

# **Nutrition and Health Claim Guide**

for food supervisors and food business operators





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Product Safety

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## 1 INTRODUCTION

Nutrition and health claims made in foodstuffs labelling, presentation or advertising are regulated by Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods (hereinafter referred to as "Regulation"), which has been applied since 1 July 2007.

The goal of this Evira guide is to facilitate and harmonise application of the Regulation in Finland. The guide is intended for use by both government Supervisory authorities and industry operators.

Government functions should be founded on statutory authority and closely observe the law. The legal aspects of official guidelines are not applicable to other authorities or actors. Ultimately, issues pertaining to the application of laws are determined by a court of law.

This guide contains both direct citations from legislation and interpretations regarding the application of laws. Legislation is clearly distinguished from other legal passages mentioned in this guide. The legal interpretations presented in this guide are views held by Evira regarding how legislation should be applied.

### 1.1 Legislation

Legislation and guidelines regulating nutrition and health claims presented on foodstuffs:

- Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods (hereinafter referred to as " Regulation" )
- Commission Regulation (EU) No. 116/2010, amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims
- up-to-date list of authorised and rejected health claims and Commission Regulations governing them  
[http://ec.europa.eu/food/food/labellingnutrition/claims/community\\_register/health\\_claims\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/health_claims_en.htm)

and

- Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (hereinafter referred to as " general food regulation" )
- Food Act 23/2006
- Decree of the Ministry of Trade and Industry on the Labelling of Foodstuffs (1084/2004) (hereinafter referred to as " labelling decree" )
- Decree of the Ministry of Agriculture and Forestry on Nutrition Labelling for Foodstuffs (588/2009) (hereinafter referred to as " nutrition labelling decree" )
- Decree of the Ministry of Agriculture and Forestry on Food Supplements (78/2010)

- Ministry of Agriculture and Forestry Decree on Foods for Special Dietary Uses (121/2010)
- The European Commission is currently drafting a regulation, which will regulate information on foodstuffs to be provided to consumers, such as package and nutrition labelling (hereinafter referred to as "consumer information regulation" ) (Labelling Directive 2000/13/EC and Nutrition Labelling Directive 90/496/EEC (amended))
- Commission`s Guidance on the implementation of Regulation N° 1924/2006 on nutrition and health claims made on food  
[http://ec.europa.eu/food/food/labellingnutrition/claims/guidance\\_claim\\_14-12-07.pdf](http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf)

## 1.2 Nutrition and health claims

The Regulation regulates nutrition and health claims used in food labelling, presentation and advertising. A claim is any non-mandatory message or representation which states or implies that a given food possesses certain characteristics. In addition to written messages, a claim may also be a picture, symbol or graphical representation. Food trademarks, product names or fictive names also fall within the purview of the Regulation.

A nutrition claim is any claim that deals with the beneficial nutritional content of a given food, such as "Contains calcium".

A health claim is any claim that addresses a link between a given food and its impact on health, such as "Calcium is essential to the normal growth and development of children's bones". Health claims are divided into the following types: functional claims; reduction of disease risk claims; and claims referring to children`s development and health.

The difference between nutrition and health claims is described in Table 1. The Regulation specifies the requirements, according to which nutrition and health claims may be linked to a given product, thus establishing common rules and authorisation protocols for the use of claims in all EU member states.

Claims that fall within the purview of the Regulation comprehend all claims made in commercial communications that involve the beneficial properties of foodstuffs and that are used in the labelling, presentation or advertising of foodstuffs intended for the final consumer. The Regulation is only applied in cases involving commercial communications, not, for example, dietary guidelines or advice issued by public health authorities or bodies, or non-commercial communications and information in the press and in scientific publications.

Evira has published Guideline 17014/1 - Use of recommendations of or endorsements made by national associations of medical, nutrition or dietetic professionals and health-related charities in the labelling and marketing of foods (in Finnish).  
[http://www.evira.fi/attachments/elintarvikkeet/valvonta\\_ja\\_yrittajat/terveysvaitteet/eviran\\_ohje\\_vaiteasetuksen\\_art\\_11\\_soveltamisesta\\_17014\\_1.pdf](http://www.evira.fi/attachments/elintarvikkeet/valvonta_ja_yrittajat/terveysvaitteet/eviran_ohje_vaiteasetuksen_art_11_soveltamisesta_17014_1.pdf)

Table 1. The Regulation specifies authorised nutrition and health claims and the conditions of their use. Health claims are divided into different types, as specified in Articles 13 and 14.

<b><u>Nutrition claims</u></b>	<b><u>Health claims</u></b>	
Claims describing the beneficial nutritional properties of foodstuffs	Claims that suggest that a relationship exists between a food category, a food or one of its constituents and health	
Only nutritional claims listed in the regulation are authorised	Article 13 = functional claims	Article 14
The energy (calorific value) that it: <ul style="list-style-type: none"> <li>• provides</li> <li>• provides at a reduced or increased rate, or</li> <li>• does not provide</li> </ul>	(1)(a) Claims related to growth, development and functions of the body	(1)(a) Reduction of disease risk claims
The nutrient or other substance it: <ul style="list-style-type: none"> <li>• contains</li> <li>• contains in reduced or increased proportions</li> <li>• does not contain</li> </ul>	(1)(b) Claims related to psychological and behavioural functions	(1)(b) Claims referring to children's development and health
	(1)(c) Claims related to slimming, weight-control, etc.	
	(5) Claims based on newly developed scientific evidence or in cases where proprietary data is to be protected	

## 2 NUTRITION CLAIMS

Authorised nutrition claims are listed in the Regulation annex and its amendments. The European Commission website maintains an up-to-date list of nutrition claims: [http://ec.europa.eu/food/food/labellingnutrition/claims/community\\_register/nutrition\\_claims\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/nutrition_claims_en.htm)

Nutrition claims which presumably have the same meaning for consumers as those found in the regulation annexes should be subject to the same conditions of use. Annex 1 of this guideline contains a list of currently authorised nutrition claims, the applicable conditions and examples of equivalent wording used by Evira. If an operator uses these wordings, they must ensure that they have the same meaning for consumers.

### 2.1 Quantity of nutrients

The Regulation annex contains authorised nutrition claims and conditions applying to them. The specification for nutrition claims states how much a given nutrient must be found in a given food in order for use of the nutrition claim to be authorised. These limits are also specified in Annex 1 of this guideline.

For example, a food can be referred to as a source of fibre, provided that the product contains at least 3 g/100 g or 1.5 g/100 kcal of dietary fibre. Correspondingly, a food can be referred to as high fibre, provided that the product contains at least 6 g/100 g or 3 g/100 kcal of dietary fibre.

A condition for using some nutrition claims is that the nutrient in question must provide a certain percentage of the total energy (calorific value) of the product. For example, the condition for using the claim "source of protein" is that at least 12% of the energy value of the food is provided by protein. This is calculated by dividing the amount of energy provided by protein with the total energy of the product.

Example: A 100 g product contains 3 g of protein and 100 kcal of energy. The energy provided by protein is  $3 \text{ g} \times 4 \text{ kcal/g} = 12 \text{ kcal}$ . This portion of the total energy is  $12 \text{ kcal} / 100 \text{ kcal} = 12\%$ . Thus, the product contains the required amount of protein to use "source of protein" claim.

The energy provided by fat is calculated similarly, but in this case it must be kept in mind that one gram of fat provides 9 kcal of energy.

## 2.2 Vitamins and minerals

In accordance with the Regulation, a food may be referred to as a source of vitamins or minerals, provided that the product contains at least a significant amount of the vitamin or mineral in question as defined in Directive 90/496/EEC. Directive 90/496/EEC is amended by Commission Directive 2008/100/EC and Regulation (EC) No 1137/2008 of the European Parliament and of the Council. At the national level, these have been enforced with the nutrition labelling decree (588/2009).

The product must contain 15% of the recommended daily allowance as defined in the nutrition labelling decree in order for the product to be considered as containing a significant amount of the nutrient in question and allowing it to be labelled as a "source of" the nutrient in question. Correspondingly, the claim "high in vitamins and/or minerals" can be used, provided that the product contains 30% of the recommended daily allowance of the nutrient in question as defined in the nutrition labelling decree annex.

The recommended daily allowance of the nutrient should come from a 100 gram, 100 ml or single serving package. Table 2 lists the recommended daily allowances compliant with the nutrition labelling decree and the limit values for use of the claims "source of" and "high in".

The Commission expert working group on nutrition and health claims has proposed that the criteria for use of the claim "source of vitamins and/or minerals" be changed in connection with the drafting of the consumer information regulation. The conditions will probably be revised in such a way that the requirement for using the claims in question for liquid foodstuffs (excluding vegetable oils and similar products) would be 7.5% of the recommended daily allowance in a 100 ml serving.

