introduced after revision of the legislation by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (US, 1997) and opened up an expedited route for the authorization of health claims on the basis of authoritative statements from a scientific body of the government, or the National Academy of Sciences. Five FDAMA health claims have been authorized (US FDA, 2020a), which, however, can be used only on conventional foods and not on food supplements.
- (c) **Qualified health claims (QHCs)** were introduced after the U.S. Court of Appeals’ decision in *Pearson vs. Shalala* (DC Circuit, 1999) questioned the agency’s restrictive requirements regarding use of health claims on some food supplements on First Amendment freedom of speech grounds. QHCs are claims where there is some credible scientific evidence for a food constituent/disease relationship, but the strength of the evidence falls below the SSA standard. After the announcement of the Consumer Health Information for Better Nutrition initiative in 2003, such claims are also possible on conventional foods (US FDA, 2003a). QHCs are different than SSA health claims because they have to be accompanied by a disclaimer or qualified in some other way. The wording of QHCs is therefore tailored to address the level and quality of the

science that the FDA found in support of the claim (US FDA, 2020c). Typically, the wording of such claims also contains a disclaimer, for example that “the FDA has concluded that there is very little scientific evidence for this claim.” The usefulness of such claims for the food business and consumers has thus been questioned (Hasler, 2008).

On the other hand, *structure and function claims* are not covered by the above-mentioned definition of a health claim (US FDA, 2020d). In the USA, structure and function claims have historically appeared on the labels of both conventional foods and food supplements and were defined in the Dietary Supplement Health and Education Act of 1994 (DSHEA) (US, 1994). The legislation distinguishes: (a) *structure and function claims*, and two related types of claims, (b) *claims of general well-being*; and (c) *claims related to a nutrient deficiency disease*. Structure and function claims describe the role of a food constituent in body structures and functions, whereas general well-being claims describe general well-being arising from the consumption of a nutrient or other food constituents. Nutrient deficiency disease claims describe a benefit related to a nutrient deficiency disease, but such claims are allowed only if they also say how widespread such a disease is in the USA (US FDA, 2020d). Contrary to the above-defined health claims, no preapproval is needed for using structure and function claims. It should be noted that some reports suggest the current laws and enforcement actions are inadequate for preventing the growing use unverifiable and misleading structure and function claims (Hoffmann & Schwartz, 2016), indicating the need for better regulation of this area.

Interestingly, the claim “*healthy*,” which would be considered a health claim in the EU, is considered an implied *nutrient content claim* in the USA. Such a claim can be used on foods with particular composition requirements (limited fat content, saturated fat, sodium, cholesterol, and being a source of protein, fiber, vitamin C, vitamin A, calcium, or iron). It should be noted that expressed nutrient content claims are only permitted for nutrients with an established Daily Reference Value or a Reference Daily Intake.

3.4 | Canada

Health claims on foods have been regulated in Canada since 2002 when *Food and Drugs Regulations* (FDR) were amended and permitted the first five reduction of disease risk claims (CA, 2009). However, in line with the *Food and Drug Act* (CA, 1985, 2016), foods labeled with RDR claims were regulated as drugs until a revision of the classifica-

tion issues between foods and drugs in 2010 (HC, 2010). It should also be noted that, in Canada, food supplements are considered *natural health products* and regulated under a different regulatory framework (CA, 2008). *Natural health products* include “vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics, and other products like amino acids and essential fatty acids that are sold over the counter without a prescription” (HC, 2020c). Before the classification issues between foods and drugs were clarified in 2010, the natural health products pathway was also occasionally used for marketing foods labeled with health claims.

Although there is no formal definition of health claims in the Canadian regulations (L’Abbe, Dumais, Chao, & Junkins, 2008), such a definition is provided by Health Canada (HC, 2020a) and in the guidance document repository on food labeling for industry prepared by the Canadian Food Inspection Agency (CFIA) (CFIA, 2020c). In this guidance document, a *health claim* is defined as “any representation in labelling or advertising that states, suggests, or implies that a relationship exists between the consumption of a food and health.”

In Canada, preapproval is needed for *disease risk reduction claims* (hereinafter referred to as *RDR claims*) and for *therapeutic claims*. According to the guidance (CFIA, 2020c), *RDR claims* are “statements that link a food or food constituent to a reduced risk of developing a diet-related disease or condition in the context of the overall diet (for example, reducing the risk of cardiovascular disease), while *therapeutic claims* refer to the treatment or mitigation of a disease or health-related condition, or about restoring, correcting, or modifying body functions (lowering blood cholesterol, for example).” In addition to RDR claims provided in the FDR, food businesses can also use claims with a favorable assessment by Health Canada. A list of such acceptable RDR and therapeutic claims is available (HC, 2020b) that also includes a summary of the scientific assessment and conditions for foods to carry these claims. For some RDR claims, various variations of wordings are provided. Approved wordings cannot be further modified by a food company. RDR and therapeutic claims are not allowed on foods intended solely for children of less than two years of age, such as infant cereal and pureed fruits and vegetables, and on foods represented for use in very low energy diets (CA, 2009). There are no common core nutritional criteria for food carrying health claims, except those provided in the conditions for use of each particular claim.

The CFIA Guidance also defines *general health claims* and *function claims* (CFIA, 2020c), but the use of claims that do not bring the food within the definition of a drug does not require premarket approval or regulatory

amendment. However, such claims should be nonmisleading and manufacturers are expected to have in-house evidence substantiating the health claim when this issue is questioned by enforcement authorities.

General health claims are “broad claims that promote health through healthy eating or provide dietary guidance, without referring to a specific or general health effect, disease, or health condition” (CFIA, 2020b). These claims are not specifically regulated and can be used on foods when the message of the claim is in accordance with the dietary recommendations published in Canada’s Food Guide. For example, guidelines specify that the use of the word “healthy” on foods that cannot be classified as healthy according to the recommendations of Canada’s Food Guide could be deceiving.

Function claims are defined as “claims referring to the specific beneficial effects the consumption of a food or food constituent has on the body’s normal functions or biological activities” (CFIA, 2020c). A function claim should be addressing the treatment, mitigation, or prevention of any disease, disorder, or abnormal physical state, or of their symptoms directly or indirectly. Moreover, claims about restoring or correcting malfunctions of the body or modifying health beyond normal physiological effects of foods are considered drug claims, not function claims. A subset of function claims are nutrient function claims, which describe well-established roles of energy or nutrients that are essential for maintaining optimal health or for normal growth and development (CA, 2009; CFIA, 2020d). The nutrient in these claims must have an established recommended dietary allowance, adequate intake or acceptable macronutrient distribution range by the Institute of Medicine (IOM) of the U.S. National Academies. Probiotic claims which refer to (healthy) gut flora are also considered as function claims; the guidance provides eligible bacterial species and acceptable nonstrain specific probiotic claims, together with specific conditions for their use, including minimum content levels. No premarket approval is needed for function claims, although lists with examples of acceptable nutrient function (CFIA, 2020d), probiotic (CFIA, 2020e), and other function claims (CFIA, 2020a) are available.

3.5 | Australia and New Zealand

Pursuant to the FSANZ Act of 1991, Australia and New Zealand share a joint regulatory system for food composition and labeling. The system is defined by the Australia New Zealand Food Standards Code that was developed by FSANZ. Requirements for nutrition, health, and related claims are defined in Standard 1.2.7, which was

first gazetted in 2013 (FSANZ, 2013b) with a three-year transitional period. Since January 2016, food businesses need to comply with the new standard (FSANZ, 2015b), which was last revised in 2017 (FSANZ, 2017c). The standard covers the use of nutrition and health claims in both food labeling and associated advertising. The process of developing the standard started in 2003 with several delays (FSANZ, 2013c). Prior to this, health claims were regulated by Transitional Standard 1.1A.2 (FSANZ, 2013a), which was more restrictive (Tapsell, 2008) and prohibited all health claims related to disease prevention, with the exception of a health claim related to maternal folate consumption and a reduced risk of fetal neural tube defects. It should be noted that in the last few years, the Australia New Zealand Food Standards Code has been considerably revised (FSANZ, 2017a). The new code also includes schedules with a nutrient profiling scoring method (FSANZ, 2017b) and the elements required for a systematic review (FSANZ, 2015a). These standards do not directly target food supplements (only conventional foods). Although in New Zealand food supplements are regulated by a special standard (MPI, 2016) that incorporates a reference to Standard 1.2.7, in Australia supplements are generally not classified as food but as complementary medicine, and regulated by the Therapeutic Goods Administration (TGA, 2013) with a very different regulatory framework and different evidence required to support claims and indications. However, formulated meal replacements and formulated supplementary foods are regulated with Standard 2.9.3. (FSANZ, 2017d).

According to Standard 1.2.7, a *health claim* “states, suggests, or implies that a food or a property of food has, or may have, a health effect. Such effects include: (a) a biochemical process or outcome; (b) a physiological process or outcome; (c) a functional process or outcome; (d) growth and development; (e) physical performance; (f) mental performance; (g) a disease, disorder, or condition; or a combination of such effects.” The standard distinguishes two types of health claims: *high-level health claims* (HLHC), which refer to a serious disease or a biomarker of a serious disease, and require preapproval by FSANZ, whereas *general-level health claims* (GLHC) are all other health claims and mostly refer to body structure and functions. These can be either preapproved or self-substantiated by the specific company using the claim, but the rigor of the self-substantiation process has been questioned (Wellard-Cole, Watson, Hughes, & Chapman, 2019). The exact wording of claims is not predefined, but it must state both the food or food constituent and the specific health effect. Preapproved relationships for HLHC are listed in schedule 4 to Standard 1.2.7 (FSANZ, 2017a), together with their associated conditions. In the case of

specific target groups, the wording should include a statement about that population group in conjunction with the health claim. Considering the nature of a specific food or food constituent, food labels also need to include an appropriate statement that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods.

A health claim cannot be made about kava, foods containing more than 1.15% alcohol, and infant formula products. To make a health claim, foods must meet the nutrient profiling scoring criterion as described in schedule 5 to Standard 1.2.7 (FSANZ, 2017b). Easy-to-follow guidelines for food operators on how to comply with nutrition- and health-claims-related standards are also available (ISFR, 2018).

