

Entwurf der Europäischen Kommission

“Guidance on the implementation of Regulation N° 1924/2006 on nutrition and health claims made on foods conclusions of the standing committee on the food chain and animal health”

I. Interaction with other community legislation

Regulation (EC) N° 1924/2006 applies to the use of claims, which in accordance with the definition provided for claims in the Regulation is any message or representation, which is not mandatory under Community or national legislation [...]. Consequently, claims i.e. messages made on a voluntary basis should be distinguished from the mandatory labelling indications that can be required by other Community or national legislation.

I.1. Interaction with Community provisions laid down in Directive 89/398/EEC and Directives adopted relating to foodstuffs for particular nutritional uses (PARNUTS)

Article 1 (5) of the Regulation states that it shall apply without prejudice to the Community provisions laid down in, inter alia, Directive 89/398/EEC and Directives adopted relating to foodstuffs for particular nutritional uses (PARNUTS).

Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC provides specific rules for nutrition and health claims made on infant formulae. The only permitted claims for infant formulae are listed in Annex IV of Directive 2006/141/EC and should be made in accordance with the conditions set out therein. In accordance with the third subparagraph of Article 4 (1) of Directive 89/398/EEC, modification of that list of nutrition and health claims should be adopted, when necessary, after EFSA consultation.

As no similar provision is laid down for follow-on formulae, nutrition and health claims made on such products are governed by Regulation 1924/2006. The other foodstuffs governed by PARNUTS Directives adopted on the basis of Directive 89/398/EEC, nota-

bly processed cereal-based foods and baby foods for infants and young children (Commission Directive 2006/125/EC), may bear claims authorised on the basis of Regulation 1924/2006, as no provision in these Directives concerns the use of nutrition and health claims.

I.2. Interaction with Regulation (EC) N° 258/97 concerning novel foods and novel food ingredients

Regulation (EC) N° 258/97 defines novel foods as foods and food ingredients that have not been used for human consumption to a significant degree within the Community before 15 May 1997. Regulation (EC) N° 258/97 lays out detailed rules for the authorisation of novel foods and novel food ingredients. Foods marketed in at least one Member State before the entry into force of the Regulation on novel foods on 15 May 1997, are on the EU market under the “principle of mutual recognition”. In order to ensure the highest level of protection of human health, novel foods must undergo a safety assessment before being placed on the EU market. Only those products considered to be safe for human consumption can be authorised for marketing.

The Regulation on claims only regulates the use of health and nutrition claims. Consequently, the procedure eventually applicable pursuant to that regulation, regarding a claim to be used for a novel food or a novel ingredient shall stay completely separated from the authorisation procedure laid down in the novel food Regulation for such food or ingredient. Consequently, claims on food or food ingredients considered to be novel could be only allowed in accordance with the provisions of the Regulation on claims once novel foods or novel food ingredients have been authorised in accordance with the provisions of Regulation (EC) N° 258/97.

II. Comparative claims

II.1. Provisions of the Regulation

Comparative claims are governed by the following provisions:

II.1.1. Article 9 of the Regulation

1. Without prejudice to Directive 84/450/EEC, 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.

2. Comparative nutrition claims shall compare the composition of the food in question 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.

Recital 21 also mentions that “for comparative claims it is necessary that the products being compared be clearly identified to the final consumer.”

Article 8, paragraph 1 stipulates that “Nutrition claims shall only be permitted if they are listed in the Annex”.

II.1.2. Annex of the Regulation

The only comparative claims listed in the annex are the claims increased [name of the nutrient], reduced [name of the nutrient], and light, for which specific conditions are given:

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 % 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 % 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.

Energy-reduced

A claim that a food is energy-reduced, and any claim likely to have the same meaning for the con-

sumer, may only be made where the 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.

Light/lite

A claim stating that a product is “light” or “lite”, and any claim likely 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”.

II.2. Guidance for the use of comparative claims

Comparative claims are nutrition claims. The only permitted nutrition claims are listed in the annex of the Regulation. It should be noted that the claims “as much as” or any claim having the same meaning are not considered to be comparative claims as Article 9 specifies that a comparative claim should indicate the difference in the quantity of a nutrient or the energy value. Neither are the claims “super light” authorised.

II.2.1. Food category

Article 9, paragraph 1, limits the use of comparative claims between foods of the same category. The Regulation does not provide definition of food categories. In line with the general principles set up in Article 3 for the use of all claims, the comparison should not be misleading for the consumer, but rather helpful to make informed choices. To that end, the products being compared should therefore be foods belonging to a group of foods that are similar in terms of composition and of nutritional content. For example, a “milk product” food category would be too large and would allow for non-significant comparison of fat content of cheese with fat content of milk. Therefore, in that example, only food categories such as “milks”, “fresh cheeses”, or “yoghurts” should be considered as “categories” for the application of this provision.