It is for this reason that Evira feels that daily intake quantities could be taken into account where liquid products are concerned. Liquid foodstuffs primarily consumed in large, daily servings, can apply the 7.5% recommended daily allowance/100 ml as a requirement for using the claim "source of vitamins and/or minerals".

Table 2. The recommended daily allowances compliant with the nutrition labelling decree (588/2009) and the limit values for use of the claims "source of" and "high in". The recommended daily allowance of the nutrient should come from a 100 gram, 100 ml or single serving package. The quantities of vitamins and minerals shown in the table must be listed in nutrition labelling.

	<b>Recommended daily allowance</b>	<b>Source of (15 %)</b>	<b>High in (30%)</b>
Vitamin A (µg)	800	120	240
Vitamin D (µg)	5	0.75	1.5
Vitamin E (mg)	12	1.8	3.6
Vitamin K (µg)	75	11.25	22.5
Vitamin C (mg)	80	12	24
Thiamine (mg)	1.1	0.165	0.33
Riboflavin (mg)	1.4	0.21	0.42
Niacin (mg)	16	2.4	4.8
Vitamin B6 (mg)	1.4	0.21	0.42
Folic acid (µg)	200	30	60
Vitamin B12 (µg)	2.5	0.375	0.75
Biotin (µg)	50	7.5	15
Pantothenic acid (mg)	6	0.9	1.8
Potassium (mg)	2000	300	600
Chloride (mg)	800	120	240
Calcium (mg)	800	120	240
Phosphorous (mg)	700	105	210
Magnesium (mg)	375	56.25	112.5
Iron (mg)	14	2.1	4.2
Zinc (mg)	10	1.5	3
Copper (mg)	1	0.15	0.3
Manganese (mg)	2	0.3	0.6
Fluoride (mg)	3.5	0.525	1.05
Selenium (µg)	55	8.25	16.5
Chromium (µg)	40	6	12
Molybdenum (µg)	50	7.5	15
Iodine (µg)	150	22.5	45

### 2.3 Nutrients and other substances

The nutrition claim "contains nutrients or other substances" can also be used for vitamins and minerals other than those listed in Table 2. Although there are no clearly defined limit values set for the conditions of use concerning the nutrients in question, the conditions specified in the Regulation must be met.

The operator is responsible for demonstrating that the Regulation requirements have been met, i.e. the substance in question has a proven beneficial nutritional or physiological effect and there is a significant quantity of said substance in the product. In Evira's view, this should be part of the operator's self-monitoring function. A scientifically proven beneficial effect can be based on, for example, statements issued by the EFSA.

## 2.4 Rejected nutrition claims

Nutrition claims that are not authorised in accordance with the Regulation and that may not be used include the following:

- cholesterol-free, low-cholesterol
- does not contain trans fatty acids, 0% trans fats
- super-light, ultralight
- "equal to" comparisons
- low-carbohydrate

## 2.5 Claims which are not considered nutrition claims

Information on the quality or quantity of a nutrient, which is required elsewhere in legislation, is not considered a nutrition claim.

Furthermore, the listing of ingredients used or not used in the manufacture of the food item or that describe the ingredient properties, are not deemed nutrition claims:

- with added sugar (N.B. conversely, "sugar-free", "no added sugars" and "without added sugar" are considered to be nutrition claims)
- unsweetened
- sweetened with Xylitol/fructose
- no fats used in manufacture
- does not contain any milk components
- milk-free
- additive-free
- preservative-free

"Lactose-free", "low-lactose", "gluten-free" and "very low gluten" are not nutrition claims, but rather are regulated by legislation concerning foods for particular nutritional uses.

## 2.6 Misleading claims

The Commission has published guidance on the implementation of the Regulation.

It states that emphasising properties that have no bearing on the total intake of the nutrient in question is considered misleading. For example, use of the claim "reduced fat" in bread, which is already in and of itself low in fat, would be misleading, because reducing the amount of fat contained therein would have no essential impact on the total intake of fat. It is for the same reason that the "added" claim can only be used for products which meet the requirements for use of the "source of" claim.

## 3 HEALTH CLAIMS

### 3.1 Health claim authorisation system

The basis for use of health claims is that the scientific evidence that supports the claims must be authorised in advance, prior to their actual use.

The European Food Safety Authority (EFSA) assesses the scientific evidence of health claims and the wording of claims. A statement issued by the EFSA is not yet a health claim decision. After deliberations between the Commission and EU member states, the claim is either authorised or rejected by a Commission decree. Evira serves as the national Finnish authority for submitting claim applications to the EFSA for assessment.

A list of authorised claims compliant with Article 13(3) of the Regulation will be published in early 2012. After this, only claims on the list of authorised claims may be used in the marketing and labelling of foodstuffs. Rejected claims are given a six-month transition period, during which the claims in question must be removed from labelling, advertising, presentations, websites and any other materials.

Health claims compliant with Article 13(1) whose assessment process is still under-way may be used until a decision concerning them has been rendered by the Commission. This applies primarily to health claims on the Commission "grey list" as well as certain botanicals.

The grey list is a list of health claims, whose constituent microorganisms have not been adequately characterised. The list also contains a few nutrients or constituents, whose submitted research evidence was not considered adequate enough for the EFSA to issue its final statement. Health claims for which additional data was submitted in the autumn of 2011 in accordance with Commission guidelines may be used until such time as the claims are added to the authorised or rejected list. Conversely, health claims on the grey list for which no additional data has been submitted are automatically added to the rejected claims list.

The assessment of health claims related to botanicals and, on the other hand, different criteria used in the classification of traditional herbal medicines has been criticised. It is for this reason that the Commission has announced that the authorisation of health claims for botanicals shall be audited as a separate entity, apart from other health claims.

### 3.2 Authorised health claims

The use of health claims in labelling, advertising or other presentations requires that the claims be authorised and included on the list of authorised claims as specified in Articles 13 and 14 of the Regulation.

Health claims compliant with Article 13(1) of the Regulation and still under consideration by the EFSA may be used at the discretion of the operator until such time as an official Commission decree concerning the claim in question has been issued. However, claims must be compliant with the Regulation and applicable national regulations. Products should have all labelling required by the Regulation and the conditions of use set for the claim must be met by the food item in question.

Health claims compliant with Article 13(1) still under consideration can be viewed on the EFSA register at:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ND&foodsectorarea=26>

### 3.3 Rejected health claims

According to Article 12 of the Regulation, the following health claims are considered rejected:

- claims which suggest that health could be affected by not consuming the food
- claims which make reference to the rate or amount of weight loss  
Evira also considers references to, for example, a reduction in waist size or clothing size to be prohibited.
- claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11.

The Commission expert working group has outlined a policy, wherein the decision on who is considered a health professional must be made on a case-by-case basis. The decision is based largely on the impression made and message content.

For example, the following can be considered rejected health claims:

- a health professional talks about how a food item affects the health or about their own experiences
- a health care student talks about how a food item affects the health or about their own experiences
- actors portraying health professionals talk about how a food item affects the health or about their experiences

According to Article 6 of the Regulation, claims made concerning foodstuffs must be based on generally accepted scientific evidence. Marketing the user experience of an individual consumer can be seen as misleading, because an individual experience cannot be considered as meeting the legal requirements for presenting health claims. Individual consumer experiences may not even make reference to intended medical uses or make other claims rejected in the Regulation.

### 3.4 Health claim applications

A food business operator must submit a health claim application, if they want to use a health claim not found on the list of authorised claims. The claim may not be used until it has been authorised by Commission decree.

Additional information on claim applications can be found at the following addresses:

- Evira website:  
[http://www.evira.fi/portal/en/food/manufacture\\_and\\_sales/labelling/nutrition\\_and\\_health\\_claims/health\\_claim\\_applications/](http://www.evira.fi/portal/en/food/manufacture_and_sales/labelling/nutrition_and_health_claims/health_claim_applications/)
- EFSA website:  
<http://www.efsa.europa.eu/en/ndaclaims/ndaguidelines.htm>

In accordance with the procedure specified in Article 18 of the Regulation, the following additions to the list of health claims specified in Article 13 are made:

- claims based on newly developed scientific evidence
- claims for which protection of proprietary data is being sought

In accordance with the procedure specified in Articles 15, 16, 17 and 19 of the Regulation, health claims referred to in Article 14 are approved based on an application submitted:

- reduction of disease risk (= risk factor) claims
- claims referring to children's development and health

An up-to-date list of authorised and rejected health claims can be found on the Commission website at:

[http://ec.europa.eu/food/food/labellingnutrition/claims/community\\_register/health\\_claims\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/health_claims_en.htm)

## 4 PRINCIPLES FOR THE USE OF CLAIMS

According to Section 9 of the Food Act, "In food packaging, presentation and advertising, or in some other way in connection with marketing... information given about food must be truthful and it must be sufficient..." "...information given about food must not be misleading;"

"...food must not be presented as having properties related to prevention, treatment or curing of human diseases or refer to such information, unless otherwise provided elsewhere in the law."