4 | THE HEALTH CLAIM AUTHORIZATION PROCESS AND SCIENTIFIC SUBSTANTIATION REQUIREMENTS

4.1 | Codex Alimentarius food standards

In accordance with the CAC guidelines for the use of nutrition and health claims (CAC, 2013), health claims must be substantiated with the latest relevant scientific knowledge, whereas the evidence must be sufficient to support the type of claimed effect and the relationship to health as recognized by a generally accepted scientific review of the data. The scientific substantiation should be reassessed when new evidence becomes available. It is also advised that every health claim is accepted by or be allowed by the competent authorities of the country where the product can be purchased. Health claims should also have a clear regulatory framework with qualifying and/or disqualifying conditions for eligibility for its use, including the possibility of the responsible national authorities to ban claims made for foods that contain nutrients or other constituents in amounts that increase the risk of certain diseases or trigger an adverse health-related condition.

4.2 | The European Union

The process of scientifically assessing health claims in the EU was particularly influenced by the results of the PASS-CLAIM project where a consensus on the criteria was first established (Aggett, 2009; Aggett et al., 2005). Implementing rules for applications for health claim authorization were provided soon after the NHCR was accepted (EC, 2008) and are revised from time to time. The guidance was

last revised in 2017 (EFSA NDA Panel, 2017a), with many more details regarding how to present the results of unpublished studies.

To authorize a new health claim, an application needs to be submitted to an EU country's competent authority that checks its admissibility before transmitting it to the EFSA (EFSA NDA Panel, 2017a). The EFSA then informs the EC and the competent authorities in all EU member states of the receipt of the application and publishes details of the submission in the EFSA's Register of Questions database (EFSA, 2020b). The EFSA's scientific evaluation is performed by the Panel on Nutrition, Novel Foods and Food Allergens (NDA Panel), composed of 16 people appointed as independent scientific experts on the basis of their specific skills and knowledge. Following the completeness check, the evaluation procedure takes about 5 months, with the possibility of a stop-the-clock procedure if further information is requested from the applicant. All NDA Panel opinions are published in the *EFSA Journal*—an open-access publication (also see scheme of the health claims application procedure; EFSA, 2020a). Applicants have the possibility to withdraw their application until an opinion is finalized. On the basis of the opinion, the EC prepares a draft decision and submits it to the Standing Committee on Plants, Animals, Food, and Feed. If the committee decides favorably, the European Parliament and the Council may still overpower the proposed decision. In case there is no objection, the EC confirms the decision. The whole evaluation and authorization process do not incur fees and takes at least 10 months. In the drafting phase of the decision, the EC harmonizes the wording and conditions of use of the health claim with all member states, which can considerably affect the authorization timeline (Pravst, 2012).

In the process of scientific evaluation of a health claim, food safety assessment is not included, although the EFSA's opinions sometimes include comments related to food safety. If a food or food constituent is not authorized for sale on the EU market, its safety needs to be assessed in a separate process for authorization of a novel food (ingredient) (EC, 2015b). In 2016, the EFSA has published a second revision of its general guidance for stakeholders on the evaluation of all types of health claims (EFSA NDA Panel, 2016b). There is also a series of specific guidance documents on the scientific requirements related to appetite ratings, weight management, and blood glucose concentrations (EFSA NDA Panel, 2012a), bone, joints, skin, and oral health (EFSA NDA Panel, 2012b), functions of the nervous system, including psychological functions (EFSA NDA Panel, 2012c), the immune system, the gastrointestinal tract and defense against pathogenic microorganisms (EFSA NDA Panel, 2016c), muscle function and physical performance (EFSA NDA Panel, 2018b), and antioxidants,

oxidative damage, and cardiovascular health (EFSA NDA Panel, 2018a). Key questions addressed by the NDA Panel when starting the scientific evaluation of a new health claim are whether: (a) the food or food constituent is sufficiently defined and characterized; (b) the claimed effect is sufficiently defined and if it is a beneficial nutritional or physiological effect; and (c) pertinent human studies have been presented to substantiate the claim. If this is the case, the NDA Panel weighs up the evidence of all pertinent studies (EFSA NDA Panel, 2016b).

In theory, health claims can be approved for either a food category, food, or food constituents, but most of the authorized claims refer to food constituents—particularly to nutrients, and in some cases also to other substances. The NHCR defines these as substances other than nutrients that have a nutritional or physiological effect. Although the regulation does not provide different evaluation standards for different constituents, it should be mentioned that for the nutrients there is a well-established consensus among scientists on many of their physiological functions. The evaluation of health claims for nutrients may rely on such a consensus and, in such cases, the review of the primary scientific studies on the claimed effect of the food may not be needed (EFSA NDA Panel, 2016b). A number of function claims for vitamins and minerals were approved in this way.

A health claim application should cover only one relation between the food or food constituent and a single claimed effect (EC, 2008). The wording of RDR claims should always refer to the specific risk factor for the disease, and not to the disease alone. The proposed wording of all specific health claims must reflect the scientific evidence and be easily understandable to an average consumer. Although applicants do not need to provide any evidence of such understanding, it should be noted that the EC has funded a collaborative research project *Role of health-related CLaims and SYMBOLs in consumer behavior* (CLYMBOL, www.clymbol.eu) with the aim to determine consumers' understanding of health-related symbols and claims in the context of the entire product, and their influence on purchase and consumption decisions, taking into account both individual differences in needs, wants, motivation, and attitude, and country-specific differences (Hieke et al., 2015). Further, experiences from past health claim authorizations show that the applicants' proposed claim wording can be notably modified during the authorization process.

Proprietary data should be indicated and verifiable justification for this should be included in a separate part of the application. The application should also contain details of the international regulatory status of the proposed health claim, the proposed conditions of use, full characterization of the subject food (consistent), including details of manu-

facturing, stability, and bioavailability data (where applicable), and all available pertinent scientific data (EFSA NDA Panel, 2016b).

In the characterization section, analytical methods must be provided, together with the physical and chemical properties and the composition of the subject food or food constituent. If composition variations are possible, batch-to-batch variability should be addressed together with stability taking into account storage conditions during shelf life. If applicable, bioavailability of a food constituent must be shown, together with a rationale on how the constituent in question reaches target sites. A claim can also be written for a specific combination of constituents, in which case the combination must be exhaustively characterized, particularly in relation to the active constituents. For claims related to microorganisms, genotyping at the strain level with internationally recognized molecular methods is necessary, as well as naming the strain according to the International Code of Nomenclature. Deposition of samples in an internationally recognized culture collection for control purposes is advisable. For plant products, the scientific name of the plant should be specified, along with the part of the plant used and details of the preparation employed, including details of the manufacturing process (extraction, drying, etc.) (EFSA NDA Panel, 2016b).

The application section containing the scientific data should include all pertinent studies in both tabulated form and with written summaries and conclusions. The studies provided should primarily consist of human efficacy studies. Studies need be presented according to a hierarchy of study designs, reflecting the relative strength of the evidence stemming from different types of studies (EC, 2008). Although it is the applicant's responsibility to provide the totality of the available data, an assessment may also encompass data not included in the application if considered pertinent to the claim (EFSA NDA Panel, 2016b). It is advised that studies be performed using subjects which are representative of the target population group. For example, claims referring to children's development and health are ideally substantiated in children. If studies substantiating the claim were not performed on a population targeted by the claim, evidence for possible extrapolation of findings is needed. It is important to note that patients are usually considered an inappropriate study group, although the suitability of the evidence is decided on a case-by-case basis. As an example, subjects with underlying hypertension were found to be a pertinent study population for the substantiation of a claim on maintaining normal blood pressure in the general population. Similarly, studies using irritable bowel syndrome patients are considered appropriate for the substantiation of claims on bowel function and gastrointestinal discomfort (EFSA NDA Panel, 2016b).

The application should also contain a review of available human data, addressing the relationship between the food or food constituent and the claimed effect in a comprehensive, systematic, and transparent manner. Taking into account the totality of the data (including evidence in favor as well as not in favor) and careful weighing of all available evidence, the final opinion should distinctly determine the extent to which (a) the claimed effect of the food or food constituent influences human health; (b) a causality is established between the food or food constituent and the observed effect in humans (in terms of potency, consistency, specificity, dose-response, and biological validity of the relationship); (c) the quantity of the food or food constituent and pattern of consumption required to obtain the claimed effect could reasonably be consumed as part of a balanced diet; and (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended. A key aspect of a health claim application is the quality of the evidence on cause–effect relationships between consumption of the food or food constituent and the claimed health effect. Applicants therefore need to ensure that their studies are conducted appropriately (Martínez & Siani, 2017; Navas-Carretero & Martínez, 2015). In fact, many health claims applications were declined in practice due to a lack of scientific evidence (Verhagen & van Loveren, 2016). A critical appraisal tool was provided by the EFSA in 2015 to allow structured and consistent guidance on assessing the methodological quality of various types of studies, including systematic reviews of intervention studies, and human randomized controlled trials (EFSA, 2015). These recommendations focus on the risk of bias/appropriateness of the design and conduct of the studies.

In the EU, applicants for new health claims have a unique opportunity to request the protection of data. If a health claim is supported with (an unpublished) proprietary data and if it cannot be substantiated without such proprietary data, the applicant can request five years of protection for such data (EC, 2006). This gives food businesses an advantage in use of the authorized claim before competitors can apply it. If a competitor wants to use such a claim, it would need to submit a new application with its own substantiation documentation, in which it cannot use the data for which the proprietary data protection was granted. The idea was to protect and stimulate investments in innovations in the food sector, yet it should be noted that proprietary claims are related with considerable investments, and some researchers express doubts as to whether the existing regulation of health claims actually contributes to innovativeness in the sector (Bröring, Khedkar, & Ciliberti, 2017; Khedkar, Ciliberti, & Bröring, 2016).

Data protection has only been granted for a few function health claims (Table 3) (EC, 2020c). Although applicants commonly request data protection, the EFSA has in many cases considered that the outcome of the opinion would be the same without the data for which the protection is requested, and therefore protection is not granted.

