codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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AGENDA ITEM NO. 6 **CX/FL 03/06**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
THIRTY-FIRST SESSION
OTTAWA, CANADA, 28 APRIL - 2 MAY 2003

DRAFT GUIDELINES FOR USE OF HEALTH AND NUTRITION CLAIMS
(ALINORM 03/22, APPENDIX VII)

GOVERNMENT COMMENTS AT STEP 6

COMMENTS FROM:

AUSTRALIA
BRAZIL
COLOMBIA
DENMARK
NEW ZEALAND
UNITED KINGDOM
CONFEDERATION OF THE FOOD & DRINK INDUSTRIES OF THE EU (CIAA)
INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)
ASSOCIATION OF THE FOOD INDUSTRIES FOR PARTICULAR NUTRITIONAL USES OF THE EU (IDACE)
INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI)
INTERNATIONAL SOFT DRINKS COUNCIL (ISDC)
INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

DRAFT GUIDELINES FOR USE OF HEALTH AND NUTRITION CLAIMS - (ALINORM 03/22, APPENDIX VII)

GOVERNMENT COMMENTS AT STEP 6

AUSTRALIA:

Australia wishes to provide the following comment in relation to CL 2002/37 –FL Draft Guidelines for Use of Health and Nutrition Claims (at Step 6).

1. SCOPE

Australia proposes an amendment to 1.1. Australia notes that the Terms of Reference for the Codex Committee on Food Labelling include "to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions". Therefore, Australia believes that these guidelines should extend to food advertising. In Australia, health claims have been considered with regard to food labelling and food advertising. Australia's food regulations prohibit an advertisement for food to contain any statement, information, design or representation where the same statement, information, design or representation is prohibited on the label of the food.

Australia proposes:-

1.1 These guidelines relate to the use of nutrition and health claims in food labelling **and advertising**.

Australia supports 1.4:-

"1.4 Nutrition and health claims are not permitted for foods for infants and young children unless specifically provided for in relevant Codex standards*", on the basis that 'foods' includes such products as infant formula. Please note paragraph 76, Alinorm 03/26A (report of the Codex Committee on Nutrition and Foods for Special Dietary Uses) that cereal-based foods are not considered as breast milk substitutes.*

Australia supports 1.4 as being consistent with the requirements of the *WHO International Code of Marketing of Breast Milk Substitutes* by way of preventing the provision of information that could discourage breastfeeding. In recent comments to the Codex Committee on Nutrition and Foods for Special Dietary Uses, Australia has also supported the proposed prohibition on health claims as expressed in section 9.1.5 of the Proposed Draft Revised Standard For Infant Formula (Alinorm 03/26A Appendix 3 at Step 3), and also proposed extending the prohibition in that draft standard to include nutrition function claims as defined by these guidelines.

7. HEALTH CLAIMS

Australia proposes an additional item under section 7.5. The benefits of eating a variety of foods are well documented. Diet-disease relationships are multi-factorial in nature. Australia believes that the message of the importance of a varied diet must always accompany health claims to ensure the message

about variety is constantly reinforced. In the absence of such a statement, consumers could place undue emphasis on health claims on product labels and risk skewing their dietary intake in an undesirable way.

7.5 The following information should appear on the label or labelling of the food bearing health claims:

7.5.7 A statement on the importance of maintaining a varied diet.

BRAZIL:

Preamble

Brazil requests to delete the square brackets, maintaining the text with the following drafting:

" Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. **Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful** diets and be supported by specific consumer education. The impact of health claims on consumers´ eating behaviors and dietary patterns should be monitored. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited. "

1. Scope

1.4 To exclude the square brackets from the expression: "Nutrition and", keeping it on the text. To include "infants and" after the expression " Health claims are not permitted for foods for…". The text will be like the following:

"Nutrition and Health claims are not permitted for foods for infants and **Health claims are not permitted for foods for** young children unless specifically provided for in relevant Codex Standards".

Justification: The Brazilian Legislation on Infant and Young Children Food Publicity, based on WHO recommendations, does not allow in the Packaging and or Labelling of Infant and Young Children Formulas the use of sentences or expressions that indicate health claims of that product.

Item 2. Definitions

2.1 To include **"dietary fibre"** to be coherent with the item 4.1.

2.2.1 To maintain the text and the examples for a clearer understanding.

To exclude the term "good/excellent" from the last example.
The text will be like the following:

" Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development. Food X is a ~~good/excellent~~ source of nutrient A".

Justification: There is no parameter to establish the values for these expressions.

2.2.2. [Other] Function Claims

To delete the square brackets from the expression "or psychological", keeping it on the text, considering that it should exist some substances that can influence the psychological state of a person, as the caffeine.

4. Nutritional Claims

4.1 To substitute the term "**fibre"** for **"dietary fibre"**.

To include on the item 4.1, after "(...) Nutrition Labelling"**,** the following sentence: ...**or those nutrients which are mentioned on an officially recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim."**

Justification: the item 4.1 must be revised to be coherent with the item 7.1.6 of this Draft Guide. Proposal presented by New Zealand (para. 89, Alinorm 03/22).

7. Health Claims

7.1.5 (i). To delete the word "significant" from the expression: "a ~~significant or~~ high source".

Justification: To be coherent with the item (ii), where the claims refer on the CAC/GL 23-1997.

7.5 We suggest to include the word "**advertising"** after the expression "label and"**.**
The text will be like the following:
The following information should appear on the label, labelling and advertising of the food bearing health claims: (...)

Justification: The inclusion aims to assure that the claims, which are different from those declared on the labelling, must not be presented on the publicity of the products,.
This suggestion was based on Item 3.2, Codex Stan 146 – 1985: " Nothing in the labelling and advertising of foods to which this standard applies shall that advice from a qualified person is not needed."