Regarding the use of nutrition and health claims, attention should be given to the following points, which are also taken into consideration in the oversight of claims:

- Only authorised nutrition claims may be used.
- Only authorised health claims or health claims subject to transition period measures may be used. These include health claims compliant with Article 13(1) that are under consideration as well as rejected health claims given a 6-month transition period.
- The conditions of claim use must be met.
- Nutrition labelling must be in order.
- The general principles of using claims must be met.
- Health claims must include the required additional labelling.
- Additional labelling specified in Article 14 must be included with claims concerning the reduction of disease risk factors.
- Ensuring the accuracy of nutrition and health claims used must be a part of self-monitoring.

Annex 2 depicts a decision tree, which is intended as an aid in checking the correct use of claims.

### 4.1 Labelling

General labelling regulations apply to all foodstuffs and comprehend the most common labelling used on food packaging. Evira has published a labelling guide, which can be downloaded from the Evira website at:

<http://www.evira.fi/portal/fi/evira/julkaisut/?a=view&productId=114>. (in Finnish)

As stipulated in the labelling decree, mandatory labelling must be done in Finnish and Swedish, Norwegian or Danish labelling can be used in place of Swedish. In accordance with the nutrition labelling decree, nutrition labelling is mandatory when a nutri-

tion or health claim has been made about the food item. Even if the claim is made on something other than the product packaging, such as on the Internet or in print advertising, nutrition labelling is still required on the packaging.

Evira states that nutrition labelling must always be done in Finnish and Swedish when a nutrition or health claim has been made. Also in cases where the nutrition or health claim is made on a product in a language other than Finnish, nutrition labelling is mandatory and must be done in Finnish and Swedish. All information provided on the food item, regardless of the language used, must be accurate and must not be misleading.

## 4.2. Nutrition labelling

Use of nutrition and health claims always requires nutrition labelling. Information on nutritional value should be listed using either short or long-form labelling. Nutrition labelling is regulated by the nutrition labelling decree. Evira has published a nutrition labelling guide, which can be downloaded from the Evira website at: <http://www.evira.fi/portal/fi/evira/julkaisut/?a=view&productId=112> (in Finnish)

### Short-form nutrition labelling

If the nutrition claim presented concerns energy content, protein, carbohydrates or fats, short-form nutrition labelling will suffice. If the nutrition claim concerns vitamins or minerals listed in the applicable nutrition labelling decree annex, the nutrient(s) in question can be presented as part of short-form labelling.

Example of short-form nutrition labelling:

A 100 gram serving of rye bread contains:

- 930 kJ (220 kcal) of energy
- 7.9 grams of protein
- 43 grams of carbohydrates
- 1.8 grams of fat

### Long-form nutrition labelling

Long-form nutrition labelling should be used if the nutrition claim concerns sugars, saturated fatty acids, dietary fibre or sodium. Long-form nutrition labelling should always be used when making a health claim.

Example of long-form nutrition labelling:

100 grams of high-fibre rye bread contains:

- 780 kJ (185 kcal) of energy
- 7.9 grams of protein
- 35 grams of carbohydrates
  - 1.4 grams of which are sugars
- 1.5 grams of fat
  - 0.2 grams of which are saturated fatty acids
- 7.9 grams of dietary fibre
- 0.29 grams of sodium

If the nutrition claim concerns a substance not mentioned in the nutrition labelling in accordance with the nutrition labelling decree, its amount must be specified in the

same field with other nutritional content information. The decision to use short or long-form labelling is made according to the above-mentioned regulations.

### **Food supplements**

The nutrition labelling decree does not apply to the presentation of nutritional content information for foodstuffs that fall within the purview of legislation on food supplements. Instead, the quantity of characteristic substances in food supplement must be presented in accordance with the food supplement decree. Neither short nor long-form labelling is done for food supplements, even if a nutrition or health claim has been made concerning them. However, if a nutrition or health claim has been made for a food supplement, the quantity of the substance that is the subject of the claim must be presented.

### **4.3. Additional labelling required for health claims**

When using health claims, additional labelling must be included with the mandatory labelling. According to Article 10(2) of the Regulation: "Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:

- a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
- b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
- c) where appropriate, a statement addressed to persons who should avoid using the food; and
- d) an appropriate warning for products that are likely to present a health risk if consumed to excess."

According to Article 14(2): "...for reduction of disease risk claims the labelling or, if no such labelling exists, the presentation or advertising shall also bear a statement indicating that...:

- the disease to which the claim is referring has multiple risk factors and...
- ...altering one of these risk factors may or may not have a beneficial effect."

Article 10(3) of the Regulation states that: "Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14."

In Evira's view, claims such as "heart-friendly", "good for your stomach", "superfood" and "health chocolate" are generic and unspecific in nature. These types of claims must be accompanied by an authorised health claim that indicates the specific effect they have on health or a health claim subject to transition period measures.

Annex 3 contains descriptions and examples of additional labelling requirements resulting from various claims made.

### **4.4 General principles for the use of claims**

In addition to packaging intended for the final consumer, the Regulation is applied to product marketing and advertising in all its forms, for example, print products, on the Internet, in electronic form, on the radio and TV, and in product presentations. In or-

der to use nutrition or health claims in the labelling, presentation or advertising of foodstuffs, the claim and food in question must meet applicable principles and requirements, particularly those specified in Articles 3 and 5 of the Regulation.

The Regulation is also applied in situations where the consumer associates a claim made with a certain product, even if the product is not directly stated as having the claimed property. As a result, even the perceived image of a product must be in accordance with the Regulation, particularly Article 3.

For example, if the online marketing of omega-3 fatty acid products cites scientific articles on omega-3 fatty acids, this is considered a health claim. Correspondingly, if an online website marketing food talks about an ingredient used in a food item—in this case, the conventional use of omega-3 fatty acids in folk remedies—this is considered a health claim or rejected medicinal claim, depending on the actual claim made.

### **General principles concerning claims – Article 3**

"The use of nutrition and health claims shall not:

- a) be false, ambiguous or misleading;
- b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;
- c) encourage or condone excess consumption of a food;
- d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general...
- e) refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations."

In Evira's view, it is forbidden to state, for example, in the marketing of products containing vitamin D, that ordinary Finnish food does not contain a sufficient amount of vitamin D, thus instilling a feeling of fear in consumers by describing illnesses resulting from a vitamin D deficiency.

### **General conditions, Article 5**

The general conditions for the use of claims are specified in Article 5. In brief, the substance that is the subject of the claim should have a proven beneficial effect and there should be a sufficient amount of said substance present in the product.

"The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:

- a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;
- b) the nutrient or other substance for which the claim is made:
  - i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or
  - ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;
- c) where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;

- d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;"

Authorised nutrition and health claims meet these conditions, provided that the conditions of claim use are observed.

The nutrition claim "contains nutrients or other substances" does not specify the conditions of use for the substance that is the subject of the claim. Particularly where these nutrition claims are concerned, the operator should ensure that the general conditions specified in Article 5 are met.

## 5 RESPONSIBILITIES

### 5.1 Food business operators

According to the general food regulation: "Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met." A food business operator must ensure that all information provided in foodstuff labelling, presentation or advertising is in compliance with applicable regulations.

According to the Food Act: "In food packaging, presentation and advertising, or in some other way in connection with marketing... information given about food must be truthful and it must be sufficient." These things must also be taken into consideration in the operator's self-monitoring plan.

#### 5.1.1 Self-monitoring

The food business operator is obligated to ensure that labelling and other information concerning a given food item are sufficient, consistent with the product properties and do not mislead the consumer. Operator self-monitoring should comprehend labelling and verification of the accuracy of nutrition and health claims used as part of verifying the accuracy of labelling information.

According to the Regulation, "A food business operator making a nutrition or health claim shall justify the use of the claim." The operator must establish that the substance that is the subject of the claim is verifiably beneficial and present in sufficient quantities in the product. In simple terms, this is done based on a statement issued by the EFSA.

The self-monitoring plan must describe how to ensure that the conditions for using claims are being met and what measures will be taken if any discrepancies are found. The operator must ensure that the food contains the nutrient or other substance specified in the claim to the amount stated therein. This can be done based on, for example, a laboratory analysis or computational information sources, such as trusted food composition tables.

Evira recommends that claims use the wording authorised for them. According to the Regulation, the operator may use the wording of an authorised claim or another claim

that presumably has the same meaning for the consumer. However, the average consumer must be able to understand the benefits stated in the claim. If the operator uses wording other than the authorised version, they must ensure that said wording has an equivalent meaning for the consumer by means of, for example, a consumer survey.

According to Article 6(3) of the Regulation: "The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this Regulation. In Evira's view, food business operators can meet this requirement by, for example, presenting information specified in Annex 4.