II.2.2. Reference product

Concerning the reference product, paragraph 2 of Article 9 specifies that a range of foods of the same category should be taken into account, including food of other brands. This is to avoid a situation where a comparison with a single product may not be representative of the product and mislead the consumer. For example a food company could develop a light version of a standard product having a higher energy content than competitor’s products. The light version could have 30% less energy, but the comparison could be misleading, as the reference product would not be representative of the products of the market.

Article 9 paragraph 2 also indicates that the comparison shall be made with a range of foods, "which do not have a composition which allows them to bear a claim". If the 30% reduction is achieved for a standard product, which is representative of the market, the label can mention a single product to establish the comparison. In this case, the name of the product itself can provide this information when it is followed by the claim "light" or any claims having the same meaning. For example, "X light", when X is the standard product, provides the information relative to the reference product.

II.2.3. Significant comparison

Furthermore, to avoid consumers to be misled and following the requirement of Article 9 paragraph 2 that the comparison shall be made with a range of foods, "which do not have a composition which allows them to bear a claim" it will not be possible for operators to make for instance a reduction claim where the 30 % reduction could be matched, but the difference between the standard and the light version would not have any significance from a nutritional point of view. For similar reasons of significant quantity, the conditions governing the claim "increased [name of the nutrient]" are that the food bearing the claim "increased [name of the nutrient]" should meet the conditions for the claim "source of".

II.2.4. Indication of the difference in the quantity of a nutrient and/or the energy value

Article 9 requires the indication of the difference in the quantity of a nutrient and/or the energy value. The difference can be expressed notably with a percentage or with an absolute value. When the claim "light" is used, the characteristic(s) which make(s) the food "light" must be indicated. A single indication can fulfil the requirements of both Article 9 and the conditions for using the "light" claim. For example, a label stating "light – minus 50 % sugar". When the nutrient is removed from the composition of the product, this indication can be provided by a claim referring to this absence of nutrient. For example "light – no sugar".

III. Classification of claims

The following definitions are taken from Article 2 of the Regulation.

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

- (a) the energy (calorific value) it
 - (i) provides;
 - (ii) provides at a reduced or increased rate; or
 - (iii) does not provide; and/or

- (b) the nutrients or other substances it
 - (i) contains;
 - (ii) contains in reduced or increased proportions; or
 - (iii) does not contain.

"Health claim" means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. "Reduction of disease risk claim" means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

III.1. Nutrition claims/health function claims

The first classification issue is related to the claim "contains [name of the nutrient or other substance]". This claim is part of the list of allowed nutrition claims, for which the following conditions apply:

Contains [name of the nutrient or other substance]

A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in this Regulation, or any claim likely to have the same meaning for the consumer, may only be made where 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.

These provisions classify the claim "contains" as a nutrition claim. However, some "contains" claims refer to groups of substances with a specific effect rather than individual substances. The important difference between the definitions of nutrition claim and health claim is the relationship to health that characterises health claims. Where the "contains" claim is used for a group of substances describing a function in the body, such as "contains antioxidants", which describes a group of substances with an antioxidant effect, this should therefore be classified as a health claim and be required to go through the appropriate authorisation procedure. In contrast, claims which only describe the nutrient content, such as "contains lycopene" would be covered by the "contains" claim in the Annex.

The distinction should be as follows:

- If in the naming of the "substance" or category of substances there is a description or indication of a functionality or effect on health, the "contain" claim is a health claim. In other words, if the function is mentioned – even in the naming of a substance or substances – this relates to a health claim.

Examples: "contains antioxidants" (the function is an antioxidising effect); "contains [name of probiotics/prebiotics]" (the definition of probiotic implies a health benefit).

- If in the naming of the “substance” or category of substances there is only factual information [of the content of the active ingredient and not claimed effect], the “contains” claim is a nutrition claim.

Examples: “contains lycopene”; “contains lutein”.

- As an extension, claims which make an indication of a functionality in the description of a nutrient or a substance (for instance as an adjective to the substance) should also be classified as a health claim.

Examples: “with prebiotic fibres” or “contains prebiotic fibres”.

It should be remembered that all claims are subject to the general principles laid down in Article 3 and 5. In the case of the claim “contains”, this means notably that the substance subject to the claim is present in a significant quantity and has been shown to have a beneficial nutritional or physiological effect. In addition, it should be reminded that in accordance with Article 7 the use of health and nutrition claims triggers an obligation to provide nutritional information pursuant to Directive 90/496/ECC.

