

Nutrition and Health Claim Guide for Food Control Officers and Food Business Operators



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Evira Guideline 17052/4

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Adopted 22.8.2017

Chemical Food Safety Unit
Food Composition Section

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Content

1	PREFACE.....	5
2	LEGISLATION AND NORMS.....	5
3	MEDICINAL CLAIMS ARE PROHIBITED ON FOODS.....	6
4	NUTRITION AND HEALTH CLAIMS REGULATION.....	7
4.1	What is a claim.....	7
4.2	Difference between nutrition and health claims.....	7
4.3	Claims Regulation is applied to commercial communications.....	9
5	NUTRITION CLAIMS.....	10
5.1	Conditions for use of nutrition claims.....	10
5.1.1	Vitamins and minerals.....	10
5.1.2	Nutrients and other substances.....	11
5.1.3	Source of fibre.....	12
5.1.4	Source of protein.....	12
5.1.5	"No added sugar".....	13
5.1.6	Comparative nutrition claims.....	13
5.1.6.1	Addition of vitamins and/or minerals.....	14
5.1.6.2	Light/lite.....	15
5.1.6.3	Reduced salt.....	15
5.2	Claims not construed as nutrition claims.....	16
5.3	Prohibited nutrition claims.....	16
5.3.1	Misleading nutrition claims.....	16
5.4	"The heart symbol – a better choice" is construed as a nutrition claim.....	17
6	HEALTH CLAIMS.....	18
6.1	Article 13(1) health claims, i.e. functional health claims.....	18
6.2	Article 13(5) and 14 health claims.....	19
6.3	Authorised health claims.....	20
6.3.1	Conditions of use of health claims.....	20
6.3.2	Use of equivalent wordings.....	20
6.3.3	Dual claims.....	21
6.3.4	Authorised claims are not specific to one product or applicant.....	21
6.3.5	Claims may not be linked directly with the commercial name of the food product.....	21
6.3.6	Health claims on products intended for children.....	22
6.3.7	Article 10(3) general, non-specific statements.....	22
6.3.8	Trademarks and product names considered to be claims.....	23
6.3.9	Pictorial, symbolic and graphic representations that include a claim.....	23
6.4	Prohibited health claims.....	24
6.4.1	Experiences of individual consumers.....	24
6.4.2	Authorisation of a health claim does not affect medicine classification or novel food status.....	25
7	PRINCIPLES OF USE OF CLAIMS.....	25
7.1	General principles of use of claims.....	25
7.1.1	General principles of use of claims, Article 3.....	26
7.1.2	Claims may only be made on healthy foods, Article 4.....	26
7.1.3	General conditions, Article 5.....	26
7.2	Labelling.....	27
7.3	Nutrition labelling.....	27
7.3.1	Nutrient declaration in compliance with Food Information Regulation.....	28
7.3.2	Verification of amount of nutrient.....	28
7.3.3	Claims shall refer to food ready for consumption.....	28
7.4	Mandatory information required due to the use of a health claim.....	29
7.4.1	Article 10(2)b.....	29
7.4.2	Article 10(2)c-d.....	30
7.5	Unpacked foods.....	30

7.6 Food supplements.....	31
7.6.1 Nutrition labelling.....	31
7.6.2 Article 10(2)a.....	31
7.6.3 Article 10(2)b.....	31
7.7 Use of claims in marketing	32
7.8 Information provided to professionals.....	33
8 IN-HOUSE CONTROL AND REGULATORY CONTROL.....	33
8.1 In-house control by food business operators	33
8.2 Regulatory control	35
Appendix 1. Authorised nutrition claims and examples of claim wordings considered equivalent by Evira	36
Appendix 2. Examples of additional labelling information required due to various claims.....	39
Appendix 3. Quick-guide for using claims	44
Appendix 4. Guidelines for use of EU Commission's Register on nutrition and health claims, and EFSA's Register of questions.....	45

LIST OF REVISIONS

Revisions made in Nutrition and Health Claim Guide on 22.8.2017

Section	Revision
Content	Updated
2 Legislation and norms	Revoked: Decrees removed: Decree of Ministry of Trade and Industry (1084/2004), Decrees of Ministry of Agriculture and Forestry (588/2009) and (121/2010). Added: Commission Regulation (EU) No 609/2013 on food for special medical purposes.
4.2 Difference between nutrition and health claims (Table 1)	Updated with respect to claim example presented in Article 14.1a.
4.3 Claims Regulation is applied to commercial communications	Definition provided in Food Information Regulation for presentation, and examples added.
5.1.6.3 Reduced salt	Number of national decree pertaining to indication of high salt content updated.
6.4.1 Experiences of individual consumers	More specific pre-condition presented for using in advertising claims made by an individual consumer.
7.3, 7.3.1, 7.3.2, 7.3.3, 7.6.1, 8.1 and Appendices 2 and 3	Removed: references to revoked Decree of Ministry of Agriculture and Forestry (588/2009) on nutrient labelling. Nutritional labelling is based only on Food Information Regulation (EC) No 1169/2011.
7.8 Information provided to professionals	Added: Decision of the European Court of Justice on the application of the Claims Regulation to information provided to professionals.
Appendix 4. Guidelines for use of Commission Register of Nutrition and Health Claims, and EFSA Register of Questions	Guidelines for use of EFSA Register of Questions and Commission Register of Nutrition and Health Claims updated.

1 PREFACE

These guidelines are designed for food control authorities and operators within the food business.

Public authority action shall be based on legislative competence conferred to the authority and be consistent with legislation. Authoritative guidelines are not, by their legal nature, binding on other authorities or operators. Issues pertaining to the application of legislative regulations are in the last instance settled by a court of law.

These guidelines present both direct quotations from legislation and interpretations on the application of legislation. The interpretations presented in these Guidelines constitute Evira's views on how legislative regulations should be applied.

2 LEGISLATION AND NORMS

Legislation and norms that provide for nutrition and health claims:

- 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 "Claims Regulation")
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20121129:EN:PDF>
- 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
- Commission Regulation (EU) No. 1047/2012, amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims.
- Commission Regulation (EU) No 432/2012, establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:136:0001:0040:EN:PDF>
- Commission Regulations under which health claims referring to the reduction of disease risk and to children's development and health have been rejected are listed in the Commission's Register at <http://ec.europa.eu/nuhclaims/>

and

- Regulation (EC) No 178/2002 of the European Parliament and of the Council 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
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council, on the provision of food information to consumers, (hereinafter referred to as "Food Information Regulation") <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:en:PDF>

- Decree 78/2010 of the Ministry of Agriculture and Forestry on Food Supplements (hereinafter referred to as "Food Supplement Decree")
- Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control
- Directive 2006/114/EC of the European Parliament and of the Council concerning misleading and comparative advertising <http://eur-lex.europa.eu/legal-content/FI/TXT/PDF/?uri=CELEX:32006L0114&qid=1402552741882&from=FI>
- Guidance on the implementation of Claims Regulation, published by the Commission http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf
- Commission Implementing Decision adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:022:0025:0028:EN:PDF>
- Common guidelines for member countries regarding the flexibility of health claim wording principles http://www.evira.fi/files/attachments/fi/elintarvikkeet/valmistus_ja_myynti/pakkausmerkinnat/health_claims_-_flexibility_of_wording_principles_14_dec_2012.pdf
- Evira 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/terveysvaatteen/eviran_ohje_vaiteasetuksen_art_11_soveltamisesta_17014_1.pdf
- Evira Guideline 17060/1, Guidelines for Control of Nutrition and Health Claims

3 MEDICINAL CLAIMS ARE PROHIBITED ON FOODS

Under Section 9 of the Food Act, truthful and sufficient information shall be given about the food in food packaging, presentation and advertising, or in some other way in connection with marketing. The issuance of misleading information about food is prohibited. Food must not be presented as having properties related to prevention, treatment or curing of human diseases, i.e. medicinal claims, and reference may not be made to such information.

Evira is of the view that using medicinal claims with references to scientific studies or other data as well as indicating medicinal purposes of use in connection with the distribution and marketing of foods e.g. on websites are also in violation of Section 9 of Food Act 23/2006. The consumer is through them given to understand that the foods marketed by the company or the ingredients contained in them have properties related to prevention, treatment or curing of human diseases. Even if studies are published separately from the actual marketing material of the products, they are still non-compliant, if the consumer can link the claimed property to the marketed products.

References to use as herbal or folk remedies can also be considered to be medicinal claims.

4 NUTRITION AND HEALTH CLAIMS REGULATION

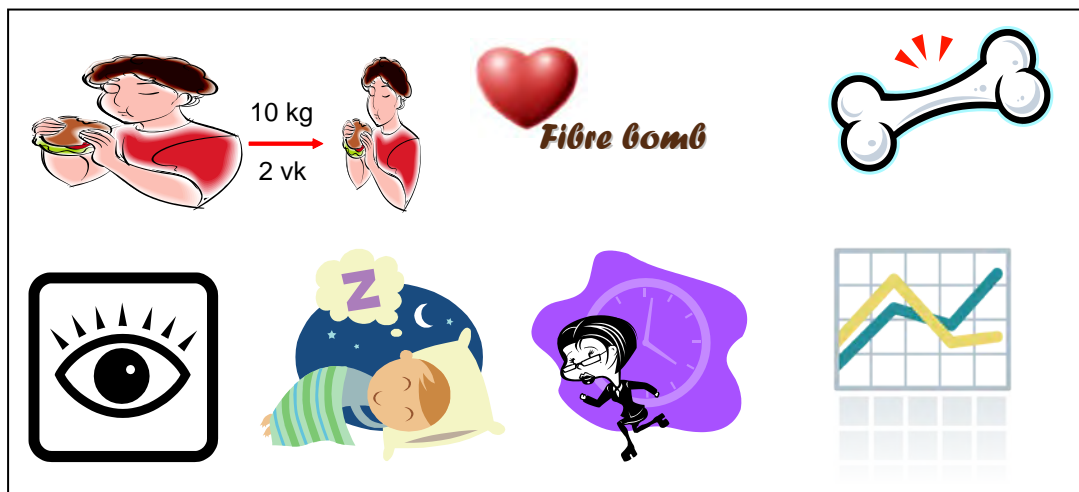
Nutrition and health claims used in the labelling, presentation and advertising of foodstuffs are provided for by Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods (hereinafter referred to as the Claims Regulation), which was adopted on 1 July 2007.

The Claims Regulation defines the conditions on which foodstuffs may be promoted with nutrition and health claims and consequently determines common rules and approval procedures for the use of such claims in all EU states.

4.1 What is a claim

A claim refers to a voluntary presentation or description, which states, suggests or implies that a food has particular properties. In addition to text, a claim can also be a pictorial, graphic or symbolic representation. Trademarks, brand names and fancy names of foodstuffs are also included within the scope of the Claims Regulation.

Figure 1. Examples of pictorial, symbolic and graphic representations that can be construed as claims.



4.2 Difference between nutrition and health claims

A nutrition claim means a claim that refers to the beneficial nutritional content of the food. For example, "contains calcium".

