CIAA COMMENTS ON DG SANCO

DISCUSSION PAPER

ON NUTRITIONAL

AND FUNCTIONAL CLAIMS

SANCO/1341/2001

CIAA KEY PRINCIPLES ON CLAIMS

The Food and Drink industry has responded to government and consumer interest, which has been expressed over a considerable number of years concerning the relationship between diet and health. Private and public research has been put in place, which has yielded and continues to yield very positive results. The Food and Drink industry wishes to make these products with health and nutrition benefits available to consumers, and in order to do so, must be able to communicate those benefits by using claims.

In order to avoid the inconsistent approach currently existing at national level, the European Food & Drink Industry represented by CIAA (the Confederation of the Food and Drink industries of the European Union) is of the opinion that the Commission should develop a harmonised framework to cover the use of all types of health related claims on foodstuffs, including disease risk reduction claims.

The Food and Drink industry is, therefore, very disappointed that this current text only partially addresses the issue of claims. It is important that the Commission should clearly communicate its intentions and develop **a comprehensive European strategy for health related claims with a harmonised framework, which is efficient, transparent, proportionate and predictable**.

CIAA strongly endorses the principle that any food should be able to carry a nutrition and/or health claim provided that it can be substantiated. Harmonised rules should be based on the principle that a claim may be made provided that it meets the following criteria:

- The manufacturer should be able to substantiate the claim.
- The substantiation should be proportionate: i.e. the level of the claim should be in line with level of substantiation available.
- Claims should be made in the context of the total diet.
- The claimed health benefit should be appropriately communicated so as to foster consumer understanding.

The Food and Drink Industry believes that harmonised rules should be incorporated within the existing legislation such as the Labelling Directive and the Nutrition Labelling Directive, and should take into account the principles of the Misleading Advertising Directive. It should not be contradicted by other legislation such as Medicinal Products Directive.

The European Commission, national authorities, consumer organisations and the Food and Drink Industry should work together to create such a framework, which will enable industry to respond to the demand for foods with health benefits, which will help the consumer to make an informed choice, and which will promote consumer confidence in the validity of claims.

CIAA welcomes the DG Sanco Discussion Paper, which opens the debate on claims. CIAA is convinced that the need to address the whole spectrum of health related claims will appear clearly in the drafting process. Nevertheless detailed comments on the considerations of the DG Sanco Discussion Paper are attached.

Detailed comments on DG Sanco Discussion Paper on nutritional and functional claims Sanco/1341/2001

FOREWORD

As stated in the general comments, CIAA is of the opinion that the Commission should address all types of claims. Therefore any proposed measure to regulate nutritional and functional claims should put in place a framework that might also be used for regulating health claims. CIAA is of the opinion that different rules and procedures should apply according to the type of claim made. More importantly proportionality between the claim being made, the level of substantiation required and measures of control should be accepted as a rule.

CIAA is of the opinion that, at several occasions in DG Sanco's Discussion Paper[1], the options and/or questions raised address more specifically health related claims despite only covering nutritional and functional claims. Such confusion will be highlighted and addressed where appropriate in the following comments.

The following detailed comments of the individual paragraphs of the DG Sanco Discussion Paper have been grouped under specific headings, which entail the essence of the CIAA position on claims namely:
Claims are in everybody's interest provided that they are scientifically substantiated, made in the context of the total diet and appropriately communicated to consumers. A European regulatory framework, harmonising all claims including health claims is required. It should apply to all foods and be based on existing rules accepted internationally.

CLAIMS ARE IN EVERYBODY'S INTEREST…

para. 1 Consumers are becoming increasingly interested in their diet, its relationship to health and the composition of food. They are now being provided with a range of "scientific" information about foods and nutrition through a variety of international media. Indeed, even claims linking food and health are usually permitted generically, although they are banned or severely restricted in labelling and advertising of specific foods. Manufacturers and retailers of pre-packed foods wish to be able to convey the same beneficial information about the relationship between food and health to their customers.

[1] Paragraph numbers refer to the DG Sanco Discussion Paper Sanco/1341/2001

para. 3 CIAA welcomes any attempt by the authorities to ensure that only scientifically justified claims are made and advocates a clear and harmonised European legal framework, which would serve not only consumers and industry but also enforcement authorities.

If a product has a beneficial effect on health that can be demonstrated on the basis of a sound scientific dossier, then a company should be allowed to inform the consumer of such a health benefit. The fact that the beneficial effect of a product is used as an argument to sell a product is perfectly legitimate and should not be used against the industry.