The information listed in Annex 4 are part of a responsible food business operator's product and marketing planning and quality control. By maintaining and updating this information, companies can ensure or, if necessary, demonstrate the functionality of nutrition and health claim self-monitoring. Annex 5 contains an example of using a claim table in self-monitoring.

## 5.2 Supervisory authorities

"Municipalities must ensure that control as laid down in this Act (municipal food control) is undertaken within their respective areas (Food Act, Section 32)". This also includes oversight in accordance with the Regulation.

Oversight of nutrition and health claims is concentrated on the oversight of information listed in Annex 4. Supervisory authorities must verify that the operator takes into consideration claims made in labelling as well as in other marketing materials, brochures or websites when self-monitoring.

If monitoring reveals any misuse of nutrition and health claims, the authority shall order the claims to be rectified within a reasonable amount of time (Food Act, Section 55).

## 5.3 Evira

Evira's authority is defined in Section 30 of the Food Act. This authority does not include the authorisation of foodstuffs or their labelling prior to their entry to market. Therefore, Evira is not entitled to pre-authorise products or the claims used for them.

If necessary, Evira can take administrative coercive measures under the Food Act to ensure the compliance with regulations on food information in the marketing of foodstuffs, such as on TV, the Internet and print advertising.

## 6 Q&A

### 6.1 Nutrition claims

#### **Are "additive-free" and "preservative-free" nutrition claims?**

A nutrition claim is any claim that states a food has particular beneficial nutritional properties, due to its energy or nutrient content. These claims describe the properties of a product's ingredients, not the product's nutrient content, and are therefore not considered nutrition claims.

#### **The claims "lactose-free", "low lactose" and "gluten-free" are not listed in the Regulation annex. Can't they be used anymore?**

These claims do not fall under this category, but rather are regulated by legislation concerning foods for particular nutritional uses. For more information, please visit the Evira website at:

[http://www.evira.fi/portal/en/food/manufacture\\_and\\_sales/foodstuffs\\_for\\_particular\\_nutritional\\_use/](http://www.evira.fi/portal/en/food/manufacture_and_sales/foodstuffs_for_particular_nutritional_use/)

#### **Are "probiotic" and "antioxidant" nutrition claims?**

Because the names suggest a function or health effect, these are considered health claims, not nutrition claims.

#### **Are "contains lycopene" and "contains lutein" nutrition claims?**

Yes, because the claims refer to substances found in the food item.

#### **The product name is the same as the nutrient name. Is this a nutrition claim?**

Under the Regulation, product names and various symbols can also be claims. Therefore, the product and information presented on it must comply with the Regulation. For example, a product called "FibreBread" should contain at least as much fibre as required by the claim "source of fibre".

#### **A product claims to contain a high amount of flavonoids. What kind of information on this product needs to be shown?**

Nutrition labelling has to state which flavonoids are found in the product and what quantity. The burden of proof is on the operator, particularly with regard to meeting the requirements specified in Article 5, i.e. the substance that is the subject of the nutrition claim must have a proven beneficial effect and the product must contain a sufficient amount of said substance.

Unless the nutrient in question or a significant quantity of another substance has a generally specified limit value, the operator must be able to verify that the quantity of nutrients found in the product is significant. The nutrient quantity must be based on generally accepted scientific evidence, such as an EFSA statement, and it must be possible to show the quantity, if necessary.

#### **The claim "cholesterol-free" is not in the Regulation annex. Is it no longer acceptable for use?**

Only nutrition claims shown on the list may be used. Experts consider that there is no evidence to support the usefulness of the "cholesterol-free" claim. In accordance with the nutrition labelling decree, the amount of cholesterol in a food item can be listed in the product labelling.

#### **Is "added taurine" a nutrition claim?**

The appropriate entries for each fortified food must be made in the ingredient listing and nutrition labelling. If an added nutrient is mentioned elsewhere, it can be considered a nutrition claim.

The Regulation specifies the conditions for using "contains" and "added" claims. Article 5 of the Regulation should be given special attention. When using an "added" claim, the taurine content of the product in question should be checked in comparison to other energy drinks, because there is no recommended daily allowance reference value for taurine.

### **Can the "no added sugars" claim be used for a product that contains sweeteners?**

The Regulation specifies the following: "A claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'." This comprehends sweet food items, such as honey or juice. If sugar occurs naturally in a food item, the package should also bear the following statement: "Contains naturally occurring sugars".

Use of a sweetener cannot therefore prevent use of the nutrition claim in question, provided that the product and information on it are otherwise in accordance with the Regulation. When using sweeteners, it should be kept in mind that, in accordance with legislation concerning additives, their use is only permitted in certain food items.

### **When using a nutrition claim, is nutrition labelling required on all products, even tea and coffee packages?**

Use of a nutrition claim always requires nutrition labelling. If a product is said to contain, for example, vitamins, the nutrition labelling must state which vitamins and what quantity are found in the product. It must also be kept in mind that use of a nutrition claim requires that the food item contains a significant quantity of the vitamins in question.

According to the Regulation, a nutrition claim refers to food items which are ready for consumption in accordance with manufacturer instructions. Under the nutrition labelling decree, nutrition labelling information may only be shown on food that are ready for consumption, if sufficiently detailed manufacturing instructions and information only apply to the food item manufactured in this manner.

According to Evira, semi-processed foodstuffs, which have sufficiently detailed and clear manufacturing instructions and in whose manufacture clearly defined ingredients are used, must state the nutritional content of foods ready for consumption. These types of products include teas, coffees, various powdered drink mixes, soup mixes, juice concentrates and equivalent products, to which water is added. If claims are used in various meal ingredients and similar products, to which several constituent parts affecting the nutritional content are added, the situation must be examined on a case-specific basis.

### **Should I apply the Regulation to cheeses, sausages or low-fat minced beef?**

Information on the quality or quantity of a nutrient, as required elsewhere in legislation, such as specifying the fat content of powdered milk, cheeses and various sausages, is not considered a nutrition claim.

### **There are nutrition claims on websites advertising a product, but not on the packaging itself. Is nutrition labelling still required on the packaging?**

The Regulation applies to claims used in commercial communications in the labelling, presentation and advertising of foodstuffs intended for the final consumer. Use of a nutrition claim always requires nutrition labelling. Therefore, nutrition claims made on websites or in print media require that nutrition labelling be included on the packaging itself.

**Does the product name "Light FizzyDrink" meet Regulation requirements?**

The Regulation stipulates that comparison is only permitted between foodstuffs in the same category, wherein attention is given to several food items belonging to the same category as well as items produced by other manufacturers. This prevents a situation in which the consumer is misled into choosing products suitable for the advertiser's purposes as a point of comparison that are not, however, representative of the food category.

Provided that the trade name is representative of its own category's products, it can be used as a point of comparison. In other words, if a certain product's composition represents the average composition of products being marketed, the product name itself may contain a comparative reference, provided that it is followed by the claim "Light". If a standard product is called, for example, X, then "X Light" indicates the item referred to.

Thus, if the original "FizzyDrink" is representative of its foodstuffs category, it is possible to use the product name "Light FizzyDrink", provided that this product and its provided information are otherwise compliant with the Regulation.

**What products are used as reference products when making the "reduced salt" and "less salt" nutrition claims.**

The comparison of foodstuffs manufactured in Finland is done based on the minimum limits of the claim "High salt content" compliant with the labelling decree.

For foreign foodstuffs and foodstuffs manufactured in Finland that are not subject to any salt content limits, comparisons are made with similar foodstuffs available on the market, and the manufacturer must be able to indicate the reference product/product category they are using. This is the procedure to follow if claims referring to the reduction of salt are to be added to, for example, mettwurst or other cured sausage.

**Is it possible to provide basic nutritional education on a product package?**

The Regulation's scope of application is very broad and applies to all claims made in commercial communications. In accordance with this, any basic nutritional education given on product packaging or in other commercial communications should comply with the Regulation. The product in question should also comply with Regulation requirements.

For example, a package of rye cookies may not present the high fibre properties of rye as basic nutritional education, unless the cookies actually contain the amount of fibre required to use the claim "source of fibre".

**Can the "high in protein" claim be used for meats or "contains beta-carotene" claim for carrots?**

Use of a claim requires that the product contain at least the amount of the nutrient in question required for the claim. The product and its provided information must otherwise meet Regulation requirements.

**Can the claim "source of omega-3 fatty acids" be used for fish meatballs?**

Fish meatballs must meet the requirements for the nutrition claim in question, i.e. they must contain the required amount of the fatty acids in question. The product and its provided information must otherwise meet Regulation requirements.

If the product itself does not meet the conditions of the nutrition claim in question, none of its constituent parts may be advertised as sources of fatty acids. For example, in this situation it would be misleading to state that fish, which is a source of omega-3 fatty acids, was used in the manufacture of this product if the product itself does not meet the requirements of the stated claim.

