



# Nutrition and health claims in the European Union in 2022

**Nuala Collins, BSc, Dip PgCert, and Hans Verhagen, PhD**

Nutrition and health claims are widely used on food labels and may positively influence consumer perceptions and intentions to buy food. Regulation (EC) 1924/2006 on nutrition and health claims aims to ensure claims are clear, scientifically substantiated, and supports consumers to make informed decisions. The European Commission (EC) is working to introduce a legislative proposal on nutrient profiles in 2022 to restrict the use of claims on foods high in saturated fat, sugar, or salt. The EC must also find a solution to the inequality in the scientific substantiation of nonbotanical versus botanical claims.

**Keywords** – claims, health, nutrition, Regulation 1924/2006

## **Introduction**

Functional foods include foods with improvements, such as reducing negative aspects (e.g., lower in calories, sugar, sodium) as well as the incorporation of other constituents (e.g., vitamins, minerals, plant sterols, probiotics, prebiotics). Functional foods with health claims were among the first claims used on food

©2022 Regulatory Affairs Professionals Society

labels in the 1980s, whereas today, nutrition claims are more widely used. In the EU, the objective of Regulation (EC) 1924/2006,<sup>1</sup> which was introduced in 2007, is to ensure that any nutrition and health claim made in commercial communication to consumers or health professionals (by labelling, presentation, or advertising) is clear and accurate. A claim is defined as “any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic, or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.”<sup>1</sup> There are two categories of claims on foods in the EU: nutrition claims and health claims (**Figure 1**). Nutrition claims refer to what a food contains: content claims and comparative claims. Health claims refer to what a food does and refer to general function claims, claims related to a reduction of disease risk, and claims related to the growth and development of children. Nutrition and health claims are commonly used on food product labels to positively influence consumers perception of the product and to persuade them to purchase foods with claims.<sup>2,3</sup>

### Nutrition claims

Under Article 2 of Regulation (EC) 1924/2006, a nutrition claim is defined as any claim that states, suggests, or implies a food has a particular nutrition property in relation to the energy, nutrients, and other substances it contains, in higher or lower amounts, or not at all.

**Figure 1. Overview of nutrition and health claims in the EU under Regulation (EC) 1924/2006<sup>1,a</sup>**

Nutrition Claims		Health Claims				Nutrition & Health Claims
What the food contains		What the food does				
<b>Article 8</b> Content Claim	<b>Article 9</b> Comparative Claim	<b>Article 10(3)</b> General, Non-Specific Claim	<b>Article 13(1)</b> Function Claim	<b>Article 14(1a)</b> Reduction of Disease Risk	<b>Article 28(2)</b> Trade Marks or Brand Names	
Refers to the nutritional composition of a food that meets a specific amount criterion  e.g., “Source of vitamin D”	Comparisons of the nutritional composition of a range of foods within the same food category  e.g., “30% less fat”	A general benefit of a nutrient or food for overall good health or well-being  e.g., “healthy for you”  Must be accompanied by a related Article 13 or 14 health claim.	Supported by <b>generally accepted scientific evidence</b> . Directly links a nutrient or substance to a health claim  e.g., “Calcium contributes to normal muscle function”  <b>Article 13(5)</b> Function Claim  Supported by <b>newly developed scientific research and/or protection of proprietary data</b> . Directly links a nutrient or substance to a health claim in adults  e.g., “Water-Soluble Tomato Concentrate I and II helps maintain normal platelet aggregation, which contributes to healthy blood flow”.	Directly links a nutrient with a risk factor for disease  e.g., “Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease”  <b>Article 14(1b)</b> Children’s Health Claim  Claims referring to children’s development and health  e.g., “Calcium is needed for normal growth and development of bone in children”	All food products with trade marks or brand names which are a <b>nutrition or health claim</b> must comply with the provisions of the Regulation  e.g., “For better focus”	
<b>Commonly used descriptions for Nutrition Claims</b> <ul style="list-style-type: none"> <li>Contains / source of</li> <li>High in</li> <li>Increased / Reduced</li> <li>Light/Lite</li> <li>(Very) Low</li> <li>Free</li> <li>No added</li> <li>Natural</li> </ul>						

<sup>a</sup>Health claims in yellow require submission of an application dossier and its scientific data may be protected for 5 years from the date of authorization.

Currently, there are 30 nutrition claims permitted (**Table 1**). Any food business operator can use a nutrition claim on a food label provided the conditions to make a claim are satisfied as outlined in Annex 1 of Regulation (EC) 1924/2006.

