

DISCUSSION PAPER ON NUTRITIONAL CLAIMS AND FUNCTIONAL CLAIMS

CEEREAL COMMENTS

CEEREAL, which represents the breakfast cereal and oat milling industries in the European Union, welcomes the opportunity to comment on the Discussion Paper on Nutritional and Functional Claims. CEEREAL supports the position of the Confederation of the Food and Drink Industries of the EU (CIAA) and in addition would like to emphasise the following key points for the breakfast cereal sector.

EXECUTIVE SUMMARY

- CEEREAL welcomes the Commission's initiative to create a European regulatory framework for the use of nutritional and functional claims, as this subject is key both to consumers and to food manufacturers. However, we are disappointed and indeed concerned with the scope of this paper, and in particular the Commission's decision not to address health related claims, including disease risk reduction claims.
- CEEREAL believes that the European Commission should undertake a more comprehensive review of legislation relating to claims and should consider the establishment of a framework applicable to all types of claims related to nutrition and health, including implementation measures. This regulatory framework should address product-specific claims as well as claims regarding the relation between diet and health. In establishing such a framework, CEEREAL urges the Commission to determine clear legislative measures governing the use of health related claims.
- CEEREAL supports the development of clear definitions in future EU legislation. These should reflect the definitions already adopted by Codex (nutritional and nutrient function claims) and those currently under discussion (health claims). As stated in DG Sanco's discussion document (paragraph 37), CEEREAL agrees that the definition of nutrient function claims should encompass both nutrients and other substances (i.e. ingredients and other food components) that play a physiological role in growth, development and normal functions of the body.
- An appropriate regulatory framework should ensure consistent definition and use of claims so as to promote improved consumer understanding of the relationship between diet and health. The reinforcement of nutrition education in the Member States, called for in the Council Resolution on Health and Nutrition of 14 December 2000, will also enable consumers to better understand and utilise information provided by all sources, including claims communicated by food manufacturers.
- Future harmonisation of rules on the use of claims should be based on a number of key principles:
 - all claims related to health should be substantiated by scientific evidence;
 - responsibility for claims substantiation lies with food manufacturers;
 - the level of substantiation and measures of control should be proportional to the claim made;
 - claims should be made in the context of the total diet;
 - responsible consumer communications by food manufacturers should ensure clear understanding of the claim being made and contribute to overall efforts to promote healthy diets and lifestyle.

A balanced regulatory framework on claims will allow all European consumers to access essential information regarding diet and health. CEEREAL, therefore, urges the Commission to develop a harmonised framework covering the use of all types of claims on foodstuffs. In parallel, CEEREAL calls on the Commission to adopt specific measures governing the use of health related claims, including the revision of Directive 2000/13 on Food Labelling.

I. GENERAL REMARKS

CEEREAL fully supports the Commission's initiative to finally address at the European level the questions of nutritional claims and functional claims, which are of key interest to consumers, the scientific community, Member States and the food industry alike.

However, we are disappointed that the document does not reflect the debate and advances made at international level on the subject of nutrition and health claims. By not addressing the subject of claims related to health, the Commission appears to be abdicating its role and responsibilities of ensuring a Single Market and securing a European framework for the responsible communication by food manufacturers of nutrition and health information.

1. There is a need for a comprehensive regulatory framework on claims

CEEREAL believes that the Commission should undertake a much broader and more comprehensive approach regarding the harmonisation of claims, including all claims related to nutrition and health, as well as implementation measures.

We consider that such a European framework could be structured in 4 parts including:

- a. **Definitions** for all claims based on the definitions already adopted by Codex Alimentarius (nutritional and nutrient function claims) and those currently under discussion (health claims), as well as the **general principles** applicable to all claims and existing in Codex standards. These could be further strengthened by a principle ensuring proportionality between the level of substantiation and the nature of the claim.
- b. **Criteria** for making **quantitative nutritional claims** based on the work of the Codex committees and ensuring that all claims made are of nutritional significance.
- c. **Criteria** for making **nutrient function claims** on the basis of the work undertaken at Codex and possibly including a link to quantitative nutrition claims.
- d. **Criteria** for making **health claims** based on the work undertaken by Codex and the Council of Europe. Until European harmonisation has been achieved, referral to national legislations and/or codes of practice should be made, while confirming the application of the principle of mutual recognition in this context.