COLOMBIA:

The Codex Contact Point for Colombia is sending comments regarding Proposed Draft Guidelines for the Use of Health and Nutrition Claims.

	Comments	
2.2.2 ***[Other] Function Claims*** - These claims concern specific beneficial effects of the consumption of foods and their constituents in the context of the total diet on physiological [or	We do not agree, as it is not possible to demonstrate the beneficial effect of a nutrient on psychological functions.	

psychological] functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.		
2.2.3 *Reduction of disease risk claims* - …Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims. **Examples:** "A diet low in substance A may reduce the risk of disease D. Food X is low in substance A."	Include the following examples, as they are multifactor factors (Sic.). Example: "Regular physical exercise and a varied and healthy diet having a low content of (nutrient xxx) helps (a specific group xxx) to be in good health and can reduce risk of (illness)." "Regular physical exercise and a varied and healthy diet having a high content of (nutrient xxx) helps (a specific group xxx) to be in good health and can reduce risk of (illness)."	
TABLE OF CONDITIONS FOR NUTRIENT CONTENTS	Include in the column of conditions that may be declared by portion, and also a foot note indicating "as long as size of the food portion is fixed at the national level, this may be used" as established in the document of Appendix III in Step 6 of the minutes of the 23rd meeting of the Codex Committee on Nutrition and Special Diets	

DENMARK:

General comments

As commented before, Denmark would like to emphasize that health claims should only be allowed if they are consistent with national health and/or nutrition policy. As the purpose of health claims is to aid

consumers in choosing a healthy diet it is important that health claims are true and not suited for misleading. It is essential that the use of health claims is based on the principle that it is the total diet and not a single food that is important for health. It is also important that the claim is true for a realistic intake of the food, and claims must not be used for foods with properties that increase the risk of disease. Furthermore, the claim must be based on all scientific evidence, and be in accordance with national authorities' requirements for documentation. We appreciate that these elements are covered by the present proposal.

DK promised at the 30th session in Halifax to inform the Committee about the work done in Denmark concerning the issue on scientific substantiation of health claims. Please find this enclosed.

Title
We find that the term "nutrition" should be mentioned before "health", as is also done in 1.1. and 1.2., so the wording will be: "**Proposed draft guidelines for use of nutrition and health claims**."

Preamble
We agree that health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, and that health claims should provide truthful and non-misleading information to aid consumers in choosing healthy diets. Therefore we support that the square brackets should be deleted.

We also welcome that the issue concerning monitoring of the impact of health claims on consumers' eating behaviour is included in the preamble. We would like to add that this should be a task for the competent authorities, and the sentence read as follows: "The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored **by the competent authorities**."

1. Scope
1.4 We support that foods intended for infants and young children should not bear a nutritional or a health claim. So the square brackets should be deleted.

2. Definitions

2.2. "**Health claims**" should be put in bold figures in consistency with the rest of the document. Furthermore, we find that there is a need to describe that all health claims should consist of two parts. This is not only the case for reduction of disease risk claims. Referring to the given examples this is already taken into consideration. Therefore, the text in section 2.2.3 should be moved to 2.2, reading as follows:
"Health claims means any representation that states, suggest, or implies that a relationship exists between a food or a constituent of that food and health. The claim must consist of two parts:
1) Information on an accepted diet-health relationship; followed by

2) Information on the composition of the product relevant to the relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food. Health claims include the following:"

2.2.1 and 2.2.2.
Regarding the two different definitions of "function claims" there might still be some obscurity. It is important to clarify if it is the *function* or the *constituent*/*substance* that makes the difference between the two.

A claim that describes the role nutrients play on physiological functions or biological activities is also a "**nutrient function claim**". However, we do not find a need to amend the text in 2.2.1 to include "biological activity" as this is included in the term "normal function" of the body. There has been an argument that "enhanced function claims" involves functions that "goes beyond normal function of the body". We want to emphasise, that it is an impossible task to distinguish between the different types of terminology of "physiological functions", as regards to what is a normal physiological function of the body, and at which stage the physiological process can be defined as a pathological function.

Referring to the report of last years working group - CX/FL 02/9-CRD.29- section 2.2.2 describe function claims related to foods and their constituents without official recommended intakes. In other words we interpret "other function claims" to involve constituents or substances, which are not nutrients, and therefore fall outside the definition of "nutrient function claims". There has been an argument, that "enhanced function" is describing a function that goes beyond the adequate nutritional need of the body, in other words claiming an effect of a nutrient with a higher dose than the present recommendation subscribes, or claiming a nutrient without official recommendation. We want to emphasise, that if a general need for higher intake is scientifically proved, this should give rise to new recommendations.

For a better clarification of the text, we propose that the text in 2.2.2. is changed to:
"**2.2.2 Other function claims** – these claims concern specific beneficial effect of the consumption of food **or the constituents of food other than nutrients**, in the context of the total diet on normal physiological functions of the body, **but do not include pharmacological or medical claims** ."
The last sentence beginning with "Such claims relate to a positive contribution…." can be deleted, as this understanding/definition is already included in the general definition of all health claims in section 2.2. Furthermore we do not find that an effect on psychological function should be accepted.

With the above mentioned understanding of "other function claims" this can easily lead to a medication of foods as the boarder line to substances having a pharmaceutical effect is very close. Therefore we find that further guidelines must be established to limit which foods and/or "substances" that can be subject to a claim. This should be clarified in section 7. (See proposal of a new section 7.1.7)

Regarding examples:
We agree that the examples given should be generic examples.
In 2.2.2 however, we want to draw the attention to the fact that it could be misleading to refer to a specific content (x grams) of substance Y if there is no recommendation of daily intake.

