Evira guideline 17060/1 en

Guideline for control of nutrition and health claims

Content

1. Preface

These guidelines are designed for food control authorities and operators within the food business. Evira's Guide 17052/2, Nutrition and Health Claim Guide for Food Control Officers and Food Business Operators, is to be read alongside these guidelines for control. The Guide describes in more detail questions related to the application of the Nutrient and Health Claim Regulation.

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

- 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 "Claim 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/
- Decree of the Ministry of Agriculture and Forestry on Nutrition Labelling for Foodstuffs (588/2009) (hereinafter referred to as "Nutrition Labelling Decree")
  http://www.finlex.fi/fi/laki/alkup/2009/20090588 (in Finnish)
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council, on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the

Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (hereinafter referred to as the Food Information Regulation)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN: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
- Evira's Guide 17052/2, Nutrition and Health Claim Guide for Food Control Officers and Food Business Operators http://www.evira.fi/portal/en/about+evira/publications/?a=category&cid=23

3. Requirements pertaining to nutrition and health claims made on food

Nutrition and health claims used in the labelling 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 Claim Regulation).

In the Claim Regulation, a claim refers to a voluntary presentation or description, which states, suggests or implies that a food has particular beneficial nutritional 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 Claim Regulation.

A nutrition claim means a claim that refers to the beneficial nutritional content of the food. Authorised nutrition claims and conditions for their use are listed in the Annex to the Claim Regulation.

A health claim means a claim that refers to a relationship between a food and health. Health claims are divided into function claims (Article 13), claims that refer to the reduction of disease risk (article 14.1a) and claims that refer to children's development and health (14.1b) (Table 1).

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 Claim Regulation. The Claim 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.

Table 1. Division of health claims into Article 13 and Article 14 claims

Health claims Claims that refer to a relationship between a food category, a food or its ingredient and health.	
Article 13 = function claims	Article 14
(1)(a) Claims related to growth, development and the functions of the body	(1)(a) Claims related to reduction of disease risk
(1)(b) Claims related to psychological and behavioural functions	(1)(b) Claims referring to children's development and health
(1)(c) Claims related to slimming or weight-control, etc.	
(5) Claims based on newly developed scientific evidence or which include a request for the protection of proprietary data	

The Claim 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.

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 the claim is authorised for use by the European Commission. The conditions for use to be fulfilled in order for the claim to be used in the marketing of the product have been specified for each authorised claim.

More information about nutrition and health claims is provided in the Nutrition and Health Claim Guide published by Evira:
http://www.evira.fi/portal/en/about+evira/publications/?a=category&cid=23

4. Operator's in-house control

4.1. Operator responsibility

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 Claim 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 Claim Regulation. Food business operators shall be able to demonstrate due diligence and steps taken to comply with each part of the Claim Regulation.

- Using only authorised claims in compliance with the Claim 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.

Items that are critical with respect to food safety and food regulations shall be recorded in the operator's in-house plan.

Food business operators are responsible for the compliance of their products and the information provided on them. Operators shall identify and manage the criteria laid

down in food regulations for these substances and their use. The verification of compliance shall be part of the operator's in-house control.

Operators shall have a plan in place of what action is to be taken and on what schedule, if deficiencies or defects are found in the in-house control of the use of health claims.

If operators find out or are informed that a product they have produced, has been produced for them, or they have imported, packed or sold does not meet the requirements laid down for safety, they must initiate action to withdraw the product from the market and to inform consumers.

Reasons resulting in withdrawal include, for example:

- medicinal claims are used in the marketing of food which may cause danger to the consumer's health because e.g.
    - the food is marketed for the treatment of a specific disease, or
    - there is cause to suspect that due to marketing, the food is used as a substitute for appropriate medicinal treatment

More detailed information about withdrawals and operator responsibilities is provided on Evira's website at http://www.evira.fi/portal/en/food/manufacture+and+sales/guidelines+on+withdrawal+of+products/

More information (in Finnish) about in-house control is provided on Evira's website at http://www.evira.fi/portal/fi/elintarvikkeet/hygieniaosaaminen/tietopaketti/omavalvonta/

4.2 In-house control implemented by operators who produce or have foodstuffs produced for them, or import or pack foodstuffs

Food business operators must possess sufficient and accurate information about the food, which they produce, have produced for them, import (from the internal market and/or from third countries) or pack and about the legislation pertaining to it (Food Act, Section 19). Operators may not forward products they know or have reason to suspect to be in violation of legislation.

