

Netherlands – Food Health Claims Guidelines

Full title	<p>Guideline document on the use of health claims made on food based on REGULATION (EC) 1924/2006 of 20 December 2006 (for short: ClaimsREG Guideline Document)</p> <p>This document is a translation of the KOAG/KAG document dated August 2018 and found here: https://www.keuringsraad.nl/getmedia/1e324ca0-5020-43dd-ab82-52c528b678f6/Richtsnoerdocument-ClaimsVO-versie-augustus-2018_v1-0-DEF.aspx</p> <p>The document can also be sourced from the SRC Advertising Code for Food Products, NL version: https://www.reclamecode.nl/nrc/rvv2019/</p> <p>Except that the April 2017 version is deployed (together with a list of example words) https://www.reclamecode.nl/wp-content/uploads/2018/05/Richtsnoerdocument-ClaimsVO-versie-april-2017-aangepaste-versie.pdf</p>
Heading	Introduction and Goal (concept) of the guideline document
Clause	<p>Introduction</p> <p>The aim of Regulation (EC) 1924/2006 of 20 December 2006 (in short: ClaimsREG) is to guarantee a high level of consumer protection. Claims concerning foods must be understandable to the consumer and all substances for which a claim is made must have a (scientifically) proven beneficial nutritional or physiological effect. The ClaimsREG further envisions harmonizing differences between national provisions relating to claims in order to guarantee the free movement of foods and avoid unequal conditions of competition. The ClaimsREG applies to all nutrition and health claims made in commercial communications regarding foods intended for final consumers. Trademarks and other brand names and fantasy names which may be construed as nutrition or health claims also fall under the ClaimsREG.</p> <hr/> <p>Aim</p> <p>The aim of the guideline document is to make (stakeholders of) the food and food supplement industry aware of the ClaimsREG criteria when they make health claims on their products and engage in (public) advertising for them. The guideline document offers practical pointers and does not replace the current laws and regulations. Part 1 of the guideline document includes a general explanation of the ClaimsREG and its application, part 2 includes a guideline for the use of the Health Claims Database with alternative wording.</p> <hr/> <p>Part 1 of the guideline document</p> <hr/> <p>Definitions</p>

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Claim¹: 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;

Nutrition claim²: any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

- a) the energy (calorific value) it
 - i) provides,
 - ii) provides at a reduced or increased rate, or
 - iii) does not provide; and / or
- b) the nutrients or other substances it
 - i) contains,
 - ii) contains in reduced or increased proportions, or
 - iii) does not contain;

Health claim^{3,4}: any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

Health claims describe or refer to the following:

- a) the role of a nutrient or other substance in growth, development and the functions of the body, or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet,

Reduction of disease risk claim⁵: any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;

Child (Health) Claim⁶: a claim that states, suggests or implies that the consumption of a food category, a food, or one of its constituents is related to the development and health of children.

Food supplements⁷: foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

Nutrient⁸: protein, carbohydrate, fat, fiber, sodium, vitamins and minerals listed in the Annex to Directive 90/496/EEC, and substances which belong to or are components of one of those categories.

¹ Regulation (EC) 1924/2006, Article 2 (2)(1)

² Regulation (EC) 1924/2006, Article 2 (2)(4)

³ Regulation (EC) 1924/2006, Article 2 (2) (5)

⁴ Regulation (EC) 1924/2006, Article 13

⁵ Regulation (EC) 1924/2006, Article 2 (6)

⁶ Regulation (EC) 1924/2006, mix of Arts 2(2)(5) and 14(1)(b)

⁷ Directive 2002/46/EC, Article 2 (2)(b)

⁸ Regulation (EC) 1924/2006, Article 2 (2)(2)

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Other substance⁹: a substance other than a nutrient that has a nutritional or physiological effect.

Content / Ingredient claim¹⁰: A content claim is a statement of the ingredient(s) present, exclusively for identification of the product, without directly or indirectly suggesting a health or nutrition claim. Content claims can only be made for ingredients that do not have any approved health or nutrition claims, or if the conditions of use that apply to a health claim are not met. An example of permissible applications of a content claim are indications of the origin or quality of the ingredient. An indication of the ingredient's absorption, by contrast, is not permissible. This suggests at least a nutritional effect of the ingredient.

