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**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**

Table of content

INTRODUCTION	3
I. INTERACTION WITH OTHER COMMUNITY LEGISLATION	4
I.1. Interaction with Community provisions laid down in Directive 89/398/EEC and Directives adopted relating to foodstuffs for particular nutritional uses (PARNUTS)	4
I.2. Interaction with Regulation (EC) No 258/97 concerning novel foods and novel food ingredients and relevant measures	5
II. COMPARATIVE CLAIMS	6
II.1. Provisions of the Regulation	6
Comparative claims are governed by Article 9 of the Regulation.	6
II.2. Guidance for the use of comparative claims	7
II.2.1. Food category	7
II.2.2. Reference product	8
II.2.3. Significant comparison	8
II.2.4. Indication of the difference in the quantity of a nutrient and/or the energy value	9
III. CLASSIFICATION OF CLAIMS	10
III.1. Nutrition claims / health claims	10
III.2. Health claims classification	12
III.2.1 Borderline cases between "function claims" and "reduction of disease risk claims"	13
III.2.2 Borderline between claims referring to children's development and health and other health claims	13
III.2.3 Impact of classification between Article 13 and 14	14

INTRODUCTION

Regulation (EC) N° 1924/2006^{*} of the European Parliament and of the Council on nutrition and health claims made on foods (hereafter “the Regulation”) was adopted on 20 December 2006. This Regulation lays down harmonised rules for the use of nutrition and health claims and contributes to a high level of consumer protection. It ensures that any claim made on a food label in the EU is clear, accurate and substantiated, enabling consumers to make informed and meaningful choices. The Regulation also aims to ensure fair competition and promote and protect innovation in the area of food.

Following an informal working practice, the Commission’s Health and Consumer protection Directorate General has set up a Working Group with experts from Member States in order to examine a series of issues concerning the implementation of the Regulation, notably on the classification of claims.

The Standing Committee on the Food Chain and Animal Health has approved the following conclusions at its meeting on the 14 December 2007.

The present document aims to assist the interested stakeholders to better understand and to apply correctly and in a uniform way the Regulation. However, this document has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

^{*} OJ L 12, 18.1.2007, p. 3

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 are 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 specific Directives adopted relating to foodstuffs for particular nutritional uses (PARNUTS).

Directive 89/398/EEC includes a general provision that the labelling of foods for particular nutritional uses should describe the particular nutritional characteristics of the products. In addition, the specific Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC provide 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 shall be adopted by Comitology, when necessary, after consultation of the European Food Safety authority (EFSA).

As no similar provision is laid down for **follow-on formulae, nutrition and health claims made on such products are governed by Regulation (EC) N°1924/2006**. The other foodstuffs governed by PARNUTS Directives adopted on the basis of Directive 89/398/EEC, notably **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 these Directives do not include specific provisions on the use of nutrition and health claims.

Mandatory elements in the labelling, the presentation or the advertising of foods for special dietary uses required by Directive 89/398/EEC or by the specific PARNUTS Directives adopted on the basis of Directive 89/398/EEC, to describe the particular nutritional characteristics of these foods or the purpose for which they are intended are of course outside the scope of Regulation 1924/2006.

I.2. Interaction with Regulation (EC) No 258/97 concerning novel foods and novel food ingredients and relevant measures

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.

Request for authorisation of novel foods shall be submitted through Regulation (EC) No 258/97. Any request for a claim relating to a novel food for which a request for authorisation has been submitted shall be made separately and in accordance with the provisions of Regulation (EC) N° 1924/2006 on claims.

Regulation (EC) N° 258/97 also provides the possibility for mandatory labelling associated with novel foods or novel food ingredients. However, as stated in section I, mandatory statements required by Community law shall not be considered as claims and are not in the scope of the Regulation, which covers only claims made on a voluntary basis. For example, the statements on cholesterol for products containing phytosterols, phytostanols, or their esters required by Commission Regulation (EC) No. 608/2004 concerning the labelling of foods and food ingredients with such added compounds are not under the scope of Regulation (EC) 1924/2006.