Operators who produce foodstuffs, have foodstuffs produced for them, or import or pack foodstuffs shall through in-house control ensure the safety of the foodstuffs and the accuracy of the information provided on them.

Implementation of following matters shall be verified through in-house control:
• Personnel have adequate knowhow regarding use of claims o A person has been appointed who is responsible for compliance of the use of claims and the additional labelling required due to them
• Prohibited claims are not used in the labelling or marketing of foods o Medicinal claims are not used in labelling or marketing o Prohibited claims referred to in Article 3 or 12 of the Claim Regulation are not used in labelling or marketing
• Only authorised claims are used in the labelling or marketing of foods o 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) o Reference to general, non-specific benefits is accompanied by an authorised health claim (Article 10(3)) o Any trademark, pictorial or graphic representation, etc. included in the claim has been taken into consideration and they comply with the Claim Regulation (any transition periods, the trademark/pictorial or graphic representation included in the claim is accompanied by an authorised claim)
• The conditions of use of the claims are fulfilled o 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)
• The labelling requirements pertaining to the use of claims are met o The packaging carries the required nutrition labelling (nutrition labelling requirement does not apply to food supplements) o The amount of the substance referred to in the claim is indicated in labelling o The information referred to in Article 10(2)a-b is provided in labelling (health claims) o The information referred to in Article 10(2)c-d and 14(2) is provided in labelling (health claims) o 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.
• Withdrawals are initiated, if necessary

The most important in-house control tools of operators, who import or pack foods or have them produced for them, are functioning work practices and work instructions regarding

- selection of material suppliers (e.g. the producer has a quality system, supplier audits)
- selection of new products (e.g. up-to-date product descriptions, specifications)
- acquisition and forwarding of information about the production conditions and composition of the products
- competence of personnel, appointment of responsible persons

4.3 In-house control implemented by operators who market foods

Food business operators, who market foods, must possess sufficient and accurate information about the food they produce, process and distribute and about the legislation pertaining to it (Food Act, Section 19). Operators, who market foods may also not forward products they know or have reason to suspect to be in violation of legislation. The same obligations apply to all operators, who market foods, regardless of whether the operation is limited to e.g. a food establishment, a virtual establishment, an online store, network marketing or distance marketing.

As concerns packed food, the responsibility for the accuracy of labelling rests with the operator under whose name or business name the food is marketed. If the operator apart from marketing foodstuffs on which nutrition or health claims are made also produces them or has them produced or imports or packs them, they shall implement in-house control according to the requirements laid down in Section 4.2.

Operators are responsible for the claims used in the marketing material produced by them, e.g. placards, brochures, print advertisements, internet, radio, TV. The use of claims in such marketing material must not be inconsistent with the information presented in labelling.

Certain labelling information is mandatory, if nutrition or health claims are presented in marketing materials:

- The packaging carries the required nutrition labelling (the 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, if necessary (health claims)

The operator who markets the food cannot make nutrition or health claims on the product even in marketing material produced by the operator, unless this mandatory information is provided in labelling.

5. 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 Claim 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.