Although the health claim assessment procedure in the EU was notably improved since 2006, there is still room for improvements to support functional food innovation, for example, with providing scientific advice to applicants during the development of the dossiers (Lenssen et al., 2018). It should also be noted that recommendations for successful substantiation of new health claims in the EU were developed within the REDICLAIM project (Pravst et al., 2018).

4.3 | The United States

Structure and function claims do not need preapproval, but the food operator using such claims must have substantiation that the claim is truthful and not misleading. Although structure and function claims on food supplements may focus on nonnutritive as well as nutritive effects, on conventional foods such claims should focus on effects derived from the nutritive value (US FDA, 2020d). When used on food supplements, “structure and function claims must be equipped with a disclaimer that the FDA has not evaluated the claim and that the product is not intended to diagnose, treat, cure, or prevent any disease.” Such a disclaimer is not needed for conventional foods (US FDA, 2020d).

On the other hand, claims falling under the U.S. definition of a health claim need to be preapproved. The authorization process for SSA health claims was defined with the NLEA; health claim applications are subject to the extensive review of the FDA, which evaluates whether the food constituent/disease relationship is well established and supported by the entirety of the available scientific evidence (SSA standard) (US FDA, 2020b). The NLEA mandated the FDA to review existing constituent/disease relationships and SSA was determined for 8 out of 10 of such relationships (Table 2; Supporting Information Table S1). The NLEA also enabled the submission of applications for new health claims by petitioners, for example, by food business or trade associations; however, only a few of such SSA claims were approved through this route (US FDA, 2020b). These claims almost exclusively target coronary heart disease, except for a claim for dietary noncariogenic carbohydrate sweeteners, which refers to dental caries. The regulation provides 540 days (after the application date) as the definitive time limit for publication of the

TABLE 3 Authorized health claims in the European Union for which the protection of proprietary data has been granted (status as at April 17, 2020)

Food (constituent)	Authorized health claim	Simplified conditions of use	Benefiter
Slowly digestible starch	Consumption of products high in slowly digestible starch (SDS) raises blood glucose concentration less after a meal compared with products low in SDS	Digestible carbohydrates need to provide at least 60% of the total energy and at least 55% of those carbohydrates need to be digestible starch, of which at least 40% SDS.	Mondelez International group (until September 23, 2018)
Reformulated, nonalcoholic, acidic drink	Replacing sugar-containing, acidic drinks, such as soft drinks (typically 8–12 g sugars/100 ml), with reformulated drinks contributes to the maintenance of tooth mineralization	Reformulated acidic drinks shall comply with: less than 1 g fermentable carbohydrate per 100 ml; calcium 0.3–8 mol per mol acidulant; pH 3.7–4.0.	Lucozade Ribena Suntory Limited and its affiliates (until September 23, 2018)
Water-Soluble Tomato Concentrate (WSTC) I and II	Water-Soluble Tomato Concentrate (WSTC) I and II helps maintain normal platelet aggregation, which contributes to healthy blood flow	Information to the consumer that the beneficial effect is obtained with a daily consumption of 3 g WSTC I or 150 mg WSTC II in (a) up to 250 ml of either fruit juices, flavored drinks or yogurt drinks, or (b) daily recommended dosage of a food supplement.	Provexis Natural Products Limited (until December 18, 2014)
Cocoa flavanols	Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 200 mg of cocoa flavanols. The claim can be used only on the following products that provide at least a daily intake of 200 mg of cocoa flavanols with a degree of polymerization 1–10: cocoa beverages, dark chocolate, capsules, or tablets.	Barry Callebaut Belgium (until September 23, 2018—for cocoa beverages and dark chocolate; until April 20, 2020—for capsules or tablets)
Native chicory inulin	Chicory inulin contributes to normal bowel function by increasing stool frequency	Information shall be provided to the consumer that the beneficial effect is obtained with a daily intake of 12 g chicory inulin. The claim can be used only for food which provides at least a daily intake of 12 g of native chicory inulin, a nonfractionated mixture of monosaccharides (<10%), disaccharides, inulin-type fructans and inulin extracted from chicory, with a mean degree of polymerization > or = 9.	BENEO-Orafti S.A Belgium (until January 1, 2021)

Source: (EC, 2020c).

final rule on rejection or authorization of an SSA health claim.

Health claims supported by some scientific evidence but where the science supporting the claim does not meet the SSA standard can be approved as QHC provided the claim about the relationship is stated or “qualified” in such a

way as to not mislead consumers (US FDA, 2020c). Unlike SSA health claims which are authorized by a final rule, QHC claims are approved with a letter of enforcement discretion which is issued within 270 days of submission of the application, although this deadline can be extended by mutual agreement of the applicant and the FDA. A letter

of enforcement discretion is sent by the FDA to the applicant, specifying the details of the Qualified Health Claim for which the FDA intends to consider the exercise of its enforcement discretion. If such letter has been issued, the FDA will not object the use of the claim specified in the letter given that products carrying the claim are in line with the stated criteria.

Specific requirements for the authorization of new health claims and guidelines for the dossier are provided in the U.S. Code of Federal Regulations (US, 2014c) and in special guidance documents (US FDA, 2009, 2013). The safety of using a food or food constituent subject to a health claim authorization needs to be determined before the health claim application is submitted (e.g., the food constituent should be either generally recognized as safe, approved as a food additive, or authorized by a preceding sanction issued by the agency). Health claim dossiers should consist of a detailed examination of the potential effects the proposed claim may have on food consumption; in particular any changes resulting from significant alterations in eating habits and corresponding changes in nutrient intakes stemming from such food consumption changes (specifically addressing the effect on the intake of nutrients that have beneficial and negative consequences within the overall diet). Analytical methods for measuring the content of the food constituent in final products need to be provided as references to AOAC international methods; where this is not possible, the assay method and data establishing the validity of the method for assaying food constituent should be provided. The application should contain one or more model health claims to characterize the relationship between the food or food constituent to a disease or health-related condition that is justified by the scientific data provided.

In the application for authorization of a health claim, the applicant may request the application be reviewed under the interim procedures for either an SSA health claim or QHC.

The regulation makes it clear that a submission must include all information pertinent to evaluation of the proposed health claim, both favorable and unfavorable. The summary of scientific data should provide the basis upon which authorizing a health claim can be justified as providing the health benefit. In the case of SSA health claims, the conclusions must state that based on the entire publicly accessible scientific evidence (including evidence from well-designed studies conducted consistently with generally recognized scientific methods and principles), there is a clear scientific agreement that the claim is sufficiently backed by scientific evidence. On the contrary, QHCs are still based on the totality of publicly available evidence but the scientific support does not have to be as strong as that for SSA claims. In past authorizations, the FDA

provided four levels of scientific evidence using interim guidance (US FDA, 2003b). The highest rank of scientific evidence is where the substance/disease relationship met the SSA standard (resulting in SSA health claims). Three lower levels of scientific evidence resulted in qualified health claims, whereas the fourth level (representing an extremely low level of evidence strength) did not enable QHCs. It should be noted that the last version of guidance for the industry (US FDA, 2009) mostly focuses on grading human studies and assessment of their methodological quality, and on the evaluation of the totality of the scientific evidence. It is much less specific regarding the levels and wordings, yet it is noted that QHCs must reflect the level of scientific evidence with specificity and accuracy (US FDA, 2009).

Any reference to published information must be accompanied by reprints, and details of unpublished studies need to be provided. All data and information provided in the application are available for public disclosure. The authorization procedure incurs no specific fees for applicants. Advance notice of proposed rulemaking is used to ensure a consideration of an applicant's comments on the agency's decisions (US FDA, 2013). The evaluation of a health claim application is performed by the FDA's Nutrition Science review staff.

The acceptance of the FDAMA in 1997 provided a more expeditious route for new health claims based on authoritative statements from a scientific body of the government, or the National Academy of Sciences. For such applications, the FDA has a 120-day deadline to notify the applicant whether the proposed claim meets the regulatory requirements. However, only five of such health claims have been authorized via this route (US FDA, 2020a).

Health claims authorized in the USA are not brand-specific and can be used on any product meeting the conditions of use as defined in the regulation. Authorized health claims may be reevaluated in response to an applicant or on the FDA's own initiative, for example, when new information becomes available which would change an existing SSA or qualified health claim. Such a revision could result in a revision of the claim wording, a change in an SSA claim to a QHC (or contrary), or raise safety concerns about the food constituent that is the subject of a health claim (US FDA, 2009).

Labeling regulations for conventional foods and dietary supplements were revised in 2013 (US FDA, 2013). A revision of the nutrition and supplement facts labels was published in 2016 (US FDA, 2016b), providing updated nutrition information on the label (changing the list of nutrients required or permitted to be declared; updating Daily Reference Values and Reference Daily Intake values; amending requirements for foods intended for children under the age of four years and pregnant and lactating women; and

establishing nutrient reference values for these population subgroups). However, the new rules do not affect the authorization of new health claims.

4.4 | Canada

As in the USA, *function claims* in Canada do not need preapproval but food companies must obtain enough sufficient scientific evidence supporting the claim before they start using it on food labels or in advertisements. Food companies are encouraged to contact the Food Directorate of Health Canada for advice on the acceptability of any claim not included in the online list of acceptable function claims (CFIA, 2020c). Claims reviewed and found to be acceptable are added to the list. As explained below, Health Canada has also published criteria used when considering the acceptability of different types of new function claims.

For new *nutrient function claims*, the function should reflect an agreement within broader scientific community, which needs to be published by an authoritative scientific body such as IOM or EFSA within last 15 years. When seeking the advice of Health Canada, a food company should provide the name of the authoritative organization with the exact phrasing of the scientific evidence supporting the claim, a copy of the original document in which the evidence was published, an analysis of the review process used by the organization to come to the conclusive evidence statement, and an indication that there are no conflicting authoritative statements available. For other *function claims*, there should be acceptable standards of evidence supporting the claim, for example: the evidence must be directly translatable to the target population of the claim; the amount of the food or food constituent required to achieve the claimed physiological effect must be based on the evidence supporting the claim; the target population must be able to consume the amount of food or food constituent required to achieve the effect as part of a healthy, balanced diet. The claim should clearly state a specific physiological effect, and must not give the impression that the food is “healthier” than, or “nutritionally superior” to, other similar foods not bearing the claims. The CFIA list of acceptable function claims currently only includes claims for coarse wheat bran and psyllium seed (in relation to laxation and regularity), and green tea unfermented leaves and/or bud from *Camellia sinensis* (in relation to an antioxidant effect on blood lipids) (CFIA, 2020a).