Definitions of terms in the context of the ClaimsREG

Scientifically proven: This can only be used in combination with a nutrition or health claim positively assessed by the European Food Safety Authority (EFSA) and approved by the EU Commission.

Healthy: This refers to health; it is a reference to a general, non-specific benefit and is permitted if it is accompanied by a specific health claim (in accordance with Article 10 (3) of the ClaimsREG)

Nutritious: this refers to the nutritional value of the food and is thus a nutrition claim. It must be clearly indicated why the product can be considered as such (for example, it is a source of multiple vitamins and/or minerals and these are mentioned).

Superfood: this term is too general to be assessed. It can refer to various properties of the food. It is too general to be construed as a nutritional or health effect. When clearly used in a nutritional context or in the context of a health effect, it must be followed by a specific, allowed health claim.

The use of claims in compliance with legislation

What sort of claims are they?

The ClaimsREG distinguishes four types of claims: nutrition claim, including comparative nutrition claims (ClaimsREG Articles 8 and 9), reduction of disease risk claims (ClaimsREG Articles 14 (1) a), claims connected with the development and health of children (ClaimsVO Articles 14 (1) b), and health claims that do not address reduction of disease risk and the development and health of children (ClaimsREG Article 13 (1)). These latter are also called "generic" health claims.

For whom is the claim intended?

The ClaimsREG stipulates that claims regarding foods must be understandable to the average consumer. The Court of Justice of the European Communities has developed as the criterion for the average consumer that in assessing a trade practice, the starting point must be the perception of the reasonably informed, cautious and observant consumer, with consideration also given to social and cultural factors¹¹. It further stipulates that where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. Claims that concern the development and health of children are named separately in the ClaimsREG. See also the passage on interfaces.

Which health relationships can I use?

⁹ Regulation (EC) 1924/2006, Article 2 (2)(3)

¹⁰ Own self-regulation definition

¹¹ Recitals Unfair Commercial Practices Directive 2005/29/EC

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The allowed (and rejected) health claims are (and will be) included in the EU Register for claims (see <http://ec.europa.eu/nuhclaims>). All other nutrition and health claims are prohibited, unless the final decision on the allowance or rejection of the claim is suspended. This applies to claims on the so-called "on hold list." There are also health claims that are not filed with the EFSA. These claims may no longer be used. For the record, it is noted here that claims other than nutrition and health ones will never be included because these are not regulated by the ClaimsREG.

The wording of the allowed nutrition and health claims does not have to be followed literally. Other terms are allowed, provided they have the same meaning for the consumer. Among other things, it is important that the terms be understandable to the consumer, reflect scientific proof established by the EFSA ("EFSA opinions") of a nutritional and/or physiological effect, and are not medical in nature in their phrasing.

For an approved nutrition or health claim, the function in the body of the nutrient, substance, food or food category concerned can be explained through the available communication channels so the consumer understands what is involved. This can be based on general knowledge and/or the EFSA opinion.

For example:

The health claim "Vitamin C contributes to normal collagen formation for the proper functioning of blood vessels" is an approved health claim. Most consumers will not know what collagen is, let alone what significance this has for the blood vessels. An advertiser or producer would then have to be able to explain what collagen is and what meaning it has for the blood vessels. For the record: the intention is not that the explanation be worded such that it is a medical claim, or that the explanation makes the claim's scope broader than what is approved by the European Commission! The explanation must provide a clarification of the function in the body without medical connotations.

What about the "on hold" claims?

The health claims put "on hold" by the European Commission cannot be considered to be authorised. These claims may still be used. They must meet the general requirements set out in the ClaimsVO and the user must be able to demonstrate that the claims used are plausible or state that they have been provisionally permitted. The former KOAG / KAG Guidelines apply to the separation of a health claim and a medical claim.

When is there a (prohibited) medical claim?