5.1 Risk based approach

Pursuant to Section 6 a of the Food Act, the following shall be taken into account regarding the activity carried out by the operator when implementing the obligations (operators) laid down in the Food Act and in controlling compliance with them

- extent of activity (local / national operation)
- type of activity (e.g. products designed for special consumer groups)
- safety (e.g. medicinal claims, warning statements in labelling, instructions for use)
- consumer protection
    - o preventing the misleading of consumers (e.g. prohibited claims, using only authorised nutrition and health claims)
    - o provision of information to consumers for making of choices (e.g. mandatory information in labelling required when claims are used)

5.2 Control authorities

Municipalities are entrusted with the execution of the control of nutrition and health claims made on foods regarding operators in the area of the municipality. In addition to claims made in labelling, this also applies to the control of claims used in other marketing materials, including placards, brochures, print advertisements, internet, radio, TV. Municipal control authorities shall ensure that operators correct any non-compliant nutrition and health claims made in labelling and marketing materials. The use of claims in such marketing material must not be inconsistent with the information presented in labelling. In obvious cases, at least, the municipal control authorities shall implement the administrative coercive measures referred to in the Food Act, if necessary, to verify that the labelling or marketing materials are corrected.

Regional State Administrative Agencies are responsible for the planning, guiding and supervision of the control of nutrition and health claims and for the control of compliance with requirements related to nutrition and health claims.

Evira is in charge of the planning, guiding and development of the control of nutrition and health claims on national level. If necessary, Evira can implement the administrative coercive measures referred to in the Food Act to ensure the compliance of the marketing of foods.

Evira's inspection veterinarians control the effectiveness and implementation of in-house control in their own region, and also take into account requirements related to nutrition and health claims.

Other control authorities (National Supervisory Authority for Welfare and Health, the Defence Forces, the Customs and border veterinarians) implement for their part control of nutrition and health claims made on foods.

In special cases, where municipal food control authorities or other control authorities have actively exhausted their own control measures, they can contact Evira, if implementation of control requires that marketing be prohibited or corrected by virtue of the Food Act (Section 65 and Section 66, respectively).

5.3 Implementation of control

Regulatory control of nutrition and health claims focuses on

- review of the scope, adequacy and implementation of in-house plan;
- controls of labelling and documents;
- review of practical activities;
- recipe reviews, if necessary (guidelines in Evira Guide 17055/1, Guidelines for controlling food labelling).

Review of in-house plan and its implementation is designed to verify that

- operators manage through their own control of their activities (in-house control) the compliance of the nutrition and health claims made on foods;
- the quality assurance procedures implemented by the operator, such as instructions and documentation, are adequate.

Reviews of labelling and documents, and if necessary, reviews of recipes, are carried out to verify that the foods produced or distributed by the operator are

- safe and
- the information provided on the product is accurate

6. Scope of control

Control shall focus on aspects, which operators can influence with their own activities. The content of in-house control implemented by operators of different types is described in Section 4. The focus of control shall be on these aspects. If the control authorities find in the products defects or deficiencies, which are outside the direct control of the operator, control activities shall be targeted at the operator responsible for labelling or marketing claims.

The scope of control is explained in more detail below. More examples and application instructions are provided in Evira's Guide 17052/2, Nutrition and Health Claim Guide for Food Control Officers and Food Business Operators.

6.1 Prohibited claims are not used in the labelling or marketing of foods

- Medicinal claims are not used in labelling or marketing

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.

- Prohibited claims referred to in Article 3 or 12 of the Claim Regulation are not used in labelling or marketing

Pursuant to Article 3 of the Claim Regulation, 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.

Pursuant to Article 12 of the Claim Regulation, the following nutrition and 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;
    - o 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

6.2 Only authorised claims are used in the labelling or marketing of foods

o 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)

Nutrition claims
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/.

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 the claim is then either authorised or rejected under a Commission Regulation.

The European Commission maintains a register of authorised and non-authorised claims. The register can be found on the Commission's website at: http://ec.europa.eu/nuhclaims/. For certain claims the Commission's decision is still pending, and they may be used until further notice in food marketing (cf. Article 13(1) health claims).

The starting point is that the operator shall be able to prove that the claim used in the marketing of the food product can either be found on the list of authorised claims or that the transitional period is applied to the claim. The control officer may require the operator to present in the control event the required documents from legislation or from the registers of the European Commission and EFSA.