Any measures of application taken to implement this framework should be carried out by Standing Committee procedure.

2. In addition, clear regulatory measures should govern health claims

Parallel to the implementation of such a European regulatory framework, CEEREAL requests that work be undertaken to establish legislative provisions specific to health claims, including the necessary modification of Directive 2000/13 (Article 2b in particular). These measures should not only cover product-specific claims, but also claims regarding the relationship between diet and health, including reduction of disease risk.

We are extremely concerned with DG Sanco's suggestion that health claims should be addressed separately and at a later stage. In our view, this approach is inappropriate and unrealistic for a number of reasons, which are outlined below.

a. Consumers are interested in the relationship between diet and health

Nutrition science constantly reveals new information confirming the important relationship between diet and health, including its role in the reduction of disease risk. Consumers are interested in nutrition and its link to health and would like information on diet and its relation to disease risk reduction to be communicated by manufacturers (IPSOS, Gallup 1999; IRB Europe 1998). The discussion paper acknowledges this fact, stressing that consumers have become more interested in their diet and its relationship to health. Yet, there is no clear regulatory framework in Europe allowing the food industry to communicate the role that specific products can play in a balanced diet, supported by scientific research.

b. Health claims are closely related to nutritional and functional claims

In practice, nutritional and functional claims cannot be separated from enhanced function claims and disease risk reduction claims, as shown by the Codex Alimentarius discussions, where all types of claims are addressed in a single framework. It is not possible to exclude certain claims from the discussion when it is acknowledged that there are no clear definitions to establish the limit between the different types of claims.

c. Different standards of consumer protection and barriers to trade

The Commission stresses that the different definitions, laws and approaches adopted by the Member States in the area of claims could result in barriers to trade and hinder the overarching objective of a high level of consumer protection (paragraph 5, page 3). Whilst this undoubtedly applies to nutrition and functional claims, it is even more relevant in the case of enhanced function and disease risk reduction claims. In the absence of a clear EU regulatory framework, several Member States (for instance the United Kingdom, Sweden, The Netherlands, France, Finland, etc.) are developing their own guidelines and codes of practice to define health claims and regulate their use. This may not only lead to barriers to trade, but could also create different standards of consumer protection and levels of consumer understanding.

d. Absence of coherence with EU nutrition policy

The EU is keen to actively promote nutrition and healthy eating, as highlighted by the current initiative in favour of a comprehensive and coherent nutrition policy and by the discussions on a public health action programme. The Commission itself has launched an olive oil campaign to provide valuable advice to consumers on the positive contribution of olive oil in reducing the risk of coronary heart disease. However, EU legislation still prevents the food industry from communicating the health benefits of foods, including the provision of similar information on the role that individual foods can play, as part of a total dietary pattern, in reducing disease risk. This deprives the food industry of the opportunity to support the efforts of health educators, as well as the Commission's own initiatives, to promote healthy diets in the European Union.

e. European stakeholders are calling for EU initiatives

The approach presented in the discussion paper goes against the results of a recent study carried out for the Health and Consumer Protection Directorate-General. The Study on Nutritional, Health and Ethical Claims published by DG Sanco in the Summer of 2000 demonstrates that almost all EU Member States support a revision of European legislation to address the question of health related claims. This view is shared by consumer groups and the food industry across Europe. The Study highlights that consumer organisations consider current legislation on health claims to be inadequate or inadequately enforced and are, therefore, calling for action at the EU level. This is confirmed by BEUC's position on the use of health related claims for foodstuffs, which stresses that no harmonised system for the use of health claims is in place in Europe and that there should be a new EU approach to claims.¹ The food industry is also calling for amendments to the Food Labelling Directive in order to allow new types of claims, in particular enhanced function claims and disease risk reduction claims.