Regulation (EU) 1169/2011 contains a general prohibition of information in which a medicinal property is attributed to food (medical claims are used). Any assertion and/or statement that attributes properties to food relating to the prevention, treatment or cure of a human disease or alludes to such properties is not permitted. In this case, such information is not considered to be a health claim.

Subject to derogations stipulated in the Union legislation concerning natural mineral water and food intended for specific groups¹², the food information may not attribute any properties to

¹² Regulation (EU) No [609/2013](#) of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009

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foodstuffs concerning the occurrence, treatment or cure of a human disease or allude to such properties.¹³

Article 13, generic health claims, is about maintenance of good health. Maintaining good health includes caring, supporting, assisting, maintaining, protecting, etc. the normal operation of an organ or a bodily function.

Example: the claim "aids digestion" (*ter ondersteuning van de spijsvertering*) is a health claim. Digestion is a normal function of the body. Every healthy person has a digestive system. The claim by no means suggests that the (original) digestive system is "not good." By contrast, the claim "stimulates (too) slow digestion" (*ter bevordering van een (te) trage spijsvertering*) is not allowed as a health claim. (Too) slow digestion is not part of a normal physiological functioning of the body. It is an improvement of a person's physiological function and therefore "discolours" in the direction of a medical claim.

The assessment of whether it is a medical claim must also consider the overall context (including the image and layout) in addition to the wording. The context can "discolor" an authorised health claim to a prohibited medical claim. In the same way that depicting a doctor in a white coat can do so.

Can claims be used that allude to a deficiency?

If it is represented that there is a relationship between a deficiency of nutrient X and disease Y in the immune system, this suggests a relationship between nutrient X and the immune system. Nutrient X therefore supports the immune system. It may not be stated that nutrient X stimulates the (healthy) immune system. Of course, it also may not be claimed that nutrient X prevents or cures disease Y. It is not permitted to state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general (Article 3 (3) ClaimsREG).

May I make a general, non-specific health claim?

Under ClaimsREG¹⁴ it is allowed only to use claims that are authorised. The only exception to this is references to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being provided this is accompanied by a specific health claim that is authorized. Health claims that are rejected under Articles 13/14 because they are not specific enough also belong to the category "references (...)" if accompanied by a specific health claim that is authorized."

For example, the claim "This product is healthy!" (*dit product is gezond!*) must be combined with, for example, an authorized health claim on this product or a constituent of it, such as "good for the digestive system" (*goed voor de spijsvertering*) and this product must also meet the conditions of use for the claim. This "substantiation with a specific claim" should be made "in addition to/ alongside/next to" or "after" the general, non-specific benefits of the nutrient or food. For a different result we refer to the Commission Implementing Decision regarding the specific conditions for the use of health claims laid down in Article 10 of Reg. 1924/2006, dated 24 January 2013 ([2013/63/EU](#))

What conditions apply to the use of a claim?

Claims must meet a number of general conditions¹⁵. There must be a proven beneficial nutritional effect, there must be a sufficient or proper presence of the substance claimed, and this substance must be in a form that can be processed by the human body. The amount of the

¹³ Regulation (EU) No [1169/2011](#) of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

¹⁴ ClaimsREG Article 10 (3)

¹⁵ ClaimsREG Article 5 and Article 10 (2)

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particular product a consumer can reasonably consume (in the existing diet) must also be adequate. In addition, all allowed claims in the ClaimsREG have specific conditions under which these claims may be made. Most of these include the (minimum) amounts that must be present for the claim to be made. Conditions can also be imposed on restriction or use of the foodstuff and possible additional information or warnings that must be provided.

It can happen that the food matrix within which the nutrient is offered is of importance. If it is evident from the scientific substantiation established by the EFSA that the claimed health effect only appears in a particular food matrix, it would be misleading to also make these claims for other foodstuffs¹⁶. If this is the case, this must clearly be communicated in the claim's conditions for use.

The ClaimsREG has stipulated that so-called nutrient profiles will be established¹⁷. Once these profiles are in effect, in principle nutrient and health claims will only be allowed for foods that meet these nutrient profiles.