- A register maintained by the European Commission of authorities and unauthorised claims (in English) http://ec.europa.eu/nuhclaims/
- EFSA's register, which can be used to check health claims referred to in Article 13(1) that are still under consideration http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=NDA&foodsectorarea=26

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 such 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 Claim 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 Claim Regulation and the national provisions applied to claims.

- Claims can be made using the same or a 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 Claim Regulation, Evira interprets it to not be a health claim compliant with the Claim

Regulation and the claim may not be used in the labelling or marketing of food.

After the Commission has issued a decision 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

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.

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/.

In Evira's view, authorised claims referring to children's development and health may be used on foods targeted at 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.

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 listed in the Annex to the Claim Regulation and authorised Article 14(1)b health claims may both be used on follow-up formulae.

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. So far data protection has not been granted to any authorised health claim.

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.

Use of equivalent wordings
In addition to the authorised nutrition claims listed in the Annex to the Claim Regulation, also nutrition claims likely to have the same meaning for the consumer are permitted. Evira has collected examples of what in Evira's view are equivalent nutrition claim wordings in Evira's Guide 17052/2, Nutrition and Health Claim Guide for Food Control Officers and Food Business Operators.

The Claim 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

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.

Experiences of individual consumers
Pursuant to Article 6 of the Claim Regulation, nutrition and health claims made on foods shall be based on generally accepted scientific data. The personal experience of individuals, although perfectly true in their case, does not fulfil the requirement of the Claim Regulation for scientific data. For this reason, the marketing of food with the experiences of an individual consumer can be considered misleading.

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.

Health claims may not be made on alcoholic beverages
Beverages containing more than 1.2% by volume of alcohol may not bear health claims. As far as nutrition claims are concerned, only the following references are allowed

- references to low alcohol content,
- references to reduction of alcohol content or
- references to reduction of energy content.

o Reference to general, non-specific benefits shall be accompanied by an authorised health claim (Article 10(3))

Article 10(3) general, non-specific statements
According to Article 10(3) of the Claim 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 adopting guidelines for the implementation of Article 10 of the Claim 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.

The authorised health claim must be easy to understand and easily visible to consumers before they make the purchase decision. This means that it is not possible, for example, to present a general claim in labelling and only specify the health effect on the website.

It was concluded during the scientific assessment of health claims that some of the proposed claims were too general and non-specific in nature and could therefore not be assessed. These claims could not be authorised, but have been included in the list of unauthorised claims. These claims can be considered to be general, non-specific health claims referred to in Article 10(3). These claims can be used provided they are accompanied by an authorised Article 13 or 14 health claim, which specifies the health effect.

- Any trademark, pictorial or graphic representation, etc. included in the claim has been taken into consideration and they comply with the Claim Regulation (any transition periods, the trademark/pictorial or graphic representation included in the claim is accompanied by an authorised claim)

Trademarks and product names considered to be claims

Pursuant to Article 1(3) of the Claim 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 Claim 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 Claim Regulation, products bearing trademarks or brand names existing before 1 January 2005 which do not comply with the Claim

Regulation may continue to be marketed until 19 January 2022 after which time the provisions of the Claim 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.

Pictorial, symbolic and graphic representations that include a claim
Pursuant to Article 2(2) of the Claim 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 Claim 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.

6.3 The conditions of use of the claims are fulfilled

o 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)

Specific conditions of use have been determined for each authorised nutrition and health claim, and in some cases also the conditions or restrictions of use or a warning statement that should accompany the claim. 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/.

Vitamins and minerals

For several nutrition and 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".

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 at least 30% of the daily reference intake of the nutrient in question, or if 100 millilitres of a beverage contains15% 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 2.

Table 2. 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.