f. Inconsistency with the Council of Europe approach

DG Sanco's approach is inconsistent with the work of the Council Europe, which has now established Guidelines on the scientific substantiation of health claims for functional foods.² Whilst these guidelines are not legally binding, they are considered by the participating Member States – including all EU Members (apart from Greece, which did not participate in the discussion), some applicant countries and the European Commission as an observer – to be a faithful reflection of current thinking. Such thinking covers two interconnected types of claims: “enhanced function claims” and “reduction of risk of disease claims”. Any initiative to address these aspects separately would be arbitrary and contrary to the position of the Member States.

g. Contrary to the Opinion of the European Parliament

Such a move fails to respond to repeated calls by the European Parliament for urgent action to legislate for the provision of disease risk reduction information by food manufacturers. The 1998 European Parliament Opinion on the Green Paper on Food Law³ called for claims regarding “nutritional value and healthy diet and their importance to health and/or in reducing the risk of disease” to be allowed. More recently, the European Parliament Resolution on the Commission's White Paper on Food Safety of October 2000⁴, urged the Commission to address health claims, and more specifically “enhanced function claims” and “disease reduction claims”, in its proposal to amend the Directive on the Labelling, Presentation and Advertising of Foodstuffs (Directive 2000/13).

For all the reasons stated above, CEEREAL urges the Commission to extend the current discussion to that of health claims, including enhanced function claims and disease risk reduction claims.

¹ BEUC/220/2000.

² Council of Europe Partial Agreement in the Social and Public Health Field, Committee of Experts on Nutrition, Food Safety and Consumer Health: “Guidelines concerning the scientific substantiation of health related claims for functional foods”, 31 May 2001.

³ A4-0009/98

⁴ A5-0272/2000.

II. DETAILED COMMENTS

1. Introductory remarks

- **Paragraph 3**

The discussion document appears to criticise the use of nutrition and health claims as marketing tools. The food industry provides consumers with products that meet their needs in terms of taste, quality, convenience, nutrition and health and promotes these benefits to consumers. Given growing consumer interest in the relation between the foods they eat and their health, as well as scientific research conducted both by private and public sectors confirming the relation between certain dietary patterns and health (including reduction of disease risk), it is only logical that the food industry be allowed to communicate to consumers the benefits associated with foods that can make a significant contribution to nutrition and health. This is even more pertinent where a food has been designed to provide a specific health benefit which consumers are seeking.

Furthermore, CEEREAL would like to underline that, in addition to encouraging consumers to buy a product, claims also provide valuable information to consumers about the properties of the products that they purchase. It is interesting and relevant to note for instance that consumer awareness regarding the relation between folic acid and neural tube defects is highest in the UK where national information campaigns have been conducted, including the possibility for food manufacturers to carry a folic acid flash on product labelling (Ipsos, 1999; Health Education Authority, *the HEA folic acid campaign 1995-1998*).

- **Paragraph 6**

While Directive 2000/13 Directive (Article 2b) indicates that labelling and advertising should not mislead consumers about the characteristics and properties of foods, it prohibits attributing to a product properties regarding prevention, treatment or cure of a human disease or reference to such properties. This article is interpreted differently today by Member States, and CEEREAL believes that it should be modified in order to allow the food industry to inform consumers about the health benefits associated with their products and/or dietary patterns beneficial to health. Different interpretations by Member State authorities could also lead to trade barriers in the event that claims made in one market are not allowed in the other.

- **Paragraph 7**

CEEREAL agrees with the general principle that claims should not undermine or take precedence over the importance of a balanced and varied diet. However, in some instances, it may not be possible to reach recommended intake levels in nutrients through a traditional, balanced diet. This is the case for instance for folic acid and iron, where it may be difficult for women of child bearing age to reach intake levels required. For instance, in the UK, it is estimated that women would need to increase their folic acid intakes 2-3 fold in order to reach the level recommended for the prevention of neural tube defects, an increase impossible to achieve without recourse to fortified foods and/or dietary supplements.

- **Paragraph 8**

While CEEREAL agrees that the various means of communication (including visuals, images, logos as well as wording), should not be misleading it does not seem possible to include such detailed aspects in legislation. This objective could be better addressed by strengthening general principles regarding claims and also possible reference to codes of practice or guidelines regarding claims. An appropriate

regulatory framework should ensure consistent definition and use of claims, to the benefit of consumer understanding. CEEREAL would also like to underline the need to strengthen nutrition education, which will also provide a context allowing consumers to better understand and utilise information and claims made by all sources, including food manufacturers.

- **Paragraph 9**

CEEREAL concurs with the Commission that there are no “good” or “bad” foods as dietary balance is reached by an overall dietary pattern. The use of claims should therefore not be restricted to certain categories of products. Certain foods can have beneficial properties while containing nutrients that should only be consumed in small quantities (for instance margarine).

- **Paragraph 10**

CEEREAL agrees with the overall intent that a claim should be valid and substantiated until the end of a product’s shelflife. However we would like to underline that assessment of bioavailability cannot be limited to a nutrient form per se, or even to the foodstuff in and of itself, as the availability/absorption of a nutrient is influenced by presence of activators/inhibitor of absorption, other foods and beverages consumed at the meal, and even the individual’s own dietary status. Where bioavailability is relevant, this consideration falls under the general requirement that a claim should be substantiated.

- **Paragraph 11**

CEEREAL agrees that claims should be made based on the food as sold or where appropriate, such claims may refer to the foodstuff after preparation in accordance with instructions for use indicated on the label (for example, for dehydrated or concentrated foods and drinks which cannot be consumed “as sold” but must be reconstituted with water or another liquid). This ensures consistency with Article 4 of the Directive on Nutrition Labelling (90/496/EEC), which states that the amounts mentioned shall be those of the food as sold or, where appropriate, this information may relate to the foodstuff after preparation.

2. Definitions (paragraphs 12-15)

The discussion paper recognises that the lack of common understanding of the terminology used in referring to claims has caused confusion. CEEREAL agrees with the need for a generic definition of the term “claim” and believes that the Codex definition provides an appropriate basis for an EC definition. We also support the development of clear definitions on the various types of claims in future Community legislation. These should reflect the definitions agreed or under discussion within Codex Alimentarius.

While definitions proposed by Codex for the 4 types of food claims (nutritional claims, nutrient function claims, enhanced function claims and disease risk reduction claims) can at times be difficult to differentiate, it is nevertheless useful to pursue discussions regarding their definition, particularly as the nature and level of substantiation will differ according to the type of claim being made. The number of claim categories could be reduced (for instance by differentiating between claims relating to nutrient content and those relating to function) if general principles applicable to all claims are defined. Quantitative nutrition claims should in any case be considered separately, as in Codex, since these are defined according to quantitative criteria and do not have substantiation requirements per se.

3. Nutrition claims

a. Different types of nutrition claims

- **Paragraph 17**

While we endorse the Codex guidelines on nutritional claims, we believe that the concept of a “nutrient” should be extended to encompass all the foods, ingredients and their components which are demonstrated to play a significant role in bodily development and maintenance, and the maintenance of health, including the reduction of disease risk.

Regarding quantitative nutritional claims, only those nutrients (or substances as indicated above) for which RDAs have been defined or for which recommended intake levels exist should be included. Fibre is defined as a nutrient in the context of the Nutrition Labelling Directive 90/496. It is a major dietary component and does have a significant effect on nutrient intake; its importance is not restricted to physiological effects (for example on gut transit).

It is indeed difficult to differentiate as such between nutritional and physiological effects as nutritional status is regulated by physiology. For substances such as lycopene, lactic bacteria etc., claims should relate to the quantity required to obtain the desired effect or function in the body (nutrient function or enhanced function claim, depending on the benefit). Such claims should be allowed provided that they can be substantiated.