Contrary to function claims, all new *RDR claims* must be preapproved by Health Canada. Claims can be authorized for foods, food constituents (nutrients, other bioactive ingredients), or food categories, yet all currently authorized RDR claims refer to a food constituent, whereas the

conditions of use can limit the use of a claim to certain foods or food categories. To ensure that health claims are substantiated in a systematic, comprehensive, and transparent manner, Health Canada published a guidance document for preparing a submission for food health claims (HC, 2009) and a specific guidance for submissions based on an existing systematic review (HC, 2011). Guidance documents also suggest a format for compiling and recording the submission information. Submissions are evaluated by the Nutrition Evaluation Division, Bureau of Nutritional Sciences, Health Canada. According to the guidance documents, applicants should expect a response to a submission within approximately 6–9 months of receipt of a fully documented submission. The evaluation process is without fees. If the food or food constituent is considered a novel food, a separate novel food application must be completed and submitted to Health Canada preceding or concurrent with the health claim application (HC, 2009).

The application dossier needs to provide complete documentation for substantiation of the health claim, including the characterization of the food or food constituent, the proposed wording of the claim and regulatory status in other jurisdictions, proposed criteria for foods to carry the health claim, the target population, characterization of a health effect and its evaluation. The guidelines (HC, 2009) explain the following steps for evaluating a claim's validity: “(1) describe the search strategy for literature retrieval; (2) implement the search strategy for literature retrieval; (3) develop inclusion and exclusion criteria to filter the literature retrieved; (4) filter the literature; (5) generate reference lists of included and excluded studies; (6) tabulate studies; (7) evaluate the study quality; (8) tabulate study findings per health outcome; (9) assess causality (rate consistency and the strength of the association, and discuss the relationship between the food exposure and the health effect); (10) discuss generalizability of the data to the target population; (11) discuss the physiological meaningfulness of the effect of the food exposure; (12) discuss the feasibility of consuming an effective amount of the food; and (13) make conclusions.”

The guidelines provide detailed guidance on the inclusion and exclusion criteria for literature review. Inclusion criteria include full-length study reports of original research in humans, human intervention studies, prospective observational studies (cohort and nested case-control studies), systematic reviews and meta-analyses of original research in humans, and authoritative statements by a credible scientific bodies (IOM, WHO, etc.). Exclusion criteria include abstracts and short communications, abbreviated unpublished study reports, animal and *in vitro* studies, retrospective studies (retrospective cohort, case-control, cross-sectional, ecological, time-series, or demographic studies), studies without or with inappropriate

controls, with a nonrepresentative study population, inappropriate measuring techniques or design, or not including statistical assessment. A scoring system is provided to assess the quality of pertinent studies, and also for rating the consistency in terms of the effect based on all available studies. In the final step, the conclusion should justify a health claim for a food or food constituent based on all the available evidence. The body of evidence must consistently back up the causality between the food or food constituent consumption and a disease risk reduction.

In the application, all confidential or proprietary data should be clearly identified. However, if a claim is approved it can be used by all food companies in a position to meet the provided conditions of use. Submissions to Health Canada are not publicly communicated until the publication of a final decision. Only three assessments for unacceptable RDR/therapeutic claims have been published and they were all assessed as part of Health Canada's commitment to review health claims approved in the USA: (1) whole grains and coronary heart disease; (2) dietary fat and cancer; and (3) dietary fiber and cancer (HC, 2020a). However, for applications started by the food business negative assessments are not published in practice: when during the evaluation process Health Canada requests more (additional) substantiation data than the applicant can provide, the process is stopped before the final decision. This means there are no details available on such nonauthorized health claim applications or the reasons for not authorizing those claims. It should also be noted that Health Canada only published a summary of the assessment, without full details. A step toward greater transparency in the authorizing of new claims was a decision by Health Canada for a public consultation on the proposal to approve a new health claim about soy products being cholesterol lowering (Benkhedda et al., 2014). Although some comments were received (from 13 interested parties including academics, consultants, scientific services representatives, industry representatives and industry associations—mostly in support of the proposal), such a consultation approach did not result in new claims that were authorized in 2016.

Health Canada may reassess an already approved health claim due to newly available scientific evidence, which may impact the validity of the claim or the conditions of its use on request of the applicant or on its own (HC, 2009). Further, the Food Labeling Modernization (FLM) initiative started in Canada in 2013 with the overall objective to develop recommendations that lead to a more modern and innovative food labeling system. Overview of the proposed regulatory changes for the FLM initiative (until year 2026) was published recently (CFIA, 2020f), but there is no indications of future changes in regulating health claims on foods.

4.5 | Australia and New Zealand

GLHCs can be either self-substantiated by a food company or preapproved. In the case of self-substantiation, a food company needs to conduct a systematic review according to the requirements outlined in Schedule 6 of Standard 1.2.7 (FSANZ, 2015a), providing evidence of a cause-and-effect relationship between the food or food constituent and the health effect, and notify FSANZ about the self-substantiated food–health relationship (FSANZ, 2020d). The agency has published a guidance document on establishing food–health relationships for general-level health claims (FSANZ, 2020b). It should be mentioned that notified claims are placed on the website without a checking process and that the rigor of the self-substantiation process has been questioned (Wellard-Cole et al., 2019). The standard also includes 183 food–health relationships that were previously authorized in the EU, whereas additional 32 EU-approved claims were subject of evaluation by FSANZ (FSANZ, 2016). Until now, the FSANZ has completed work on 29 of the 32 EU-authorized health claims, but none of those was included to the standard (FSANZ, 2017e). Typical reasons for this were that FSANZ considered a claim about the relationship is (a) similar to another general-level health claim (i.e., for claim “Meal replacement for weight control”), (b) the construct of the claim does not fit explicitly within the current health claims framework (i.e., for claim “Sugar-free chewing gum helps reduce tooth demineralisation”), (c) claim is therapeutic (i.e., for claim “Potassium contributes to the maintenance of normal blood pressure”), and (d) not possible to establish the relationship (to a high degree of certainty) based on the evidence obtained from high quality studies (FSANZ, 2017e). It should be noted that some EU-approved health claims (carbohydrate electrolyte solutions and maintenance of endurance performance during prolonged endurance exercise; carbohydrate electrolyte solutions and the absorption of water during physical exercise; resistant starch and postprandial blood glucose rise) were not yet evaluated.

Self-substantiated GLHCs are included on a publicly available list of notified food–health relationships (FSANZ, 2020c) maintained by FSANZ, but the substantiation documentation is not published. Notified relationships are not subject to an FSANZ review, and there is therefore no assurance that the listed relationships are sufficiently substantiated. To date, there are 177 such health relationships in the register, covering a variety of food constituents, including probiotics and various types of fiber (FSANZ, 2020c). The authorities may require the food industry to provide a systematic review to assess whether the claim meets the requirements and whether the relationship proposed comes from a reasonable conclusion of

the evidence presented in the systematic review. Because self-substantiated GLHC can only be used by businesses, which have completed the notification procedure, such claims enable the in-house protection of proprietary data, although there is no firm guarantee the relationship provided in the review will be accepted by the authorities if challenged. Food businesses also have an option to start a preapproval process of GLHC, as described below.

Preapproval by the FSANZ is required for all HLHC and can also be voluntarily used for GLHCs. An applicant needs to prepare a dossier containing the application in line with the requirements explained in the standards (FSANZ, 2015a, 2017a) and Application handbook (FSANZ, 2019). The authorization process does not specifically address the safety of the food or food constituent; if not already permitted, another application (for example, a novel food or novel food ingredient application) must be submitted simultaneously with the application for the health claim and both applications are processed at the same time.

A systematic review is a key element of the application and should address standards provided in schedule 6 of the code (FSANZ, 2015a). A review should include a description of the food or food constituent and the proposed health relationship; a description of the search strategy (including the inclusion and exclusion criteria); a final list of studies based on the inclusion and exclusion criteria and a summary with key information for each such study (reference, study design, and objectives; sample size in the study groups, the participant characteristics; measurement methods; confounders; and the study results, including effect size, statistical significance, and adverse effects if applicable), and assessment of their quality. The review should also include a conclusion on whether a causal relationship has been established between the food or food constituent and the health effect based on the totality and weight of the evidence; and the amount of the subject food or food constituent required to achieve such a health effect. The standard clearly mentions that human studies are essential for the scientific substantiation of health claims and that a food–health relationship cannot be established by animal and *in vitro* studies alone (FSANZ, 2015a).

In the evaluation process, FSANZ considers the evidence and whether there is a causal relationship between the food or food constituent and the health effect. All requests are subject to an opinion of a scientific committee, namely, the FSANZ HLHC Committee (FSANZ, 2015c). There is no exclusivity for the relationships listed in the Food Standards Code. However, health claim applications can be processed without public consultation if requested by the applicant, giving the food company a first-to-market benefit. In such a procedure, there is no public disclosure of the started procedure until the gazettal publication

of the final decision. The deadline for FSANZ to approve the draft food regulatory measure is 9–12 months from commencement of the assessment, with the possibility of extending the deadline according to the stop-the-clock procedure (current procedures are listed in the FSANZ Work Plan: FSANZ, 2020a). The fees for the FSANZ assessment procedure (high-level health claim variation) start from USD 57,382 (for up to 240 hours), but can also exceed USD 125,000 if more than 680 hours is required (FSANZ, 2019).