	Daily reference intake	Source of (15%)	High in (30%)
Vitamin A (µg)	800	120	240
Vitamin D (µg)	5	0.75	1.5
Vitamin E (mg)	12	1.8	3.6
Vitamin K (µg)	75	11.25	22.5
Vitamin C (mg)	80	12	24
Thiamine (mg)	1.1	0.165	0.33
Riboflavin (mg)	1.4	0.21	0.42
Niacin (mg)	16	2.4	4.8
Vitamin B6 (mg)	1.4	0.21	0.42
Folic acid (µg)	200	30	60
Vitamin B12 (µg)	2.5	0.375	0.75
Biotin (µg)	50	7.5	15
Pantothenic acid (mg)	6	0.9	1.8
Potassium (mg)	2000	300	600
Chloride (mg)	800	120	240
Calcium (mg)	800	120	240

Phosphor (mg)	700	105	210
Magnesium (mg)	375	56.25	112.5
Iron (mg)	14	2.1	4.2
Zinc (mg)	10	1.5	3
Copper (mg)	1	0.15	0.3
Manganese (mg)	2	0.3	0.6
Fluoride (mg)	3.5	0.525	1.05
Selenium (µg)	55	8.25	16.5
Chrome (µg)	40	6	12
Molybdenum (µg)	50	7.5	15
Iodine (µg)	150	22.5	45

Verification of amount
Pursuant to the Nutrition Labelling Decree and the Food Information Regulation, the 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.

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".

6.4 The labelling requirements pertaining to the use of claims are met

General labelling regulations pertain to all foodstuffs and cover the most common labelling used on food packages. Evira's Guide 17005/4, Labelling Guide, can be found on Evira's website (in Finnish) at

http://www.evira.fi/portal/fi/evira/julkaisut/?a=view&productId=114

Pursuant to the Labelling Decree of the Ministry of Trade and Industry (1084/2004) and the Food Information Regulation, 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.

- The packaging carries the required nutrition labelling (the nutrition labelling requirement does not apply to food supplements)

Nutrition labelling
Nutrition labelling is provided for in Nutrition Labelling Decree 588/2009 of the Ministry of Agriculture and Forestry and in the Food Information Regulation. If a nutrition or health claim is made on food, a declaration of nutrients is always mandatory. As of 13 December 2016, mandatory nutrition labelling shall be presented in compliance with the requirements of the Food Information Regulation. Until then, nutrition labelling can be presented in compliance with either Nutrition Labelling Decree 588/2009 of the Ministry of Agriculture and Forestry or the Food Information Regulation.

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.

Nutrition labelling in compliance with Nutrition Labelling Decree
If the nutrition claim presented concerns energy content, protein, carbohydrates or fats, the short-form nutrition labelling referred to in the Nutrition Labelling Decree will suffice. If the nutrition claim concerns vitamins or minerals listed in the Annex to the Nutrition Labelling Decree, the nutrient in question can be presented as part of short-form labelling. Long-form nutrition labelling should be used if the nutrition claim concerns sugars, saturated fatty acids, dietary fibre or sodium.

When a health claim is used, nutritional value information shall always be presented using long-form nutrition labelling. Long-form labelling indicates the amount of

energy, protein, carbohydrates, sugars, fat, saturated fatty acids, fibre and sodium contained in the food.

If the nutrition claim concerns a substance not indicated in the nutrition labelling in accordance with the Nutrition Labelling Decree, its amount must be specified in the same field with nutritional content information.

More information about nutrition labelling is provided in Nutrition Labelling Guide 17030/1 published by Evira at (in Finnish):
http://www.evira.fi/portal/fi/evira/julkaisut/?a=view&productId=112

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:EN:PDF

Unpacked food
Pursuant to Article 1(2) of the Claim Regulation, nutrition labelling requirements do 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.

Food supplements
The Nutrition Labelling Decree does not apply to the presentation of nutritional content information for foodstuffs that fall within the purview of legislation on food supplements. Instead, the 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,

- The amount of the substance referred to in the claim is indicated in labelling

Amount of substance referred to in the claim
The amount of the substance referred to in the nutrient or health claim shall always be indicated in the nutrient declaration in the labelling or in its immediate vicinity.

For food supplements, the amount of the substance referred to in the claim shall be indicated in the list of characteristic substances or in connection with it.