### Health claims

There are four main-types of health claims in the EU:

- **sGeneral, nonspecific health claims.** These types of claims refer to health or well-being (Article 10). They must be supported by a related specific Article 13 or 14 health claim close to the general claim or suitably signposted, for example, with an asterisk.<sup>5</sup>
- **Health claims other than those referring to the reduction of disease risk (Article 13).** These can relate to the growth, development, and functions of the body; to psychological and behavioral functions; or to slimming or weight-control. (However, claims that refer to the rate or amount of weight loss are not allowed). Article 13(1) function claims are based on “generally accepted scientific data;” whereas Article 13(5) claims are based on newly developed scientific data.
- **Reduction of disease risk claims (Article 14 1a).** These claims should also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.
- **Children’s growth and development (Article 14 1b).** These claims are supported by scientific studies in children. There are 12 authorized health claims<sup>6</sup> for children’s growth and development. Food products for children cannot bear adult claims.

**Table 1. Categorization of nutrition claims in the EU<sup>4</sup>**

Low/ very low	Free	No added	Contains/ source of	High in	Increased/ reduced
Low sugar	Sugar free	With no added sugars	Source of fiber	High-fiber	Energy reduced
Low sodium/salt	Sodium free/ salt free	No added sodium/salt	Source of protein	High protein	Light/lite
Very low sodium/salt		Naturally/ natural	Contains [name of nutrient/other substance]		Increased [name of nutrient]
Low fat	Fat free		Source of [name of vitamin/s and/or mineral/s]	High [name of vitamin/s and/or mineral/s]	Reduced [name of nutrient]
Low saturated fat	Saturated fat free		Source of omega-3-fatty acids	High omega-3-fatty acids	
Low energy	Energy free			High unsaturated/ monounsaturated/ polyunsaturated fat	

Health claims on foods must be supported by scientific evidence. Regulation 1924/2006 states that “Health claims should only be authorized for use in the Community after a scientific assessment of the highest possible standard. In order to ensure harmonized scientific assessment of these claims, the European Food Safety Authority [EFSA] should carry out such assessments.”

By January 2008, a total of 4,637 health claim proposals were submitted by the EU member states based on Article 13(1) criteria for function claims. These proposals did not require a full substantiation dossier, only the submission of relevant scientific references.

Applicants must submit a formal dossier for Article 13(5) and Article 14 (1.a and 1.b) claims. To inform an application, the EFSA has developed a guidance for the preparation and presentation of a health claim application,<sup>7</sup> which includes information on the new presubmission phase, introduced as part of the Transparency Regulation (EU) 2019/1381.<sup>8</sup> To further enhance transparency in the handling of health claim applications, the EFSA has also published administrative guidance<sup>9</sup> for the processing of regulated products, including health claims.

When evaluating a health claim dossier, the EFSA evaluates the extent to which:

- The food/constituent is defined/characterized,
- The claimed effect is “beneficial to human health,” and
- Scientific evidence of a cause-and-effect relationship is established.

A negative answer in any of the three steps indicates the claim is not suitable for authorization. Points 1 and 3 are straightforward, but for point 2 (beneficial to human health), the EFSA has published a series of guidance documents<sup>12</sup> on the scientific requirements for health claims related to:

- Functions of the nervous system, including psychological functions;
- Physical performance;
- Bone, joints, skin, and oral health;
- Appetite ratings, weight management, and blood glucose concentrations;
- The immune system, the gastrointestinal tract, and defence against pathogenic microorganisms; and
- Antioxidants, oxidative damage, and cardiovascular health.

The EFSA evaluates each health claim application, and the result is published as a scientific opinion. To date, EFSA has evaluated over 3,000 health claims. **Table 2** (p. 5) shows an overview of the current state of the evaluation process. The conclusions of an EFSA scientific opinion evaluating a health claim can be:

- A cause-and-effect relationship has been established,
- There is insufficient evidence to establish a cause-and-effect relationship, or
- A cause-and-effect relationship has not been established.