5 | CONCLUSIONS

Health claim substantiation process should be based on strong scientific evidence and plausible mechanisms of actions to ensure highest level of consumer protection, while also ensuring transparency for applicants and international comparability. The comparison of how health claims are categorized in the selected jurisdictions has shown there are comparable procedures and conditions for use of RDR claims, whereas considerable differences were identified for the other types of claims. In all selected jurisdictions, RDR claims require approval before they can be used on the market. There is an option for the food industry to apply for the authorization of new RDR claims; procedures are uniformly established. Applicants are responsible for preparing the application dossiers. The processes of evaluating the submitted applications and authorizing new health claims are mostly free of charge, except in Australia/New Zealand. A general description of the strength of scientific evidence required for the approval of such health claims is “generally accepted scientific evidence of beneficial physiological effect in humans” in the EU, “significant scientific agreement” in the USA and Canada, and an “established food–health relationship based on the totality and weight of evidence” in Australia/New Zealand. Only a few RDR claims have been authorized, and are mostly comparable between different jurisdictions. However, notable differences are observed in the wordings and conditions of use for such claims. While in the EU RDR claims can only communicate the reduction of disease risk factor, the reduction of disease can be directly communicated in the USA, Canada, and Australia and New Zealand. All jurisdictions enable the use of confidential information for the scientific substantiation of health claims, but regulatory protection of the proprietary data is possible only in the EU. In the USA, Canada, and Australia and New Zealand, authorized health claims can be used by all food companies that meet predefined conditions of use. In the EU, applicants have an opportunity to request five years of protection of their proprietary data if such data are essential to substantiate the relationship between the

consumption of the food or food constituent and the claimed health effect. This gives food businesses an important advantage of using the authorized claim before their competitors, although only a few of such claims have been authorized. On the contrary, the process of authorizing a new health claim is fully public in the USA, while in Canada and Australia and New Zealand, the evaluation can be confidential, giving the applicant a first-to-market advantage. The USA is also the only jurisdiction that enables the authorization of RDR claims where the strength of the scientific evidence falls below generally accepted standards. The wording of such QHCs is tailored to address the level and quality of the science involved.

Particularly notable differences can be observed for *nutrient function claims* and *other function claims*. Although in the EU, new function claims need to be preapproved and substantiated with scientific evidence using standards comparable to RDR claims, in the USA, Canada, and Australia and New Zealand such claims can be self-substantiated by food companies. This enables food businesses to make a variety of different claims without disclosing internal documentation. However, a voluntarily precheck of such claims is possible in Canada and Australia/New Zealand; in both jurisdictions, lists of such claims are publicly available. In addition, food businesses need to provide substantiation documentation to authorities if the validity of a claim is being questioned.

Overall qualifying compositional criteria for labeling foods with health claims are defined in the USA (but only for RDR claims) and in Australia/New Zealand. In the EU, the legislation that provided nutrient profiling restrictions was not implemented and is currently under evaluation.

ACKNOWLEDGMENTS

The authors would like to thank all those included in the interviews, and all members of the REDICLAIM consortium, particularly C. Hodgkins, R. N. Malcolm, H. Gage, and A. Cleary (University of Surrey, UK), N. Zupanič, Ž. Lavriša, and K. Miklavec (Nutrition Institute, Ljubljana, Slovenia), V. Kulikovskaja (Aarhus University, Denmark), and M. Klopčič (University of Ljubljana, Slovenia). This work was supported by the EU's Seventh Framework Program for research, technological development and demonstration (contract number FP7-603036) and by the Slovenian Research Agency (P3-0395). The authors would also like to acknowledge that I.P. has led/participated in various other research projects in the area of nutrition/public health/food technology, which were (co)funded by the Slovenian Research Agency, the Ministry of Health of the Republic of Slovenia, the Ministry of Agriculture, Forestry and Food of the Republic of Slovenia, and in case of specific applied research projects also by food businesses; M. Raats' research center has provided consultancy to and received

travel funds to present research results from organizations supported by food and drinks companies. The MAPP Centre (L.L.) has worked on public projects that may have been co-funded by private sources.

AUTHOR CONTRIBUTIONS

A.K., K.Ž., and I.P. were responsible for conception, A.K. for planning, I.P. for execution, I.P. wrote first draft and A.K., K.Ž., L.L. M.M.R. participated in writing final manuscript.

CONFLICTS OF INTEREST

There are no conflicts of interest to declare. The funding organizations had no role in the design, analysis, or writing of this paper. The content of the article only reflects the views of the authors; the European Commission is not liable for any use that may be made of the information contained in this article.

ORCID

Anita Kušar  <https://orcid.org/0000-0001-9168-9728>

Katja Žmitek  <https://orcid.org/0000-0002-0032-318X>

Liisa Lähteenmäki  <https://orcid.org/0000-0002-8104-6275>

Igor Pravst  <https://orcid.org/0000-0001-8634-1778>

REFERENCES

- Aggett, P., Hathcock, J., Jukes, D., Richardson, D., Calder, P., Bischoff-Ferrari, H., Prock, P. (2012). Nutrition issues in Codex: Health claims, nutrient reference values and WTO agreements: A conference report. *European Journal of Nutrition*, 51(1), 1–7. <https://doi.org/10.1007/s00394-012-0306-8>
- Aggett, P. J. (2009). The process for the assessment of scientific support for claims on food. *European Journal of Nutrition*, 48, S23–S26. <https://doi.org/10.1007/s00394-009-0072-4>
- Aggett, P. J., Antoine, J. M., Asp, N. G., Bellisle, F., Contor, L., Cummings, J. H., Verhagen, H. (2005). PASSCLAIM – Consensus on criteria. *European Journal of Nutrition*, 44, 5–30.
- Al-Ani, H. H., Devi, A., Eyles, H., Swinburn, B., & Vandevijvere, S. (2016). Nutrition and health claims on healthy and less-healthy packaged food products in New Zealand. *British Journal of Nutrition*, 116(6), 1087–1094. <https://doi.org/10.1017/S0007114516002981>
- Baldwin, N., & Poon, T. (2014). General comparison of health claims with regards to food and supplement legislation frameworks in Europe, the United States, and Canada. *International News on Fats, Oils and Related Materials*, 25(6), 394–396. Retrieved from <http://www.scopus.com/inward/record.url?eid=2-s2.0-84903214921&partnerID=40&md5=b81a44e1a69233463bf80651ea7bb1c1>
- Benkhedda, K., Boudrault, C., Sinclair, S. E., Marles, R. J., Xiao, C. W., & Underhill, L. (2014). Health Canada's proposal to accept a health claim about soy products and cholesterol lowering. *International Food Risk Analysis Journal*, 4(22), 1–12. <https://doi.org/10.5772/59675>

- Brecher, S. J., Bender, M. M., Wilkening, V. L., McCabe, N. M., & Anderson, E. M. (2000). Status of nutrition labeling, health claims, and nutrient content claims for processed foods: 1997 Food Label and Package Survey. *Journal of the American Dietetic Association*, 100(9), 1057–1062. [https://doi.org/10.1016/s0002-8223\(00\)00308-4](https://doi.org/10.1016/s0002-8223(00)00308-4)
- Bröring, S., Khedkar, S., & Ciliberti, S. (2017). Reviewing the Nutrition and Health Claims Regulation (EC) No. 1924/2006: What do we know about its challenges and potential impact on innovation? *International Journal of Food Sciences and Nutrition*, 68(1), 1–9. <https://doi.org/10.1080/09637486.2016.1212816>
- CA. (1985). Food and Drugs Act. Retrieved from <http://www.wipo.int/edocs/lexdocs/laws/en/ca/ca015en.pdf>.
- CA. (2008). Natural Health Products Regulations. SOR/2003-196. Retrieved from <http://laws-lois.justice.gc.ca/PDF/SOR-2003-196.pdf>.
- CA. (2009). Food and Drug Regulations. Consolidated Regulations of Canada, c. 870. Retrieved from http://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf.
- CA. (2016). Food and Drugs Act. Revised Statutes of Canada, c. F-27. Retrieved from <http://laws.justice.gc.ca/PDF/F-27.pdf>.
- CAC. (2013). Guidelines for use of nutrition and health claims [CAC/GL 23–1997, rev. 2013]. Retrieved from http://www.codexalimentarius.org/download/standards/351/CXG_023e.pdf.
- Cappuccio, F. P., & Pravst, I. (2011). Health claims on foods: Promoting healthy food choices or high salt intake? *British Journal of Nutrition*, 106, 1770–1771. <https://doi.org/10.1017/S0007114511002856>
- CFIA. (2020a). Food labelling for industry: Function claims. Retrieved from <https://www.inspection.gc.ca/food-label-requirements/labelling/industry/health-claims-on-food-labels/eng/1392834838383/1392834887794?chap=8#s13c8>.
- CFIA. (2020b). Food Labelling for Industry: General health claims. Retrieved from <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/health-claims/eng/1392834838383/1392834887794?chap=11>.
- CFIA. (2020c). Food labelling for industry: Health claims. Retrieved from <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/health-claims/eng/1392834838383/1392834887794>.
- CFIA. (2020d). Food labelling for industry: Nutrient function claims. Retrieved from <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/health-claims/eng/1392834838383/1392834887794?chap=8>.
- CFIA. (2020e). Food labelling for industry: Probiotic claims. Retrieved from <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/health-claims/eng/1392834838383/1392834887794?chap=9>.
- CFIA. (2020f). Overview of the proposed regulatory changes for the food labelling modernization initiative. Retrieved from <https://www.inspection.gc.ca/consultations-and-engagement/proposed-regulatory-changes/eng/1560907775533/1560907775762>.
- Colby, S. E., Johnson, L., Scheett, A., & Hoverson, B. (2010). Nutrition marketing on food labels. *Journal of nutrition education and behavior*, 42(2), 92–98. <https://doi.org/10.1016/j.jneb.2008.11.002>
- DC Circuit. (1999). *Pearson vs. Shalala*, 164 F.3d 650. Retrieved from <https://casetext.com/case/pearson-v-shalala>.
- de Boer, A., & Bast, A. (2015a). International legislation on nutrition and health claims. *Food Policy*, 55, 61–70. <https://doi.org/10.1016/j.foodpol.2015.06.002>
- de Boer, A., & Bast, A. (2015b). Stakeholders' perception of the nutrition and health claim regulation. *International Journal of Food Sciences and Nutrition*, 66(3), 321–328. <https://doi.org/10.3109/09637486.2014.986071>
- de Boer, A., Urlings, M. J. E., & Bast, A. (2016). Active ingredients leading in health claims on functional foods. *Journal of Functional Foods*, 20, 587–593. <https://doi.org/10.1016/j.jff.2015.11.025>
- Devi, A., Eyles, H., Rayner, M., Ni Mhurchu, C., Swinburn, B., Lonsdale-Cooper, E., & Vandevijvere, S. (2014). Nutritional quality, labelling and promotion of breakfast cereals on the New Zealand market. *Appetite*, 81, 253–260. <https://doi.org/10.1016/j.appet.2014.06.019>
- EC. (2006). Regulation (EC) No 1924/2006 of the European Parliament and of the council on nutrition and health claims made on foods. Retrieved from <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1924-20141213>.
- EC. (2007). Guidance on the implementation of Regulation No 1924/2006 on nutrition and health claims made on foods: Conclusions of the Standing committee on the food chain and animal health. Retrieved from https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf.
- EC. (2008). Commission Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. Retrieved from <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R0353:20091221:EN:PDF>.
- EC. (2013a). Commission implementing decision 2013/63/EU adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006. Retrieved from <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D0063&from=EN>.
- EC. (2013b). Commission Regulation (EU) No 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations). Retrieved from <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0907&from=EN>.
- EC. (2015a). Commission decision of 19.5.2020 establishing the REFIT Platform Retrieved from https://ec.europa.eu/info/sites/info/files/commission-decision-establishing-refit-platform_may2015_en_1.pdf.
- EC. (2015b). Regulation (EU) 2015/2283 of the European Parliament and the Council of 25 November 2015 on novel foods. Retrieved from <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283>.
- EC. (2017). REFIT – Evaluation of the regulation on nutrition and health claims. Retrieved from https://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en.
- EC. (2020a). EU Register of nutrition and health claims made on foods. Retrieved from <http://ec.europa.eu/nuhclaims/>.
- EC. (2020b). European Commission Executive summary of the evaluation of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods. Retrieved from https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-claims_swd_2020-96_sum_en.pdf.
- EC. (2020c). Health claims for which protection of proprietary data is granted. Retrieved from http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=getListOfPropClaims.