Furthermore, the ClaimsREG says the claim shall refer to a food that is ready for consumption in accordance with the manufacturer's instructions¹⁸. In most cases this involves products as sold. In some cases a food must be dissolved (e.g. lemon concentrate), or absorbs other substances during the preparation (such as water). In such cases, it is very important to consider the following points:

If the product must be dissolved in or mixed with water, the health claim must be applicable to the product after preparation.

If the product must be dissolved in or mixed with water in a product that itself also has a particular nutritional value (for example, crumbs in milk, warm snacks in frying oil) that can vary depending on the amount or type, it is recommended to make the claim applicable to the product as sold. After all, one cannot always know for certain whether the instructions for use are followed.

Do nutritional education and nutritional advice fall within the scope of the ClaimsREG?

This depends on how it is used. For example, if it is included in the commercial communication then it falls within the scope of the ClaimsREG. If it is used in non-commercial communication, it falls outside the scope of the ClaimsREG. Companies can refer to national campaigns, but when a link is thereby made between a product and health, it can be a health claim.

Must the conditions of use be followed literally?

The conditions of use must be complied with at all times. For example, if the dosage is less than indicated in the conditions of use, it cannot be stated that to achieve the health effect the remaining part is provided "additionally by a normal diet" or the like. The conditions of use and any additional information and/or warnings need not be adopted literally. The consumer must give it the same significance.

Must the conditions of use indicated in Article 10.2 also be applied to information channels other than labeling?

The conditions of use indicated in Article 10.2 are only applicable to the labelling, or if no such labelling exists, in the presentation and advertising:

How are illustrations, graphic images and symbols assessed?

All illustrations, graphic representations and symbols which state, suggest or imply that the food has particular beneficial properties must also comply with the ClaimsREG and be assessed

¹⁶ ClaimsREG, Article 5 (1) under c

¹⁷ ClaimsREG, Article 4

¹⁸ ClaimsREG, Article 5 (3)

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in connection with texts used¹⁹. The image of a heart in the proximity of nutrition claims on saturated fat and sodium implies a positive influence on cardiac health (and that is considered a health claim), and for this reason falls under the ClaimsREG. An image of a heart on a box of chocolates with a "for Valentine's Day" bow does not imply any health effect and does not fall under the ClaimsREG. A package of sugar-free chewing gum with an image of healthy, cavity-free teeth implies a health claim about oral health. An image of a mouth and teeth consuming something without being accompanied by a nutrition or health claim does not imply this by definition.

Where must I be careful when choosing a trade mark or brand / product name?

Any trade mark or brand name appearing in the labelling or presentation of a food or its advertising and which may be construed as a nutrition or health claim must comply with the provisions of the ClaimsREG²⁰. However, there is a long transition period: trademarks or brand names existing before 1 January 2005 which do not comply with the ClaimsREG may continue to be marketed until 19 January 2022.²¹

This transition period also applies to so-called generic names of products. These are traditional names of products that can imply something health-promoting or even medical but where everyone knows this is not actually the case. Known examples are Stophoest and Antaflu candies. The European Commission will develop a procedure so that an exception can be requested for such products²². One can submit an application for categories of products for which such properties apply (such as 'hoestbonbons'; *term used to describe cough sweets*)

How do claims fit into the context of a balanced, varied diet?

Claims may not discourage consumers from avoiding a balanced and varied diet. It may not be stated, suggested or implied that a balanced, varied diet generally cannot provide sufficient amounts of nutrients, or that a food is the only source of a particular nutrient, or that it is hard to obtain an adequate intake given a balanced, varied diet²³. Consumers must be made aware that consuming a specific food must be part of a varied, balanced diet and that must not be eaten too much or such as to conflict with good eating habits. It must be made clear to the consumer that eating the food to which the health claim relates is only one aspect of a healthy lifestyle in the context of a varied, balanced diet.

Claims may also not give rise to doubt about the safety and / or the nutritional adequacy of other foods²⁴.