In the examples given in section 2.2.3 we find that "nutrients" also should be included in the text. Otherwise it could indicate that only "other substances than nutrients" are allowed here. The exact wording could be: "Food X is low in nutrient or substance A" and "Food X is high in nutrient or substance A".

7. Health claims
7.1.1 We agree. See also our comments regarding weighing of evidence and conditions for documentation, enclosed below.

We want to draw the attention to the fact that a "function claim" often is connected to "reduction of disease risk " even if this is not mentioned in specific wording on the product. For instance claiming that "a substance A reduces blood cholesterol level", automatically leads the thoughts to a "reduction of the risk of heart disease", or this connection is seen described in other marketing material. It is important that if a physiological function or biomarker is claimed, it must be scientifically substantiated that a connection between the biomarker and a reduced risk of disease exists. Otherwise the consumer will be mislead if he/she interpret such claims to the effect that eating the food will reduce the risk of disease.

Therefore it should be added to the text, that a relationship to health must be present, as follows:
"**7.1.1** Health claims must be based on current scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect **and the relationship to health** as recognized by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available."

7.1.6 This section should apply to all health claims, and not only nutrient function claims, when the claim involves a specific nutrient. Section 2.2.3 (risk reduction) also involves claiming an effect of nutrients, and consequently only those nutrients mentioned in 7.1.6 should be subject to a reduction of disease risk claim. Therefore the wording "nutrient function claim" should be replaced by **health claim"** at the end of the sentence.

We agree that section 4.1 need revising according to 7.1.6.

Parallel to 7.1.6 describing which nutrients that should be subject to a health claim, we propose that the guidelines should mention the criteria concerning which foods or constituents of foods other than nutrients that should be subject to a claim. Referring to our comments under 2.2.2 we propose that it is mentioned in section 7, that substances of well-known medical use, e.g. substances that are active

components in medicinal products or herbal remedies should not be subject to a health claim. The text could read as follows:

"**7.1.7 Substances of well-known medical use, e.g. substances that are active components in medicinal products or herbal remedies should not be subject to a health claim.**"

As a consequence of moving 7.4 to the preamble, the following sections should be renumbered.

Regarding scientific evidence of health claims
In Denmark a working group was established by the Danish Veterinary and Food Administration to propose guidelines and conditions for the use of health claims on foods. An overview of the proposal from the working group has been published in **Scandinavian Journal of Nutrition, vol. 45:35-39, 2001:**
Guidelines and conditions for use of health claims in Denmark, by Heddie Mejborn, Lars Ove Dragsted, Jørn Dyerberg, Bente Koch, Morten Poulsen and Lars Ovesen.

The working group concluded that the scientific evidence behind a health claim must be based on a systematic review of all scientific publications with relevance for the claim in question. The designs of human research can be ranked due to their strength of scientific proof. Health claims should always have their basis in high-ranking scientific evidence. The following is quoted from the article:

Weighing of evidence and conditions for documentation
The scientific evidence must always be based on a *systematic review* of relevant scientific literature according to scientifically accepted principles (12).
The total evidence requires careful weighing of both the type and the strength of the contributions coming from the kinds of studies mentioned above. It takes considerable experience to do this. Therefore, the level of evidence is usually arrived at by several consenting experts. There are, however, some conditions, which, when present, strengthen the evidence for a connection between diet and health (the design of the controlled trial takes several of these conditions into account):

1. Consistency. *The findings must be demonstrated more than once, and preferably by other scientists, in different human populations and/or animal species, under different conditions and at different times.*
2. Strength and quality. *The study design must be suitable for examining the actual connections, and the results must be statistically significant.*
3. Biological plausibility. *Preferably, the connection should be supported by a mechanistic theory, consistent with the physiological and biochemical circumstances.* In vitro *methods, animal experiments and biomarkers contribute considerably to that evidence*.
4. Dose-response relationship. *Preferably, a dose-response relationship should be demonstrated and the minimal effective dose should be determined. Animal experiments are well suited for that, but observational and experimental studies and meta-analyses can contribute.*

5. Temporality. *A change in diet must be followed by a change in health outcome. The temporality requirements are fulfilled in controlled experiments in animals and humans.*
6. Specificity. *The evidence is strengthened when the (degree of) change in health outcome is specific for the dietary factor in question. All kinds of experiments can contribute to fulfil this condition.*

Despite the fact that the different human study methods have their independent merits and to some extent raise different questions – and therefore give different answers – it is possible to rank the individual methods according to their scientific strength for proving diet-health relations. A ranking of the methods after this principle can be referred to as "the hierarchy of evidence" (table 1). Animal studies can never stand alone in the evaluation of a positive health effect in humans (contrary to the case for negative effects), but in principle are comparable to controlled trials. If the knowledge about the animal model as a model for humans is less than complete, then evidence from animal studies typically ranks lower than studies performed in humans. In vitro methods alone rank very low as scientific evidence, but can support other results to make the total evidence stronger.

Meta-analyses – based on experimental as well as observational studies – are so far not sufficiently standardised for use as the only basis for a health claim, but can be used to support the scientific evidence (13).
The scientific requirements for documentation should vary depending on the wording of the health claim but in general certain minimum conditions must always be fulfilled:

1. The claim must be based on all scientific evidence, not only experiments supporting the claim.
2. The claim must be based on human experiments, and the claim must be in accordance with the results of these experiments.
3. A general consensus among independent and qualified scientists must exist.

