Nutrition and health claims: Further reading

Definitions
The European Commission's guidance provides further information and advice on the classification of claims.

Scope
The Regulation applies 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. In the Department of Health’s view this includes product labelling of packaging to be delivered to final consumer, print and broadcast media, statements made on the internet or direct mail, promotional features in print media, in-store promotion, catalogues or product directories and any commercial communication, which could include leaflets and menus. The Regulation also applies to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers. It does not apply to claims which are made in non-commercial communications, such as transactions between one business and another, dietary guidelines or advice issued by public health authorities and bodies, Government health messages (unless they make an explicit nutrition or health claim) or non-commercial communications and information in the press and in scientific publications. Healthy catering award schemes could fall within the scope of the Regulation, depending on how the ‘badge’ is used. The Department of Health guidance also provides advice on when menus provided to hospital in-patients or in schools would be seen as commercial communication.

A trade mark, 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 without undergoing the authorisation procedures, provided it is accompanied by a related nutrition or health claim which complies with the Regulation. Trademarks and brand names in use before January 2005 and which could be construed as claims are not caught by this provision until 19 January 2022.

The Regulation does not include specific rules concerning recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities. However, if the recommendation or endorsement implies a nutrition or health claim, it must comply with the general provisions of the Regulation.
For generic descriptions which have traditionally been used to indicate specific foods or beverages which could imply an effect on human health (e.g. ‘digestive’ or ‘cough drops’), derogations from the authorisation procedure may be adopted on application to the Commission via the national competent authority, by the food business operator concerned. Commission Regulation (EU) No 907/2013 of 20 September 2013 setting the rules for applications concerning the use of generic descriptors (denominations) lays down the rules for the submission and content of applications. Trade Associations are permitted to submit applications on behalf of their members, to avoid multiple applications, and a generic descriptor should have at least 20 years proven usage within the Member State(s), prior to the entry into force of the Regulation in order to qualify for exemption.

Where specific legislation controls claims, it will take precedence, eg. for PARNUTS foods and natural mineral water, spring water and bottled water. Further advice on this area is provided by the Commission’s guidance. In all other cases, the Regulation on nutrition and health claims will apply.

Mandatory statements required on novel foods and novel food ingredients are not considered as claims and therefore not within the scope of nutrition and health claims regulation, which covers only claims made on a voluntary basis. Further details are provided in the Commission’s guidance.

**General principles for all claims**

Nutrition and health claims must 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 (exemptions may be adopted);

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.

Nutrient profiles will set certain nutritional criteria that a product must meet to be able to make nutrition or health claims. The nutrient profiles will be established taking into account:

a. The quantities of certain nutrients and other substances contained in the food, such as fat, sugars and salt;

b. The role and importance of the food (or category of food) and the contribution to the diet of the population in general, or, as appropriate, of certain risk groups including children;

c. The overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.
The nutrient profiles will be based on scientific knowledge about diet and nutrition and their relation to health.

What claims can be made will depend on the extent to which a product complies with the profile:

- Meets the profile - nutrition and health claims can be made, if they comply with the other requirements of the Regulation;

- Fails on one nutrient - no health claim can be made. Nutrition claims can only be made if the statement 'high [name of nutrient that fails the profile] content' is also made. This must be done in close proximity to and with the same prominence as the nutrition claim;

- Fails on more than one nutrient - no nutrition or health claim can be made, except for certain reduced claims, where the reduced claim relates to a nutrient that fails the profile.

The Regulation allows for further exemptions to the application of nutrient profiles to be set during their development.

There is currently no indication from the Commission as to when work on the development of the nutrient profiles will begin.

The UK has a nutrient profile type system in place, based on fat, salt and sugar, for controlling the TV advertising of foods to children. Other Member States may have developed national systems for similar purposes, but there has been no indication that such systems may form a basis for the development of the controls on nutrition or health claims made in labelling.

The use of nutrition and health claims is only permitted if:

a. The presence, absence or reduced content in a food or category of food of a nutrient, or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;

b. The nutrient or other substance for which the claim is made:
   i. is contained in the final product in a significant quantity (as defined in Community legislation), or a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or
   ii. is not present or is present in a reduced quantity so as to produce the nutritional or physiological effect claimed, as established by generally accepted scientific evidence. This will apply to claims such as ‘low fat’ and ‘reduced fat’;

c. Where applicable, the nutrient or other substance for which the claim is made must be in a form that is available to be used by the body;
d. The quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence and is available to be used by the body;

e. It complies with the specific conditions laid down.

The use of nutrition and health claims is only permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.