PROVIDED THEY ARE SCIENTIFICALLY SUBSTANTIATED

para. 46 CIAA fully supports that 'Claims should be based on generally accepted scientific evidence that is kept under regular review'. The individual company making a claim should also be obliged to keep claims under review.

para. 44 Validated methods are necessary to ensure that the claimed quantity of the nutrient or other component is effectively present in the food. This is important for the nutritional claims (i.e. the content claims), but it is not necessarily systematically applicable for all functional claims particularly product specific functional claims.

para. 10 The claim should be scientifically substantiated and valid for the food until the end of the shelf life. The need for bio-availability is not always appropriate, e.g. for fibre. If bio-availability is relevant, then this consideration falls under the more general requirement that a claim needs to be substantiated

para.47 CIAA agrees that some of the principles outlined in paragraph 47 apply to all types of claims. Nevertheless there should be an agreement on the degree of scientific substantiation that is required according to the type of claim that is made.
The discussions at Codex Alimentarius and in the Council of Europe relate to health claims (i.e. enhanced function claims and disease risk reduction claims) and not specifically to nutrient function claims.

PROVIDED THEY ARE MADE IN THE CONTEXT OF THE TOTAL DIET

para. 7 CIAA strongly supports that the acceptability of a foodstuff for bearing a claim depends not only of the foodstuff itself but has to be considered in the context of the total consumed diet. However, while CIAA agrees with such general principles, in some instances, it may not be possible to reach recommended intakes 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 childbearing age to reach the required intake levels. 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 reduction of the risk of neural tube defects, an increase impossible to achieve without recourse to fortified foods and/or dietary supplements.

CIAA also agrees that it is essential that consumer education with respect to dietary behaviour be cared for. This activity is the prime responsibility of the public authorities. Although it is not the primary role of the food industry (or food labelling per se) to ensure the appropriate education of consumers, there is no doubt that information communicated by manufacturers via labelling, nutrition labelling and even claims play a role in improving consumer understanding regarding diet, nutrition and its relation to health.

para. 9 CIAA strongly endorses the principle that any food and any ingredient should be able to carry nutrition and health claims provided that these can be substantiated. All foods, including those containing ingredients likely to have a beneficial effect on physiological, psychological or biological functions, may well also contain other ingredients not generally regarded as likely to make a significant overall contribution to a healthier diet. However, if eaten as part of a balanced diet, such products could have a beneficial effect on health. There is no such thing as a “good” or a “bad” food.

para. 42 Terms such as "significant source" and "recommended" are too vague and need to be clarified or taken out. Moreover, the issue that is addressed here is particularly relevant for quantitative nutrition claims.
In case of functional claims, a more appropriate means of achieving the same aim would be to refer to the need for the food to cause or contribute to a significant physiological benefit (CIAA may provide a more detailed contribution on that specific point when and where appropriate).

AND PROVIDED THEY ARE APPROPRIATELY COMMUNICATED TO CONSUMERS

para.1 CIAA fully agrees that information about foodstuffs appearing on the labelling and used for their presentation, marketing and advertising should be clear, accurate and meaningful.

para. 3 On that basis, industry should be entitled to convey to consumers information about a beneficial effect on health that is scientifically substantiated. It is then the role of the enforcement authorities to make sure that the legal principles as enshrined in law and guiding such communication are respected.

para. 6 While Directive 2000/13/EEC 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. CIAA believes that it should be modified in order to allow the food industry to inform consumers about the health benefits associated with its products and/or more generally the benefit of specific dietary patterns on health.
Within any potential legal framework, it would be necessary to consider precisely what is meant by “all similar products” and to what extent the presence of a low level of any particular beneficial ingredient – naturally or by deliberate addition - would change the perception of consumers and/or regulators regarding a given food. An over-rigid interpretation of such a provision could preclude broad categories of wholesome foods from conveying their benefits to the consumer (e.g. calcium in milk or fatty acids in fish).

para. 8 Consumer information in general, and from all sources (ie not limited to that communicated by food manufacturers) will only be effective when the information is both available and understood.

CIAA does not believe it will be possible to legislate for all the details of every potential claim, particularly where it is the consumer’s subjective perception that is critical to the concept of “implied” claims. The inference to be drawn by an individual consumer from the use of particular words, logos and images will differ according to the nature of the claim, their existing knowledge and understanding about the potential benefits of a particular food and the overall, subjective effect of the communication in the context of the surrounding circumstances.

Manufacturers do evaluate the understanding of claims in the context of consumer research conducted to assess new communications concepts prior to market launch.

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Appropriate educational programmes on diet, nutrition and health, conducted by public health authorities will of course also facilitate the understanding by consumers of information provided on foods.

Setting a framework permitting all types of claims will contribute to communication of unambiguous and precise claims that are more likely to be understood by consumers.

para. 11 CIAA 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.

para. 20, 21 and 29 CIAA would question whether these types of claims legitimately fall within the scope of the current discussion. Such claims are regulated by the general principles applicable to any type of communication and cannot be regarded as specific nutrition claims for which thresholds should be set. The properties that are promoted do not specifically related to nutrition nor health (additives are submitted to a specific legislation and additives are not necessarily nutrients).

para.24 Low cholesterol claims should be regulated according to the Codex conditions.

para.25 Consumer education in the field of nutrition is needed and should be urgently provided for by public authorities.

para.28 The potential misunderstanding of “x % fat free” claims might be solved by regulating that an additional claim has to be made in the sense “see nutrition panel”, as consumers will find the actual fat level stated in the table.

para. 30 CIAA believes these types of claims are helpful to the consumer. However it is important to set one definition for “low fat” and to apply it consistently whether a product is “naturally” low in fat or not.

para.31 The issue of determining the level of nutritional significance, 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/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**.**

para. 32 CIAA would like the Commission to clarify what is meant by “comparative nutrient claims”. It is questioned whether the quantification of the difference is necessary. Depending on the definition the rules on comparative advertisement should be taken into account.

para. 43 The types of claim raised in para. 43 are quantitative nutrition claims and therefore require the setting of a threshold and the availability of an analytical method.

para. 45 CIAA fully accepts that it is essential that the consumer should be able to understand the claim and the context in which it is made. The general principle governing any claims must be that no claim should be misleading to a material degree, as already laid down in legislation. However controlling only labelling aspects cannot ensure meaningful communications about nutritional and physiological properties of foods. Defining only the specific wording of the claim that may be permitted to feature on the pack label will be insufficient, since consumers will need more information in order to be able to understand the claim (see also comments under para. 25).

HARMONISATION OF RULES APPLICABLE TO CLAIMS IS NEEDED

para. 2 and 4 The adoption of a harmonised framework based on a single and consistent interpretation of Article 2 of Directive 2000/13 is required...

para. 37 - 39

However, this clearly will not be the case if the Commission intends to regulate nutrition and functional claims only, and therefore leaves enhanced function and disease risk reduction claims to be regulated at the national level.
It is necessary to clarify terminology. These claims should be called 'nutrient function claims' in lieu of "functional claims". This change of terminology would of course have to be consistent throughout the document.

As long as harmonised legislation relates only to nutrient function claims, it is understood that enhanced function and risk reduction claims are not prohibited. They would continue to be subject to national legislation/codes of practice, as they are today.

The Codex discussions provide guidelines for definitions for health claims, which are consistent with the Council of Europe document and the ILSI Consensus Statement, as well as with those existing at national level. These documents include guidelines for the substantiation of product-specific claims related to health. Both in the USA and – more recently- in Canada[2], legislation is in place that includes definitions.

[2] Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrition Claims and Health Claims), Canada Gazette Part I, June 16 2001

para. 48-49 CIAA is opposed to any type of pre-marketing clearance for nutritional and functional claims (i.e. nutrient function claims) as these are based on widely published and accepted nutritional science. However CIAA is in favour of independent scrutiny of the scientific substantiation. Such role could be attributed at EU level to the European Food Authority.
As mentioned above in the foreword, CIAA is in favour of proportionality between the level of the claim, the level of the substantiation and the control procedure of the claim.

para. 50 The Swedish two step system is not considered to be the most appropriate for product specific claims. Indeed the substantiation for product specific claims is based on the whole matrix of the foodstuff and not only on one component of the foodstuff (for instance fermented milk is active due to its ferments and to its metabolites).
CIAA would like to point out the recent developments in Sweden regarding the extension of the current system with product specific physiological claims[3]. This initiative is taken as a temporary measure while awaiting a harmonized EU legislation**.**
CIAA questions the fact that only the Swedish system is mentioned in the Discussion Paper as a possible option for regulating functional claims whilst there are other national systems in place that could equally be considered notably in the UK and the Netherlands**.**

THAT SHOULD APPLY TO ALL FOODS

para. 27 CIAA strongly supports the consideration that rules on claims should apply to all foods and not only to a specific group of foods (see CIAA code of practice)[4]. Every food has a function thus there is no need to create a special "functional food" category. If rules on claims are to be laid down, they should apply to all foods, including Parnuts.

AND BE BASED ON EXISTING INTERNATIONALLY ACCEPTED RULES

para. 12–15 CIAA agrees that definitions are needed in order to define a legal framework for the use of claims. Definitions, when deemed necessary, should as much as possible be uniform throughout the international community. As correctly stated consumers do not distinguish between different categories of claims. Their concern is related to the truthfulness and credibility of the claim. Therefore the definitions of the categories of claims should be used as a guide to the type of justification that is necessary, without necessarily laying down in law a complex categorisation of claims.

[3] Extension of the Swedish code to Product-specific Physiological Claims, *Swedish Nutrition Foundation*, press release June 12 2001
[4] http://www.ciaa.be/en/Documents/positions/scientreg/MIN06699EF.html

para. 17 Regarding quantitative nutritional claims, only those nutrients for which RDA's have been defined or recommended intake levels exist should be retained at EU level as well. Fiber is defined as a nutrient in the context of Nutrition Labelling directive 90/496/3C. Fiber is a major dietary component and does have a significant effect on nutrient intake; i.e. its importance is not restricted to physiological effects (e.g. 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 (i.e. nutrient function or enhanced function claim, depending on the benefit). Such claims should be allowed provided of course that they can be substantiated.

The definition of a nutrition claim given in the Codex guidelines for the use of nutrition claims (CAC/GL 23-1997) should be the reference retained at EU as well. This definition refers to claims that:

- describe the level of a nutrient contained in a food,
- compare the nutrient levels and/or energy value of two or more foods and
- describe the physiological role of a nutrient in growth, development and the normal functions of the body.

However the Proposed draft guidelines for use of health and nutrition claims (Alinorm 01/22A) that are currently discussed at Codex level should also be taken into consideration including their distinction between nutrition claims and health claims.

For specific substances like lactic bacteria, phytosterols, antioxidants for which no RDA have yet been defined, the claim will relate to the physiological effect of the substance and should therefore be regarded as a functional claim rather than a nutritional claim.

There is a continuum between the various types of claims and not a clear-cut distinction, therefore the discussion paper should cover all types of claims.

para. 18 The compilation of existing legislation/guidelines (annex of the discussion paper) does not incorporate the provisions foreseen in Regulation 2991/94 on fat spreads. "Reduced fat" may be used for fat spreads containing 41-62% fat, whereas "low fat" and "light" may be used for products below 41% fat. For certain products, it is well justified to have specific claims. Comments in that respect will be sent individually by industrial sectoral organisations.

para. 23 CIAA would prefer the wording “same category product” instead of “same brand product” as this leads to confusion with “branding” as expression of intellectual property rights. The basis for comparative claims is clearly fundamental to the concept. Where a ‘same brand’ standard product already exists, the basis for comparison is straightforward. Even where other ‘standard’ products exist, made by a different manufacturer, it remains legitimate for a new product to be compared against the existing product. However, it has been suggested by some that, where no immediate standard product exists, it is not possible to launch any products carrying qualitative, descriptive claims. We would refute this. There exist many traditions in the different sectors and Member States for the use of particular qualities of ingredients and classic recipes for broad categories of products. If a manufacturer chooses to select particularly “healthy” variants of the traditional ingredients (e.g. lower fat), then we believe it should remain perfectly acceptable to describe the finished, new product accordingly. The judgement about what is the reference product must be made case by case.

para. 26 Sodium claims should be made available to all foods although reference to suitability for low sodium diets could be reserved for dietetic products. CIAA understands that low / very low sodium products have not yet been removed from the Annex of Directive 89/398. Claims relating to the sodium / salt content of all foods should be permitted in accordance with the general rules for other nutrients. The widespread public confusion between sodium and salt is primarily a matter of consumer education.

Food labelling aspects should be related to the sodium content, rather than ‘salt equivalent’ values in order to avoid further public confusion in the cases where foods do not contain any added salt but would otherwise be required to declare a salt content on the label.

para. 33 The level of 25% increase or reduction of a nutrient that is the subject of a claim is acceptable.

para. 35 Terms like NRV, RNV, RDA should be defined. CIAA believes that every attempt must be made to construct the simplest framework, compatible with a sound scientific basis, in order to promote consumer understanding and confidence in the system and its controls. Such simplicity would also facilitate its application by SMEs, who do not have the resource to interpret complex criteria.

Comments on the annex

Sugar – free: Codex recommends 0.5 (not 0.2) g per 100g or 100 ml.