Table 1. The hierarchy of evidence for human study methods ranked in descending order of scientific weight.

1A. Systematic review of (several) controlled studies of good quality where all the results point in the same direction.
1B. Isolated or few controlled studies of good quality with narrow confidence intervals where the results point in the same direction.
2A. Systematic review of (several) prospective cohort studies where the results point in the same direction.
2B Isolated or few prospective cohort studies of good quality, and isolated randomised controlled studies with broad confidence intervals.
2C. Systematic review of (several) case-control studies where the results point in the same

direction.

2D. Isolated or few case-control studies of good quality.

3A. Correlation studies, cross-sectional studies, time-series studies.

3B. Case reports, and cohort studies and case-control studies of low quality.

Risk assessment

It is very important to perform an overall risk assessment of a dietary component to obtain a comprehensive view both in relation to safety and nutritional aspects. There is no advantage in raising the intake of a food to obtain a modest health advantage, if at the same time there is risk that adverse effects will overshadow the beneficial effects. As a basis for the risk assessment both results from concrete experiments and considerations of possible side effects based on known effects of the dietary component should be taken into consideration.

Studies in animals and in vitro are important tools for the risk assessment, and for this purpose international validated guidelines are developed (e.g., OECD-guidelines (5)). When extrapolating from observations in animals to humans, differences in reactions between animals and humans and between humans are allowed for. A factor of 10 is often used as a safety margin for each of these two steps (14). I addition, corrections must be made for eventual differences in absorption, metabolism, and excretion, and the magnitude of used dose corrected for weight, or even better corrected for species differences in basal metabolism (15).

To this comes the attention that must be paid to suggestive negative effects in human studies. A negative effect of a dietary component must not be "proven" in the same way as a positive effect, but any suspicion of a negative effect must lead to a closer examination or dismissal of the food in question. This part of the evidence for a health claim (i.e., the safety aspect) can be as extensive as the basis for judging the positive effects.

References:

5. OECD guidelines for testing of chemicals, section 4 – Health effects. Environment Directorate, Organisation for Economic Co-operation and Development, Paris, 1996.

12. Meade MO, Richardson WS: Selecting and appraising studies for a systematic review. Ann Intern Med 1997:1847-52.

13. Jüni P, Witschi A, Block R, Egger M: The hazards of scoring the quality of clinical trials for meta-analysis. JAMA 1999; 282:1054-60.

14. Renwick AG: Data-derived safety factors for the evaluation of food additives and environmental contaminants. Food Additives Contam 1993; 10:275-305.

15. Travis CC, White RK, Wards RC: Interspecies extrapolation of pharmacokinetics. J Theor Biol 1990; 142:285-304.

NEW ZEALAND:

The New Zealand Government would like to make the following comments:

General

In the preamble who is envisaged to carry out the task of monitoring the impact of health claims on consumers' eating behaviours and dietary patterns? What is to be done with the monitored information? Who is setting the action standards?

There should be consistency in the order of the words *"health"* and *"nutrition"*. In the title the order is health and nutrition claims. However in points 1.1 and 1.2 the order is reversed to read *"nutrition and health claims"*.

Section 1.4
New Zealand agrees with the inclusion of the text in square brackets.

Sections 2.2.1, 2.2.2 and 2.2.3
The examples given in these sections have been made very generic to the point where they are not so easy to interpret. Is there any reason why specific examples (eg, Calcium aids in the development of strong bones and teeth) cannot also be included?

Section 2.2.2
New Zealand does not support the use of the word *"other"*. It is preferable to revert to the wording in the previous draft *"Enhanced"* rather that *"Other"*.

Section 2.2.3
Would it be better to use the word *"balanced"* instead of the word *"healthful"* in the second example?

Section 4.1
To be consistent with 7.1.6 and the proposed draft amendment to the Codex Guidelines on Nutrition Labelling the words *"or officially recognized guidelines of the national authority having jurisdiction"* should be inserted after *"Nutrient Reference Values (NRVs)"*.

Section 7.1.3
It is proposed to move this point to 7.5. This would then require points 7.1.4, 7.1.5 and 7.1.6 to be renumbered.

Table of Conditions for Nutrient Contents
Guidance is required on solids versus liquids for powdered/reconstituted products. Should the conditions set in the table be used for foods "as sold" or "as consumed"? New Zealand believes this needs to be clearly specified in the table. This point has been raised several times in the past but to date no clarification has been given.

For the table to be consistent in layout the line between *"source"* and *"high"* should be removed for the *"Protein"* and *"Vitamin and Minerals"*.

The previous draft contained a table *"Different types of claims subject to the conditions in these guidelines"*. The table is not shown in the current text as strikeout text; is there any reason for the table

being removed? New Zealand supports the inclusion of the table to help clarify the differences between different types of health and nutrition claims

UNITED KINGDOM:

General comments:

- The guidelines should allow true information about all the potential health benefits of foods to be communicated to consumers, including their potential to reduce disease risk

Specific comments are as follows:

- (1.4) The UK suggest that the wording be amended to "Nutrition and health claims are not permitted for foods for special dietary uses for infants and young children unless specifically provided for in relevant Codex standards"
- (3) The UK support the requirement to include nutrition labelling when making a health claim
- (6.4) The UK support defining "light" as equivalent to "reduced"
- (7) We suggest that the following general principle be added to Section 7:

Health claims should not unfairly denigrate any other food or imply that normal foods cannot provide a healthy diet.