**Table 2. EU health claims status as of June 2022<sup>10</sup>**

Type of claim	Received	Withdrawn	Adopted	In progress/ under validation	Authorized by EU/ member state	% authorized
Article 13.1 (general function)	4,637	331	2,849	2,078 <sup>11</sup>	229	5
Article 13.5 (new science/ proprietary)	218	43	163	3	12	6
Article 14.1a (disease risk reduction)	74	26	45	1	14	19
Article 14.1b (growth, devel. of children)	229	133	87	1	12	5

After finalization of a scientific opinion by the EFSA, it is up to the EC and member states to decide on authorization of a health claim. Only health claims that carry the conclusion “a cause-and-effect has been established” qualify for authorization. With some exceptions (e.g., glucose and cognition, lactose and gastrointestinal discomfort, and caffeine in relation to alertness, attention, and exercise), health claims that were considered by the EFSA as “scientifically substantiated” have been authorized. The EU Register of Nutrition and Health Claims lists all permitted nutrition claims and all authorized and nonauthorized health claims.<sup>6</sup>

### Evolution in the use of claims

The types of claims on food packaging have evolved over time. Immune health claims and cholesterol-lowering health claims were mainly used in the 1980s, when functional foods first became available.<sup>13</sup> However, consumer research has shown a preference for nutrition claims over health claims, and food labels now reflect that consumer preference (**Table 3**). The extensive use of nutrition and health claims on food labels worldwide suggests food businesses consider them a competitive advantage. Some food categories, more than others, such as yoghurts<sup>14</sup> and breakfast cereals,<sup>15</sup> make significant use of nutrition and health claims.

**Table 3. Percentage of products using nutrition and health claims worldwide**

Country	Year	Total Products, n	Products using nutrition claim, %	Products using health claim, %
Ireland <sup>a</sup>	2010	1,880	47.3	17.8
UK <sup>b</sup>	2016	382	29	15
New Zealand <sup>c</sup>	2016	7,058	35	15
Mexico <sup>d</sup>	2021	17,264	33.8	3.4
Australia <sup>e</sup>	2021	340	93.9	4

<sup>a</sup>Lalor et al. <https://bit.ly/3PXNAWv>. <sup>b</sup>Kaur et al. <https://bit.ly/3AwwNny>. <sup>c</sup>Al-Ani et al. <https://bit.ly/3wFggwv>.

<sup>d</sup>Cruz-Casarrubias et al. <https://bit.ly/3KrnABv>. <sup>e</sup>Wadhwa et al. <https://bit.ly/3TolxCf>.

### Contemporary issues

In May 2020, the EC completed its evaluation of the regulation on nutrition and health claims<sup>16</sup> and some issues around nutrition and health claims have not been resolved to date, such as the setting of “nutrient profiles” and health claims around “botanicals.”

The original intention was that nutrient profiles (NPs) would be set by January 2009 to protect consumers from being misled by claims on products high in saturated fat, salt, and sugar. However, the NPs have still not been established. Many different NPs are used globally. They have been used for different purposes: To restrict the promotion of unhealthy food to children, to ensure food products that bear a nutrition or health claim are healthy, and to evaluate the nutritional quality of foods to underpin front-of-pack nutrition labelling (FoPNL).

A synthesis of the characteristics of numerous NPs has been completed using a visual arrow model,<sup>17</sup> developed in 2008 and revised and updated to include nutrient profiles for FoPNL.<sup>18,19</sup> The EC’s Farm to Fork Strategy<sup>20</sup> states that NPs will be set to restrict the promotion of food high in nutrients such as salt, sugars, and/or fat as foreseen in the nutrition and health claims regulation. A legislative proposal to revise existing legislation on food information to consumers is expected to be completed by the end of 2022.

The EFSA have provided scientific advice<sup>21</sup> to support the EC in the development of NPs and FoPNL. The advice outlines the nutrients of public health importance in the EU population diet, nutrients, and nonnutrients (energy and fiber) to be considered by a nutrient profiling model, and the contribution of food groups to national diets for EU populations and subgroups. The EFSA panel stated that the same scientific considerations could underpin the setting of nutrient profiling models for both the restriction of health claims and front of pack nutrition labelling purposes. The final decision will be made by the EC in consultation with member states.

Regarding botanical health claims for plants and their preparations, there are “on hold” health claims that have yet to be reviewed by the EFSA and authorized by the EC. Although many plants have a history of being consumed, they do not have the scientific substantiation required by the EFSA to support an authorized health claim. In practice, “on hold” means some botanical health claims are used in food because risk managers and national rules permit them in the member state. The EC acknowledges that it could be appropriate to take into account the specific situation of plants and/or their preparations, which have a long traditional history of use linked to health benefits.<sup>11</sup> While this is not resolved, 2,078 claims<sup>11</sup> on botanical substances can be used in combination with a disclaimer that the health claim has not been evaluated and provided it is not a medicinal substance in the member state.