A health claim means a claim that refers to a relationship between a food and health. For example, "calcium is necessary for the normal growth and development of bone in children". Health claims are divided into functional claims, claims that refer to the reduction of disease risk and claims that refer to children's development and health.

The difference between nutrition and health claims is described in Table 1.

Table 1. The Regulation specifies approved nutrition and health claims and the conditions of their use. Health claims are divided into Article 13 health claims and Article 14 health claims.

<u>Nutrition claims</u>	<u>Health claims</u>
Claims describing the beneficial nutritional properties of foodstuffs	Claims implying that there is a relationship between a food category, a food or its ingredient and health.
Only the health claims listed in the Regulation are authorised	Article 13 = functional claims Article 14
The energy it <ul style="list-style-type: none"> • provides • provides at a reduced or increased rate, or • does not provide 	(1)(a) Claims related to growth, development and the functions of the body (1)(a) Claims that refer to the reduction of disease risk
Nutrients or other substances it <ul style="list-style-type: none"> • contains • contains in reduced or increased proportions, or • does not contain 	(1)(b) Claims related to psychological and behavioural functions (1)(b) Claims that refer to children's development and health
	(1)(c) Claims related to slimming or weight-control, etc.
	(5) Claims based on newly developed scientific evidence or which include a request for the protection of proprietary data

Table 2 contains examples of nutrition and health claims and prohibited medicinal claims.

Table 2. Examples of nutrition and health claims and prohibited medicinal claims.

Claim type	Example
Nutrition claim	<ul style="list-style-type: none"> • Source of calcium • Contains calcium • High in calcium
Article 13.1 health claim = functional health claims	<ul style="list-style-type: none"> • Calcium is needed for the maintenance of normal bones. • Calcium promotes normal muscle operation.
Article 14.1b health claim = Claims that refer to children's development and health	<ul style="list-style-type: none"> • Calcium is needed for the healthy bone growth of children
Article 14.1a health claim = Claims that refer to the reduction of disease risk	<ul style="list-style-type: none"> • Calcium helps reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor in the development of osteoporotic bone fractures.
Prohibited medicinal claim	<ul style="list-style-type: none"> • Calcium reduces the risk of osteoporosis • Calcium heals osteoporosis damage • Calcium is a treatment for osteoporosis • Calcium prevents osteoporosis

4.3 Claims Regulation is applied to commercial communications

All claims made in commercial communications regarding the beneficial properties of foods and used in the labelling, presentation or advertising of foodstuffs intended for the final consumer are considered to be health claims within the scope of the Claims Regulation. Pursuant to Article 7 of Food Information Regulation (EC) 1169/2011, the presentation of foods refers, in particular, to their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed. Thus, the way in which foods are grouped on shelves in retail store and in online stores falls within the concept of presentation. Pursuant to Directive 2006/114/EC of the European Parliament and of the Council concerning misleading and comparative advertising, advertising means the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services.

The Claims Regulation is only applied to commercial communications, not to dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications.

It is not always easy to determine explicitly what commercial communication is. This determination has to be carried out case by case. The following questions may help determine what is commercial communication and thus within the scope of the Claims Regulation.

- Why and in what context the claim is presented, what is its primary object and purpose?
- Does the presentation of the claim bring financial or some other commercial gain to the producer, importer, distributor, marketer, etc.?
- How does the consumer perceive the information and can the consumer link the claim with a specific product? Is there an obvious relationship between the product and the claim?

In Evira's view, the following, for example, are commercial communications:

- Labelling related to the product, as well as oral or written material related to a specific product in the social media (Facebook, Twitter etc.), on radio, television, in stores, network marketing, fairs, etc.
- Websites, which provide information about the impact of various substances on health, body functions, etc. and enable the consumer to directly link the matters with a specific product (e.g. direct link to a product marketed on another site)
- A web link on the website of the company to another website, if this may cause the consumer to associate the information provided on the linked website with the product marketed by the company, or with an ingredient of the product.
- Publications designed for sales promotion of stores, etc.
- Press releases related to the marketing of a specific product
- Information provided by the company in some other way on the product marketed by the company (e.g. interviews in the media)

In Evira's view, non-commercial communications include, for example:

- Scientific publications
- Articles published in newspapers and magazines (which do not market any products)
- Websites, which do not present any trademarks or have direct links to a product marketed on another site

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

5 NUTRITION CLAIMS

Nutrition claims are claims describing the beneficial nutritional content of foodstuffs. The beneficial nutritional property referred to in a nutrition claim can be related to:

- The energy the food
 - provides
 - provides at a reduced or increased rate, or
 - does not provide
- Nutrients or other substances the food
 - contains
 - contains in reduced or increased proportions, or
 - does not contain

Authorised nutrition claims are listed in the Annex to the Regulation on Nutrition and Health Claims and in its Amendments. A register of authorised nutrition claims maintained by the European Commission can be found at: <http://ec.europa.eu/nuhclaims/>.

Nutrition claims likely to have the same meaning for the consumer are also permitted. The nutrition claims authorised at the time of the updating of this Guide, the conditions applied to them and examples of what in Evira's view are equivalent nutrition claim wordings are collected in Appendix 1 to this Guide. If the operator uses some other equivalent wording, the operator shall ensure that the wording is likely to have the same meaning for the consumer.

5.1 Conditions for use of nutrition claims

The minimum amount that the product shall contain of the nutrient referred to in the nutrition claim for the nutrition claim to be made has been specified for authorised nutrition claims. The claim may be used in the labelling or marketing of products provided the conditions of use of the claim are fulfilled in the product and in the labelling.

5.1.1 Vitamins and minerals

Pursuant to the Claims Regulation, a food may be called a source of a vitamin or mineral, if it contains a significant amount of the vitamin or mineral in question.

In this case 100 grams or 100 millilitres of the product or a package containing one portion shall contain at least 15% of the daily reference intake of the vitamin or mineral. For beverages, a content of 7.5% of the daily reference intake in 100 millilitres of the beverage is adequate.

Correspondingly, nutrition claim "high in vitamin or mineral" can be used, if 100 grams or 100 millilitres of the product or a package containing one portion contains

30% of the daily reference intake of the nutrient in question, or if 100 millilitres of a beverage contains 15% of the daily reference intake.

If a food package contains several portions, 100 grams or 100 millilitres of the product shall contain a significant amount of the vitamin or mineral in question.

The same conditions are applied to food supplements. A food supplement may only be marketed as a source of a vitamin and/or mineral and a vitamin and/or mineral may only be included in the list of characteristic substances, provided the daily intake of the vitamin and/or mineral from the food supplement is at least 15 per cent of the reference daily intake, when consumed according to the dosage instructions. If the food supplement is sold specifically as an excellent or good source of nutrients, or marketed as being high in vitamins or nutrients, Evira is of the view that the daily intake from the food supplement, when consumed according to the dosage instructions, must be at least 30% of the daily reference intake.

The daily reference intake values of vitamins and minerals are specified in Nutrient Labelling Decree 588/2009 of the Ministry of Agriculture and Forestry and in Annex XIII to Food Information Regulation 1169/2011:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF>

Daily intake reference values and the limit values for nutrition claims "source of" and "high in" are presented in Table 3.

5.1.2 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 3. Although clear limit values for the nutrients in question have not been set in the conditions of use, the conditions specified in the Claims Regulation must be fulfilled.

Examples of claims of this type include "contains lycopene", "contains lutein", "contains flavonoids".

The operator is responsible for demonstrating the fulfilment of the requirements of the Claims Regulation, i.e. the substance in question has a proven beneficial nutritional or physiological effect and the product contains a significant amount of the substance. In Evira's view, this should be part of the operator's in-house control. A scientifically proven beneficial effect can be based on, for example, statements issued by EFSA.

Evira is of the view that nutrition and health claims can be made on both processed and unprocessed foods provided the food fulfils the conditions of the use of the claim, the claim is used in compliance with the requirements of the Claims Regulation and the consumer is not misled. Thus, the claim "source of protein", for example, could be used on meat, or the claim "contains b-carotene" on carrots.

Table 3. Daily intake reference values and the limit values for nutrition claims "source of" and "high in". The amount equal to the reference percentage shall be obtained from 100 grams or 100 ml of the product or from a package of one portion. The amounts shown in the Table for minerals and vitamins shall be indicated in nutrition labelling.

	Daily reference intake	Source of (7.5 %, drinks)	Source of (15%)	High in (30%)
Vitamin A (µg)	800	60	120	240
Vitamin D (µg)	5	0,375	0.75	1.5
Vitamin E (mg)	12	0,9	1.8	3.6
Vitamin K (µg)	75	5,625	11.25	22.5
Vitamin C (mg)	80	6	12	24
Thiamine (mg)	1.1	0,0825	0.165	0.33
Riboflavin (mg)	1.4	0,105	0.21	0.42
Niacin (mg)	16	1,2	2.4	4.8
Vitamin B6 (mg)	1.4	0,105	0.21	0.42
Folic acid (µg)	200	15	30	60
Vitamin B12 (µg)	2.5	0,1875	0.375	0.75
Biotin (µg)	50	3,75	7.5	15
Pantothenic acid (mg)	6	0,45	0.9	1.8
Potassium (mg)	2000	150	300	600
Chloride (mg)	800	60	120	240
Calcium (mg)	800	60	120	240
Phosphor (mg)	700	52,5	105	210
Magnesium (mg)	375	28,125	56.25	112.5
Iron (mg)	14	1,05	2.1	4.2
Zinc (mg)	10	0,75	1.5	3
Copper (mg)	1	0,075	0.15	0.3
Manganese (mg)	2	0,15	0.3	0.6
Fluoride (mg)	3.5	0,2625	0.525	1.05
Selenium (µg)	55	4,125	8.25	16.5
Chrome (µg)	40	3	6	12
Molybdenum (µg)	50	3,75	7.5	15
Iodine (µg)	150	11,25	22.5	45

5.1.3 Source of fibre

For example, a food can be referred to as a source of fibre, if the content of dietary fibre in the food is at least 3 g/100 g or 1.5 g/100 kcal. Correspondingly, a food can be referred to as high in fibre, if the content of dietary fibre is at least 6 g/100 g or 3 g/100 kcal.

5.1.4 Source of protein

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

Example:

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

The energy provided by fat is calculated similarly, but bearing in mind that one gram of fat provides 9 kcal of energy

5.1.5 "No added sugar"

The Claims Regulation specifies the following conditions of use for the nutrition claim "no added sugar": 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. Evira interprets this to mean sweet foods, such as honey or juice. If sugars are naturally present in the food, the following indication should also appear on the label: "contains naturally occurring sugars".

According to Evira's interpretation, the use of a sweetener does not prevent the use of the nutrition claim "no added sugar" as long as the product and the information provided on it are otherwise in compliance with the Regulation. When using sweeteners, it should be remembered that pursuant to legislation concerning additives, their use is only permitted in certain foods.