- (7.1.1) The UK support the requirement that health claims must be based on relevant scientific substantiation and the level of proof must be sufficient to substantiate the claimed effect

CONFEDERATION OF THE FOOD AND DRINK INDUSTRIES OF THE EU (CIAA):

I. GENERAL COMMENTS

1. The Confederation of the Food and Drink Industries of the EU (CIAA) urges the Codex Alimentarius Commission and the CCFL to advance the discussion about health claims given the importance of this subject to consumers around the world and the need for a regulatory framework, which balances consumer protection and consumer information against the freedom of manufacturers to communicate information about benefits of a product and the free movement of foodstuffs.

2. The aim of health and nutrition claims is to provide consumers with useful information, which may assist them in choosing products in the context of a healthy and balanced diet. The use of health claims on the labels of food products can play a significant role in assisting an individual in making dietary choices and thus contribute positively towards maintenance of good health and the reduction of the risk of various disease conditions.

3. CIAA emphasises that a claim should be complete, truthful and not misleading and supported by appropriate evidence.

4. CIAA therefore welcomes the development of guidelines for scientific criteria for health claims by the Codex Committee on Nutrition and Foods for Special Dietary Uses, which will be annexed, to the present guidelines. CIAA offers its assistance in this exercise.

5. Moreover, CIAA has developed a Code of Practice for the Use of Health Claims, which lays down general principles and guidelines for substantiation and assessment as well as for their communication.

6. The Codex proposed draft guidelines for the use of health and nutrition claims currently at step 6 of the procedure provide a good basis for a framework for the use of health and nutrition claims. As they currently stand, the guidelines recognise the important role food has to play in consumer health and reflect work in nutritional science that has firmly established the link between food and risk reduction. More importantly, the guidelines provide, for the first time, a framework, which embraces two key principles, the protection of consumer health by requiring the scientific substantiation of health claims according to agreed criteria and by the provision of accurate and scientifically grounded information.

7. CIAA wishes to recall that Codex standards should establish general principles and should therefore be concise and precise in order to be recognised worldwide for their vital role in protecting consumers and facilitating international trade.

II. DETAILED COMMENTS:

Codex Proposed Draft	CIAA Comments
~~Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed.~~	*Delete*. Incompatible with the concept of international trade. Could be replaced by: **"Nutrition claims should be appropriate to the population at whom the product is aimed in the market in which the product is sold"**
~~Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable.~~	*Delete or replace with:* **"Health claims should be made only when there is sufficient scientific evidence of a contribution to good dietary practice."** This box could potentially create barriers to trade and should be removed. Monitoring, in particular, is a matter for national competent authorities. It is likely that most health claims would be consistent with national health policy (e.g. heart disease). Nevertheless, it should also be possible to make a claim for another benefit, (e.g. gut health) where this is substantiated.
Health claims [should supported by a sound and sufficient body of scientific evidence to substantiate the claims, provide truthful and non-misleading information to aid consumers in choosing healthful diets and	This sentence is acceptable and the square brackets should be deleted.

Codex Proposed Draft	CIAA Comments
be] supported by specific consumer education. The impact of health claims on consumer's eating behaviours and dietary patterns should be monitored. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.	Monitoring must be undertaken by national competent authorities. We suggest the following addition to the end of the sentence:"…monitored **by competent national authorities."**
1. Scope 1.1 These guidelines relate to the use of nutrition and health claims in food labelling	
1.2 These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses ~~and Foods for Special Medical Purposes.~~	*Delete.* Foods for Special Medical Purposes are, by definition, Foods for Special Dietary Uses.
1.3 These guidelines are intended to supplement the Codex General Guidelines on Claims and do not supersede any prohibitions contained therein.	
1.4 ~~[Nutrition and] Health claims are not permitted for foods for infants and young children unless specifically provided for in relevant Codex standards.~~	*Delete.* The Guidelines should not contain any general prohibition of claims on specific categories of foodstuffs. If claims are appropriate, truthful, scientifically substantiated and not misleading, for this specific group of the population, there is no reason to prohibit them. They provide important information about the product.
2. Definitions **2.1 Nutrition claim** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute nutrition claims : a) the mention of substances in the list of ingredients; b) the mention of nutrients as a mandatory part of nutrition labelling; c) quantitative or qualitative	

Codex Proposed Draft		CIAA Comments
	declaration of certain nutrients or ingredients on the label if required by national legislation.	
2.1.1	**Nutrient content claim** is a nutrition claim that describes the level of a nutrient contained in a food (ex.: "source of calcium"; "high in fibre and low in fat")	
2.1.2	**Comparative claim** is a claim that compares the nutrient levels and/or energy value of two or more foods (ex: "reduced"; "less than"; "fewer"; "increased"; "more than".)	
2.2	Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:	
2.2.1	***Nutrient Function Claims*** – a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body [ex: ~~"calcium aids in the development of strong bones and teeth", "protein helps build and repair body tissues", "iron is a factor in red blood cell formation", "vitamin E protects the fat in body tissues from oxidation", "contains folic acid: folic acid contributes to the normal growth of the fetus"~~] "Nutrient A (naming a physiological role of the nutrient A in the body in the maintenance of health and promotion of the normal growth and development). Food X is a good/excellent source of nutrient A".	The format and the wording of claims should not be standardised. The wording of the claim should remain the manufacturer's responsibility. The wording of the example in quotation marks should be considered as an example only and not as a mandatory standardised format.
2.2.2	***[Other] Function Claims*** – These claims concern specific beneficial effects of the consumption of foods and their constituents ~~in the context of the total diet~~ on physiological [or psychological] functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health. Examples: "Substance A (naming	*Remove*: **"in the context of the total diet".** CIAA agrees with the principle but considers that this provision should be laid down under "conditions for use". CIAA supports the changes (i.e. the introduction of "psychological" after "physiological") and is of the opinion that the square brackets should be removed. Manufacturers should bear the responsibility