Another contemporary issue concerns micro-organisms. To date, not a single health claim from the many applications on “probiotics” has been authorized,

except for an effect on the digestion of lactose. Some member states<sup>22,23</sup> interpret the regulation to allow the use of the term “probiotic.” It is now used, for example, as a general health claim on yoghurt or fermented milk products and supported by a specific Article 13(1) health claim relating to improved lactose digestion (provided the products meet the condition of use regarding *lactobacillus delbrueckii subsp. bulgaricus* and *streptococcus thermophilus* concentration).

Finally, the list of health claims in the EU Register have been retained by the UK since its exit from the EU and are now on the Great Britain Nutrition and Health Claims Register. New applications for health claims are validated by the Department of Health and Social Care in England. The application is then passed to the United Kingdom Nutrition and Health Claims Committee, which follows an approach similar to the EFSA’s regarding scientific assessment. Although the UK regulatory procedures are different, the scientific requirements for new claims are similar to those of the EU.<sup>24</sup>

#### Acronyms and abbreviations

**EC**, European Commission; **EFSA**, European Food Safety Authority; **EU**, European Union; **FoPNL**, front-of-pack nutrition labelling; **NP**, nutrient profile; **UK**, United Kingdom.

#### About the authors

**Nuala Collins, BSc, Dip PgCert**, works as lead for the Food Reformulation Task Force, Ireland. She has almost 35 years’ experience in dietetics, nutritional science, food allergy, and food regulation. Collins has worked in clinical settings and in the food industry having qualified as a dietician from Trinity College, Dublin, Ireland. She is currently working toward a master’s degree in food regulatory affairs, a collaborative postgraduate programme between Ulster University (UK) and University College Dublin (Republic of Ireland). She can be contacted at [nualacollins.foodfacts@gmail.com](mailto:nualacollins.foodfacts@gmail.com)

**Hans Verhagen, PhD**, is a board-certified toxicologist and board-certified nutritionist with more than 39 years of professional experience in food safety and nutrition. Verhagen has worked at universities in Nijmegen, Maastricht, Ulster, and Copenhagen; in contract research and industry; for the Netherland’s National Institute for Public Health and the Environment; and for EFSA from 2015-2020. From 2006-2015, he was a member of the EFSA-NDA panel working on health claims and novel foods. Verhagen is currently a visiting professor at the University of Ulster, Northern Ireland, and at the Technical University Denmark. Since 2020, he has been owner and consultant of Food Safety & Nutrition Consultancy. He can be contacted at [h.verhagen@ulster.ac.uk](mailto:h.verhagen@ulster.ac.uk); [FSNConsultancy@hotmail.com](mailto:FSNConsultancy@hotmail.com); and [hansver@food.dtu.dk](mailto:hansver@food.dtu.dk)

**Citation** Collins N, Verhagen H. Nutrition and health claims in the European Union in 2022. Regulatory Focus. Published online 3 September 2022. <https://www.raps.org/news-and-articles/news-articles/2022/9/nutrition-and-health-claims-in-the-european-union>

#### References

All references accessed and/or verified 26 August 2022.

1. European Commission. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Last updated 29 November 2012. <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32006R1924>
2. Kaur et al. A systematic review, and meta-analyses, of the impact of health-related claims on dietary choices. Int J Behav Nutr Phys Act. Published online 17 July 2017. <https://doi.org/10.1186/s12966-017-0548-1>
3. Oostenbach LH, et al. Systematic review of the impact of nutrition claims related to fat, sugar and energy content on food choices and energy intake. BMC Public Health. sPublished 15 October 2019. <https://doi.org/10.1186/s12889-019-7622-3>