### **Should liquid products contain as much nutrients as solid products in order for a nutrition claim to be used?**

The nutrition labelling decree annex lists 15% as being a significant amount of the recommended daily allowance of vitamins and minerals. The amount equivalent to the recommended daily allowance should be obtained from 100 g or 100 ml of a food item or single service package.

The Commission expert working group proposed that the criteria for "source or vitamins and/or minerals" claim be changed in connection with the drafting of the consumer information regulation. The conditions will probably be revised so that the condition for using the claims in question for liquid foodstuffs (excluding vegetable oils and similar products) will be 7.5% of the recommended daily allowance.

It is for this reason that Evira believes that the daily intake amounts of a given food item can be taken into consideration where liquid products are concerned. Liquid foodstuffs primarily consumed in large, daily servings, can apply the 7.5% recommended daily allowance/100 ml as a requirement for using the claim "source of vitamins and/or minerals".

For example, although the amount of riboflavin obtained from milk in a 100 ml serving falls just below the 15% limit, milk is generally consumed in large enough quantities that the amount of riboflavin obtained can be considered significant. Conversely, the intake quantities of, for example, salad dressing, are so small that the vitamins or minerals contained in 100 g of dressing, although possibly exceeding the 15% limit, do not have any real impact on intake levels.

### **Some foodstuffs use the Heart Symbol. Is this a nutrition or health claim?**

In Finland, the authorities have determined that the "Heart Symbol – A Better Choice" system administered by the Finnish Heart Association and Finnish Diabetes Association is a nutrition claim as specified in Article 2 of the Regulation, which states that: "... 'Nutrition claim' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties..."

The purpose of the Symbol is to promote national health by making it easier to choose a healthy diet.

The impetus for building a labelling system stems from major nutritional problems related to the health of Finns. The Symbol is not only aimed at cardiac health. Products bearing the "Heart Symbol – A Better Choice" are better choices in terms of fat and salt intake. The authorities have been involved in developing the Symbol and its criteria. The Symbol is also found in the National Nutrition Council nutritional recommendation consumer brochure (Ravinto ja liikunta tasapainoon (Integrating Nutrition and Physical Activity), 2006).

Under Article 28(4)(a) of the Regulation: "Member States shall communicate to the Commission, by 31 January 2008 at the latest, such nutrition claims and the national provisions or rules applicable, accompanied by scientific data in support of such provisions or rules..." The Ministry of Agriculture and Forestry submitted material concerning the Heart Symbol- A Better Choice to the Commission within the prescribed period. As a result, the Symbol may be used, even though it does not contain any of the authorised nutrition claims listed in the Regulation annex.

### **Various health and food business organisations talk about the beneficial properties of foodstuffs and the ingredients used in them on their respective websites. Is the Regulation applicable in these cases?**

The Regulation is only applied in cases involving commercial communications, not, for example, nutritional guidelines or recommendations made by public health authorities or agencies, or non-commercial communications and information published in

the press and scientific publications. Alternatively, if the websites are advertising a specific food item, the Regulation is applicable.

## 6.2 Health claims

### **Can functional health claims listed under Article 13(1) be used for children's products?**

Where the Regulation is concerned, a child is any person under 18 years of age. As specified in Article 14, claims referring to children's development and health may be used for children's products.

### **Is it possible to submit a new application for rejected Article 13(1) health claims?**

Yes, provided that the operator possesses new scientific evidence related to the claim that was not previously presented to the EFSA for deliberation. The application is submitted as a claim in accordance with Article 13(5). The EFSA publishes its statements in connection with the scientific evidence used in assessing the claim. This allows the applicant to check whether its proposed evidence has already been approved by the EFSA.

### **Can new scientific evidence be submitted for Article 13(1) health claims that are under consideration?**

At present, additional information may not be submitted for claims under consideration. If additional evidence that supports the claim has come to light, it is possible to submit a new claim application in accordance with Article 13(5). As authorities will not submit any additional evidence, the operator must submit a new application.

### **Can health claims backed by the EFSA be implemented prior to receiving Commission approval?**

Health claims compliant with Article 13(1) of the claim regulation and still under consideration by the EFSA may be used at the discretion of the operator until such time as an official Commission decree concerning the claim in question has been issued. However, claims must be compliant with the claim regulation and applicable national regulations.

### **At what point are health claims, for which the EFSA has found no scientific justification, prohibited in Finland?**

Only authorised health claims or health claims subject to transition period regulations may be used. Article 13(1) health claims rejected by a Commission decision are given a six-month transition period. During that time, the rejected claim must be removed from use. Supervisory authorities may always intervene in cases involving the use of misleading claims.

### **Can Article 13(5) and 14 health claims be used immediately upon submission of an application?**

Health claims compliant with Articles 13(5) and 14 may not be used until they have been authorised by Commission decree.

### **A business uses its website to sell foods manufactured by another company and the claims concerning these foods come directly from the food manufacturers. Who is responsible for ensuring that the claims made are in compliance with applicable foodstuffs legislation?**

The food manufacturer is always responsible for ensuring that its food products and the claims made concerning them are compliant with applicable food legislation. Even if another manufacturer's products are sold online and the marketing materials are obtained from the manufacturer, the online merchant is responsible for all materi-

als/information published on its website. In cases like these, the online merchant should provide information on the manufacturer from which it has obtained said materials/information and require that the manufacturer provide marketing materials that comply with food legislation.

**Do the requirements concerning the above claims also apply to, for example, word-of-mouth marketing and network marketing?**

Yes. The Regulation is also applicable in these cases. One should also keep in mind that it is always prohibited in the marketing of foodstuffs to make statements suggesting that a food has properties related to prevention, treatment or curing of diseases.

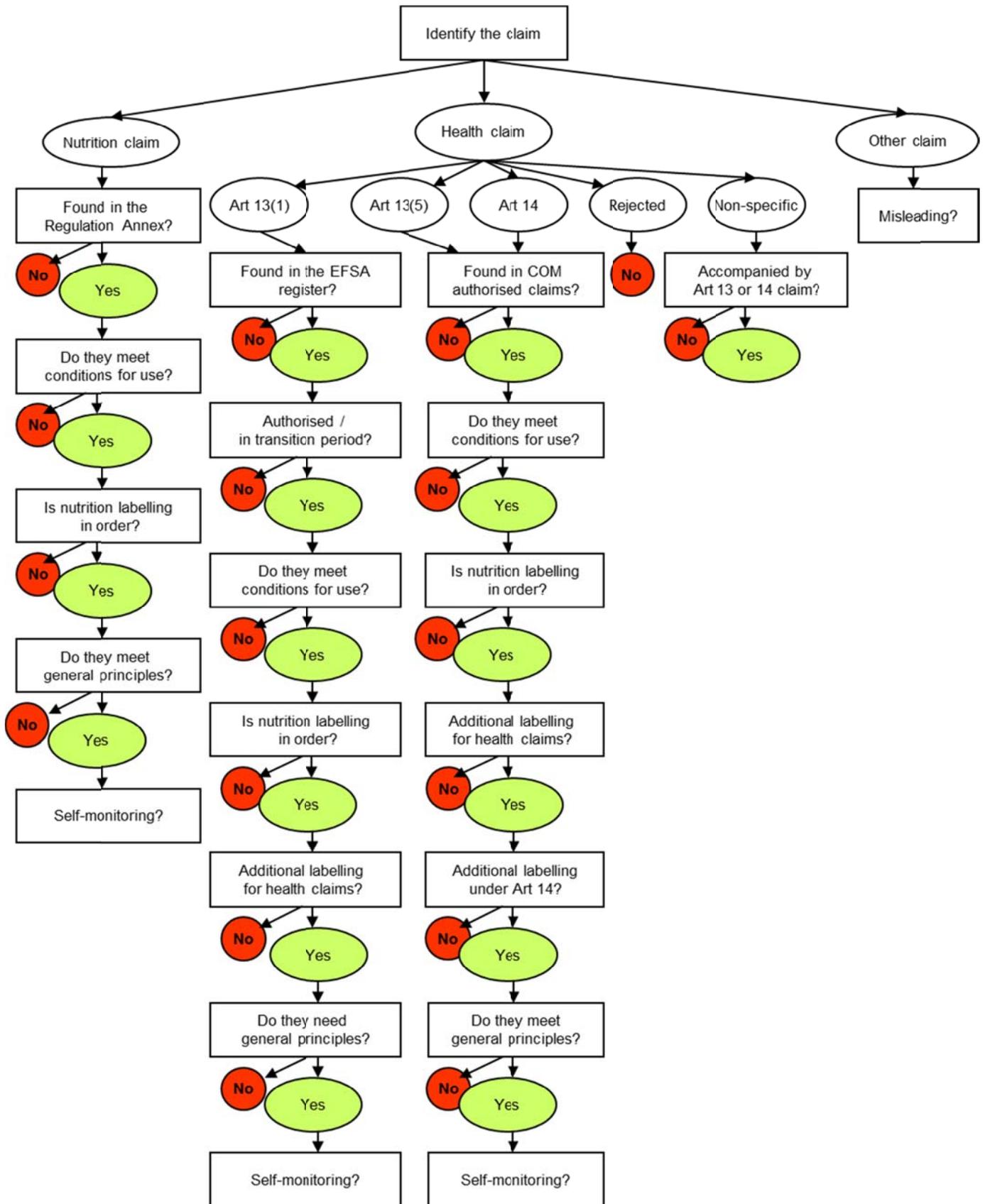
**Annex 1.** Authorised nutrition claims and examples of equivalent wordings used by Evira