5.1.6 Comparative nutrition claims

Comparative nutrition claims are claims that compare the composition of the food in question with another food. Comparative nutrition claims are addressed in Article 9 of the Claims Regulation which states that a comparison may only be made between foods of the same category, taking into consideration a range of foods of that category. The difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food. The composition shall be compared with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands.

The only comparative nutrition claims permitted in the Annex to the Regulation are "increased [name of the nutrient]", "reduced [name of the nutrient]", "energy-reduced" and "light/lite" for which the Annex defines the following conditions:

INCREASED [NAME OF THE NUTRIENT]

A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim "source of" and the increase in content is at least 30 per cent compared to a similar product.

REDUCED [NAME OF THE NUTRIENT]

A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30 per cent compared to a similar product, An exception to this is micronutrients where a 10 per cent difference in the reference values as set in Council Directive 90/496/EEC shall be acceptable and for sodium, or the equivalent value for salt, where a 25 per cent difference shall be acceptable.

ENERGY-REDUCED

A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 per cent. The characteristic(s) which make(s) the food reduced in its total energy value shall also be indicated

A claim stating that the content of saturated fatty acids in a food has been reduced, and any claim likely to have the same meaning for the consumer, may only be made if

- a) the reduction in the sum of saturated fatty acids and trans-fatty acids in the product is at least 30 percent compared to the sum of saturated fatty acids and trans-fatty acids in a similar product; and*
- b) the content of trans-fatty acids in the product is equal to or lower than in a similar product.*

A claim stating that the content of sugar in a food has been reduced, and any claim likely to have the same meaning for the consumer, may only be made if the energy content of the product is equal to or lower than in a similar product.

LIGHT/LITE

A claim stating that a product is "light" or "lite" and any claim like to have the same meaning for the consumer, shall follow the same conditions as those set for the term "reduced". The claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food "light" or "lite".

The Guidance published by the Commission on 14 December 2007 on the implementation of the Claims Regulation provides more detailed guidance for the use of comparative claims. According to it, comparative claims are always nutrition claims and a comparative claim shall always indicate the difference in the quantity of a nutrient or the energy value. Comparison is only permitted based on the nutritional content between foods of the same category. This means that comparison between e.g. milk and butter is not possible. For a comparison, a range of foods of the same category shall be taken into account, taking several foods of the same category into consideration, including also foods of other brands in the market area where the product is to be marketed. The requirement for comparison of a range of products is designed to prevent situations where comparison to a single product will mislead the consumer, in case the reference product is not a representative example of the food category. The larger the range of comparable products on the market, the larger the range of products considered in the comparison shall be to ensure that the range of products is adequately large and representative. If the selection available on the market changes frequently, the comparison shall be updated on a regular basis, at intervals of ca. 2 years.

5.1.6.1 Addition of vitamins and/or minerals

The conditions specified for the use of nutrition claim "*added [nutrient]*" in the Annex to the Claims Regulations do not enable the use of a claim stating "*added vitamin/mineral*". However, recital 20 in the Claims Regulation states that "*Any claim considered to have the same meaning for consumers as a nutrition claim included in the aforementioned list should be subject to the same conditions of use indicated therein*". For example, claims related to the addition of vitamins and minerals such as

"with ...", "restored ...", "added ...", or "enriched ..." should be subject to the conditions set for the claim "source of ...".

In Evira's view, the inconsistency is caused by reasons related to translation. The English version of the Claims Regulation uses two terms for claims related to addition; "added" and "increased [NAME OF NUTRIENT]". In the Swedish version these are translated "tillsatt" and "Ökat innehåll av [NAMN PÅ NÄRINGSÄMNET]". In the Finnish translation both are translated with "Lisätty" (added).

Because of this, Evira is of the view that:

- Claims referring to the **addition** of vitamins and minerals in foods (pursuant to Regulation (EU) No 1925/2006), such as "restored [name of vitamin and/or mineral] ", "increased [name of vitamin and/or mineral] and "added [name of vitamin and or mineral]" can be considered to have the same meaning as the claims "with" or "...source of" if the products meet the conditions set for the claim "source of...".
- However, the claim "increased [vitamin and or mineral]" may not be used **for purposes of comparison** to similar products, because the conditions set for the use of the claim "increased [nutrient]" rule out this possibility for vitamins and minerals. Because of this, comparative nutrition claims such as "more vitamin C", "50% more calcium" or "vitamin D doubled" may not be used.

5.1.6.2 Light/lite

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

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

5.1.6.3 Reduced salt

In Finland, the old interpretation is for the time being followed as concerns comparison of products regarding the "reduced salt" claim. The interpretation may change, however, when the Food Information Regulation is amended.

The comparison of foodstuffs manufactured in Finland is as a rule carried out based on the minimum limits of the claim "High salt content" compliant with the Decree of the Ministry of Agriculture and Forestry (1010/2014). For foreign foodstuffs and foodstuffs manufactured in Finland to which no limits of salt content are applied, 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 sausages or other cured sausages.

5.2 Claims not construed as nutrition claims

Information on the quality or quantity of a nutrient, which is required elsewhere in legislation, is not construed as a nutrition claim. For example, indications of the fat content of cheeses and certain sausages are not construed as nutrition claims.

Furthermore, the listing of ingredients used or not used in the production of the food or which describe the properties of the ingredients, are not construed as nutrition claims:

- with added sugar (N.B. claims "sugar-free", "no added sugars" and "without added sugar", on the other hand, are nutrition claims)
- sweetened
- sweetened with Xylitol/fructose
- no fats used in manufacture
- does not contain any milk constituents
- milk-free
- additive-free
- preservative-free

"Lactose-free", "low-lactose", "gluten-free" and "very low gluten" are not nutrition claims; instead they are provided for in legislation concerning foods for particular nutritional uses and in the future in the Food Information Regulation.

The claims "contains probiotics" and "contains antioxidants" are not construed as nutrition claims. Because the names suggest a function or a health effect, they are health claims, not nutrition claims.

5.3 Prohibited nutrition claims

Nutrition claims that are not authorised pursuant to the Claims Regulation and may not be used include the following, for example:

- cholesterol-free, low-cholesterol
- does not contain trans fatty acids, 0% trans fats
- super-light, ultralight
- "equal to" comparisons
- low-carbohydrate
- more vitamin C
- vitamin D doubled
- 50% more calcium

5.3.1 Misleading nutrition claims

The Commission has published guidance on the implementation of the Claims Regulation. It states that emphasising properties, which have no bearing on the total intake of the nutrient in question is considered misleading.

- For example, using the claim "reduced fat" in bread, which is already in and of itself low in fat, would be misleading, because a reduction of the amount of fat would have no essential impact on the total intake of fat.
- For the same reason the "added" claim can only be used for products, which fulfil the conditions of use of the "source of" claim.

It would be misleading to emphasise the nutritional properties of an individual ingredient of a food, unless the food product itself fulfils the conditions of use of the nutrition claim in question.

- For example, it would be misleading to state that fish containing omega-3 fatty acids was used in the production of fish balls, unless the fish balls fulfil the conditions of use of the claim presented.

Public nutrition education

The scope of application of the Claims Regulation is very broad and it applies to all claims made in commercial communications. Accordingly, public nutrition education provided on product packaging or any other commercial communications shall also comply with the Claims Regulation. The products and their labelling shall meet the requirements of the Claims Regulation.

The nutrition education message may not mislead the consumer or give a false idea of the nutritional value of the food or its quality in other respects.

- For example, a package of rye cookies may not refer to the high fibre content of rye as public nutrition education, unless the cookies contain the amount of fibre required to use the claim "source of fibre".

Referring to nutrition recommendations

The Claims Regulation does not directly advise on the use of nutrition recommendations, but it is stated in the recitals that the Regulation does not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies. No interpretation of the use of nutrition recommendations has been made on Community level.

Evira is of the view that nutrition recommendations can be referred to in commercial communications on a general level, for example:

- *"Nutrition recommendations advise the use of fat-free or low-fat milk products as meal-time drinks" or*
- *"Nutrition recommendations advise eating at least half a kilogram of vegetables, berries and fruit every day".*

The nutrition recommendations shall have been issued by official bodies, such as the National Nutrition Council. The recommendation shall apply to the whole food category, e.g. fat-free milk products, and not to individual products. However, consumers may not be misled by the use of recommendations. Recommendations that contain a clear claim, e.g. *"Nutrition recommendations advise the use of fat-free or low-fat milk products as meal-time drinks, because it is good for your heart"*, must meet the criteria of the Claims Regulation.

5.4 "The heart symbol – a better choice" is construed as a nutrition claim

In Finland, the authorities have determined that "The heart symbol – a better choice" symbol granted by the Finnish Heart Association and Finnish Diabetes Association is a nutrition claim referred to in Article 2 of the Claims Regulation; it states, suggests or implies that a food has particular beneficial nutritional properties. The purpose of the symbol is to promote public health by making it easier to choose a healthy diet.

The impetus for building the symbol label system stems from the major nutritional problems related to the health of Finnish people. The symbol is not associated only with cardiac health. Products bearing "The heart symbol – a better choice" symbol are better choices in terms of fat and salt intake. The authorities have been involved in the development of the symbol and its criteria. The symbol is also referred to in the

consumer brochure of nutritional recommendations published by the National Nutrition Council (Ravinto ja liikunta tasapainoon (Integrating Nutrition and Physical Activity), 2006).

Article 28(4)(a) of the Claims Regulation required that Member States communicate to the Commission, by 31 January 2008 at the latest, any nutrition claims in the form of pictorial, graphic or symbolic representation and the national provisions or rules applied to them. 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, although it is not included in the authorised nutrition claims listed in the Annex to the Claims Regulation.

6 HEALTH CLAIMS

The starting point for the use of health claims is that claims cannot be used until the scientific substantiation for the claim has been approved. The European Food Safety Authority EFSA assesses the substantiation on which the claim is based and after that the claim is authorised or rejected by the European Commission under a regulation.

The European Commission maintains a register of authorised and unauthorised claims. The register can be found on the website of the Commission at: <http://ec.europa.eu/nuhclaims/>. Moreover, certain claims are still waiting for the Commission's final decision and therefore these claims may for the time being be used in the marketing of food (cf. Article 13(1) health claims).

6.1 Article 13(1) health claims, i.e. functional health claims

The first Regulation (EU) No. 432/2012 establishing authorised Article 13(1) health claims, i.e. functional health claims was adopted on 14 June 2012. The application of the Regulation started on 14 December 2012. This means that the Article 13(1) health claims on which the European Commission has issued a rejection decision may not be used after that date in the labelling or marketing of food.

As this is a Community level Regulation, it is not possible to provide for national exceptions to it. For this reason it is also not possible to grant national transition periods or extensions of time during which stocks of food packages bearing unauthorised health claims may continue to be sold until exhausted.

Evira is of the view that food packages bearing unauthorised health claims may in some cases be modified by means of e.g. stickers to make them marketable.