- The information referred to in Article 10(2)a-b is provided in labelling (health claims)

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 Claim 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;

Unpacked food
Pursuant to Article 1(2) of the Claim Regulation, 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, Article 10(2)(a) and (b) shall not apply.

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.

Article 10(2)a and food supplements

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 Claim 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 Claim 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 Claim 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 Claim 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.

Article 10(2)b

The Claim 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.

For example, 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. In order to bear the claim 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." In Evira's view, the consumer shall further be informed of the amount of beta-glucans in one portion of the product.

For several authorised nutrition and 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 the nutrition claim "source of". In Evira's view, it can be impossible in the case of these health claims to specify the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect. This requirement was not specified by EFSA or the European Commission, when the health claim was authorised, and thus it may be impossible also for the food business operator to

make the specification. In cases like this, Evira would not require presentation of the information referred to in Article 10(2)b.

- The information referred to in Article 10(2)c-d and 14(2) is provided in labelling (health claims)

Article 10(2)c-d
Pursuant to Article 10(2) of the Claim 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:

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.

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".

Article 14(2)
Pursuant to Article 14(2) of the Claim 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.

Unpacked food
Pursuant to Article 1(2) of the Claim Regulation, in the case of non-prepackaged foodstuffs, requirements laid down in Article 10(2)(a) and (b) shall not apply. 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.

- 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

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, 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.

6.5 Withdrawals are initiated, if necessary

Reasons that will result in withdrawal include, for example:

- medicinal claims are used in the marketing of food which may cause danger to the consumer's health because e.g.
  - the food is marketed for the treatment of a specific disease, or
  - there is cause to suspect that due to marketing, the food is used as a substitute for appropriate medicinal treatment

7. Action

If control authorities find that the food operator violates valid food regulations, they shall take action as necessary to ensure compliance with the regulations. **If necessary, the administrative coercive measures referred to in the Food Act shall be implemented.** If the control authorities find in the products defects or deficiencies, which are outside the direct control of the operator, control activities shall be targeted at the operator responsible for labelling or marketing claims.

Control instruction 12.3 "Marketing" in Evira's food safety information publication system OIVA determines the measures to be taken when defects are found in the control of nutrition and health claims made on foods

.

If the defects are minor and do not impair food safety or mislead consumers, an adequately long deadline can in Evira's view be set for corrections, taking into account the amount of packaging material in stock.

Examples of such minor defects:

- The nutrition and health claims presented as a rule comply with legislation regarding claims, but some of the wordings used are not consistent with

the original authorised claim. • The additional information provided in connection with the use of claims is deficient. → Grade in Oiva assessment scale GOOD
If there are defects in labelling which impair food safety or mislead consumers, then depending on the situation the control officer shall either advise or order the defects to be rectified by a set deadline. Examples of defects, which in Evira's view need to be rectified within a deadline of at most a few months: • overall misleading impression • prohibited (unauthorised) nutrition or health claims are made on the food • the specific conditions of use of the claims are not fulfilled • the amounts of the substances referred to in the claims are not indicated • nutrition labelling is not provided • the required additional information is not provided in labelling in connection with the use of health claims (Articles 10(2)a, 10(2)b and if necessary 14(2) of the Claim Regulation). → Grade in Oiva assessment scale TO BE CORRECTED
If there are defects in labelling which jeopardise food safety or considerably mislead consumers, then depending on the situation the control officer shall ensure that the defects are either immediately rectified or withdrawal of the product is initiated. Examples of defects, which require immediate action: • a required warning statement is missing (Articles 10(2)c and d of the Claim Regulation) • medicinal claims are made on the food • prohibited (unauthorised) nutrition or health claims are repeatedly made on the food Reasons that will result in withdrawal include, for example: • medicinal claims are used in the marketing of food which may cause danger to the consumer's health because e.g. o the food is marketed for the treatment of a specific disease, or o there is cause to suspect that due to marketing, consumption of the food is used as a substitute for appropriate medicinal treatment → Grade in Oiva assessment scale POOR

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