4. European Commission. What is a nutrition claim? Not dated.  
[https://ec.europa.eu/food/safety/labelling-and-nutrition/nutrition-and-health-claims/nutrition-claims\\_en](https://ec.europa.eu/food/safety/labelling-and-nutrition/nutrition-and-health-claims/nutrition-claims_en)
5. Case C-524/18. Judgment, 30 January, 2020.  
<https://curia.europa.eu/juris/document/document.jsf?jsessionid=223376B5870582323C1826F45E769453?text=&docid=222888&pageIndex=0&doclang=en&mode=lst&dir=&oc=c=first&part=1&cid=35185397>
6. European Commission. EU Register: Nutrition and health claims made on foods (v.3.6).  
[https://ec.europa.eu/food/safety/labelling\\_nutrition/claims/register/public/](https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/)
7. European Food Safety Authority. Scientific and technical guidance for the preparation and presentation of a health claim application. EFSA J. 2021;19(3):6554.  
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6554>
8. Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain [incl. amendments]. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1381&from=EN>
9. European Food Safety Authority. Administrative guidance for the processing of applications for regulated products (update 2021). Dated 3 March 2021.  
<https://www.efsa.europa.eu/en/supporting/pub/en-6471>
10. [Behind paywall] Verhagen H, van Loveren H. Status of nutrition and health claims in Europe by mid 2015. ). Trends Food Sci Technol. 2016;56:39-45.  
<https://www.sciencedirect.com/science/article/abs/pii/S0924224415301321>
11. European Commission. 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 [staff working document and executive summary of evaluation. Dated 20 May 2020.  
[https://ec.europa.eu/food/system/files/2020-05/labelling\\_nutrition-claims\\_swd\\_2020-96\\_sum\\_en.pdf](https://ec.europa.eu/food/system/files/2020-05/labelling_nutrition-claims_swd_2020-96_sum_en.pdf)
12. European Food Safety Authority. Nutrition applications: Regulations and guidance.  
<https://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance>
13. [Behind paywall] Hilliam M. The market for functional foods. Int Dairy J. 1998;8(5-6):349-353. [https://doi.org/10.1016/S0958-6946\(98\)00057-0](https://doi.org/10.1016/S0958-6946(98)00057-0)
14. Cruz-Casarrubias C. Estimated effects of the implementation of the Mexican warning labels regulation on the use of health and nutrition claims on packaged foods. Int J Behav Nutr Phys Act. Published online 10 June 2021. <https://doi.org/10.1186/s12966-021-01148-1>
15. Vermote M, et al. Nutritional content, labelling and marketing of breakfast cereals on the Belgian market and their reformulation in anticipation of the implementation of the nutri-score front-of-pack labelling system. Nutrients. Published 25 March 2020.  
<https://doi.org/10.3390/nu12040884>
16. European Commission. Evaluation of the regulation on nutrition and health claims.  
[https://ec.europa.eu/food/safety/labelling-and-nutrition/nutrition-and-health-claims/evaluation-regulation-nutrition-and\\_en](https://ec.europa.eu/food/safety/labelling-and-nutrition/nutrition-and-health-claims/evaluation-regulation-nutrition-and_en)
17. Verhagen H, van den Berg H. A simple visual model to compare existing nutrient profiling schemes. Food Nutr Res. 2008.  
<https://foodandnutritionresearch.net/index.php/fnr/article/view/1117/4380>
18. van der Bend D, et al. A simple visual model to compare existing front-of-pack nutrient profiling schemes. Eur J Nutr Food Safety. 2014;4(4):429-534.  
<http://www.sciencedomain.org/abstract.php?iid=513&id=30&aid=5399>
19. van der Bend DLM, Lissner L. Differences and similarities between front-of-pack nutrition labels in Europe: A comparison of functional and visual aspects. Nutrients. Published online 14 March 2019.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6471039/>
20. European Commission. Farm to fork strategy. 2020.  
[https://ec.europa.eu/food/system/files/2020-05/f2f\\_action-plan\\_2020\\_strategy-info\\_en.pdf](https://ec.europa.eu/food/system/files/2020-05/f2f_action-plan_2020_strategy-info_en.pdf)
21. European Food Safety Authority. Scientific advice related to nutrient profiling for the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods. Dated 2022.  
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7259>



22. [In Spanish] Probióticos en los alimentos. Dated 27 October 2020.  
[https://www.aesan.gob.es/AECOSAN/web/seguridad\\_alimentaria/subdetalle/probioticos.htm](https://www.aesan.gob.es/AECOSAN/web/seguridad_alimentaria/subdetalle/probioticos.htm)
23. [In Italian] Probiotici e prebiotici. Current as of 7 July 2021.  
[https://www.salute.gov.it/portale/temi/p2\\_6.jsp?area=Alimenti%20particolari%20e%20integratori&id=1426&lingua=italiano&menu=integratori](https://www.salute.gov.it/portale/temi/p2_6.jsp?area=Alimenti%20particolari%20e%20integratori&id=1426&lingua=italiano&menu=integratori)
24. [UK] Department of Health and Social Care. Guidance on nutrition and health claims on foods. Last updated 10 November 2021.  
<https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods>