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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**

INTRODUCTION.....3
COMPARATIVE CLAIMS4
 Provisisons of the Regulation4
 Article 9 of the Regulation.....4
 Annex of the Regulation4
 Guidance for the use of comparative claims.....5
 Food category.....5
 Reference product5
 Significant comparison6
CLASSIFICATION OF CLAIMS.....7
 Nutrition claims / health function claims......7
 Health claims classification8
 Borderline between function and reduction of disease risk disease claims.9
 Borderline between claims referring to children’s development and health and other health claims9

INTRODUCTION

Regulation (EC) N° 1924/2006¹ 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 health or nutritional claims and contributes to a higher 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 and reach consensus on a series of issues concerning the implementation and interpretation 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 of XXXXX and considers these conclusions shall be made widely available to interested parties.

The present document aims to assist the interested stakeholders all 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.

¹ OJ L 12, 18.1.2007, p. 3

I. COMPARATIVE CLAIMS

I.1. Provisions of the Regulation

Comparative claims are governed by the following provisions:

I.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".

I.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 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".

I.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 prohibited, as well as the claims "superlight".

I.2.1. Food category

Article 9, paragraph 1, limits the use of comparative claims between foods of the same category. The Regulation does not specify these food categories.

The general principle that should be used to apply this provision is that the comparison should not be misleading for the consumer, but rather helpful to make informed choices.

The product being compared should therefore be alternatives for consumption, rather than foods belonging to a specific food category. They should have also a similar nutritional content.

A milk product food category would put together skimmed milk, yoghurts, and cheeses, which have a very different nutritional content. Comparing the fat content of a yoghurt with the fat content of a cheese would not be helpful for the consumer, but rather misleading.

However, cow milk could be compared with soy milk, as soy milk is an alternative of cow milk and is consumed in similar occasions.

I.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 consumer. For example a food company could develop a light version of

a standard product being richer in salt than competitor's products. The light version could be 30% less salty, but the comparison could be misleading, as the standard for the comparison would not be representative of the products of the market.

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.

I.2.3. Significant comparison

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".

This is to avoid a situation where a food would contain a non significant amount of a nutrient, and a light version would propose a reduction of this nutrient. The 30% reduction could be matched, but consumer would be misled, as the standard and the light version would not have any significant difference 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".

According to the annex, the claim "reduce" involves a comparison with a similar product. It is therefore a comparative claim and falls under Article 9 of the Regulation on nutrition and health claims, which limits the comparison between foods of the same category.

Note for discussion: Such claims are also a strong incentive for product reformulation, and should not be restricted in a way that would jeopardize the efforts ongoing in that field. The balance needed regarding the control of that claim is difficult to be formulated in a general frame, but should take account of both consumer protection and reformulation incentive.

II. 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;

II.1. Nutrition claims / health function claims.

The first classification issue is related with 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 nutrition claims. However, some "contains" claims refer to effect rather than substances. The important difference between the definitions of nutrition claim and health claim is the relationship to health that is characterising health claims. Name of substances describing a function in the body, such as "contains antioxidants", which describes a group of substances with an antioxidant effect – should therefore be classified as health claims 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” ; “contains probiotics/prebiotics” ;

- 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], this must be classified as a nutrition claim.

Examples: “contains lycopene” ; “contains lactic acid bacteria” ; “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”; “with functional bacteria”
“with functional enzymes”

It should be reminded that all claims are subjects to the general principles laid down in article 3 and 5. In the case of the claim contain, this means notably that the substance subject to the claim is present in significant quantity and has been shown to have a beneficial nutritional or physiological effect.

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 distinguish between:

- Claims are 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 (nutrient function claims and other function claims, as defined by Codex Guidelines on nutrition and health claims). They 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,

Borderline between function and reduction of disease risk disease claims.

It may not be possible always to draw a bright line between function and reduction of disease risk disease claims. The following principle can help the operators and the controlling authority to achieve a joint 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 factor. When the function claims mentions a disease risk factor generally recognised by scientific evidence, it is considered as an article 14 claim if a reduction of this risk factor is mentioned.

Examples:

Function claim – article 13
maintains healthy cholesterol
helps to control blood pressure

Reduction of disease risk claim – article 14
lowers blood cholesterol
reduces blood pressure

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

Article 14 claims 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 infant 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 sub group 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 group was meant to better control those claims directed to a particularly vulnerable group. The term "children" should be understood from birth until the end of the growth period (approximately 16-18 years old?? *Note for discussion Do we need to put a age limit?*).

Interaction with PARNUTS legislation

The Regulation applies without prejudice to the Community provisions laid down in 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 are listed Annex IV of Directive 2006/141/EC and should be made in accordance with the conditions set out therein.

As no similar provision is laid down for follow-on formulae, nutrition and health claims made on such products should be authorised in accordance with the Regulation 1924/2006.

The other foodstuffs governed by PARNUTS Directives adopted on the basis of Directive 89/398/EEC 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.

Article 13.a covers claim 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 larger than the one of children should be dealt as an article 13 claim. Conditions for the use of article 13 should specify the consumer group for which the claim is valid and scientifically substantiated.

Therefore, the only health claims specific to development and health of children, and that are only justified for children should be considered as article 14 claims.

For example, "calcium and children growth", "xx are necessary for nervous system development" should be considered as claims referring to children's development and health.

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, or primarily, like breakfast cereals. 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 be on the list of article 13, with conditions specifying the validity of the health benefit for the children group,
- or be on the list of article 14.