On the other hand, claims also may not be made that encourage the consumer to excess consumption of a food or condone its excessive consumption²⁵.

What type of health claims may not be made?

The following claims are not allowed²⁶:

- a) claims which suggest that health could be affected by not consuming the food;
 - b) claims which make reference to the rate or amount of weight loss. Statements indicating that a number of kilos can be lost in a certain amount of time are
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¹⁹ ClaimsREG Article 2 (2) (2)

²⁰ ClaimsREG Article 1 (3)

²¹ ClaimsREG Article 28 (2)

²² COMMISSION REGULATION (EU) No [907/2013](#) of 20 September 2013 setting the rules for applications concerning the use of generic descriptors (denominations)

²³ ClaimsREG Article 3 (d)

²⁴ ClaimsREG, Article 3 (b)

²⁵ ClaimsREG, Article 3 (c)

²⁶ ClaimsREG Article 12 (a) – (b)

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therefore prohibited. This also covers showing degree of weight loss with a "before and after" situation.

Health professionals

Can reference be made to recommendations of doctors or other health professionals?

Claims which make reference to recommendations of individual doctors or health professionals in the public health field are not permitted²⁷. A health professional in the public health field means all persons whose occupation is primarily to advise on prevention and treatment of illnesses and health-related matters. This does not include, for example, lifestyle coaches.

The ClaimsREG makes an exception for recommendations or approvals by national associations of health workers, nutrition experts or dietitians and charitable organizations in the public health field²⁸. This also involves international associations and charitable organizations known nationally (in the Netherlands). For example, the WHO (World Health Organisation). When using, for example, logos of parties identified in Article 11 that suggest an effect, this must be substantiated with an approved health claim.

Does communication to and from a doctor or health professional in the public health field also fall under the ClaimsREG?

Commercial communication regarding, for example, the health benefits of a food directed to a doctor or health professional in the public health field does also fall under the ClaimsREG²⁹. Non-commercial communication does not fall under the ClaimsREG.

Interface claims. When are we speaking of a so-called child claim and when of a generic (Article 13.1 ClaimsREG) claim for a product that is also consumed by children?

Child claims are claims connected with the development and health of children³⁰. Generic health claims (Article 13) that occur on foods and food supplements intended to also be consumed by children are not automatically child claims.

The following claims must be seen as child claims:

- Health claims that refer exclusively to the development and health of children and where the scientific substantiation is valid only for children, meaning they consist of data obtained in studies with children.
- Health claims used on products intended exclusively for children (provided for in legislation) such as follow-on formulae and baby foods as defined in Regulation (EU) No 609/2013.

Article 13 Health Claims are claims that refer to the role of a nutrient or other substance in the growth, development and functioning of the body where the scientific substantiation includes all ages or more than just the target group of children.

Part II of the guideline document

Interpretation questions related to the use of terms other than the official ones in the EU list.

[List with sample / example wording for health claims](#)

²⁷ ClaimsREG, Article 12 (c)

²⁸ ClaimsREG, Article 11

²⁹ See judgment of the Court (Third Chamber) 14 July 2016, case [C-19/15](#)

³⁰ Article 14 (1) (b)

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The so-called '[Health Claims Database](#)'³¹ accompanying this guideline document includes examples of alternative wording of claims. This "indicative list of sample/ example wording" was produced in close consultation with the NVWA. This list can serve as a source of ideas for companies wishing to use wording other than that given in the official list with claims. Claims may never be false, ambiguous or misleading³².

The formal (including in the regulation) wording (as presented and included in the register by the EFSA) does not always use terms equally clear to the consumer. For example: "Biotin contributes to the normal psychological function" (*biotine draagt bij aan de normale psychologische functie*). In practice, the need for "psychological function" must be defined more precisely. The production of the list with sample wording was guided by the associated EFSA opinion to define the scope of the claim. There are frequently indications in paragraph 2 on the scope of the claim. It describes "the perspective" from which the EFSA assessed the submitted claim(s). The scientific proof then follows in paragraph 3. This is how the alternative sample/ example wording came about.