Moreover, some 2000 health claims related to herbal substances are still waiting for EFSA's assessment and/or the Commission's decision. These health claims referred to in Article 13(1) of the Claims Regulation may be used in the marketing of food at the operator's own risk until a final decision has been made on the claim. However, the claims shall comply with the Claims Regulation and the national provisions applied to claims.

- Claims can be made using the same or an equivalent wording as the wording with which authorisation has been applied for the claim.
- The conditions of use of the claim shall be fulfilled in the food on which the claim is used.
- The food package shall carry the labelling required under legislation pertaining to claims.

- In addition to labelling, the use of the claim in marketing shall also be taken into consideration.
- If the health claim, which is still under consideration, is a medicinal claim or a claim prohibited by virtue of Article 3 or 12 of the Claims Regulation, Evira interprets it to not be a health claim compliant with the Claims Regulation and the claim may not be used in the labelling or marketing of food.

After the Commission has decided under a Regulation on the authorisation or rejection of health claims, the use of unauthorised claims in the marketing of the foods shall be discontinued within 6 months.

- Authorised and unauthorised claims are found in the register maintained by the European Commission at <http://ec.europa.eu/nuhclaims/>
- Authorised health claims referred to in Article 13(1) are found in Regulation 432/2012 at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:136:0001:0040:EN:PDF>
- Health claims referred to in Article 13(1) that are still under consideration can be checked in the register maintained by EFSA <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=NDA&foodsectorarea=26>

6.2 Article 13(5) and 14 health claims

Article 13(5) health claims refer to health claims, which are similar in content to Article 13(1) health claims, but which are based on newly developed scientific evidence or which include a request for the protection of proprietary data.

Article 14 health claims are divided into

- Article 14(1)a, reduction of disease risk claims
- Article 14(1)b, claims referring to children's development and health.

The use of both Article 13(5) claims and Article 14 claims is based on an application procedure. These health claims may not be used until the European Commission has authorised the use of the claim under a Regulation. In other words, claims may not be used already at the stage when the application regarding the claim has been submitted.

Food business operators who wish to use a health claim not included in the list of authorised claims shall submit a health claim application. A new health claim application can be submitted for claims that have already been rejected once, if the operator can present new, relevant scientific substantiation for the claim. Such new scientific evidence must be clearly presented in the new health claim application.

Authorised and unauthorised Article 13(5) and 14 claims are found in the register maintained by the European Commission at <http://ec.europa.eu/nuhclaims/>.

More information about claim applications is provided:

- on Evira's website: <http://www.evira.fi/portal/en/food/manufacture+and+sales/labelling/nutrition+and+health+claims/health+claim+applications/>
- on EFSA's website: <http://www.efsa.europa.eu/en/ndaclaims/ndaguidelines.htm>

6.3 Authorised health claims

Health claims may only be used in the labelling, advertising or other presentation of foodstuffs provided the claims have been authorised and they are included in the lists of permitted claims referred to in Articles 13 and 14.

Pursuant to the Commission's implementing decision, even authorised health claims may not be used, unless their use completely complies with all the requirements laid down in the Claims Regulation. Food business operators shall be able to demonstrate due diligence and steps taken to comply with each part of the Claims Regulation.

- Using only authorised claims in compliance with the Claims Regulation
- Authorised claims are accompanied by information mandatory for the use of the claims.

Implementing decision of the European Commission adopting guidelines for the implementation of Article 10 of the Claims Regulation

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:022:0025:0028:en:pdf>

6.3.1 Conditions of use of health claims

Specific conditions of use have been determined for each authorised health claim, and in some cases also the conditions or restrictions of use or a warning statement. If a claim is to be included in the labelling or marketing of the product, the product and its labelling shall fulfil these conditions. The conditions of use are found in the Regulation under which the product has been authorised as well as in the Commission register of claims at <http://ec.europa.eu/nuhclaims/>.

For several health claims, the condition of use is that the food contains a significant amount of the vitamin or mineral in question, i.e. fulfils the conditions of nutrition claim "source of". Cf. Section 5.1.1 for more information.

Product categories

Some health claims are authorised for use only in specific product categories. In that case it must be verified that the health claim is only used in foods included in that food category.

For example, "Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease" is an authorised Article 14(1)a health claim. The conditions of use of this claim are specified as follows: "Information to the consumer that the beneficial effect is obtained with a daily intake of 1.5-2.4 g plant sterols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the entire range "7 to 10%" and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer".

6.3.2 Use of equivalent wordings

The Claims Regulation states that in addition to the authorised wording, health claims may be made using equivalent wordings, which have the same meaning for the consumer, because they describe the same relationship between the food category, the food or an ingredient of food and health.

Evira recommends that the wording given in the Regulation is used in each nutrition and health claim. If the operator uses some other equivalent wording, the operator shall ensure that the wording is likely to have the same meaning for the consumer. It is particularly important to ensure that the presented wording is not stronger than the wording given in the Regulation.

Common guidelines for member countries regarding the flexibility of health claim wording principles

[http://www.evira.fi/files/attachments/fi/elintarvikkeet/valmistus_ja_myynti/pakkausmerkinnat/health_claims - flexibility of wording principles 14 dec 2012.pdf](http://www.evira.fi/files/attachments/fi/elintarvikkeet/valmistus_ja_myynti/pakkausmerkinnat/health_claims_-_flexibility_of_wording_principles_14_dec_2012.pdf)

6.3.3 Dual claims

Article 14(1)a claims, which refer to the reduction of disease risk, typically consist of two parts. They first indicate the risk factor reduced by the substance contained in the food and then indicate the disease the risk of which is reduced. For example: Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.

In Evira's view, the claim shall be presented in the labelling or in the advertisement at least once in full without dividing it into parts. In any case, the division of a dual claim into parts may not mislead the consumer.

6.3.4 Authorised claims are not specific to one product or applicant

Authorised nutrition and health claims are not specific to one product or applicant, but apply to a food category, a food or an ingredient of food. Any food business operator can use an authorised claim in the marketing of their own product, provided the conditions of use of the claim are fulfilled in the product and the food package carries the labelling required due to the use of the claim.

By virtue of Article 13.5, the Commission can grant data protection to an authorised health claim, whereby the use of the health claim can be restricted for a certain period of time to the benefit of the applicant.

6.3.5 Claims may not be linked directly with the commercial name of the food product

Claims shall always be related to the food or an ingredient of the food. As claims are not specific to products, they may not be formulated so that they are linked directly with the commercial name of the product.

For example, "Calcium is needed for the maintenance of normal bones" is an authorised health claim.

- Prohibited claim formulation: Product X is needed for the maintenance of normal bones.
- Permitted claim formulation: Calcium contained in product X is needed for the maintenance of normal bones.

6.3.6 Health claims on products intended for children

Article 14(1)b claims are not allowed on infant formulae. The nutrition and health claims authorised for use on infant formulae are listed in Decree 1216/2007 of the Ministry of Trade and Industry.

Authorised nutrition claims referred to in the Annex to the Claims Regulation and authorised Article 14(1)b health claims may be used on other products intended solely for children, such as follow-on formulae and processed cereal-based foods for infants and young children, and other children's foods (as provided for in Regulation (EU) No. 609/2013 of the European Parliament and of the Council). Health claims used on products solely intended for children are always considered to be the claims referred to in Article 14(1)b.

A claim describing the normal functions of the body as provided for in Article 13 may be used on common foods making reference to its validity also for children, provided the scientific data it is based on has covered the whole human life cycle, including childhood.

In Evira's view, authorised claims referring to the development and health of children may be used on foods whose target group includes both children and adults. However, the consumer may not be misled. For example, it may not be implied that a health effect found in children will also benefit adults. And vice versa, a health effect found in adults may not be implied to benefit also children.

6.3.7 Article 10(3) general, non-specific statements

According to Article 10(3) of the Claims Regulation, references 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, statements such as "for muscles", "good to heart" and "a friend of bones" are general, non-specific references. They shall be accompanied by an authorised health claim that specifies the effect on health.

Pursuant to the European Commission's implementing decision (2013/63/EU) adopting guidelines for the implementation of Article 10 of the Claims Regulation, an authorised health claim accompanying the statement making reference to general non-specific health benefits should be made "next to" or "following" such statement. In Evira's opinion, the condition "next to" or "following" is fulfilled when the authorised health claim appears in the same field of vision as the general, non-specific statement. Article 2.2(k) in Food Information Regulation (EU) No 1169/2011 defines "field of vision" as all the surfaces of a package that can be read from a single viewing point. In packages that are rectangular or box-like in shape, the general statement and the authorised health claim shall appear on the same side of the package. In cylindrical packages and bottles they shall appear in a way that makes it possible for the consumer to see both the general statement and the authorised health claim at a glance. The general statement and the authorised health claim may also be placed on different sides of the package if they are linked together with e.g. an asterisk (*). However, the consumer shall be able to easily and readily link them together and thus understand the precise benefit offered by the general health statement.

Authorised health claims shall be easy for the consumer to notice and see before making the purchasing decision. This means that it is not possible to make a general statement on the package and only describe the specific health benefit on the website, for example. Similarly, if a general statement is used in an advertisement in print, television or radio, the specific authorised health claim shall also appear in some point of the advertisement.

6.3.8 Trademarks and product names considered to be claims

Pursuant to Article 1(3) of the Claims Regulation, a trademark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used, provided that it is accompanied by a related nutrition or health claim which complies with the provisions of the Claims Regulation.

In Evira's view, a trademark or name which may be construed as a health claim shall be accompanied by a health claim, which specifies the health effect. Correspondingly, a trademark or name which may be construed as a nutrition claim shall be accompanied by a specifying nutrition claim.

For example:

- A product with the name "Fibre bomb" shall fulfil the conditions of the nutrition claim "high in" and this information shall be presented with the product name.
- The use of the name "Bone drink" implies that there is a relationship between the food and bone health. Consequently the name "Bone drink" must be accompanied by e.g. the following specific statement: The calcium contained in Bone drink is needed for the maintenance of normal bones.

By virtue of Article 28(2) of the Claims Regulation, products bearing trademarks or brand names existing before 1 January 2005 which do not comply with the Claims Regulation may continue to be marketed until 19 January 2022 after which time the provisions of the Claims Regulation shall apply.

Evira is of the view that the composition of products to which the aforementioned transition period applies shall not be modified in such a way that the brand name becomes misleading.

6.3.9 Pictorial, symbolic and graphic representations that include a claim

Pursuant to Article 2(2) of the Claims Regulation, "claim" means 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.

On the other hand, Article 10(3) of the Claims Regulation states that general, non-specific health claims shall be accompanied by an authorised Article 13 or 14 health claim, which specifies the health effect.

In other words, pictorial, symbolic and graphic representations that include a claim shall be accompanied by a health claim, which specifies the health effect. If the pictorial, symbolic or graphic representation clearly presents a nutrition claim, Evira is of the view that a nutrition claim shall accompany the representation.