<b>Nutrition claim</b>	<b>Use requirement</b>	<b>Equivalent wording</b>	<b>Remarks</b>
Low energy	the product does not contain more than <b>40 kcal (170 kJ)/100 g</b> for solids or more than <b>20 kcal (80 kJ)/100 ml</b> for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.	- low caloric content - low in calories, energy	
Energy-reduced	the product energy value is reduced by at least 30 %. The characteristic(s) which make(s) the food reduced in its total energy value must also be reported.	- less energy, calories - reduced energy	
Energy-free	the product does not contain more than <b>4 kcal (17 kJ)/100 ml</b> . For table-top sweeteners the limit of 0,4 kcal (1,7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.	- calorie-free - does not contain energy, calories	
Low fat	the product does not contain more than <b>3 g of fat per 100 g</b> for solids or <b>1,5 g of fat per 100 ml</b> for liquids (1,8 g of fat per 100 ml for semi-skimmed milk).	- low fat content - low in fat	
Fat-free	the product contains no more than 0,5 g of fat per 100 g or 100 ml.	- does not contain fat	
Low saturated fat	the sum of saturated fatty acids and trans-fatty acids in the product does not exceed <b>1,5 g per 100 g</b> for solids or <b>0,75 g/100 ml</b> for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.	- low in hard fat	
Saturated fat-free	the sum of saturated fat and trans-fatty acids does not exceed <b>0,1 g of saturated fat per 100 g or 100 ml</b> .	- no hard fat	- "does not contain trans-fatty acids" and "0% trans-fatty acids" are rejected nutrition claims
Low sugars	the product does not contain more than <b>5 g of sugars per 100 g</b> for solids or <b>2,5 g of sugars per 100 ml</b> for liquids.	- low sugar content - contains a low amount of sugar	
Sugars-free	the product contains no more than <b>0,5 g of sugars per 100 g or 100 ml</b> .	- no sugars - does not contain sugar	- "unsweetened" is not a nutrition claim and can also indicate a lack of sweeteners other than sugar
With no added sugars	the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'.	- no sugar added	when using the claim "no added sugars", the statement "contains no naturally occurring sugars" must be used - if the product contains naturally sweet ingredients, such as honey, fruits, juices, etc. -if the product contains over 0,5 g per 100 g/ml of naturally occurring sugars
Low sodium/salt	the product contains no more than <b>0,12 g</b> of sodium, or the equivalent value for salt, <b>per 100 g or per 100 ml</b> . For waters, other than natural mineral	- low salt content	- 1 g of sodium is equivalent to 2,5 g salt (NaCl) - this nutrition claim only applies to sodium and not,

	waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.		for example, potassium or magnesium
Very low sodium/salt	the product contains no more than <b>0,04 g</b> of sodium, or the equivalent value for salt, <b>per 100 g or per 100 ml</b> . This claim shall not be used for natural mineral waters and other waters.	- very low salt content	- 1 g of sodium is equivalent to 2,5 g salt (NaCl)
Sodium-free or salt-free	the product contains no more than <b>0,005 g/100 g</b> of sodium, or the equivalent value for salt.		- 1 g of sodium is equivalent to 2,5 g salt (NaCl) - "unsalted butter" is a product name/ category, not a nutrition claim
Source of fibre	the product contains at least <b>3 g of fibre per 100 g</b> or at least <b>1,5 g of fibre per 100 kcal</b> .	- contains fibre - added fibre - fibre - fibre content	- "wholegrain" and "dark" are not nutrition claims and do not mean the same thing as "source of fibre"
High fibre	the product contains at least <b>6 g of fibre per 100 g</b> or at least <b>3 g of fibre per 100 kcal</b> .	- contains a large amount of fibre - high in fibre - high fibre content - rich in fibre	
Source of protein	at least <b>12 %</b> of the energy value of the food is provided by protein.	- contains protein - protein - protein content	
High protein	at least <b>20 %</b> of the energy value of the food is provided by protein.	- high in protein - high protein content - good source of protein - rich in protein	
Source of [name of vitamin/s] and/or [name of mineral/s]	the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 6 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[1]. The product shall contain at least <b>15% of the recommended daily allowance</b>	- contains vitamin C - + vitamin C	- "contains 10 mg of vitamin C per 100 g" is a nutrition claim, if it is used anywhere other than nutrition labelling
High [name of vitamin/s] and/or [name of mineral/s]	A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of 'source of [NAME OF VITAMIN/S] and/or [NAME OF MINERAL/S]'.  The product shall contain at least <b>30% of the recommended daily allowance</b>	- good source of vitamin C - high vitamin C content	- "contains plenty of vitamins" is a vague expression and requires a more precise description of what vitamins there are in greater quantity.
Contains [name of the nutrient or other substance]	the product complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim ' <b>source of</b> ' shall apply.	- source of lycopene - contains lycopene	- The claimed nutritional or physiological effect of the nutrient should be supported by generally accepted scientific evidence, and the substance in question should comprise a significant percentage of the foodstuff, when considering its normal use. - If the substance name refers to its function or

			effect on health, it is considered a health claim (e.g. antioxidant, probiotic).
Increased [name of the nutrient]	the product meets the conditions for the claim 'source of' and the increase in content is at least <b>30 %</b> compared to a similar product.	- added fibre - added vitamin C - fortified with vitamin C	
Reduced [name of the nutrient]	the reduction in content is at least <b>30 %</b> compared to a similar product, except for micronutrients, where a 10 % difference in the reference values as set in Directive 90/496/EEC shall be acceptable, and for sodium, or the <b>equivalent value for salt</b> , where a <b>25 %</b> difference shall be acceptable.	- 40% reduction in fat - reduced salt - reduced salt content	Salt: - The comparison of foodstuffs manufactured in Finland is done based on the minimum limits of the claim "High salt content" compliant with the labeling decree. - For foreign foodstuffs and foodstuffs manufactured in Finland that are not subject to any salt content limits, comparisons are made with similar foodstuffs available on the market.
Light/Lite	shall follow the same conditions as those set for the term ' <b>reduced</b> ' the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'.	- light, 30% reduction in fat - light salt/lightly salted, salt reduced 25%	- the claims "ultralight", "very light", "lightest", etc. are not authorised nutrition claims
Naturally/natural	Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term 'naturally/natural' may be used as a prefix to the claim.	- contains naturally occurring calcium - contains a high amount of naturally occurring calcium	
Source of omega-3 fatty acids	the product contains at least <b>0,3g alpha-linolenic acid per 100g and per 100kcal</b> , or at least <b>40mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal</b> .	- source of omega-3 fatty acids	
High omega-3 fatty acids	the product contains at least <b>0,6g alpha-linolenic acid per 100g and per 100kcal</b> , or at least <b>80mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal</b> .	- good source of omega-3 fatty acids	
High monounsaturated fat	at least <b>45%</b> of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than <b>20%</b> of energy of the product.	- high amount of monounsaturated fats - good source of monounsaturated fats	
High polyunsaturated fat	at least 45% of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20% of energy of the product.	- high amount of polyunsaturated fats - good source of polyunsaturated fats	
High unsaturated fat	at least <b>70%</b> of the fatty acids present in the product derive from unsaturated fat under the condition that polyunsaturated fat provides more than <b>20%</b> of energy of the product.	- good source of unsaturated fats - good source of soft fat - high amount of soft fat	

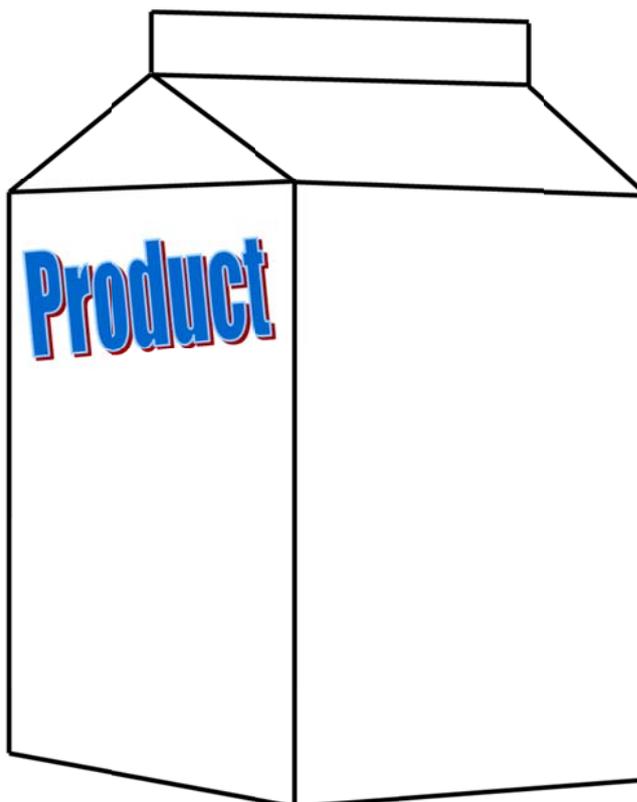
**Annex 2.** Decision tree on the correct use of claims