Can other elements from the EFSA opinion be adopted than those contained in the formal list with permitted health claims?

If in the sample claim there is something different than in the EFSA opinion used as the basis, this must be reported. Of course, it must be worded to comply with all (other) requirements imposed by the ClaimsREG. Whether this can also be applied for other nutrients with the same sample claim depends on the underlying specific EFSA opinion for the sample claim. The information desired can be found in chapters 2 and 3 of each individual EFSA opinion.

Although medical terms or deficiency illnesses can be named in an EFSA opinion, these cannot appear in the claim wording unless mention is made of this in the official wording in the law.

Can the claim be generalised?

If the claim relationship is established for the effect of a specific fatty acid, it cannot be generalized to attributing this effect to the entire fatty acid family. This depends greatly on how these are described in the EFSA opinion.

In the database with sample wording, the EFSA opinions can also be found via links to the EFSA site. It can be helpful to consult these opinions. It must be kept in mind that these opinions have no legal status. The opinion can indeed be used as substantiation for the positive assessment of terms. Only the lists of approved health claims published in the EU Official Journal, with the specific conditions for their use, have the force of law.

Is there a relationship with the "old" Keuringsraad KAG indicative list of health claims?

In the past, the Keuringsraad always dealt with the interface between health and medical claims. For this, the Keuringsraad was responsible for the indicative CAG list³³ health claims. In principle, this interface does not change with the arrival of the ClaimsREG. The main difference between the indicative CAG list and the new list with sample wording is that the latter is linked to a nutrient /other substance/ food, which often describes the health relationship in a very specific and concrete way, and is based on a scientific substantiation by the EFSA.

The new list with sample wording for health claims replaces the CAG list, it being understood that all parties to which the ClaimsREG apply can look to the list for ideas. It is certainly not an exhaustive list with permitted wording. The list is coordinated with the Ministry of Health, Welfare and Sports and the Netherlands Food and Consumer Product Safety Authority (NVWA).

³¹ <https://www.koagkag.nl/database-claimsverordening-en-indicatieve-lijst/database>

³² ClaimsREG, Article 3 (a)

³³ See <http://www.koagkag.nl/Indicatieve-lijst>

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Application of health claim list sample wording

A so-called synonyms table has been produced with, if relevant, conditions under which synonyms can be used. See also the table in the attachment to the guideline

"After eating" effect (*Effect 'na het eten'*)

If the official EFSA wording says a nutrient or food has a certain effect after eating (after a meal), this "after eating" must be explicitly included in the claim wording on the packaging as this aspect and clearly indicated in the conditions of use.

A distinction must be made between the statements "after eating" in the claim's formal wording and "after eating" in the conditions of use. The latter must always be made clear. Apart from that, the content of the EFSA opinion (H.3) must be examined. For some effects, such as those on blood sugar increase, it is clear enough to the consumer that these always occur after eating (meals, candy, etc.).

Use of the term, "probiotics"

With probiotics you can indicate on the label the mandatory category of the micronutrients or substances that characterize the food supplement.

When used in a different way, it is a health claim in itself. At present there are no approved health claims for probiotics.

If the term probiotics is part of a trade mark or brand name that already existed before 1 January 2005, then products can be put on the market through 19 January 2022.

Excessive / too much use

If the term "excessive" (*excessief*) or "too much" (*overmatig*) is used in the sample claim, this could be omitted in the final wording/ phrasing.

Can a relationship approved by the EU be weakened?

The basic idea is that everything must have the same meaning for the consumer and that the consumer may not be misled. In this context, in most cases it does not seem problematic to weaken a relationship. For example, "is necessary for" (*is nodig voor*) can be replaced by "makes a contribution to" (*levert een bijdrage aan*). The opposite, the strengthening of the approved relationship, in this same context is less obvious. It is then the total statement that determines whether it still has the same meaning.

Can one say that a nutrient is necessary for a certain effect?

Only if it is included in the approved sample claim that a nutrient or food is necessary for something can this word also be used in the actual statement. Otherwise it could be assumed that a normal and varied diet would be inadequate for good health. In this case, this conflicts with Article 3 (d) ClaimsREG.