- EFSA. (2015). Tools for critically appraising different study designs, systematic review and literature searches. *EFSA Supporting Publications*, 12(7), 836E. <https://doi.org/10.2903/sp.efsa.2015.EN-836>
- EFSA. (2020a). EFSA applications helpdesk: Health claims application procedure. Retrieved from <http://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflownutrihealthclaims.pdf>.
- EFSA. (2020b). EFSA register of questions database. Retrieved from <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL>.
- EFSA NDA Panel. (2008). The setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the regulation (EC) No 1924/2006. *The EFSA Journal*, 644, 1–44. <https://doi.org/10.2903/j.efsa.2008.644>
- EFSA NDA Panel. (2012a). Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations. *EFSA Journal*, 10(3), 2604. <https://doi.org/10.2903/j.efsa.2012.2604>
- EFSA NDA Panel. (2012b). Guidance on the scientific requirements for health claims related to bone, joints, skin, and oral health. *EFSA Journal*, 10(5), 2702. <https://doi.org/10.2903/j.efsa.2012.2702>
- EFSA NDA Panel. (2012c). Guidance on the scientific requirements for health claims related to functions of the nervous system, including psychological functions. *EFSA Journal*, 10(7), 2816. <https://doi.org/10.2903/j.efsa.2012.2816>
- EFSA NDA Panel. (2015a). Biotin and contribution to normal energy-yielding metabolism: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, 13(7), 4181. <https://doi.org/10.2903/j.efsa.2015.4181>
- EFSA NDA Panel. (2015b). Niacin and contribution to normal energy-yielding metabolism: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, 13(7), 4180. <https://doi.org/10.2903/j.efsa.2015.4180>
- EFSA NDA Panel. (2015c). Vitamin C and contribution to the normal function of the immune system: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, 13(11), 4298. <https://doi.org/10.2903/j.efsa.2015.4298>
- EFSA NDA Panel. (2015d). Vitamin D and contribution to the normal function of the immune system: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, 13(7), 4182. <https://doi.org/10.2903/j.efsa.2015.4182>
- EFSA NDA Panel. (2016a). Calcium and contribution to the normal development of bones: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, 14(10), 4587. <https://doi.org/10.2903/j.efsa.2016.4587>
- EFSA NDA Panel. (2016b). General scientific guidance for stakeholders on health claim applications *EFSA Journal*, 14(1), 4367. <https://doi.org/10.2903/j.efsa.2016.4367>
- EFSA NDA Panel. (2016c). Guidance on the scientific requirements for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms. *EFSA Journal*, 14(1), 4369. <https://doi.org/10.2903/j.efsa.2016.4369>
- EFSA NDA Panel. (2016d). Iron and contribution to the normal function of the immune system: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, 14(7), 4548. <https://doi.org/10.2903/j.efsa.2016.4548>
- EFSA NDA Panel. (2016e). Vitamin E and protection of DNA, proteins and lipids from oxidative damage: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, 14(10), 4588. <https://doi.org/10.2903/j.efsa.2016.4588>
- EFSA NDA Panel. (2017a). Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 2). *EFSA Journal*, 15(1), e04680. <https://doi.org/10.2903/j.efsa.2017.4680>
- EFSA NDA Panel. (2017b). Vitamin C and protection of DNA, proteins and lipids from oxidative damage: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, 15(1), 4685. <https://doi.org/10.2903/j.efsa.2017.4685>
- EFSA NDA Panel. (2018a). Guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health. *EFSA Journal*, 16(1), e05136. <https://doi.org/10.2903/j.efsa.2018.5136>
- EFSA NDA Panel. (2018b). Guidance on the scientific requirements for health claims related to muscle function and physical performance. *EFSA Journal*, 16(10), e05434. <https://doi.org/10.2903/j.efsa.2018.5434>
- EU. (2012). Commission Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. Retrieved from <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0432-20170822&qid=1598860651032>.
- FAO. (2006). *Understanding the Codex Alimentarius*. Rome: WHO/FAO.
- FAO. (2020). Codex Alimentarius: About codex. Retrieved from <http://www.fao.org/fao-who-codexalimentarius/about-codex/en/>.
- FSANZ. (2012). FSANZ review report P293: Nutrition, health and related claims. Retrieved from <https://www.foodstandards.gov.au/code/proposals/pages/proposalp293nutritionhealthandrelatedclaims/p293reviewreport.aspx>.
- FSANZ. (2013a). Australia New Zealand Food Standards Code: Standard 1.1A.2: Transitional Standard – Health Claims. Food Standards Gazette, F2013C00095. Retrieved from <http://www.comlaw.gov.au/Details/F2013C00095>.
- FSANZ. (2013b). Australia New Zealand Food Standards Code: Standard 1.2.7: Nutrition, Health and Related Claims Food Standards Gazette, F2014C01191. Retrieved from <http://www.comlaw.gov.au/Details/F2014C01191>.
- FSANZ. (2013c). Health claims standard timeline. Retrieved from <http://www.foodstandards.gov.au/consumer/labelling/nutrition/pages/healthclaimsstandard5081.aspx>.
- FSANZ. (2015a). Australia New Zealand Food Standards Code: Schedule 6 – Required elements of a systematic review. Food Standards Gazette, F2015L00476. Retrieved from <https://www.legislation.gov.au/Details/F2015L00476>.
- FSANZ. (2015b). Australia New Zealand Food Standards Code: Standard 1.2.7: Nutrition, health and related claims (in effect from 1 March 2016). Food Standards Gazette, F2015L00394. Retrieved from <https://www.legislation.gov.au/Series/F2015L00394>.
- FSANZ. (2015c). FSANZ high level health claims committee. Retrieved from <http://www.foodstandards.gov.au/science/expertise/Pages/High-Level-Health-Claims-Committee.aspx>.
- FSANZ. (2016). Review of health claims authorised in the European Union (EU) and existing high level health claims in Standard 1.2.7 Retrieved from <http://www.foodstandards.gov.au/industry/>