For example:

- The package or advertisement of the food shows an image of an eye. This image shall then be accompanied by a health claim, which specifies how the food or an ingredient of the food affects eye health or vision. Correspondingly, the labelling shall present the other information required due to the use of that health claim.
- The package or advertisement of the food shows an image that refers to omega-3 fatty acids. This image shall then be accompanied by a nutrition claim related to omega-3 fatty acids. Correspondingly, the labelling shall present the other information required due to the use of that nutrition claim.

6.4 Prohibited health claims

Pursuant to Article 12 of the Claims Regulation, the following health claims are not allowed:

- 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; in Evira's view, also references to reduction of waist size or size of clothes are prohibited
- c) claims which make reference to recommendations of individual doctors or health professionals and associations other than the national medical associations representing professionals in the field of medicine and nutrition and dietetics, and health-related charities 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 the message content.

According to Evira's interpretation, the following, for example, can be considered prohibited health claims:

- a health professional talks about the effects of a food product on health or about their own experiences
- a health care student talks about the effects of a food product on health or about their own experiences
- an actor portraying a health professional talks about the effects of a food product on health or about their own experiences

6.4.1 Experiences of individual consumers

Pursuant to Article 6 of the Claims Regulation, nutrition and health claims made on foods shall be based on generally accepted scientific data. Pursuant to Article 10, health claims are prohibited unless they comply with the specific requirements in the Regulation and are authorised in accordance with the Regulation and included in the lists of authorised claims provided for in Articles 13 and 14. The personal experience of individuals, although perfectly true in their case, does not fulfil the requirement of the Claims Regulation for scientific data and pre-authorisation. For this reason, the marketing of food with the experiences of an individual consumer can be considered misleading and in violation of the Claims Regulation.

In the case of authorised claims, however, Evira is of the view that an individual consumer, actor or public person can tell about the authorised nutrition or health

claim in an advertisement. In this context they can also state if they have themselves noticed the properties the food or its ingredient is claimed to have. This does not apply to the doctors and health professionals referred to in Article 12, however.

6.4.2 Authorisation of a health claim does not affect medicine classification or novel food status

The assessment process of health claims does not involve any consideration of whether the substances to which the claims pertain should be classified as foodstuffs or medicines in the Member States. National medicines authorities still have the right and the responsibility to decide on which substances are classified as medicines in each country. The authorisation of health claims does not affect this.

This is specifically emphasised in Commission Regulation 432/2012, under which Article 13(1) health claims were authorised: *(17) The addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 13(3) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff.*

[http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:136:0001:0040:en:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:136:0001:0040:en:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:136:0001:0040:en:PDF)

7 PRINCIPLES OF USE OF CLAIMS

Under Section 9 of the Food Act, truthful and sufficient information shall be given about the food in food packaging, presentation and advertising, or in some other way in connection with marketing. The issuance of misleading information about food is prohibited.

7.1 General principles of use of claims

In addition to packages marketed to the final consumer, the Claims Regulation is also applied to the marketing and advertising of products in all their forms, such as printed products, internet, in electronic form, radio, TV and product presentations. Nutrition and health claims may only be used in the labelling, presentation or advertising of foods provided the claim and the food fulfil, in particular, the requirements and conditions laid down in Articles 3 and 5 of the Claims Regulation.

The Claims Regulation is also applied in situations where the consumer can link the claim presented with a specific product, even if the product is not directly said to have the claimed property. In other words, the image created of the product shall also be compliant with the Claims Regulation and particularly Article 3 of the Regulation.

- For example, if scientific articles regarding omega-3 fatty acids are quoted on a website that markets omega-3 fatty acid products, this is construed as a health claim.
- Similarly, if a website marketing a food describes how an ingredient of the food, in this case omega-3 fatty acids, has been traditionally used as a folk remedy, this is construed as a health claim or a prohibited medicinal claim, depending on the claim.

7.1.1 General principles of use of claims, Article 3

Nutrition and health claims may 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 regular Finnish food does not contain a sufficient amount of vitamin D, thus intimidating consumers by describing illnesses resulting from a vitamin D deficiency.

7.1.2 Claims may only be made on healthy foods, Article 4

The Commission is expected to establish nutrient profiles, which must be met for claims to be used. After that, foodstuffs on which a nutrition or health claim is made shall comply with the criteria of the profile.

Nutrient profiling refers to the categorisation of foods on the basis of their composition. The aim of profiling is to avoid a situation where nutrition or health claims mask the true character of products that are detrimental to health. This way they prevent the misleading of consumers.

When the nutrient profiles have been established, Evira will provide information about the approved profiles and the action operations are required to take.

Health claims may not be made for alcoholic beverages. Nutrition claims may only be made referring to:

- low alcohol levels,
- reduction of alcohol content, or
- reduction of energy content.

7.1.3 General conditions, Article 5

The general conditions of the use of claims are specified in Article 5. In summary, the substance for which the claim is made shall have a proven beneficial effect and the product shall contain an adequate amount of the substance.

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 data;

- b) the nutrient or other substance for which the claim is made:
 - i. is contained in the final product in a significant quantity (as specified in regulations or in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data)
 - 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 data;
- c) 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 data;

Authorised nutrition and health claims fulfil these conditions, if the conditions of use of the claim are complied with.

Nutrition claim "contains a nutrient or some other substance" does not specify any conditions for the use of the substance for which the claim is made. As far as these nutrition claims are concerned, the operator shall particularly verify the fulfilment of the general conditions of Article 5.

7.2 Labelling

General labelling regulations pertain to all foodstuffs and cover the most common labelling used on food packages. Mandatory labelling shall be provided in Finnish and in Swedish. Nutrient and health claims are voluntary statements presented in labelling or marketing of food. The language requirements do not therefore apply to the presentation of claims.

However, if a nutrition or health claim is made in the labelling or other marketing of food, the labelling information required due to the use of the claim is mandatory labelling and shall be presented on the package in both Finnish and Swedish. In Evira's view, the presentation of claims using an expression or manner commonly understandable in Finland requires that the labelling information required due to the use of the claim is presented in Finnish and Swedish.

All information provided about the food, regardless of the language, shall be accurate and not misleading.

7.3 Nutrition labelling

Nutrition labelling is a precondition for the use of a nutrition or health claim. Nutrition labelling shall comply with Food Information Regulation (EC) No 1169/2011.

In Evira's view, the declaration of nutrients shall always be made in Finnish and Swedish, when a nutrient or health claim is made on food. Also when the nutrient or health claim is presented on the product in some other language than Finnish, nutrition labelling is mandatory and shall be presented in Finnish and Swedish.

7.3.1 Nutrient declaration in compliance with Food Information Regulation

Pursuant to Article 30 of the Food Information Regulation, the mandatory nutrition declaration shall include the following:

- a) energy value; and
- b) the amounts of fat, saturates, carbohydrate, sugars, protein and salt.

It may be supplemented with an indication of the amounts of one or more of the following:

- a) mono-unsaturates;
- b) polyunsaturates;
- c) polyols;
- d) starch
- e) fibre
- f) any of the vitamins or minerals listed in point 1 of Part A of Annex XIII to the Food Information Regulation, and present in significant amounts as defined in point 2 of Part A of Annex XIII.

Article 49 states that if the nutrition or health claim pertains to a substance that does not appear in the nutrition labelling, its amount shall be stated in the same field of vision as the nutrition labelling. In practice this means that the amount of such substances shall be indicated e.g. immediately following the nutrient declaration.

- For example, the amount of individual fatty acids, such as ALA, EPA and DHA shall not be stated in the nutrient declaration as fat, but e.g. immediately following the nutrient declaration.

More information is provided in Food Information Regulation 1196/2011:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:FI:PDF>

7.3.2 Verification of amount of nutrient

Pursuant to the Food Information Regulation, the nutritional content values indicated in labelling shall be average values based on:

- the manufacturer's analysis of the food;
- a calculation from the known or actual average values of the ingredients used; or
- a calculation from generally established and accepted data.

When a food is marketed as a source of a specific nutrient or a health claim is made on it, Evira recommends that the amount of the nutrients is analysed with laboratory tests or verified in some other reliable manner.

7.3.3 Claims shall refer to food ready for consumption

Pursuant to the Claims Regulation, nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions. The Food Information Regulation specifies that nutrition labelling information may be provided only on a product ready for consumption, if adequately detailed instructions for preparation are given and the information pertains to the food prepared according to these instructions.

In Evira's interpretation, if nutrition and health claims are made on semi-finished food products, which are provided with adequately detailed and explicit instructions for

preparation, the claim shall be accompanied with information about the nutritional content of the prepared food. Such products include e.g. tea, coffee, various drink powders, soup powders, diluted drinks and similar products, which are prepared by just adding water. If claims are made on meal mixes and similar products in which many ingredients that affect the nutritional content are added, each case must be assessed separately.

7.4 Mandatory information required due to the use of a health claim

When health claims are made, certain additional information shall always be provided in labelling, or if no such labelling exists, in the presentation.

Pursuant to Article 10(2) of the Claims Regulation, health claims shall only be permitted if the following information is included in 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.

Pursuant to Article 14(2) of the Claims Regulation, 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 that altering one of these risk factors may or may not have a beneficial effect.

The additional requirements pertaining to labelling as a result of various claims are described in Appendix 2 by means of examples.

7.4.1 Article 10(2)b

The Claims Regulation requires that the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect is included in labelling, or if no such labelling exists, in the presentation and advertising of foodstuffs.

The conditions set for the use of an authorised health claim specify requirements that the food in question needs to meet. The authorisation may also require that information be given to the consumer about the quantity required of the substance to which the health claim is based to obtain the beneficial effect.

Example 1.

The following Article 13(1) health claim has been authorised for beta-glucan: *"Beta-glucans contribute to the maintenance of normal blood cholesterol levels"*.

The specific conditions of use of this health claim are the following: *"The claim may be used only for food which contains at least 1 g of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of these sources per quantified portion. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of these beta-glucans."*

Evira recommends that the consumer be informed of the amount of beta-glucans in one portion (e.g. one decilitre, slice, etc.) of the product and how many daily portions are required to obtain the claimed beneficial effect.

Example 2.

The following health claim has been authorised for alpha-linolenic acid (ALA): *"ALA contributes to the maintenance of normal blood cholesterol levels"*.

The specific conditions of use of this health claim are the following: *"The claim may be used only for food which is at least a source of ALA as referred to in the claim "source of Omega-3 fatty acids" as listed in the Annex to Regulation (EC) No 1924/2006. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of ALA." A claim that a food is a source of Omega-3 fatty acids may only be made, where "the product contains at least 0.3 g alpha-linolenic acid per 100 g AND per 100 kcal, or at least 40 mg of the sum of the eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal."*

Evira recommends that information be given to the consumer of the daily quantity of the food (e.g. table spoons, teaspoons, etc.) and the pattern of consumption required to obtain the claimed beneficial effect.

7.4.2 Article 10(2)c-d

For some authorised health claims, a requirement for a mandatory warning included in labelling is specified as a condition of use.