How should the list be read?

[The 'Health Claims Database' offers two search possibilities and also in the field of application \(category\)](#)

For each claim, the associated/ corresponding EFSA Journal is added as a hyperlink. By clicking on the hyperlink, the EFSA Journal is automatically opened as a PDF file. In paragraph 3 of the EFA Journal, the EFSA foundations can usually be found. These can be consulted if there is doubt about whether or not a sample wording can be used based on what the EFSA has established.

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For each claim, except for reduction of disease risk claims, alternative example terms/ wordings are included that have the same effect as the authorized one in European law.

Scope / Demarcation of Child Claims

An example has been worked out below to clarify the demarcation. It is assumed that the conditions of use (the quantity of the substance on which the claim is made) are met.

It relates to a foodstuff (for example, a yogurt drink) where the manufacturer wants to use a health claim about phosphorus in relation to the bones.

A so-called article 13.1 health claim is permitted.

The official example wording is: "Phosphorus contributes to the maintenance of normal bones" (*Fosfor draagt bij tot de instandhouding van normale botten*) (search 'fosfor' – under 'botten – instandhouding / bone – upkeep/ conservation' in Claims Database).

If the product in question is simply positioned as a snack (good for in between meals - *lekker voor tussendoor*), a child claim is not immediately obvious. A wording can then be formulated using this guideline document (inter alia using the synonym list) or one selection from the article 13 (Health Claims database) list with example wording.

A so-called article 14 (1b) (child claim) has also been approved on phosphorus and bone. This means that a claim is allowed on phosphorus in relation to growth and development of the child (on Claims Database – search 'Botten (kinderclaim)' and click on 'fosfor').

The official wording of this health claim is: "Phosphorus is necessary for normal growth and development of the bones of children" (*Fosfor is nodig voor de normale groei en ontwikkeling van de botten van kinderen*).

In the authorization of this claim no age rating is specified. This implies that it can be used for products that are positioned as children's products, but no further requirements are set for the age rating/ category. Note: if in the application (in case the claim has not yet been approved/ authorised but is still under consideration) or in the authorisation when an age rating is indicated (for example, infants up to 12 months or children aged 3-12 years), then this age rating/ limit must be indicated either in the claim itself or separately but in the same field of vision as the child claim! Child claims that have already been approved/ authorized (via a Regulation issued for that purpose) do not contain an age rating most of the time. If an age rating does apply, it is usually included within the so-called conditions of use. Although the term children is not defined in the ClaimsREG, in the context of the use of child claims, it means the age up to the end of the growing-up period (which is indicatively set at 18 years).

Simultaneous use of health claims within the same scope/ application area

It is possible, where applicable, to use both the Article 13.1 variant and the Article 14 paragraph 1 sub b variant within the same scope, on a food, if there is an approved 13.1 and 14.1.b health claim. Particularly for products intended for both adults and children, this is a real possibility.

Specific supplementary labelling requirement when using child claims on products regulated in the Delegated Regulation (EU) 2016/127³⁴ (e.g. follow-on formulae) and Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children.

Characteristic of these products is that there are composition requirements for certain nutrients, including vitamins and minerals. As a result, the making of a child claim about one or more of the nutrients of which the presence and quantity are prescribed suggests that similar products

³⁴ Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 (PbEU 2016, L 25) on infant formulas and follow-on formulas

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do not contain these substances and therefore do not result in the health-promoting effect. However, the comparable products must also meet these legal requirements.

Therefore, if a health claim is made about the effect of a substance that is prescribed by law, it must be additionally stated that similar products also contain this nutrient or that the presence of that nutrient is legally prescribed in follow-on formulas, processed cereal products and / or baby food. This additional statement must be affixed in such a way that the previous entry does not have a promotional effect. It is recommended to do this in the same font, font size and in the same field of vision as the text of the health claim as such. However, it is possible to make this statement "not promotional" in another way.

[APPENDIX I](#) – Synonyms Table

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