- labelling/Pages/healthclaimsapprovedintheEuropeanUnion.aspx.
- FSANZ. (2017a). Australia New Zealand Food Standards Code: Schedule 4 – Nutrition, health and related claims. Food Standards Gazette, F2017C00317. Retrieved from <https://www.legislation.gov.au/Details/F2017C00317>.
- FSANZ. (2017b). Australia New Zealand Food Standards Code: Schedule 5 – Nutrient profiling scoring method. Food Standards Gazette, F2017C00318. Retrieved from <https://www.legislation.gov.au/Details/F2017C00318>.
- FSANZ. (2017c). Australia New Zealand Food Standards Code: Standard 1.2.7: Nutrition, Health and Related Claims (last revision). Food Standards Gazette, F2017C00310. Retrieved from <https://www.legislation.gov.au/Details/F2017C00310>.
- FSANZ. (2017d). Australia New Zealand Food Standards Code: Standard 2.9.3 Formulated meal replacements and formulated supplementary foods. Food Standards Gazette, F2017C00314. Retrieved from <https://www.legislation.gov.au/Details/F2017C00314>.
- FSANZ. (2017e). FSANZ outcomes from consideration of European Union-authorized health claims. Retrieved from <https://www.foodstandards.gov.au/industry/labelling/Pages/Outcomes-from-consideration-of-European-Union-authorized-health-claims.aspx>.
- FSANZ. (2019). FSANZ application handbook. Retrieved from <https://www.foodstandards.gov.au/code/changes/Documents/FSANZ%20Application%20Handbook%201%20July%202019.pdf>.
- FSANZ. (2020a). FSANZ food standards work plan. Retrieved from <http://www.foodstandards.gov.au/code/changes/workplan/pages/default.aspx>.
- FSANZ. (2020b). FSANZ information on establishing food-health relationships for general level health claims. Retrieved from <http://www.foodstandards.gov.au/publications/Documents/Information%20on%20establishing%20food%20health%20relationships.pdf>.
- FSANZ. (2020c). FSANZ notified food-health relationships. Retrieved from <http://www.foodstandards.gov.au/industry/labelling/fhr/Pages/default.aspx>.
- FSANZ. (2020d). Notifying a self-substantiated food-health relationship. Retrieved from <http://www.foodstandards.gov.au/industry/labelling/fhr/Pages/notifications.aspx>.
- Greene, H. L., Prior, T., & Frier, H. I. (2001). Foods, health claims, and the law: Comparisons of the United States and Europe. *Obesity Research*, 9(Suppl 4), 276S–283S. Retrieved from <http://www.scopus.com/inward/record.url?eid=2-s2.0-0035514602&partnerID=40&md5=7b8ca91938197746852f3b50929188ce>
- Grossklaus, R. (2009). Codex recommendations on the scientific basis of health claims. *European Journal of Nutrition*, 48(1), 15–22. <https://doi.org/10.1007/s00394-009-0077-z>
- Hasler, C. M. (2008). Health claims in the United States: An aid to the public or a source of confusion? *Journal of Nutrition*, 138(6), 1216S–1220S.
- HC. (2009). Guidance document for preparing a submission for food health claims. Retrieved from http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/legislation/health-claims_guidance-orientation_allegations-sante-eng.pdf.
- HC. (2010). Classification of products at the food-natural health product interface: Products in food formats – Version 2.0. Retrieved from http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/food-nhp-aliments-psn-guide-eng.pdf.
- HC. (2011). Guidance document for preparing a submission for food health claims using an existing systematic review. Retrieved from http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/legislation/guide-ld/systemat-revi-sub-eng.pdf.
- HC. (2020a). Food and nutrition: Health claims. Retrieved from <http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/index-eng.php>.
- HC. (2020b). Health claim assessments: Substantiation of health claims (scientific evidence). Retrieved from <http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/index-eng.php>.
- HC. (2020c). Natural and non-prescription health products. Retrieved from <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>.
- Hieke, S., Kuljanic, N., Pravst, I., Miklavec, K., Kaur, A., Brown, K. A., ... Rayner, M. (2016). Prevalence of nutrition and health-related claims on pre-packaged foods: A five-country study in Europe. *Nutrients*, 8(3), 1–16. <https://doi.org/10.3390/nu8030137>
- Hieke, S., Kuljanic, N., Wills, J. M., Pravst, I., Kaur, A., Raats, M. M., ... Grunert, K. G. (2015). The role of health-related claims and health-related symbols in consumer behaviour: Design and conceptual framework of the CLYMBOL project and initial results. *Nutrition Bulletin*, 40(1), 66–72. <https://doi.org/10.1111/nbu.12128>
- Hoffmann, D., & Schwartz, J. (2016). Stopping deceptive health claims: The need for a private right of action under federal law. *American Journal of Law and Medicine*, 42(1), 53–84. <https://doi.org/10.1177/0098858816644715>
- Hughes, C., Wellard, L., Lin, J., Suen, K. L., & Chapman, K. (2013). Regulating health claims on food labels using nutrient profiling: What will the proposed standard mean in the Australian supermarket? *Public Health Nutrition*, 16(12), 2154–2161. <https://doi.org/10.1017/S136898001200540X>
- ISFR. (2018). Getting your claims right – A guide to complying with the nutrition, health and related claims standard of the Australia New Zealand food standards code. Retrieved from <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/31BDC68CEC4A1964CA25801B00166C1F/>File/Getting-Your-Claims-Right-2018.pdf>.
- Kaur, A., Scarborough, P., Hieke, S., Kusar, A., Pravst, I., Raats, M., & Rayner, M. (2016a). The nutritional quality of foods carrying health-related claims in Germany, The Netherlands, Spain, Slovenia and the United Kingdom. *European Journal of Clinical Nutrition*, 70(12), 1388–1395. <https://doi.org/10.1038/ejcn.2016.114>
- Kaur, A., Scarborough, P., Matthews, A., Payne, S., Mizdrak, A., & Rayner, M. (2016b). How many foods in the UK carry health and nutrition claims, and are they healthier than those that do not? *Public Health Nutrition*, 19(S6), 988–997. <https://doi.org/10.1017/S1368980015002104>
- Khedkar, S., Bröring, S., & Ciliberti, S. (2017). Exploring the Nutrition and Health Claims Regulation (EC) No. 1924/2006: What is the impact on innovation in the EU food sector? *International Journal of Food Sciences and Nutrition*, 68(1), 10–17. <https://doi.org/10.1080/09637486.2016.1212818>
- Khedkar, S., Ciliberti, S., & Bröring, S. (2016). The EU health claims regulation: Implications for innovation in the EU food sector. *British Food Journal*, 118(11), 2647–2665. <https://doi.org/10.1108/bfj-01-2016-0021>

- Kušar, A., & Pravst, I. (2014). Quality and safety of botanical food products and their labelling. *Agro Food Industry Hi-Tech*, 25(2), 33–35.
- L'Abbe, M. R., Dumais, L., Chao, E., & Junkins, B. (2008). Health claims on foods in Canada. *Journal of Nutrition*, 138(6), 1221S–1227S.
- Lahteenmaki, L. (2013). Claiming health in food products. *Food Quality and Preference*, 27(2), 196–201. <https://doi.org/10.1016/j.foodqual.2012.03.006>
- Lalor, F., Kennedy, J., Flynn, M. A., & Wall, P. G. (2010). A study of nutrition and health claims—A snapshot of what's on the Irish market. *Public Health Nutrition*, 13(5), 704–711. <https://doi.org/10.1017/S1368980009991613>
- Lalor, F., & Wall, P. G. (2011). Health claims regulations: Comparison between USA, Japan and European Union. *British Food Journal*, 113(2), 298–313. <https://doi.org/10.1108/00070701111105358>
- Lapenna, S., Gemen, R., Wollgast, J., Worth, A., Maragkoudakis, P., & Caldeira, S. (2015). Assessing herbal products with health claims. *Critical Reviews in Food Science and Nutrition*, 55(13), 1918–1928. <https://doi.org/10.1080/10408398.2012.726661>
- Lenssen, K. G. M., Bast, A., & de Boer, A. (2018). Clarifying the health claim assessment procedure of EFSA will benefit functional food innovation. *Journal of Functional Foods*, 47, 386–396. <https://doi.org/10.1016/j.jff.2018.05.047>
- López-Galán, B., & De-Magistris, T. (2017). Prevalence of relevant nutritional claims related to prevention of obesity in Spanish market. *Nutricion Hospitalaria*, 34(1), 154–164. <https://doi.org/10.20960/nh.991>
- Lynam, A.-M., McKevitt, A., & Gibney, M. J. (2011). Irish consumers' use and perception of nutrition and health claims. *Public Health Nutrition*, 14(12), 2213–2219. <https://doi.org/10.1017/S1368980011000723>
- Malla, S., Hobbs, J., & Kofi Sogah, E. (2013). Functional foods and natural health products regulations in Canada and around the world: Nutrition labels and health claims. Retrieved from http://www.ag-innovation.usask.ca/cairn_briefs/publications%20for%20download/Publication%2036%20Malla%20et%20al.pdf.
- Martin, A. (2015). Assessment and management of health claims in Europe 9 years after the adoption of the regulation. *Journal of Nutritional Science and Vitaminology*, 61, S50–S52.
- Martínez, S. V., & Siani, A. (2017). Health claims made on food in the EU: The edge between scientific knowledge and regulatory requirements. *Trends in Food Science & Technology*, 69(Part B), 315–323. <https://doi.org/10.1016/j.tifs.2017.01.005>
- Miklavac, K., Pravst, I., Grunert, K. G., Klopčič, M., & Pohar, J. (2015). The influence of health claims and nutritional composition on consumers' yoghurt preferences. *Food Quality and Preference*, 43, 26–33. <https://doi.org/10.1016/j.foodqual.2015.02.006>
- MPI. (2016). New Zealand Food (Supplemented Food) Standard 2016. Retrieved from <https://www.mpi.govt.nz/document-vault/11365>.
- Navas-Carretero, S., & Martínez, J. A. (2015). Cause–effect relationships in nutritional intervention studies for health claims substantiation: Guidance for trial design. *International Journal of Food Sciences and Nutrition*, 66, S53–S61. <https://doi.org/10.3109/09637486.2015.1025720>
- Ni Mhurchu, C., Brown, R., Jiang, Y., Eyles, H., Dunford, E., & Neal, B. (2016). Nutrient profile of 23 596 packaged supermarket foods and non-alcoholic beverages in Australia and New Zealand. *Public Health Nutrition*, 19(03), 401–408. <https://doi.org/10.1017/S1368980015000968>
- Nocella, G., & Kennedy, O. (2012). Food health claims: What consumers understand. *Food Policy*, 37(5), 571–580. <https://doi.org/10.1016/j.foodpol.2012.06.001>
- Petersen, K. S. (2019). The dilemma with the soy protein health claim. *Journal of the American Heart Association*, 8(13), e013202. <https://doi.org/10.1161/JAHA.119.013202>
- Petty, R. E., & Cacioppo, J. T. (1986). The elaboration likelihood model of persuasion. In L. Berkowitz (Ed.), *Advances in Experimental Social Psychology* (Vol. 19, pp. 123–205): Academic Press.
- Pothoulaki, M., & Chrysoschoidis, G. (2009). Health claims: Consumers' matters. *Journal of Functional Foods*, 1(2), 222–228. <https://doi.org/10.1016/j.jff.2009.01.012>
- Pravst, I. (2010). The evaluation of health claims in Europe: What have we learned? *Agro Food Industry Hi-Tech*, 21(4), 4–6.
- Pravst, I. (2011). Risking public health by approving some health claims? – The case of phosphorus. *Food Policy*, 36, 725–727. <https://doi.org/10.1016/j.foodpol.2011.05.005>
- Pravst, I. (2012). Functional foods in Europe: A focus on health claims. In B. Valdez (Ed.), *Scientific, health and social aspects of the food industry*. Rijeka: InTech.
- Pravst, I., & Kušar, A. (2015). Consumers' exposure to nutrition and health claims on pre-packed foods: Use of sales weighting for assessing the food supply in Slovenia. *Nutrients*, 7(77), 9353–9368. <https://doi.org/10.3390/nu7115474>
- Pravst, I., Kušar, A., Žmitek, K., Miklavac, K., Lavriša, Ž., Lähteenmäki, L., ... Raats, M. M. (2018). Recommendations for successful substantiation of new health claims in the European Union. *Trends in Food Science & Technology*, 71, 259–263. <https://doi.org/10.1016/j.tifs.2017.10.015>
- Raats, M., Malcolm, R., Lähteenmäki, L., Pravst, I., Gage, H., Cleary, A., & Klopčič, M. (2015). Understanding the impact of European Regulation on the substantiation and use of claims on food and drinks: Design of the REDICLAIM project and initial results. *Nutrition Bulletin*, 40(4), 340–348. <https://doi.org/10.1111/nbu.12179>
- Ritz, E., Hahn, K., Ketteler, M., Kuhlmann, M. K., & Mann, J. (2012). Phosphate additives in food – A health risk. *Deutsches Ärzteblatt International*, 109(4), 49–55.
- Sacco, J. E., Sumanac, D., & Tarasuk, V. (2013). Front-of-package references to fiber on foods in Canadian supermarkets highlight the need for increased nutrition knowledge among consumers. *Journal of nutrition education and behavior*, 45(6), 518–524. <https://doi.org/10.1016/j.jneb.2013.02.003>
- Schermel, A., Emrich, T. E., Arcand, J., Wong, C. L., & L'Abbe, M. R. (2013). Nutrition marketing on processed food packages in Canada: 2010 Food Label Information Program. *Applied Physiology, Nutrition, and Metabolism*, 38(6), 666–672. <https://doi.org/10.1139/apnm-2012-0386>
- Shimizu, T. (2003). Health claims on functional foods: The Japanese regulations and an international comparison. *Nutrition Research Reviews*, 16(2), 241–252. <https://doi.org/10.1079/NRR200363>
- Shimizu, T. (2015). Health claims regulation and scientific substantiation of functional foods and the international comparison. In D. Ghosh, D. Bagchi, & T. Konishi (Eds.), *Clinical aspects of functional foods and nutraceuticals* (pp. 217–255). Boca Raton, FL: CRC Press.