**Annex 3.** Examples of additional labelling resulting from the various claims

No claims

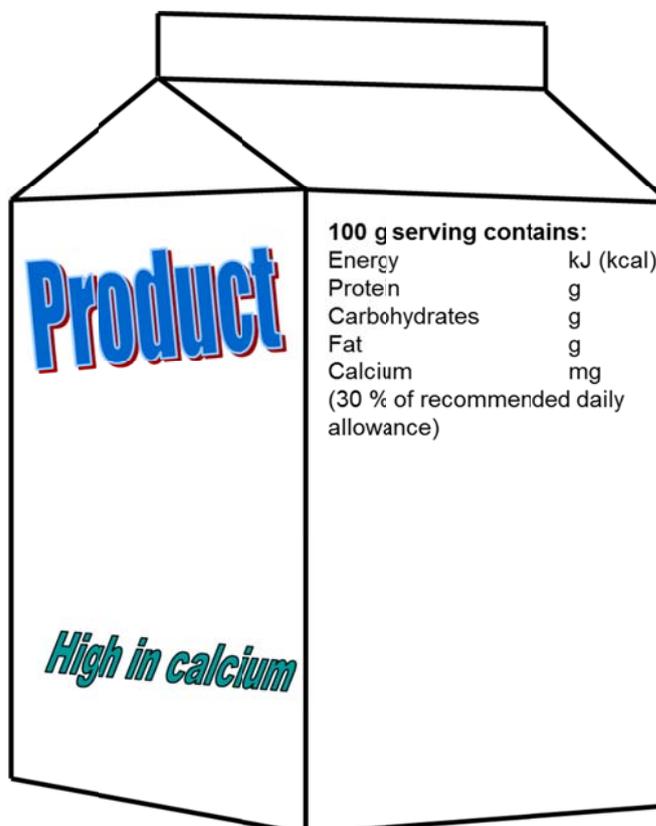
- voluntary nutrition labelling



Fictional example.

Nutrition claim

- short-form nutrition labelling
- quantity of calcium

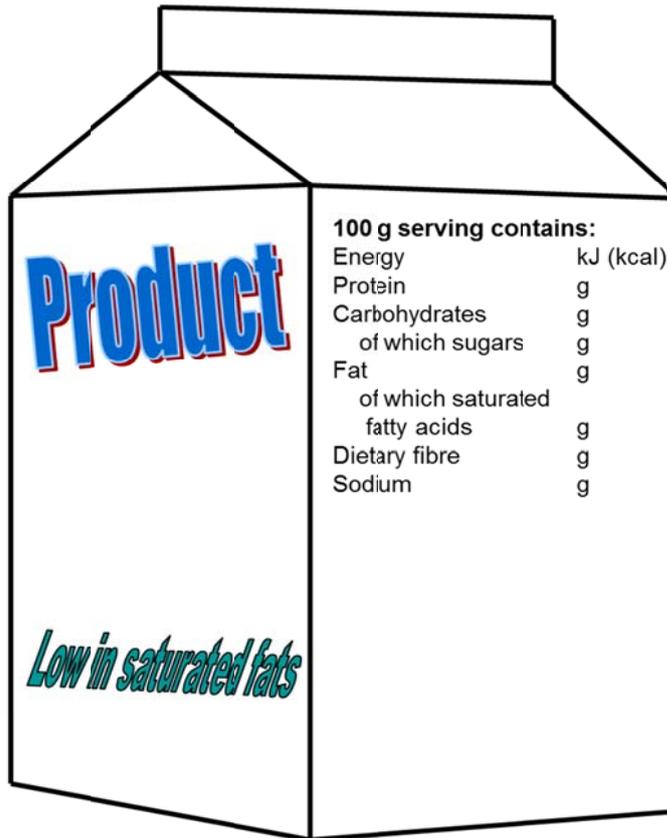


Fictional example.

Nutrition claim, which concerns

- sugars
- saturated fatty acids
- dietary fibre or
- sodium

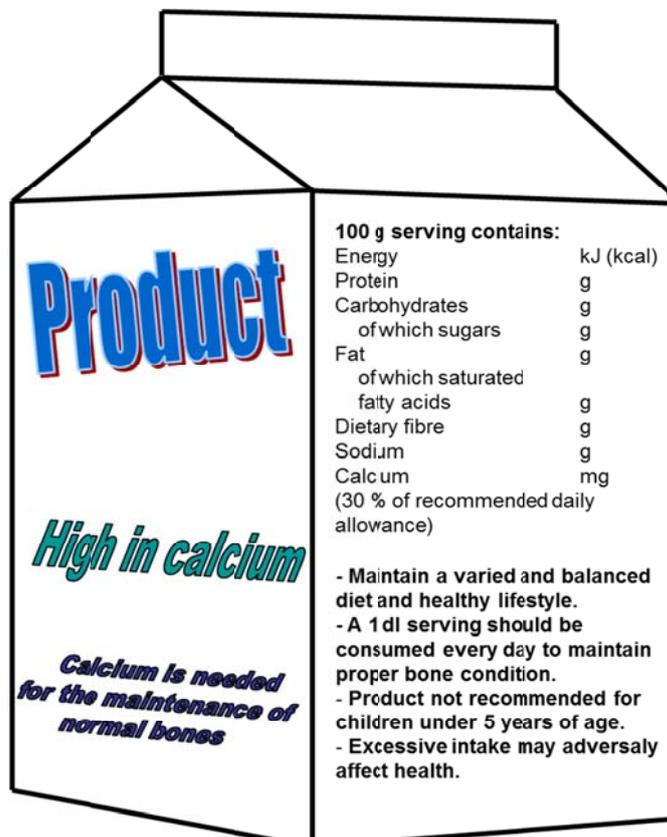
➤ long-form nutrition labelling



Fictional example.

Article 13(1) health claim

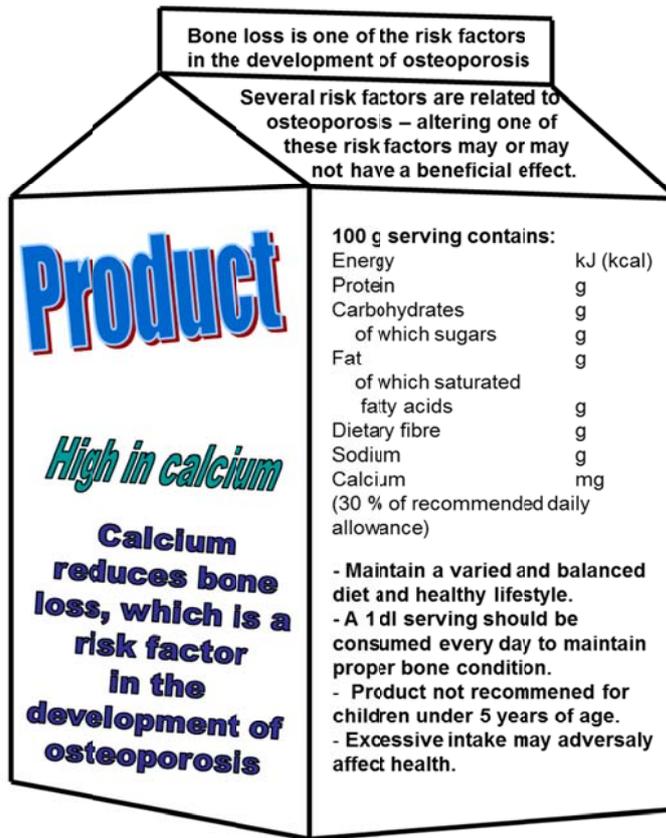
- long-form nutrition labelling
- quantity of calcium
- additional labelling for health claims



Fictional example.