Nutrition and health claims must refer to the food ready for consumption in accordance with the manufacturer's instructions. It is the Department of Health's opinion that this should only apply where the food could not or should not be consumed otherwise. For example, breakfast cereal does not have to be eaten with milk and therefore the claim should apply to the cereal as sold.

Nutrition and health claims must be based on and substantiated by generally accepted scientific evidence. A food business operator making a nutrition or health claim must be able to justify the use of the claim.

**Nutrition claims**

In accordance with Article 8(1) of Regulation (EC) No 1924/2006, nutrition claims are only permitted if they are listed in the Annex of that Regulation and are in conformity with the conditions set out in that Annex. The list and conditions are available on the Commission's website and have been summarised in the Table below.

<table>
<thead>
<tr>
<th>Nutrition claim (and any claim likely to have the same meaning for the consumer)</th>
<th>Conditions of use</th>
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<tbody>
<tr>
<td>‘Low energy’</td>
<td>Product must not contain more than 40 kcal (170kJ)/100g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17kJ)/portion, with equivalent sweetening properties to 6g of sucrose (approx 1 teaspoon of sucrose) applies.</td>
</tr>
<tr>
<td>‘Energy-reduced’</td>
<td>Energy value is reduced by at least 30%, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.</td>
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<tr>
<td>‘Energy-free’</td>
<td>Product must not contain more than 4 kcal (17kJ)/100ml. For table-top sweeteners the limit of 0.4 kcal (1.7kJ)/portion, with equivalent sweetening properties to 6g of sucrose (approx. 1 teaspoon of sucrose) applies.</td>
</tr>
<tr>
<td>Label</td>
<td>Description</td>
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<tr>
<td>‘Low fat’</td>
<td>Product must not contain more than 3g of fat per 100g for solids or 1.5g of fat per 100ml for liquids (1.8g of fat per 100ml for semi-skimmed milk).</td>
</tr>
<tr>
<td>‘Fat-free’</td>
<td>Product must not contain more than 0.5g of fat per 100g or 100ml. Claims expressed as ‘X% fat-free’ are prohibited.</td>
</tr>
<tr>
<td>‘Low saturated fat’</td>
<td>The sum of saturated fatty acids and trans-fatty acids in the product must not exceed 1.5g per 100g for solids or 0.75g/100ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10% of energy.</td>
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<tr>
<td>‘Saturated-fat free’</td>
<td>The sum of saturated fat and trans-fatty acids must not exceed 0.1g of saturated fat per 100g or 100ml.</td>
</tr>
<tr>
<td>‘Low sugars’</td>
<td>Product must not contain more than 5g of sugars per 100g for solids or 2.5g of sugars per 100ml for liquids.</td>
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<tr>
<td>‘Sugars-free’</td>
<td>Product must not contain more than 0.5g of sugars per 100g or 100ml.</td>
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<tr>
<td>‘With no added sugars’</td>
<td>Product must 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 statement ‘Contains naturally occurring sugars’ must also appear on the label.</td>
</tr>
<tr>
<td>‘Low sodium/salt’</td>
<td>Product must not contain more than 0.12g of sodium, or the equivalent value for salt, per 100g or per 100ml. For waters, other than natural mineral waters, the level must not exceed 2mg of sodium per 100ml.</td>
</tr>
<tr>
<td>‘Very low sodium/salt’</td>
<td>Product must not contain more than 0.04g of sodium, or the equivalent value for salt, per 100g or 100ml. This claim must not be used for natural mineral waters and other waters.</td>
</tr>
<tr>
<td>‘Sodium-free’ or ‘Salt free’</td>
<td>Product must not contain more than 0.005g of sodium, or the equivalent value for salt, per 100g.</td>
</tr>
<tr>
<td>No added sodium/salt</td>
<td>A claim stating that sodium/salt has 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 sodium/salt or any other ingredient containing added sodium/salt and the product contains no more than 0.12 g sodium, or the equivalent value for salt, per 100 g or 100 ml.</td>
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<tr>
<td>‘Source of fibre’</td>
<td>Product must contain at least 3g of fibre per 100g or at least 1.5g of fibre per 100 kcal.</td>
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<tr>
<td>‘High fibre’</td>
<td>Product must contain at least 6g of fibre per 100g or at least 3g of fibre per 100 kcal.</td>
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<tr>
<td>‘Source of protein’</td>
<td>At least 12% of the energy value of the food must be provided by protein.</td>
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<tr>
<td>‘High protein’</td>
<td>At least 20% of the energy value of the food must be provided by protein.</td>
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| ‘Source of ‘vitamin and/or ‘mineral’’ | Product must contain at least a significant amount as defined in Point 2 of Part A of Annex XIII of the FIC (as a rule, the following values should be taken into consideration in deciding what constitutes a significant amount:  
— 15% of the nutrient reference values supplied by 100 g or 100 ml in the case of products other than beverages,  