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the effect of the substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."	of the wording of the claim (see comment under 2.2.1). Health benefits of a whole food (e.g. fruits, vegetables or yoghurt) may be scientifically validated**.** It should be possible to make food or product specific claims rather than only claims about single substances. Therefore we suggest adding this sentence to provide an additional example. ***"Food Y modifies function X"***
[2.2.3 ***Reduction of disease risk claims*** – Claims relating to the consumption of a food or food constituent, ~~in the context of the total diet~~, to the reduced risk of developing a disease or health-related condition. ~~The claim must consist of two parts:~~	*Remove*: **"in the context of the total diet".** See comment relating to para. 2.2.2 above. *Replace by*: ***"It is recommended that the claim consists of two parts".***
1) Information on an ~~accepted~~ diet-health relationship; followed by	The reference to an "accepted" diet-health relationship gives room for diverse national interpretation and should not be a precondition for making a claim. The word "accepted" could be replaced by **"scientifically validated**".
2) Information on the composition of the product relevant to the relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.	
Risk reduction means significantly altering a major risk ~~factor(s)~~ for a disease or health-related condition.	The word **"factor"** should be deleted. The contribution of food to health should be measured by the end result and not on a "factor".
Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.]	There are many cases where the disease risk factors are not known, even though it is clear that the food can have a beneficial effect in reducing the risk of disease (e.g. fruits and vegetables).
[Ex: "A diet low in substance A may reduce the risk of disease. Food X is low in substance A"; "A healthful diet rich in substance	If a claim is validated for a product, it should be possible to make the claim as such, e.g. **"Product P helps to reduce the risk of disease D".** See comments relating to para.

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A may reduce the risk of disease D. Food X is high in substance A".	2.2.2 above.
3. Nutrition Labelling Any food for which a nutrition or health claim is made should be labelled with a nutrient declaration in accordance with section 3 of the Codex Guidelines on Nutrition Labelling.	
4. Nutrition claims 4.1 The only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fibre, sodium and vitamins and minerals for which Nutrient Reference Values (NRVs) have been laid down in the Codex Guidelines for Nutrition Labelling.	
5. Nutrient content claims 5.1 When a nutrient content claim that is listed in the Table to these Guidelines or a synonymous claim is made, the conditions specified in the Table for that claim should apply.	
5.2 Where a food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form "a low (naming the nutrient) food" or "a (naming the nutrient)-free food".	
6. Comparative claims Comparative claims should be permitted subject to the following conditions and based on the food as sold, taking into account further preparation required for consumption according to the instructions for use on the label:	
6.1 The foods being compared should be different versions of the same food or similar foods. The foods being compared should be clearly identified.	
6.2 A statement of the amount of difference in the energy value or nutrient content should be given. The following information should appear in close proximity to the	

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	comparative claim:	
6.2.1	The amount of difference related to the same quantity, expressed as a percentage, fraction, or an absolute amount. Full details of the comparison should be given.	
6.2.2	The identity of the food(s) to which the food is being compared. The food(s) should be described in such a manner that it (they) can be readily identified by consumers.	
6.3	The comparison should be based on a relative difference of at least 25 % in the energy value or nutrient content, except for micronutrients where a 10 % difference in the NRV would be acceptable, between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as "low" or as a "source" in the Table to these Guidelines.	
6.4	The use of the word "light" should follow the same criteria as for "reduced" and include an indication of the characteristics, which make the food "light".	
7.	**Health claims**	
7.1	Health claims should be permitted provided that the following conditions are met:	
7.1.1	Health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect as recognised by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available.	
7.1.2	~~Any health claim must be accepted by or be acceptable to the competent authorities of the country where the product is sold.~~	*Remove or replace by:* **"Health claims should be made only when sufficient scientific evidence can be demonstrated of a contribution to the health status of the population at whom the product is aimed."**
7.1.3.	MOVE TO 7.5 ~~The claim about a food constituent must be stated within the context of the total diet.~~	*Move to 7.5 and replace by*: **"Health claims should only be made within the context of a total dietary pattern".**
7.1.4.	The claimed benefit should arise from the consumption of a	

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	reasonable quantity of the food or food constituent in the context of a normal diet.	
7.1.5.	If the claimed benefit is attributed to a constituent in the food, the food in question should be: (i) – a significant or high source of the constituent in the case where increased consumption is recommended; or (ii) - low in, reduced in, or free of the constituent in the case where reduced consumption is recommended Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for "high", "low", "reduced", and "free".	
7.1.6.	~~Only those nutrients for which a Nutrient Reference Value (NRV) has been established in the Codex Guidelines on Nutrition Labelling or those nutrients which are mentioned in officially recognised dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim.~~	*Delete and replace by:* **"The following may be subject to nutrient function claims:** - **Nutrients for which a Nutrient Reference Value (NRV) has been established in the Codex Guidelines on Nutrition Labelling** - **Nutrients mentioned in officially recognised dietary guidelines of the national authority having jurisdiction** - **other nutrients for which recommended intake values exist based on established and recognised scientific knowledge."**
7.2	~~Health claims should have a clear framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health related condition~~. The health claim should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practice.	***Remove*** **first sentence.** **This provision allows for various interpretations, which will undermine fair practices in food trade. The concerns over the relationship between individual product and general diet are dealt with in the scientific substantiation (guidelines to be adopted in 7.1.1) and in 7.1.3 and 7.1.4.**
7.3	~~If the claimed effect is attributed to a constituent of the food, there must be a validated method to quantify the~~	*Remove.* This should be included in the scientific substantiation