For example, the authorised health claim "Glucomannan in the context of an energy restricted diet contributes to weight loss" shall be accompanied by "Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake advice on taking with plenty of water to ensure substance reaches stomach".

Even if a mandatory warning statement has not been specified for an authorised health claim, the food business operator shall verify the safety of the product, and if necessary, add an appropriate warning in the labelling of the product.

7.5 Unpacked foods

Pursuant to Article 1(2) of the Claims Regulation, the nutrition labelling requirements and the requirements of Article 10(2) a-b shall not apply in the case of non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread) put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale.

The warning statements referred to in Articles 10(2) c-d and 14(2), on the other hand, shall be presented, if necessary, also in the case of non-prepackaged foodstuffs and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale.

For example, the information brochure on carrots sold non-prepackaged in the fruit and vegetable section of a store need not present the nutrient declaration of carrots or the information referred to in Article 10(2)a-b, even if a nutrition or health claim is made on carrots. Instead, information that would be mandatory are the warnings referred to in Articles 10(2) c-d and 14(2) (if applicable). The same applies also to e.g. products sold from the bread and precooked meal counters and to foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale.

7.6 Food supplements

7.6.1 Nutrition labelling

The presentation of the nutritional labelling referred to in the Food Information Regulation does not apply to food supplements. Instead, the amount of characteristic substances in the food supplement must be presented in accordance with the Food Supplement Decree. If a nutrition or health claim is made on a food supplement, the amount of the substance on which the claim is based must be presented, however in the list of characteristic ingredients or in connection with it.

7.6.2 Article 10(2)a

Pursuant to Section 5 of the Food Supplement Decree of the Ministry of Agriculture and Forestry (78/2010), the labelling of food supplements shall indicate that the food supplement is not to be used as a substitute for a diversified diet. Article 10(2)a of the Claims Regulation, on the other hand, requires that a statement indicating the importance of a varied and balanced diet and a healthy lifestyle is included in labelling, or if no such labelling exists, in the presentation and advertising of foodstuffs.

The requirement laid down in the Claims Regulation applies also to food supplements, and thus in Evira's view the sentence referred to in the Food Supplement Decree does not alone fulfil the requirement of the Claims Regulation. The labelling of food supplements shall also include a statement referring to a balanced diet and a healthy lifestyle.

In Evira's view, the following sentence, for example, fulfils the requirements of both Section 5 of the Food Supplement Decree and Article 10(2)a of the Claims Regulation: "A food supplement is not to be used as a substitute for a varied and balanced diet or a healthy lifestyle". The content of this message can be divided into two separate sentences, if desired.

7.6.3 Article 10(2)b

Pursuant to the Claims Regulation, the quantity of the food and the pattern of consumption required to obtain the claimed beneficial effect shall be indicated in the labelling of the food, or if no such labelling exists, in the presentation and advertising. The conditions set for the use of health claims often specify the quantity of the substance on which the claim is based per 100 g or 100 kcal. These conditions for use cannot be directly applied to food supplements which are consumed in small doses and typically have a low energy value. For this reason, Evira is of the view that for food supplements the limit value shall be specified per daily dose.

Example

The following health claim has been authorised for alpha-linolenic acid (ALA): *"ALA contributes to the maintenance of normal blood cholesterol concentrations"*.

The specific conditions of use of this health claim are the following: *"The claim may be used only for food which is at least a source of ALA as referred to in the claim "source of Omega-3 fatty acids" as listed in the Annex to Regulation (EC) No 1924/2006. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of ALA." A claim that a food is a source of Omega-3 fatty acids may only be made, where "the product contains at least 0.3 g alpha-linolenic acid per 100 g AND per 100 kcal, or at least 30 mg of the sum of the eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal."*

Evira is of the view that this health claim can be made for a food supplement that contains at least 0.3 g alpha-linolenic acid per daily dose, or at least 40 mg of the sum of the eicosapentaenoic acid and docosahexaenoic acid per daily dose. However, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of alpha-linolenic acid. Evira recommends that information be given to the consumer of the daily dose of the food supplement, or the daily dose of the food supplement and some other food containing alpha-linolenic acid required to obtain the claimed beneficial effect

7.7 Use of claims in marketing

The use of nutrition or health claims in marketing (e.g. placards, brochures, press advertisements, internet, radio TV) always requires that the nutrient declaration and the mandatory additional information are included in the labelling of the food even if no claims are made on the package itself.

With the exception of information on dates and the lot marking, mandatory food information shall be available to the consumers, when they make the purchase decision. This also applies to additional information that is mandatory due to the use of claims.

- For example, when foodstuffs on which health claims are made are sold online, the labelling information mandatory due to the use of the claims shall be available to the consumers, when they place their order.

Operators are always responsible for the claims used in the marketing material produced by them. This applies to all food business operators: those who produce or have products produced for them, importers, packers, distributors, retailers, etc. The use of claims in marketing material produced by the operator (e.g. placards, brochures, print advertisements, internet, radio, TV) must not be inconsistent with the information presented in labelling.

Food business operators are always responsible for the compliance of the food and the claims made on the food with food laws. Even if products of another producer were sold online and the marketing materials were obtained from these operators, the online store operator is responsible for all the material found on their website. The operator is in such a case advised to inform the company that produces the material requiring them to provide material that fulfils the requirements of food laws.

7.8 Information provided to professionals

According to Section 9 of the Food Act, food must not in food packaging, presentation and advertising, or in some other way in connection with marketing 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. Such claims are only permitted on medicines.

The Food Act is applied to food and the conditions in which it is handled and to food business operators and food control at all stages in the production, processing and distribution of food (section 2). As the Act is applied at all food distribution stages, Evira's interpretation is that food may not be presented to have any medicinal effects in marketing targeted at professionals either.

According to Article 1(2) of Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods, the Regulation is applied to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer. The Court of Justice of the European Union gave on 14 July 2016 (case C-19/15) its judgment on the applicability of Article 1(2) of the Claims Regulation to marketing addressed to health professionals. The judgment of the Court stated: *Article 1(2) of Regulation No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods must be interpreted as meaning that nutrition or health claims made in a commercial communication on a food which is intended to be delivered as such to the final consumer, if that communication is addressed not to the final consumer, but exclusively to health professionals, falls within the scope that Regulation.*" In other words, the legislation on claims shall be complied with also in commercial communication addressed to health professionals.

8 IN-HOUSE CONTROL AND REGULATORY CONTROL

Evira's Guide 17060/1, Guidelines for Control of Nutrition and Health Claims, describes in more detail the operator's responsibility for in-house control of nutrition and health claims and the regulatory control of nutrition and health claims by authorities.

8.1 In-house control by food business operators

The European Commission has published for national control authorities and food business operators an implementing decision regarding guidelines for the implementation of Article 10 of the Claims Regulation.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:022:0025:0028:en:pdf>

Pursuant to the Commission's implementing decision, even authorised health claims may not be used, unless their use completely complies with all the requirements laid down in the Claims Regulation. Food business operators shall be able to demonstrate due diligence and steps taken to comply with each part of the Claims Regulation.

- Using only authorised claims in compliance with the Claims Regulation
- Authorised claims are accompanied by information mandatory for the use of the claims.

According to the Food Information Regulation, the food business operator responsible for the food information is the operator under whose name or business name the food is marketed. The food business operator responsible for the food information shall ensure the presence and accuracy of the food information.

Food business operators which do not affect food information shall not supply food which they know or presume to be non-compliant with legislation. They may not modify the information accompanying the food if such modification would mislead the final consumer. Food business operators are responsible for any changes they make in food information accompanying a food.

Responsibility for the use of health claims made on food is divided as follows, for example:

- Operators are responsible for the claims presented in the labelling of foods, which they produce, have produced for them, import (from the internal market and/or from third countries) or pack.
- Operators are always responsible for the claims used in the marketing material produced by them. This applies to all food business operators: those who produce or have products produced for them, importers, packers, distributors, retailers, etc. The use of claims in marketing material produced by the operator (e.g. placards, brochures, print advertisements, internet, radio, TV) must not be inconsistent with the information presented in labelling.

Implementation of following matters shall be verified through in-house control:
<ul style="list-style-type: none"> • Personnel have adequate knowhow regarding use of claims <ul style="list-style-type: none"> ○ A person has been appointed who is responsible for compliance of the use of claims and the additional labelling required due to them
<ul style="list-style-type: none"> • Prohibited claims are not used in the labelling or marketing of foods <ul style="list-style-type: none"> ○ Medicinal claims are not used in labelling or marketing ○ Prohibited claims referred to in Article 3 or 12 of the Claims Regulation are not used in labelling or marketing
<ul style="list-style-type: none"> • Only authorised claims are used in the labelling or marketing of foods <ul style="list-style-type: none"> ○ The claims used and their wording are authorised (the claim is included in the list of authorised claims or in the waiting list or a transition period is applied to the claim) ○ Reference to general, non-specific benefits is accompanied by an authorised health claim (Article 10(3)) ○ Any trademark, pictorial or graphic representation, etc. included in the claim has been taken into consideration and they comply with the Claims Regulation (any transition periods, the trademark/pictorial or graphic representation included in the claim is accompanied by an authorised claim)
<ul style="list-style-type: none"> • The conditions of use of the claims are fulfilled <ul style="list-style-type: none"> ○ The conditions of use of the claims are fulfilled in the product (e.g. amount, has it been verified that the product category is right)
<ul style="list-style-type: none"> • The labelling requirements pertaining to the use of claims are met <ul style="list-style-type: none"> ○ The packaging carries nutrition labelling (nutrition labelling requirement does not apply to food supplements) ○ The amount of the substance referred to in the claim is indicated in labelling ○ The information referred to in Article 10(2)a-b is provided in labelling (health claims) ○ The information referred to in Article 10(2)c-d and 14(2) is provided in

labelling (health claims) <ul style="list-style-type: none">○ It has been taken into consideration that the use of claims in marketing (e.g. brochures, advertisements, websites) requires the labelling presented above even if no claims are made on the package itself.
<ul style="list-style-type: none">• Withdrawals are initiated, if necessary

8.2 Regulatory control

The control of nutrition and health claims made on foods is included in the control of foods referred to in the Food Act. Control authorities shall carry out official inspections to verify compliance with the Nutrition and Health Claim Regulation in accordance with Regulation (EC) No. 882/2004

The European Commission has published for national control authorities and food business operators an implementing decision regarding guidelines for the implementation of Article 10 of the Claims Regulation.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:022:0025:0028:en:pdf>

Pursuant to the Commission's implementing decision, even authorised health claims may not be used unless their use fully complies with all the requirements of the Regulation. Accordingly, even where a claim is authorised and included in the lists of permitted health claims, national authorities should take action if its use does not comply with all the requirements of the Regulation; for example, if the mandatory information in labelling required when claims are used is missing.