— 7.5% of the nutrient reference values supplied by 100 ml in the case of beverages, or,  
— 15% of the nutrient reference values per portion if the package contains only a single portion) |
| ‘High ‘vitamin’ and/or ‘mineral’’ | Product must contain at least twice the value of ‘source of’ claim. |
| ‘Contains (name of nutrient or other substance)’ | No specific conditions laid down. Product must comply with the applicable provisions of the Regulation and in particular Article 5 on ‘general conditions’. For vitamins and minerals the conditions of the claim ‘source of’ apply. |
| ‘Increased (name of nutrient)’ | Product must comply with the conditions for the claim ‘source of’ and the increase in content is at least 30% compared to a similar product. |
| ‘Reduced (name of nutrient)’ | Reduction in content must be at least 30% compared to a similar product, except for micronutrients, where a 10% difference in the reference values in the FIC are acceptable, and for sodium, or the equivalent for salt, where a 25% difference is acceptable.  
The claim “reduced saturated fat”, and any claim likely to have the same meaning for the consumer, may only be made:  
(a) if 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) if the content in trans-fatty acids in the product bearing the claim is equal to or less than in a similar product.  
The claim “reduced sugars”, and any claim likely to have the same meaning for the consumer, may only be made if the amount of energy of the product bearing the claim is equal to or less than the amount of energy in a similar product. |
<table>
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<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td>‘Light/lite’</td>
<td>Product must comply with the conditions for use of the term ‘reduced’ and the claim must also be accompanied by an indication of the characteristic(s) which make(s) the food ‘light’ or ‘lite’.</td>
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<tr>
<td>‘Naturally/natural’</td>
<td>Where a food naturally complies with the conditions laid down for use of a nutritional claim, the term ‘naturally/natural’ may be used as a prefix to the claim.</td>
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<tr>
<td>‘Source of Omega-3 fatty acids’</td>
<td>Product must contain at least 0.3g alpha-linolenic acid per 100g and per 100kcal, or at least 40mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal.</td>
</tr>
<tr>
<td>‘High Omega-3 fatty acids’</td>
<td>Product must contain 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.</td>
</tr>
<tr>
<td>‘High monounsaturated fatty acids’</td>
<td>At least 45% of the fatty acids present in the product must be derived from monounsaturated fat under the condition that monounsaturated fat provides more than 20% of energy of the product.</td>
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<tr>
<td>‘High polyunsaturated fatty acids’</td>
<td>At least 45% of the fatty acids present in the product must be derived from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20% of energy of the product.</td>
</tr>
<tr>
<td>‘High unsaturated fat’</td>
<td>At least 70% of the fatty acids present in the product must be derived from unsaturated fat under the condition that unsaturated fat provides more than 20% of energy of the product.</td>
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The regulation only controls nutrition claims that refer to beneficial nutritional properties and does not control those that refer to non-beneficial properties, such as ‘high in fat’. In some cases, the claim will be neither beneficial nor non-beneficial and will refer to a statement of fact, such as ‘contains 10g of fat’. Such statements must not be misleading and are controlled by the Consumer Protection from Unfair Trading Regulations 2008, the Food Safety Act 1990 and the EU General Food Law Regulation, 178/2002, which make it an offence to mislead consumers. If, however, the information is presented in a way that implies it is beneficial to consumers, e.g. ‘contains only 10g of fat’, it is the Department of Health’s view that it would need to comply with Regulation 1924/2006.
For comparative claims, it is necessary that the products being compared be clearly identified to the final consumer. Comparative claims may only be made between foods of the same category, taking into account a range of foods of that category. The European Commission Guidance covers how this should be applied and states that products being compared should be foods belonging to a group of foods that are similar in terms of nutritional content. The difference in the quantity of a nutrient and/or the energy value must be stated and the comparison must relate to the same quantity of the food. Comparative claims must compare the composition of the food 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.

'Reduced', 'increased' and 'light' are comparative claims. These claims must state the difference in the quantity of the nutrient and/or energy between the same quantities of two foods, as an average and as either a percentage or an absolute value. When the claim 'light' is used, the characteristic(s) which make(s) the food 'light' must be indicated. Similarly, when the claim 'reduced energy' is used, the characteristic(s) that make(s) the food reduced in its total energy value must be indicated.

**Health claims**

Health claims are prohibited unless they comply with the general principles for all claims and the following specific requirements. They must also be authorised in accordance with the Regulation and included in the list of authorised claims provided for in the EU Register. The only exceptions to this are general, non-specific claims and trademarks or brand names that are also health claims. The Regulation puts in place special requirements for claims about general, non-specific benefits of the nutrient or food for overall good health or health-related well-being. These claims do not have to be added to the EU Register. Instead the claim may only be used if it is accompanied by an authorised claim that is included in the Register and the product would have to meet the criteria of use of the accompanying claim.

Health claims are only permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising of products that make health claims:

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.

The provisions of (a) and (b) are not required for non-prepackaged foods (including fresh products such as fruit, vegetables or bread) put up for sale to the final consumer or to mass caterers and foods packed at the point of sale at the request of the purchaser or prepackaged with a view to immediate sale.
EFSA has published scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim, as well as general guidance for stakeholders on the evaluation of Article 13(1), 13(5) and 14 health claims.

Prohibited health claims
The following health claims will not be allowed to be made on food:

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;

c. Claims which make reference to recommendations of individual doctors or health professionals and associations (other than national associations of medical, nutrition or dietetic professionals and health-related charities). Further advice on this area is included in the Department of Health’s Guidance.

Claims that state, suggest or imply that a food has the property of preventing, treating or curing a human disease are prohibited under Article 7(3) of the FIC.

Any claims about fast or rapid weight loss are prohibited under Article 12(b) of the Regulation, as are testimonials or ‘before’ and ‘after’ photographs which state or imply a rate or amount of weight loss.

Health claims other than those referring to the reduction of disease risk and to children’s development and health (i.e. Article 13 claims)
Health claims describing or referring to:

- The role of a nutrient or other substance in growth, development and the functions of the body;
- Psychological and behavioural functions;
- Slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet (without prejudice to Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction).

are classed as so-called well-established general function health claims. The authorised list of these appears in Commission Regulation (EU) No 432/2012 of 16 May 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.

Any additions of claims to the list, based on newly developed scientific evidence and/or which include a request for the protection of proprietary data, may be adopted following an established procedure in the Regulation (Article 18). Although the regulation does not define what is meant by ‘newly-developed scientific evidence’, it is the Department of Health’s understanding that in this context, such a claim may be that which has never been made before or a claim based on evidence that has become available since 31 January 2008.
Health claims relating to reduction of disease risk and claims referring to children’s development and health (i.e. Article 14 claims)

Reduction of disease risk claims and claims referring to children’s development and health may be made where they have been authorised in accordance with a procedure in the Regulation for inclusion in a permitted list.

For reduction of disease risk claims, in addition to the general and specific requirements of the Regulation, the labelling, or if no labelling exists, the presentation or advertising must 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 Department of Health guidance provides further information and a flow chart on the application and authorisation process for such claims.

EU register of permitted claims and rejected health claims

The Commission has established and will maintain a Community Register of nutrition and health claims. The Register includes:

- a. The permitted nutrition claims and conditions applying to them; no other nutrition claims are permitted (see table above);
- b. Restrictions (i.e. on foods or categories of foods other than beverages containing more than 1.2% ABV);
- c. The authorised health claims and conditions of use;
- d. A list of rejected health claims and the reasons for their rejection.

Health claims authorised on the basis of proprietary data will be recorded in a separate Annex to the Register together with other additional information.

The EU Register of nutrition and health claims is available on the Commission’s website. Claims for which finalisation is pending are listed elsewhere on the Commission’s website, by ID number, allowing them to be identified from the consolidated list. These claims, most of which relate to botanical substances, can be used until a decision is made whether to authorise them or not.

Discussions are ongoing as to how to handle claims for botanicals. More information about each claim relating to botanical substances (e.g. garlic) can be found by searching the Register of Questions database on the European Food Safety Authority (EFSA) website.

A health claim relating to a botanical substance which is not listed within the Register of Questions database is an unauthorised claim and therefore such a claim must not be made in a commercial communication.
Beverages containing more than 1.2% by volume of alcohol must not bear health claims. Nutrition claims referring to low alcohol levels, or the reduction of the alcohol content, or the reduction of the energy content for drinks containing no more than 1.2% by volume alcohol are, however, permitted. In the Department of Health’s view, the term ‘light’ could also be used as an alternative to ‘reduced alcohol’, on drinks containing no more than 1.2% alcohol, if used with sufficient care. It is recommended that such claims are only made when the alcohol value is reduced by at least 30%. 