III.2. Health claims classification

The Regulation provides the following definition for health claims:

“Health claim” means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. Furthermore, the Regulation distinguishes between:

- claims referring to children’s development and health,
- reduction of disease risk claims, which are governed by the provision of Article 14, and
- health claims other than those referring to the reduction of disease risk claims and to children’s development and health are governed by the provisions of Article 13, which distinguishes health claims describing or referring to:
 - (a) the role of a nutrient or other substance in growth, development and the functions of the body; or
 - (b) psychological and behavioural functions; or
 - (c) without prejudice to Directive 96/8/EC, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

III.2.1. Borderline between function and reduction of disease risk disease claims

The Regulation provides the following definition for a disease risk claim:

“Reduction of disease risk claim” means any health claim that states, suggests or implies that the con-

sumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

It may not be possible always to draw a clear line between function and reduction of disease risk claims. The following principle can help the operators and the controlling authority to achieve a common understanding of the content of each health claims category.

Functional claims refer rather to normal vital functions of the body whereas reduction of disease risk claims refer to reduction of risk factors. When the claim mentions a disease risk factor generally recognised by scientific evidence, it should be considered as an Article 14 claim if a reduction of this risk factor is mentioned.

Examples:

Function claim – Article 13	Reduction of disease risk claim – Article 14
maintains healthy cholesterol	lowers blood cholesterol

III.2.2. Borderline between claims referring to children’s development and health and other health claims

Article 14 mentions claims that are referring to children’s development and health. However, the Regulation does not provide for a definition of children.

- Community food law provides for the definition of infants and young children in Article 2 of Commission Directive 2006/141/EC on infant formulae and follow-on formulae:
 - “infants” means children under the age of 12 months;
 - “young children” means children aged between one and three years.

Infants and young children are subgroups of children as referred to in Article 14 of the Regulation.

In the context of the Regulation on claims, the distinction between children and other consumer groups was meant to control more closely those claims directed to a particularly vulnerable group. It might be possible to identify yet more subgroups, linked to different growth stages to which the diet and different nutrients within the diet may have a particular importance. The term “children” should be understood until the end of the growth period.

- Article 13.1.a covers claims referring to the role of a nutrient or other substance in growth, development and the functions of the body.

In order to avoid any overlapping of Article 13 and Article 14 claims, health claims that can be substantiated for a consumer group other than the one of children should be dealt as an Article 13 claim.

Conditions for the use of Article 13 claims should specify the consumer group for which the claim is valid and scientifically substantiated.

Therefore, only health claims solely referring to the development and health of children, and where the scientific substantiation is only valid for children, should be considered as Article 14 claims. In this case, the scientific substantiation consists of data obtained on studies conducted with children. An indicative age limit of 18 years can be mentioned, but this indication does not intend to define children in the frame of the Regulation. For example, "calcium and children's growth", "xx are necessary for nervous system development" should be considered as claims referring to children's development and health.

This classification has to be performed on the basis of the scientific substantiation. The applicant will propose a classification of the claims based on data its application contains. Clinical trials only performed with children would lead to an Article 14 classification. Contact with Member States authorities may help to solve classification issues.

This classification has no impact on the level of substantiation needed for the authorisation. The presentation and content of the scientific dossier is the same for both types of claims.

Classification in practice: specific cases

- The classification may evolve during its assessment by EFSA in exceptional circumstances. A scientific substantiation based on clinical trials with children only would always lead to an Article 14 claim, whereas a scientific substantiation based on clinical trials with children and clinical trials with other population groups may not lead automatically to an Article 13 claim. If EFSA concludes that the claim is only scientifically justified for children, the claim should be considered as an Article 14 claim.
- Claims referring to the role of a nutrient or other substance in growth and development based on

generally accepted scientific evidence could be authorised under Article 13 for a wide range of people, including children.

- Products can also be intended exclusively to children, like follow-on formulae. Products intended to children are also:
 - product with health claim that includes the word "children" or a similar word,
 - product or commercial with health claim and showing a picture of child(ren),
 - product or commercial with health claim and obviously intended for children (for example, cartoon).

In these situations, health claims should be:

- either on the list of Article 13, with conditions specifying the validity of the health benefit for children and other consumer groups,
- or on the list of Article 14, if, cf. the above-mentioned, the scientific substantiation is only valid for children.

As a consequence, applications for health claims, EFSA opinions and conditions for the use of Article 13 claims should specify precisely the consumer group for which the claim is scientifically substantiated and therefore valid. (Examples of consumer groups: "pregnant women", "people over 70 years old", "all the population", "adults and children over three years old".

Furthermore, Article 10.2.c specifies the additional statements linked to the consumer group that may be required:

2. Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling [...]
 - (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.



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Infos:
0810 200114 zum Ortstarif, www.sos-kinderdorf.at
Colleg für FamilienPädagogik, Gabelsbergerstr. 14, 4600 Wels

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