II. COMPARATIVE CLAIMS

Nutrition claims are only permitted if they are listed in the Annex to Regulation (EC) No 1924/2006 (Article 8, paragraph 1).

II.1. Provisions of the Regulation

Comparative claims are governed by 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 explains that *"for comparative claims it is necessary that the products being compared be clearly identified to the final consumer."*

The only comparative claims listed in the annex are the following: *"increased [name of the nutrient]"*, *"reduced [name of the nutrient]"*, *"energy reduced"* and *"light"*, for which specific conditions are given in the Annex to the Regulation:

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 consumer, 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.

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. Furthermore, the claim "as much as" is not in the Annex of the Regulation and is consequently not allowed.

The claim "super light" is also not included in the Annex and is consequently not allowed.

II.2.1. Food category

Article 9, paragraph 1, limits the use of comparative claims between foods of the same category, in order to avoid that the comparison is established between foods having different nutritional content (e. g. between milk and butter). However, the Regulation does not provide a definition of food categories.

Products being compared should therefore be foods belonging to a group of foods that are similar in terms of nutritional content.

Certain food groups are too broad to be considered as food categories for the application of this provision, and certain comparisons could be misleading. For example, a "dairy products" food category would be too large and would allow for inappropriate comparison of fat content of cheese with fat content of milk. Therefore, in that example, only food categories such as "milks" or "cheeses" should be considered as "categories" for the application of this provision.

Food similar in terms of overall nutritional content can also be alternatives of consumption, such as margarine and butter, which are both fatty products. Therefore, the notion of food category should also take account of the occasion of consumption and/or the purpose of the consumption. Consumers may be interested in the comparison of certain products and their alternatives. In those cases, in order not to mislead the consumer, taking into account the explanation provided in Recital 21 of the Regulation, Article 3 would require the reference product to be explicitly mentioned.

II.2.2. Reference product

Paragraph 2 of Article 9 specifies that a range of foods of the same category should be taken into account, including foods of other brands, for the comparison. This is to avoid a situation where a comparison with a single product may mislead the consumer because the single product may not be representative of that category of products. For example a food company could take as a reference product a product, which has a higher energy content than the average product in that food category. The light version could have 30% less energy of such reference product, but the comparison could be misleading, as the latter would not be representative of the products of that category on the market.

Provided that it is thus representative of the products of its category, a specific branded product may be used as a term for comparison. In other words, if a specific branded product has a composition which is representative of the market, the name of the product itself can provide the reference for comparison when it is followed by the claim "light". For example, "X light", when X is the standard product, provides the information on the reference product.

II.2.3. Significant comparison

Based on Article 9, paragraph 2, and in order not to mislead the consumer, it will not be possible for operators to make a "reduced" claim where the 30% reduction is achieved, but the difference between the standard and the light version would not have any significance for the overall intake of the nutrient in question. For example, it will not be possible to make a "reduced fat" claim on bread. 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 with a percentage or with an absolute value.

When the claim "*light*" or "*energy reduced*" is used, the characteristic(s) which make(s) the food "*light*" or "*energy reduced*" must be indicated. A single indication can fulfil the requirements of both article 9 and the conditions for using the "*light*" or "*energy reduced*" claim. For example, a label stating "light - 50% less sugars".

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 sugars".

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 claims

The first classification issue is related to the claim "contains [name of the nutrient or other substance]".

In accordance with the provisions of the Annex to the Regulation, 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.

Whilst claim "*contains*" is normally a nutrition claim, in some cases the use of the term "contains" in a claim refers to groups of substances with a specific functional effect. In such cases, the "*contains*" claim is a health claim and must be authorised accordingly.

The following examples aim at better explaining the difference between the two categories of claims using the term "*contains*":

A claim is a nutrition claim if in the naming of the substance or category of substances, there is only factual information;

Examples: "contains lycopene" ; "contains lutein"

A claim is a health claim if in the naming of the substance or category of substances, there is a description or indication of a functionality or an implied effect on health,

Examples: "contains antioxidants" (the function is an antioxidant effect); "contains probiotics/prebiotics" (the reference to probiotic/prebiotic implies a health benefit);

Equally, claims which refer to 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 noted that all claims are subject to the general principles laid down in Articles 3 and 5. In the case of the claim "contains", this means 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, the use of health and nutrition claims triggers an obligation to provide nutritional information pursuant to Directive 90/496/EEC in accordance with Article 7 of the Regulation.

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.*

The Regulation distinguishes between different types of health claims and provides different procedures to be followed for evaluation and authorisation:

"Article 13 claims" are 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.

They are hereafter referred to as "function claims".

On the basis of the national lists Member States have to provide by 31 January 2008, the Commission will consult EFSA and adopt a Community list of permitted claims by 31 January 2010 at the latest.

Claims based on newly developed scientific evidence and/or which include a request for the protection of proprietary data are subject to the authorisation procedure laid down in Article 18. From 1 February 2008 Member States can send valid applications to EFSA for the scientific assessment* in accordance with Article 18 (3).

"Article 14 claims" are

- Claims referring to children's development and health,
- Reduction of disease risk claims,

Health claims referring to the reduction of disease risk claims or to children's development and health: applications can be submitted from 1 July 2007, date of application of the Regulation*.

* Applications shall follow EFSA guidelines in "Opinion of the Panel on dietetic products, nutrition and allergies (NDA) on a request from the Commission related to scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim"
http://www.efsa.europa.eu/EFSA/Scientific_Opinion/nda_op_ej530_guidance_%20health_claim_en.pdf.pdf

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

The Regulation provides the following definition:

'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.

When the claim mentions a disease risk factor generally recognised by scientific evidence, it should be considered as an Article 14 claim only when a reduction of this risk factor is stated, suggested or implied. Other cases are to be considered as "function claims" i. e. as claims following in one of the categories listed in Article 13 of the Regulation.

The following table summarizes the criteria for making the distinction in cases where disease risk factors are mentioned:

The claim refers to:	Classification
- a normal function of the body - a risk factor of a disease, without stating, suggesting or implying its reduction Example: maintains [naming normal vital function of the body]	Article 13
- a reduction of a risk factor of a disease, with or without mentioning the disease name Example: lowers [naming risk factor]	Article 14

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

Article 14 covers claims that refer to "*children's development and health*". The term "children", which is not defined in the Regulation, should be understood as reaching the end of the growth period. 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.

Community food law provides for the definition of infant and young children in Article 2 of Commission Directive 2006/141/EC on infant formulae and follow-on formulae, namely;

- "*infants*" means children under the age of 12 months;
- "*young children*" means children aged between one and three years;

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

The following claims should be considered as Article 14 claims:

- Health claims solely referring to the development and health of children, and where the scientific substantiation is only valid for children. In this case, the scientific substantiation consists of data obtained on studies conducted with children.

Example: "calcium is good for children's growth"

- Health claims used on products intended exclusively to children, like follow on formulae, processed cereal-based foods and baby foods, as defined by Directive 2006/141/EC and Directive 2006/125/EC, shall be considered as Article 14 claims.

The following claims should be considered as Article 13 claims:

- Claims referring to the role of a nutrient or other substance in growth, development and to the functions of the body where the scientific substantiation covers the entire life span, or more than the children population group. In this case, applications, EFSA opinions and conditions for the use of the claim should specify precisely the consumer group for which the claim is scientifically substantiated and valid.

Example: for the reference "for children and pregnant women", an Article 13 claim is only possible if the scientific substantiation covers the children population group as well as the pregnant women population group.

III.2.3 Impact of classification between Article 13 and 14

The classification above is performed mainly on the basis of the scientific evidence submitted for its substantiation. The applicant should propose a classification of the claims based on data its application contains. Contact with Member States authorities may help to solve classification issues.

The 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.

The classification may depend on EFSA's scientific assessment in exceptional circumstances. As an example, 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.