- Stancu, V., Grunert, K. G., & Lahteenmaki, L. (2017). Consumer inferences from different versions of a beta-glucans health claim. *Food Quality and Preference*, 60, 81–95. <https://doi.org/10.1016/j.foodqual.2017.03.001>
- Storcksdieck genannt Bonsmann, S., Fernandez Celemin, L., Larranaga, A., Egger, S., Wills, J. M., Hodgkins, C., & Raats, M. M. (2010). Penetration of nutrition information on food labels across the EU-27 plus Turkey. *European Journal of Clinical Nutrition*, 64(12), 1379–1385.
- Tapsell, L. C. (2008). Evidence for health claims: A perspective from the Australia-New Zealand region. *Journal of Nutrition*, 138(6), 1206S–1209S.
- TGA. (2013). An overview of the regulation of complementary medicines in Australia. Retrieved from <https://www.tga.gov.au/overview-regulation-complementary-medicines-australia>.
- US. (1990). Nutrition labelling and education act of 1990. *Public Law*, 101–535, 104 stat. 2353. Retrieved from <http://www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg2353.pdf>.
- US. (1994). Dietary Supplement Health and Education Act of 1994. *Public Law*, 103–417, 108 stat. 4325. Retrieved from <http://www.gpo.gov/fdsys/pkg/STATUTE-108/pdf/STATUTE-108-Pg4325.pdf>.
- US. (1997). Food and drug administration modernization act of 1997 *Public Law*, 105–115, 111 stat. 2296. Retrieved from <http://www.gpo.gov/fdsys/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf>.
- US. (2010). United States Code, Title 21: Food and drugs; Chapter 9: Federal Food, Drug, and Cosmetic Act; Subchapter IV: Food; Sec. 343: Misbranded food. 21 USC 343. Retrieved from <http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapIV-sec343.html>.
- US. (2014a). Code of Federal Regulations, Title 21: Food and drugs; Chapter I: Food and drug administration department of health and human services; Subchapter B: Food for human consumption; Part 101: Food labeling: Subpart A: General Provisions; Sec. 101.13 Nutrient content claims –general principles. 21 CFR 101.13. Retrieved from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.13>.
- US. (2014b). Code of Federal Regulations, Title 21: Food and drugs; Chapter I: Food and drug administration department of health and human services; Subchapter B: Food for human consumption; Part 101: Food labeling: Subpart A: General Provisions; Sec. 101.14: Health claims: General requirements. 21 CFR 101.14. Retrieved from https://www.ecfr.gov/cgi-bin/text-idx?SID=3b3dc0b3eaede490ddb9b436779cdcd4&mc=true&node=se21.2.101_114&rgn=div8.
- US. (2014c). Code of Federal Regulations, Title 21: Food and drugs; Chapter I: Food and drug administration department of health and human services; Subchapter B: Food for human consumption; Part 101: Food labeling: Subpart E: Specific Requirements for Health Claims; Sec. 101.70: Petitions for health claims. 21 CFR 101.70. Retrieved from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.70>.
- US FDA. (2003a). Consumer health information for better nutrition initiative: Task force final report. Retrieved from <https://www.fda.gov/food/food-labeling-nutrition/consumer-health-information-better-nutrition-initiative-attachment-e-interim-procedures-qualified>.
- US FDA. (2003b). Guidance for industry and FDA: Interim evidence-based ranking system for scientific data. Retrieved from <https://www.federalregister.gov/documents/2003/07/11/03-17702/release-of-task-force-report-guidance-for-industry-and-fda-interim-evidence-based-ranking-system-for>.
- US FDA. (2009). Guidance for industry: Evidence-based review system for the scientific evaluation of health claims. Retrieved from <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm>.
- US FDA. (2013). Guidance for industry: A food labeling guide. Retrieved from <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>.
- US FDA. (2016a). Food labeling: Health claims; dietary saturated fat and cholesterol and risk of coronary heart disease. Retrieved from <https://www.gpo.gov/fdsys/pkg/FR-2016-12-19/pdf/2016-29997.pdf>.
- US FDA. (2016b). Food labeling: Revision of the nutrition and supplement facts labels. Retrieved from <https://www.federalregister.gov/documents/2016/05/27/2016-11867/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels>.
- US FDA. (2017). Food labeling: Health claims; Soy protein and coronary heart disease– Proposed rule. *Federal Register*, 82(209), 50324–50346. Retrieved from <https://www.govinfo.gov/content/pkg/FR-2017-10-31/pdf/2017-23629.pdf>.
- US FDA. (2020a). FDA Modernization Act (FDAMA) claims. Retrieved from <https://www.fda.gov/food/food-labeling-nutrition/fda-modernization-act-fdama-claims>.
- US FDA. (2020b). Health claims meeting significant scientific agreement (SSA). Retrieved from <https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard>.
- US FDA. (2020c). Qualified health claims. Retrieved from <https://www.fda.gov/food/food-labeling-nutrition/qualified-health-claims>.
- US FDA. (2020d). Structure and function Claims. Retrieved from <https://www.fda.gov/food/food-labeling-nutrition/structurefunction-claims>.
- van Trijp, H. C. M., & van der Lans, I. A. (2007). Consumer perceptions of nutrition and health claims. *Appetite*, 48(3), 305–324. <https://doi.org/10.1016/j.appet.2006.09.011>
- Van Wezemael, L., Caputo, V., Nayga, R. M., Chrystoschoidis, G., & Verbeke, W. (2014). European consumer preferences for beef with nutrition and health claims: A multi-country investigation using discrete choice experiments. *Food Policy*, 44, 167–176. <https://doi.org/10.1016/j.foodpol.2013.11.006>
- Verhagen, H., & van Loveren, H. (2016). Status of nutrition and health claims in Europe by mid 2015. *Trends in Food Science & Technology*, 56, 39–45. <https://doi.org/10.1016/j.tifs.2016.07.005>
- Verhagen, H., Vos, E., Francel, S., Heinonen, M., & van Loveren, H. (2010). Status of nutrition and health claims in Europe. *Archives of Biochemistry and Biophysics*, 501(1), 6–15. <https://doi.org/10.1016/j.abb.2010.04.012>
- Vero, V., & Gasbarrini, A. (2012). The EFSA health claims ‘learning experience’. *International Journal of Food Sciences and Nutrition*, 63, 14–16. <https://doi.org/10.3109/09637486.2011.633899>
- Walker, K. Z., Woods, J. L., Rickard, C. A., & Wong, C. K. (2008). Product variety in Australian snacks and drinks: How can the consumer make a healthy choice? *Public Health Nutrition*, 11(10), 1046–1053. <https://doi.org/10.1017/s1368980007001462>
- Wellard-Cole, L., Li, R., Tse, C., Watson, W. L., & Hughes, C. (2020). Changes in nutrition content and health claims

- post-implementation of regulation in Australia. *Public Health Nutrition*, 23(12), 2221–2227. <https://doi.org/10.1017/S1368980019004890>
- Wellard-Cole, L., Watson, W. L., Hughes, C., & Chapman, K. (2019). How effective is food industry self-substantiation of food–health relationships underpinning health claims on food labels in Australia? *Public Health Nutrition*, 22(9), 1686–1695. <https://doi.org/10.1017/S1368980018004081>
- Williams, P., Yeatman, H., Ridges, L., Houston, A., Rafferty, J., Ridges, A., Spratt, B. (2006). Nutrition function, health and related claims on packaged Australian food products - prevalence and compliance with regulations. *Asia Pacific Journal of Clinical Nutrition*, 15(1), 10–20.
- Williams, P., Yeatman, H., Zakrzewski, S., Aboozaid, B., Henshaw, S., Ingram, K., Ghani, F. (2003). Nutrition and related claims used on packaged Australian foods - implications for regulation. *Asia Pacific Journal of Clinical Nutrition*, 12(2), 138–150.
- Wills, J. M., Storcksdieck genannt Bonsmann, S., Kolka, M., & Grunert, K. G. (2012). European consumers and health claims: Attitudes, understanding and purchasing behaviour. *Proceedings of the Nutrition Society*, 71(2), 229–236. <https://doi.org/10.1017/S0029665112000043>

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Kušar A, Žmitek K, Lähteenmäki L, Raats MM, Pravst I. Comparison of requirements for using health claims on foods in the European Union, the USA, Canada, and Australia/New Zealand. *Compr Rev Food Sci Food Saf*. 2021;20:1307–1332. <https://doi.org/10.1111/1541-4337.12716>