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	~~food constituent that forms the basis of the claim~~.	
7.4	~~MOVE TO PREAMBLE: The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored~~.	*Remove.* This is a matter for national competent authorities. See our comment to the Preamble.
7.5	The following information should appear on the label or labelling of the food bearing health claims:	
7.5.1	A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.	This could constitute a requirement to provide proprietary recipe information and may not be helpful to consumers, e.g. are they likely to know what the number of beneficial bacteria in a prebiotic yoghurt should be? It should be sufficient for consumers to know that the claim has been validated and the product delivers the claimed effect under the stated conditions. Alternatively, the text should distinguish between food ingredients and components for which there is a need for quantification, e.g. vitamins and minerals where intake may come from a variety of sources, and examples such as above where this information is unlikely to be meaningful.
7.5.2	~~Information on~~ the target group, if appropriate.	*Replace by:* **"An indication of…"**
7.5.3	Information on how to use the food to obtain the claimed benefit and on other lifestyle factors where appropriate.	
7.5.4	If appropriate, advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food.	
7.5.5	Maximum safe intake of the food where necessary.	
7.5.6	MOVED From 7.1.3 Information on how the food or food constituent fits within the context of the total diet.	See our comment under 7.1.3
8.	**Claims Related to Dietary Guidelines or Healthy Diets** Claims that relate to dietary guidelines or "healthy diets" should be permitted subject to the following conditions:	
8.1	Only claims related to the pattern of eating contained in dietary guidelines officially recognised by the appropriate national authority.	
8.2	Flexibility in the wording of claims is acceptable, provided the claims remain faithful to the pattern of	

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	eating outlined in the dietary guidelines.	
8.3	Claims ~~related~~ to a "healthy diet" or any synonymous terms are considered to be claims about the pattern of eating contained in dietary guidelines and should be consistent with the guidelines.	*Replace by:* **"…referring specifically to…"**
8.4	~~Foods, which are described as part of a healthy diet, healthy balance, etc., should not be based on selective consideration of one or more aspects of the food. They should satisfy certain minimum criteria for other major nutrients related to dietary guidelines~~.	*Delete.* Certain ingredients which deliver a health benefit may not be palatable, so manufacturers need freedom to use ingredients such as sugar or fats to mask and otherwise unpleasant taste or texture to make the products more acceptable. The case is the same as for food supplements or medicines taken orally. Also, certain foods may be targeted at specific populations, e.g. the elderly, for whom the best way to deliver the benefit would be in a small but highly dense product such as a chocolate or cereal bar.
8.5	Foods should not be described as "healthy" or be represented in a manner that implies that a food in and of itself will impart health.	
8.6	Foods may be described as part of a "healthy diet" provided that the label carries a statement relating the food to the pattern of eating described in the dietary guidelines.	

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA):

The International Council of Grocery Manufacturers Associations (ICGMA) is pleased to provide input on the proposed draft Codex *Guidelines for the Use of Health and Nutrition Claims.*

Preamble

ICGMA recommends deletion of both preamble boxes. Specifically, ICGMA believes the preamble's reference to national health policy is beyond the scope of a labeling standard, and also contrary to the goals of international harmonization. In addition, we also believe the preamble's recommendation that "the impact of health claims on consumers' eating behaviours and dietary patterns should be monitored" is beyond the scope of a labeling standard, and that it is also unclear who should be responsible for such monitoring.

1.4

ICGMA requests that section 1.4 be deleted. ICGMA believes that factual nutrient content claim and/or health claims on foods for infants and young children (e.g., iron-fortified cereals) are very useful for parents purchasing products for infants and young children. Furthermore, it is unclear whether this provision would apply to only those foods specifically manufactured for infants and young children, (i.e., formula and baby food), or whether it would apply to all foods that could potentially be consumed by infants and young children, e.g., ready-to-eat cereals, fruit juices, etc. Disallowing nutrition and/or health claims on these foods would again deprive consumers of valuable information regarding the nutrition and health benefits of these foods.

2.1.2

ICGMA recommends the addition of "as much as" should also be included in the examples given for comparative claims.

2.2.2

ICGMA recommends the removal of the following language from this section: "in the context of the total diet" because 2.2.2 deals with "other function" claims. A structure function claim is likely to be product specific and therefore, the effect could be transitory. ICGMA supports removing the brackets around "or psychological."

ICGMA recommends 2.2.2 should read:

Other Function Claims - These claims concern specific beneficial effects of the consumption of foods and their constituents on physiological or psychological functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

6.1

Although ICGMA is aware that the section on comparative claims may not be under consideration, we believe it does not adequately address comparisons made between products that are not different versions of the same or similar foods, *e.g.,* calcium fortified juices and milk. In addition, we believe this section does not sufficiently address comparisons made between nutrient levels in different products, *e.g.*, calcium. We believe that "as much as" should be included as an acceptable means of making comparative claims, e.g. "a serving of this orange juice contains as much calcium as a serving of milk" or "a serving of X drink contains as much Vitamin C as a glass of orange juice."

7.1.6

ICGMA believes this provision is unnecessarily restrictive. It only allows nutrient function claims on "essential nutrients for which a Nutrient Reference Value (NRV) has been established or those nutrients which are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction." As work progresses on the benefits of various nutrients, it is likely that benefits will be discovered for nutrients that do not have either an established NRV or mentioned in dietary guidelines. In those cases, consumers would be deprived of receiving information about the health benefits of these nutrients. ICGMA suggests work needs to be done to establish a procedure for making nutrient function

claims for nutrients that do not have a NRV or nutrients that are not mentioned in national dietary guidelines.