Article 14 health claim

- long-form nutrition labelling
- quantity of calcium
- additional labelling for health claims
- additional labelling for reduction of disease risk claims

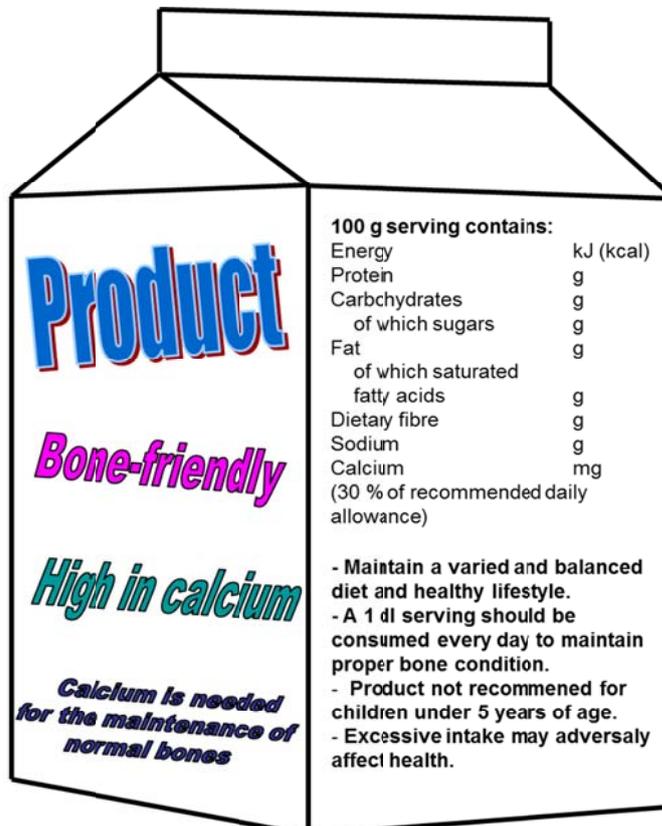


Fictional example.

General, non-specific health claim

+  
Article 13(1) health claim

- long-form nutrition labelling
- quantity of calcium
- additional labelling for health claims



Fictional example

#### Annex 4. Items to monitor in the self-monitoring of nutrition and health claims

By maintaining and updating information on the list, companies can ensure or, if necessary demonstrate the effectiveness of self-monitoring nutrition and health claims. Oversight of nutrition and health claims is focused on the monitoring of their information. Annex 5 presents an example of how claims are self-monitored.

##### Nutrition claims:

- What is the nutrition claim for the product?
- If this involves a "trade mark, brand name or fancy name" as specified in Article 1(3) that may be construed as a nutrition claim, what nutrition claim is associated with the trade mark or name? The nutrition claim must define and augment the trade mark or name.
- To what authorised nutrition claim compliant with the Regulation does it correspond?
- What are the conditions for using authorised nutrition claims as stated in the Regulation Annex?
- How much of the nutrient or other substance that is the subject of the claim is found in the product?
- Does the claim meet the conditions of use?
- How has the nutrient quantity been verified (analysed/calculated)?
- Is the nutrient or other substance that is the subject of the claim stated in the nutrition labelling? Depending on the substance in question, short or long-form nutrition labelling should be used. If there is also a health claim made about the product, long-form nutrition labelling should be used.
- Other observations?

##### Health claims:

- What is the health claim for the product?
- If this involves a "trade mark, brand name or fancy name" as specified in Article 1(3) that may be construed as a health claim, what health claim is associated with the trade mark or name? The health claim must define and augment the trade mark or name.
- If this involves a "general, non-specific" health claim as specified in Article 10(3), what health claim is associated with the product?
- To what health claim compliant with the Regulation does it correspond?
- What are the conditions for using an authorised health claim?
- How much of the nutrient or other substance that is the subject of the claim is found in the product?
- Does the claim meet the conditions of use?
- How has the nutrient quantity been verified (analysed/calculated)?
- Is the nutrient or other substance that is the subject of the claim stated in the nutrition labelling? Long-form nutrition labelling should be used.
- What labelling compliant with Article 10(2) is found on the packaging?
- If a reduction of disease risk claim, as specified in Article 14(1)(a) has been used, what labelling compliant with Article 14(2) is found on the packaging?
- Is the claim subject to any time limits or transition periods? These include a six-month transition period for rejected health claims, during which the rejected claim must removed from use.
- Other observations?

**Annex 5.** Example of using the claim monitoring table in self-monitoring

<b>Product</b>	Dairy drink								
	<b>Nutrition claims</b>								
	<b>Claim used for the product</b>	<b>Corresponding claim compliant with the Regulation</b>	<b>Conditions of use for the claim</b>	<b>Quantity of the nutrient that is the subject of the claim found in the product</b>	<b>Does the claim meet the conditions of use?</b>	<b>How has the nutrient quantity been verified (analysed/calculated)?</b>	<b>Quantity of the nutrient in question listed in nutrition labelling (short/long-form)</b>	<b>Other observations</b>	
	Contains a high amount of calcium	Contains a high amount of calcium	Calcium 240 mg/100 g	Calcium 250 mg/100 g	Yes	calculated from a formula	Yes, long-form		
	Low saturated fat	Low saturated fat	saturated and trans-fatty acids tot. less than 1.5 g/100 g and 0.75 g/100 ml AND total quantity no more than 10% energy	0.6 g/100 ml, 9 % of energy	Yes	calculated from a formula	Yes, long-form		
	<b>If this involves a "trade mark, brand name or fancy name" as specified in Article 1(3) that may be construed as a nutrition claim, what nutrition claim is associated with the trade mark or name?</b>	<b>Nutrition claim associated with trade mark or name</b>	<b>Corresponding claim compliant with the Regulation</b>	<b>Conditions of use for the claim</b>	<b>Quantity of the nutrient that is the subject of the claim found in the product</b>	<b>Does the claim meet the conditions of use?</b>	<b>How has the nutrient quantity been verified (analysed/calculated)?</b>	<b>Quantity of the nutrient in question listed in nutrition labelling (short/long-form)</b>	<b>Other observations</b>
	-								

Health claims										
Claim used for the product	Corresponding claim compliant with the Regulation	Conditions of use for the claim	Quantity of the nutrient that is the subject of the claim found in the product	Does the claim meet the conditions of use?	How has the nutrient quantity been verified (analysed/calculated)?	Quantity of the nutrient in question listed in nutrition labelling (long-form)	Labelling compliant with Art. 10(2) on the packaging	If a reduction of disease risk claim, as specified in Article 14(1)(a) has been used, what labelling compliant with Article 14(3) is found on the packaging?	Time limits related to the claim, e.g. transition period	Other observations
Calcium strengthens bones	Calcium is needed for the maintenance of normal bone	source of calcium, i.e. over 120 mg/100 g	Calcium 250 mg/100 g	Yes	calculated from a formula	Yes, long-form	a) importance of a varied and balanced diet and a healthy lifestyle b) 1 dl of the product should be consumed on a daily basis to maintain bone condition c) and d) no risks associated with the product	-	-	
Calcium reduces bone loss, which is a risk factor for contracting osteoporosis	No authorised claims	No information available	Calcium 250 mg/100 g		calculated from a formula	Yes, long-form	a) importance of a varied and balanced diet and a healthy lifestyle b) 1 dl of the product should be consumed on a daily basis to maintain bone condition c) and d) no risks associated with the product	-bone loss is a risk factor for contracting osteoporosis -several risk factors are related to osteoporosis - changing a single factor will not necessarily have an impact	Claim still under consideration. the reduction of disease risk claim specified in Art 14(1)(a) can only be used when the claim has been authorised.	The claim has been authorised. The claim is not added to the labelling until it has been authorised.

"General, non-specific" health claim as specified in Article 10(3) used for the product	Health claim specifying the effect on health	Corresponding claim compliant with the Regulation	Conditions of use for the claim	Quantity of the nutrient that is the subject of the claim found in the product	Does the claim meet the conditions of use?	How has the nutrient quantity been verified (analysed/calculated)?	Quantity of the nutrient in question listed in nutrition labelling (long-form)	Labelling compliant with Art. 10(2) on the packaging	If a reduction of disease risk claim, as specified in Article 14(1)(a) has been used, what labelling compliant with Article 14(3) is found on the packaging? Reduction of disease risk claim specified in Art. 14(1)(a), labelling compliant with Art. 14(3)	Time limits related to the claim, e.g. transition period	Other observations
bone-friendly	Calcium strengthens bones Claim OK (see above)										
"Trade mark, brand name or fancy name" as specified in Article 1(3) that may be construed as a nutrition claim	Health claim associated with trade mark or name	Corresponding claim compliant with the Regulation	Conditions of use for the claim	Quantity of the nutrient that is the subject of the claim found in the product	Does the claim meet the conditions of use?	How has the nutrient quantity been verified (analysed/calculated)?	Quantity of the nutrient in question listed in nutrition labelling (long-form)	Labelling compliant with Art. 10(2) on the packaging	If a reduction of disease risk claim, as specified in Article 14(1)(a) has been used, what labelling compliant with Article 14(3) is found on the packaging? Reduction of disease risk claim specified in Art. 14(1)(a), labelling compliant with Art. 14(3)	Time limits related to the claim, e.g. transition period	Other observations
Dairy drink	Calcium strengthens bones Claim OK (see above)										