Appendix 1. Authorised nutrition claims and examples of claim wordings considered equivalent by Evira

Nutrition claim	Condition of use	Equivalent wording	Remarks
Low energy	the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml 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 4 kcal (17 kJ)/100 ml. 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 3 g of fat per 100 g for solids or 1.5 g of fat per 100 ml 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 1.5 g per 100 g for solids or 0.75 g/100 ml 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 0.1 g of saturated fat per 100 g or 100 ml.	- 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 5 g of sugars per 100 g for solids or 2.5 g of sugars per 100 ml for liquids.	- low sugar content - contains a low amount of sugar	
Sugars-free	the product contains no more than 0.5 g of sugars per 100 g or 100 ml.	- 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 0.12 g of sodium, or the equivalent value for salt per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.	- low salt content	- 1 g of sodium is equivalent to 2.5 g salt (NaCl) - this nutrition claim only applies to sodium and not, for example, potassium or magnesium

Very low sodium/ salt	the product contains no more than 0.04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. 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 0.005 g/100 g 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
With no added sodium/salt	the product does not contain any added sodium/salt or any ingredient which contributes sodium to the product and is not more than 0.12 g sodium, or the equivalent value for salt, per 100 g or per 100 ml.		
Source of fibre	the product contains at least 3 g of fibre per 100 g or at least 1.5 g of fibre per 100 kcal.	- 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 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal.	- contains a large amount of fibre - high in fibre - high fibre content - rich in fibre	
Source of protein	at least 12% of the energy value of the food is provided by protein.	- contains protein - protein - protein content	
High protein	at least 20% 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)	- 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 - The product shall contain at least 15% of the recommended daily allowance
High [name of vitamin/s] and/or [name of mineral/s]	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 30% of the recommended daily allowance	- good source of vitamin - 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 - The product shall contain at least 30% of the recommended daily allowance
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 "source of" shall apply.	- source of lycopene - contains lycopene - with vitamin C - increased vitamin C - enriched with vitamin C - restored vitamin C	- 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. anti-oxidant, probiotic).
Increased [name of the nutrient]	the content of one or several nutrients other than vitamins or minerals has been increased	- increased fibre - increased protein	- nutrition claims pertaining to vitamins and minerals, such as:

	and the product meets the conditions for the claim "source of" and the increase in content is at least 30% compared to a similar product.	- more protein - fibre doubled - 50% more fibre	"vitamin D doubled" "more calcium" or "50% more vitamin C", are not permitted.
Reduced [name of the nutrient]	the reduction in content is at least 30% 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 equivalent value for salt, where a 25% 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 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.
Reduced saturated fat	a) the sum of saturated fatty acids and of trans-fatty acids in the product bearing the claim is at least 30% less than the sum of saturated fatty acids and of trans-fatty acids in a similar product; and b) the content in trans-fatty acids in the product bearing the claim is equal to or less than in a similar product.		
Reduced sugar	the amount of energy of the product bearing the claim is equal to or less than the amount of energy in a similar product.		
Light/Lite	shall follow the same conditions as those set for the term "reduced". 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 0.3g alpha-linolenic acid per 100 g AND per 100 kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g AND per 100kcal.	- source of omega-3 fatty acids	
High omega-3 fatty acids	the product contains at least 0.6g alpha-linolenic acid per 100g AND per 100kcal, or at least 80mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g AND per 100kcal.	- good source of omega-3 fatty acids	
High monounsaturated fat	at least 45% of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than 20% 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 70% of the fatty acids present in the product derive from unsaturated fat under the condition that polyunsaturated fat provides more than 20% of energy of the product.	- good source of unsaturated fats - good source of soft fat - high amount of soft fat	

Appendix 2. Examples of additional labelling information required due to various claims

Medicinal claim
 Claims that could exploit or rise fear
 ► FORBIDDEN



Nutrition claim
 ► short-form nutrition labelling
 ► quantity of calcium



Article 13.1 health claim

- ▶ nutrition labelling
- ▶ quantity of calcium
- ▶ additional labelling for health claims

Example 3

The diagram shows a product carton with the word "PRODUCT" on the top flap and the front panel. On the front panel, the word "PRODUCT" is written in large bold letters. Below it, the text reads: "High in calcium" and "Calcium is needed for the maintenance of normal bones". To the right, a nutrition facts table is provided:

100 g serving contains:	
Energy	kJ (kcal)
Fat	g
of which saturated	g
Carbohydrates	g
of which sugars	g
Protein	g
Salt	g
Calcium	mg* (x % of recommended daily allowance)

Below the carton, a box contains the following text:

- importance to maintain a varied and balanced diet and healthy lifestyle;
- The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
- Required warning statements;

Fictional example

General, non-specific health claim

- +
- Article 13.1 health claim which specifies the health effect
- ▶ nutrition labelling
- ▶ quantity of calcium
- ▶ additional labelling for health claims

Example 4

The diagram shows a product carton with the word "PRODUCT" on the top flap and the front panel. On the front panel, the word "PRODUCT" is written in large bold letters. Below it, the text reads: "Friend of Your Bones" and "Calcium is needed for the maintenance of normal bones". To the right, a nutrition facts table is provided:

100 g serving contains:	
Energy	kJ (kcal)
Fat	g
of which saturated	g
Carbohydrates	g
of which sugars	g
Protein	g
Salt	g
Calcium	mg* (x % of recommended daily allowance)

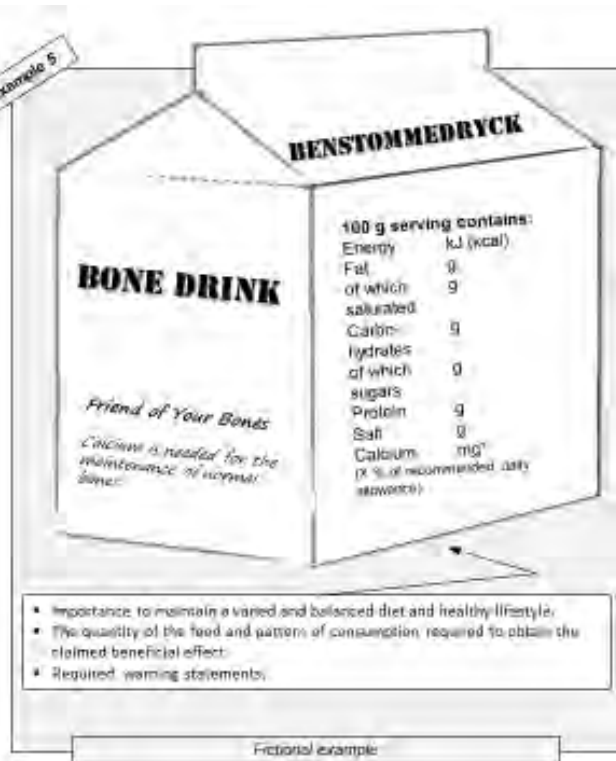
Below the carton, a box contains the following text:

- importance to maintain a varied and balanced diet and healthy lifestyle;
- The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
- Required warning statements;

Fictional example

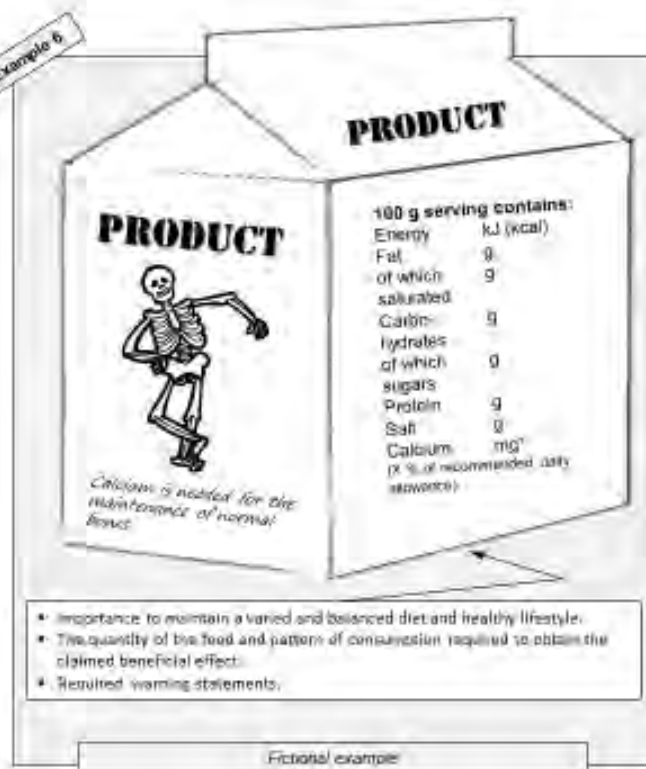
Example 5

- General, non-specific health claim
- + Article 13.1 health claim which specifies the health effect
- ▶ nutrition labelling
- ▶ quantity of calcium
- ▶ additional labelling for health claims



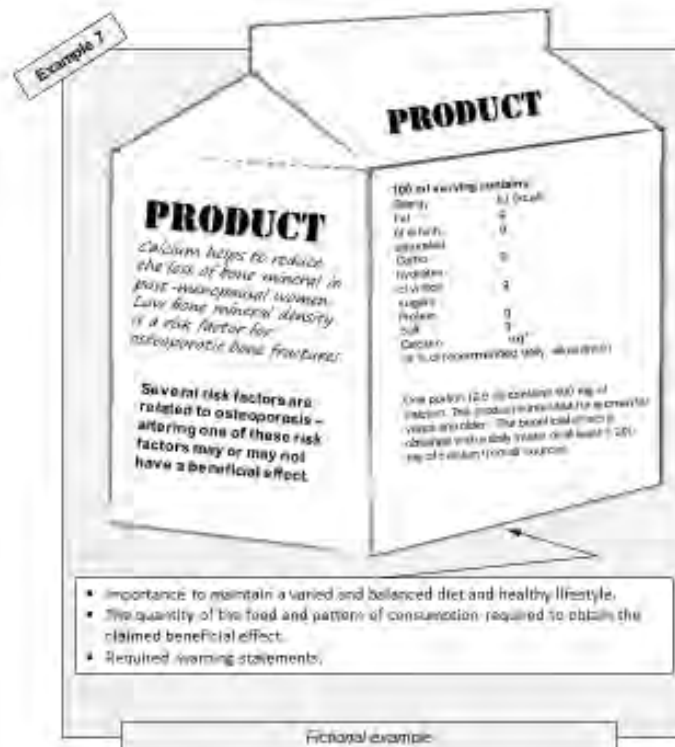
Example 6

- General, non-specific health claim
- + Article 13.1 health claim which specifies the health effect
- ▶ nutrition labelling
- ▶ quantity of calcium
- ▶ additional labelling for health claims