- **Paragraphs 18-19**

Clear benchmarks should indeed be agreed for the definition of quantitative nutrition claims so that consumers, industry, health professionals and regulators clearly understand and use the same terms objectively.

- **Paragraphs 20/21/29**

The claims referred to in these paragraphs do not refer only to nutrition and health and it could be questioned whether they legitimately fall within the scope of the current discussion. Such claims (e.g. absence of additives) are regulated by the general principles applicable to labelling and should not be considered as absolute nutrition claims requiring a specific benchmark. The term “light” for instance is legitimately used for purposes additional to any nutritional reference: to denote a low density product, a light texture etc. The derivative “lite” has come to be accepted as a colloquial form to refer to reduced fat, calorie, etc. The parameter to which the term “lite” refers should always be stated on the label or advertisement should there be any possibility of confusion.

- **Paragraph 24/25**

Claims regarding cholesterol content should be allowed according to Codex standards. While CEEREAL certainly endorses the fact that consumer education regarding diet and health should be strengthened and further developed, lack of knowledge (in this case regarding the difference between dietary and blood cholesterol) should not be the basis for restricting the possibility of making claims. For instance, while many consumers may not know that “folic acid” is a vitamin, nevertheless information regarding its importance to nutrition and health should be allowed. Furthermore, many consumers do not understand today all the components of the nutrition label (how many consumers in Europe can define what is a kiloJoule?), and while we should undertake to facilitate understanding through

appropriate format, presentation and education, this should not be the basis for deciding to remove nutrients from the nutrition label!

- **Paragraph 26**

Claims regarding sodium level should follow the same general rules as for all other nutrients and, hence, be applicable to all foods. While these should be consistent with PARNUTS standards, they should not be limited to PARNUTS.

b. Criteria for making nutrition claims

- **Paragraph 27**

CEEREAL agrees with the statement made in the DG Sanco discussion document that there is no good justification for creating a specific category of functional claims, as all foods can potentially have a functional benefit. If rules on claims are defined, these should be applicable to all foods, including PARNUTS, but perhaps excluding baby/infant foods. CEEREAL opposes the definition of a specific category of foods as “functional”.

- **Paragraph 28**

Any potential misunderstanding or confusion among consumers regarding an “X% fat free “ claim could possibly be addressed by directing the consumer to additional information, in particular the nutrition label. In any event, such claims will always be governed by the general principle that a claim should not be misleading.

- **Paragraph 30**

It should not be necessary to distinguish between “low fat” and “a low fat food,” as consumer understanding will invariably be the same. The importance is to set one definition for “low fat” and to apply consistently whether a product is “naturally” low in fat or not.

- **Paragraph 31**

Concerning the definition of nutritional significance, CEEREAL maintains that the issue with the Nutrition Labelling Directive, i.e. the level of 15% RDA quoted in the Annex of the Nutrition Labelling Directive, does not relate so much to the absolute level quoted (i.e. 15%) but to the reference quantity to which it refers (i.e. 100g or 100 ml). Indeed the specific value quoted in the Annex of the Nutrition Labelling Directive may not be appropriate for certain foods, especially for foods that have a low energy density or that are consumed in portions representing more or less than 100g /ml. CEEREAL believes that the ability to define claims based on serving size or reasonable daily intake would resolve this issue.

4. Functional claims

a. Definitions

Paragraphs 37-39

The definition and examples provided in paragraph 37 suggest that the term “functional claims” used by the Commission strictly relates to nutrient function claims as defined by Codex Alimentarius. If the Commission intends to regulate nutritional and functional claims only, leaving enhanced function and disease risk reduction claims to be regulated at the national level, then it would make more sense to use the Codex terminology (i.e. ‘nutrient function claims’ instead of ‘functional claims’). As suggested in paragraph 37 of the paper, CEEREAL would support a broadening of

the definition of nutrient function claims provided by Codex to include other substances that can play a role in growth, development and other normal functions of the body.

CEEREAL believes that EC legislation should provide a framework for making the four types of nutrition and health claims defined in Codex: nutrient content, nutrient function, enhanced function and disease risk reduction claims. However, if the harmonising legislation does relate only to nutrient function claims, then it is important to ensure that enhanced function and disease risk reduction claims can continue to be made subject to national legislation/codes of practice as they are today.

b. Criteria for the use of functional claims

• **Paragraph 41**

CEEREAL supports the Commission's statement that there are no good or bad foods. Any claim made should be considered in the context of an overall dietary pattern and should relate to the amount of food normally consumed.

• **Paragraph 42**

If the Commission includes "health claims" in this discussion, then the requirement here should not be solely that the food is a significant source of the nutrient but that sufficient information should be given as to the quantity of food required to achieve the desired effect or benefit.

• **Paragraph 43**

This paragraph refers to claims which are not nutrient function claims (e.g. lactose-free).

• **Paragraph 45**

Although claims can contribute to consumer education, this is not their primary role. Ensuring consumer understanding of claims is of course a key aspect of consumer research conducted by food manufacturers when developing any consumer communications concept, including those related to nutrition and health. While it is the responsibility of public health authorities to ensure appropriate education of consumers, there is no doubt that information communicated by manufacturers via labelling, nutrition labelling and claims can play an important role in improving consumer understanding regarding diet, nutrition and its relation to health.

• **Paragraph 47**

The discussions both at Codex and Council of Europe concern the scientific substantiation of "health claims," not nutrient function claims; hence the conditions outlined in this paragraph are not pertinent if the Commission's intent is to limit future harmonisation to nutritional and functional (nutrient function) claims. Such criteria should be taken into account in discussions for a future framework on the use of health related claims. We would also like to underline that the Council of Europe has defined guidelines for product-specific claims relating either to enhanced function or disease risk reduction; these may therefore not be appropriate for claims regarding diet and health.

- **Paragraphs 48-49**

CEEREAL is opposed to any type of pre-marketing clearance, notification etc. for nutrient function claims as these are based on widely published and accepted nutritional science.

For health claims, CEEREAL would favour the evaluation of scientific substantiation by an independent authority at European level. Such an evaluation could be conducted either by an Agency or an independent body (for instance the future European Food Authority) and should rely on a validated European methodology or process.

- **Paragraph 50**

The Swedish two-step system should not be required for nutrient function claims which relate to the normal function of a nutrient on human physiology, growth, development etc. Regarding health claims, this system may not be appropriate for “enhanced function claims,” where the health effect may not be limited to a product constituent per se but to the product itself.

5. Comments on the annex

- **Low saturates or saturated fatty acids**

This should read under Codex: “1.5 g per 100 g for solids, 0.75g/100ml for liquids and 10% of energy”.

- **Sugar(s) free/without sugar(s)**

This should read under Codex: “no more than 0.5g per 100g for solids and 0.5g per 100ml for liquids”.

- **Source of fibre**

This should read under Codex: “at least 3g per 100g or at least 1.5g/100kcal or per serving”.

- **High fibre/rich in fibre/excellent source of fibre**

This should read under Codex “... or per serving” rather than per portion.

- **Source of vitamins and minerals**

This should read under Codex “15% of the NRV/100g or 7.5% of the NRV/100ml or 5% of the NRV/100kcal or 15% of the NRV per serving”.

- **Cholesterol is missing from the list.** Codex guidelines are as follows:

Cholesterol Low: 0.02 g per 100 g (solids)
 0.01 g per 100 ml (liquids)
 Free 0.005 g per 100 g (solids)
 0.005 g per 100 ml (solids)
 and, for both claims, less than:
 1.5 g saturated fat per 100 g (solids)
 0.75 g saturated fat per 100 ml (liquids)
 and 10% of energy of saturated fat.

- **Criteria for carbohydrate (i.e. “source” and “rich in”) could be added to this list.**

We suggest similar criteria as for protein.

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