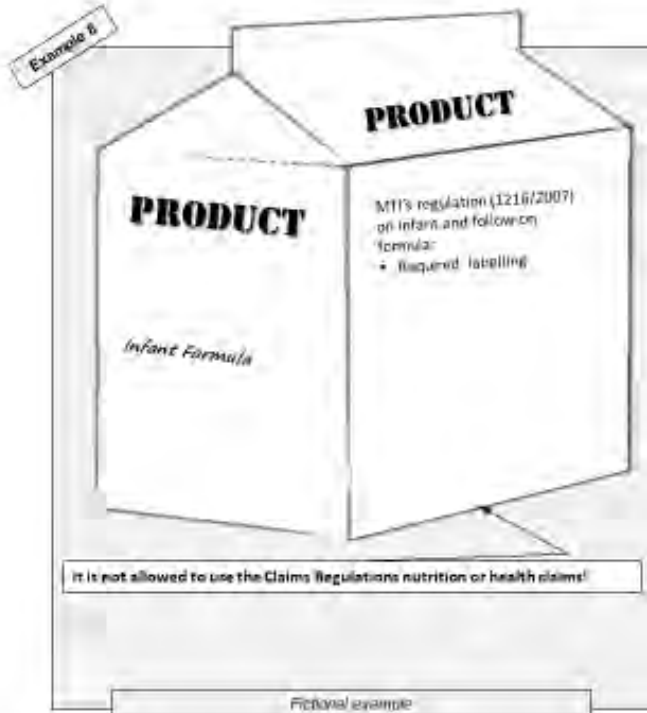
Article 14.1a health claim that refers to reduction of disease risk factor

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



Infant Formula

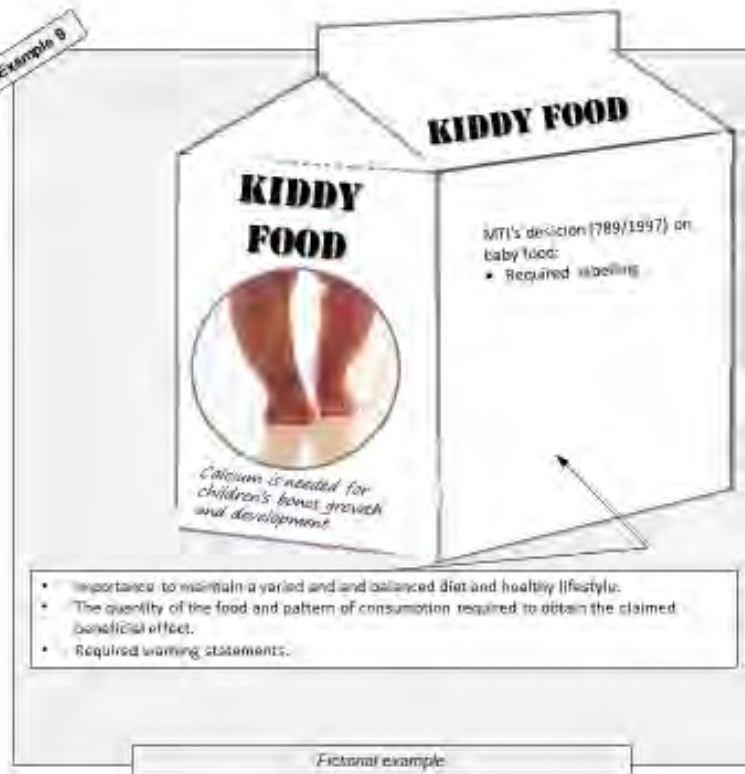
- ▶ Labelling that are required in Regulation (1216/2007)



Example 9

Article 14.1b health claim that refers to children's development and health

- ▶ labellings that are required in the decision MTT (789/1997)
- ▶ quantity of calcium
- ▶ additional labelling for health claims



Appendix 3. Quick-guide for using claims



Appendix 4. Guidelines for use of EU Commission's Register on nutrition and health claims, and EFSA's Register of questions

Commission's Register on nutrition and health claims <http://ec.europa.eu/nuhclaims/>

The Register which is provided in English contains all the health claims that have so far been authorised and non-authorised: Article 13 claims related to the normal functions of the body, Article 14(1)a claims related to the reduction of disease risk and Article 14(1)b claims related to the growth and development of children. The Register does not contain claims still under assessment by EFSA nor claims on which an authorisation or non-authorisation decision has not yet been issued. The Commission maintains a list that indicates the ID number of all pending claims http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/resources/docs/claims_pending.pdf. The claims currently under assessment by EFSA can be found in EFSA's Register of questions.

The screenshot shows the EU Register on nutrition and health claims website. The search criteria are set to 'Authorised' status, 'All' claim types, 'All' EFSA opinion references, 'All' legislation, and 'Calcium' search term. The search results show two entries for Calcium claims related to blood clotting and energy-yielding metabolism.

Claim type	Nutrient, substance, food or food category	Claim	Conditions of use of the claim / Restrictions of use / Reasons for non-authorisation	Health relationship	EFSA opinion reference / Journal reference	Commission Regulation	Status	Entry ID
Art. 13 (1)	Calcium	Calcium contributes to normal blood clotting	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	blood coagulation	2009/P(9)1216	Commission Regulation (EU) 432/2012 of 16/05/2012	Authorised	230, 236
Art. 13 (1)	Calcium	Calcium contributes to normal energy-yielding metabolism	The claim may be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF	energy-yielding metabolism	2009/P(9)1210	Commission Regulation (EU) 432/2012 of 16/05/2012	Authorised	234

Follow these guidelines:

- 1) Enter in the search field the English name of the nutrient, substance, food or food category on which you wish to find health claims.
- 2) You can make the search easier by limiting the claim status to "Authorised" or/and "Match entire phrase". Note! Pressing Enter will block the search function!
- 3) The following information is provided about the claim in the various columns:
 1. Type of claim
 2. Nutrient, substance, food or food category
 3. Claim
 4. Conditions/Restrictions of use of claim, Reasons for non-authorisation
 5. Health relationship
 6. EFSA opinion reference/Journal reference
 7. Commission Regulation under which the claim has been authorised
 8. Status (authorised/non-authorised)
 9. Entry ID

- 4) If you wish to see the Finnish or Swedish translation of the authorised claim, you can access the legislation database of the European Union (EUR-Lex) by clicking the Commission Regulation under which the claim has been authorised.
- 5) Select Finnish (fi) as the language in EUR-Lex from the pulldown menu in the top right corner to access the Regulation text in Finnish.

EFSA's Register of questions

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

EFSA's Register of questions provides information in English on all matters under assessment by EFSA, including health claims submitted for an assessment.

Mandate Number	Question Number	Subject	Unit	Panel	Status	Output Number	Last Updating
MA-2008-1061	EFSA-Q-2010-2050	14573 - Hibiscus sabdariffa L., Passiflora incarnata L. This species for, Melissa officinalis L., Rosmarinus officinalis L., Veronica officinalis L., Melissa officinalis L. Panax ginseng radix (red flower), Passiflora L. Inulin flowers, lemon balm leaves, rosemary leaves, Veronica L., Melissa L., ginseng root - Support mental activity in stress condition because of polyphenols, flavonoids, volatile oils, and ginsenosides constituents present in this plants combination.	Nutrition/NA	NA	Pending Risk Managers' decision		15/12/2016 18:39
MA-2008-4301	EFSA-Q-2010-0081	4558 - Echinacea species herba, Panax ginseng radix, Hippocrepis mammosides fructus, Organum vulgare herba, Citrus iminum amaranthum, Eucalyptus globulus amaranthum (echinacea herba, ginseng root, sea buckthorn fruit, wild marjoram herb, lemon essential oil, rosemary essential oil) - Supports for immune system because of polysaccharides, caffeine, acid, ginsenosides, vitamin C, and essential oils, constituents present in the plants combination.	Nutrition/NA	NA	Pending Risk Managers' decision		15/12/2016 18:39
MA-2008-1061	EFSA-Q-2010-0081	14577 - Echinacea species herba, Panax ginseng radix, echinacea herba, ginseng root - Maintain immune health because of polysaccharides, caffeine acid and ginsenosides, constituents present in the plants combination.	Nutrition/NA	NA	Pending Risk Managers' decision		15/12/2016 18:39
MA-2008-1061	EFSA-Q-2009-4648	3870 - Panax ginseng (Common name: Ginseng) - Ginseng and immunity	Nutrition/NA	NA	Author's Risk Assessment procedure		15/12/2016 18:39
MA-2008-1061	EFSA-Q-2009-4647	3871 - Panax ginseng (Common Name: Asian, Korean ginseng) - Glucose metabolism	Nutrition/NA	NA	Pending Risk Managers' decision		15/12/2016 18:39
MA-2008-1061	EFSA-Q-2009-4638	3870 - Panax ginseng (Common Name: Asian, Korean ginseng) - Cognitive performance	Nutrition/NA	NA	Pending Risk Managers' decision		15/12/2016 18:39
MA-2008-1061	EFSA-Q-2009-4628	3756 - Panax ginseng (Common Name: Ginseng) - Antioxidant properties	Nutrition/NA	NA	Finished (View...)	09-1482	27/09/2009 17:49
MA-2008-1061	EFSA-Q-2008-4400	3877 - Panax ginseng (Common Name: Ginseng) - Sexual health	Nutrition/NA	NA	Pending Risk Managers' decision		15/12/2016 18:39
MA-2008-1061	EFSA-Q-2008-4399	3878 - Panax ginseng (when used in combined formulation with Ginkgo biloba) - Cognitive Function	Nutrition/NA	NA	Pending Risk Managers' decision		15/12/2016 18:39
MA-2008-1061	EFSA-Q-2008-4398	3875 - Panax Ginseng - Anti-fatigue	Nutrition/NA	NA	Pending Risk Managers' decision		15/12/2016 18:39
MA-2008-1061	EFSA-Q-2009-4397	3874 - Panax Ginseng	Nutrition/NA	NA	Pending Risk Managers' decision		15/12/2016 18:39

Follow these guidelines:

- 1) Health claims are reviewed in EFSA by the Scientific Panel (Unit) on Nutrition. Select the Nutrition Unit in the *Unit Filter* menu.
- 2) Enter as the keyword the English name of the nutrient or substance, or the Latin name of the plant on which you wish to find more information about related health claims.
- 3) To find information about the assessment of Article 13 functional health claims, select in the Food Sector Area pulldown menu item Health Claims Art 13/2
- 4) The Register provides the following information on all assessment procedures related to the substance in question:
 1. The number of the Commission's Mandate
 2. Question number
 3. ID number and subject of the claim
 4. EFSA Unit related to the question

5. Status
 - i. *Pending Risk Managers' decision* = Risk Managers (Commission and member states) have not yet issued a decision.
 - ii. *Finished* = Procedure completed and statement issued, an active link is provided to the statement.
 - iii. *Withdrawn* = The applicant has withdrawn the application from the procedure
6. Output number
7. Date of last update of the matter

According to Article 28(5), health claims which are still under EFSA' assessment or on which the Commission has not yet issued a decision may be made under the responsibility of the food business operator until the assessment procedure has been completed and a decision has been issued.

The Commission maintains a list that indicates the ID number of all pending claims, see http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/resources/docs/claims_pending.pdf . However, the claims shall comply with the Claims Regulation and with existing national provisions applicable to them. Health claims which have not been submitted for an assessment and new claims may not be made until their scientific substantiation has been assessed and the claim has been included in the Commissions list of authorised claims.