7.4

ICGMA objects to the inclusion of this section in the preamble and believes it should be deleted. Monitoring of the "impact of health claims on consumers' eating behaviours and dietary patterns" is beyond the scope of a labeling standard. Furthermore, it is unclear who should be responsible for such monitoring.

7.5.3

ICGMA believes the intent of this section is unclear and should be omitted. The term "lifestyle factors" is vague and beyond the scope of a labeling standard.

7.5.5

ICGMA believes the phrase "maximum safe intake" is unclear and unnecessary. The intake of food and therefore the nutrients present in foods is self-limiting. Upper levels for specific nutrients are already being established in member states. The quantification of "maximum safe intake" levels would be difficult; in addition, these levels are likely to confuse consumers and possibly alarm them if they eat above the level.

Table of Conditions for Nutrient Contents

ICGMA supports the inclusion of other nutrient content claims to this table to allow manufacturers increased opportunities to provide useful nutrition information that consumers desire about their products. The following claims should be included:

- reduced energy
- reduced fat
- reduced saturated fat
- reduced cholesterol
- reduced sugar
- unsweetened
- unsalted
- good/excellent source of protein
- good/excellent source of vitamins and minerals

In addition, ICGMA is concerned about the portion sizes utilized for making nutrient content claims. The 100 g and 100 ml size conditions are neither realistic or useful for making claims for products with small serving sizes, nor do they accurately reflect the sizes of portions consumers actually eat. It is also unclear why the size conditions for liquids are half the size of the conditions for solids. Further, the threshold disqualifying levels for making several of the nutrient content claims are unrealistic. Below are two examples of claims that would be disallowed under the existing table of conditions:

1. low sodium
    - *Codex proposal* – food may not contain more than 0.12 g of sodium per 100 g (or 120 mg per 100 g)

- *U.S. regulation* – food may not contain more than 140 mg per reference amount customarily consumed (RACC) (and per 50 g if the RACC is small)
- *Example* – a high-fiber bran cereal that may bear a low sodium claim in the U.S. contains 129 mg of sodium per 50 g and 80 mg of sodium per 31 g serving; this claim would not be allowed under the Codex proposal because it contains 258 mg of sodium per 100 g

2. low fat
   - *Codex proposal* – food may not contain more than 3 g of fat per 100 g
   - *U.S. regulation* – food must contain 3 g or less per RACC (and per 50 g if the RACC is small
   - *Example* – a cereal bar that may bear a low fat claim in the U.S. contains 3 g of fat per 37 g serving (and per 40 g RACC); this claim would not be allowed under the Codex proposal because it contains approximately 8 g of fat per 100 g

We recommend that the table be amended to allow countries to establish levels with respect to serving sizes commonly consumed, as is done in the Australia, Canada and U.S.

ASSOCIATION OF THE FOOD INDUSTRIES FOR PARTICULAR NUTRITIONAL USES OF THE EU (IDACE):

- **"Food for Special Medical Purposes" should be deleted from section 1.2**. They are, by definition, Foods for Special Dietary Uses.

- **Section 1.4 of the Scope is redundant and should be deleted.**

If claims are appropriate, truthful, not misleading, and scientifically substantiated, for this specific group of the population, there is no reason to prohibit them. They provide important information about the product.

The Scope section would then read:

1. SCOPE

1.1 These guidelines relate to the use of nutrition and health claims in food labeling.

1.2 These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses ~~and Foods for Special Medical Purposes~~ .

1.3 These guidelines are intended to supplement the Codex General Guidelines on Claims and do not supersedes any prohibition contained therein.

~~1.4 [~~Nutrition~~] and Health claims are not permitted for foods for infants and young children unless specifically provided for in relevant Codex standards.~~

REMINDER

Foods for special dietary uses are clearly defined in the General Standard for the labeling of and claims for prepackaged foods for special dietary uses (CODEX STAN 146-1985):

> "Foods for special dietary uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physiological condition and/or disease and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary food exist."

As part of foods for special dietary uses, commodity standards already exist on the following products:

- Infant formula (CODEX STAN 72-1981
- Canned baby foods (CODEX STAN 73-1981)
- Processed cereal-based foods for infants and children (CODE STAN 74-1981)
- Follow-up formula (CODEX STAN 156-1987)
- Foods with low sodium content (CODEX STAN 53-1981)
- Gluten-free foods (CODEX STAN 118-1981)
- Labelling of and claims for foods for special medical purposes (CODEX STAN 180-1991)
- Formula foods for use in weight control diets (CODEX STAN 181-1991)
- Formula foods for use in very low energy diets for weight reduction (CODEX STAN 203-1995)

RATIONAL

Foods for Special Medical Purposes are Foods for Special Dietary Uses and should therefore be deleted from section 1.2. In the same way, provisions described in Section 1.4 are already addressed in Section 1.2 since foods for infants and young children are also Foods for Special Dietary Uses, Section 1.4 should therefore be deleted.

Moreover, if claims on foods for infants and young children are appropriate, truthful, not misleading, and scientifically substantiated, there is no reason to prohibit them. Nutrition and health claims, being true statements/information regarding the dietary properties of the foods they provide important information to parents.

In the EU, the legislation for infant formula, follow-on formula, processed cereal-based foods and baby food and food for special medical purposes is harmonized since 1989 under a specific framework legislation on Foods for Particular Nutritional Uses (Council Directive 89/398/EEC of 3 May 1989). This legislation covers an age period from 0 to 3 years and some specific claims are already clearly defined for infant formula (Annex IV of Directive 91/321/EEC on infant formula and follow-on formula).

Regarding claims for the other products for infants and young children, they will be covered by the future European Regulation on Nutrition, Functional and Health Claims Made on Foods[1].
Indeed, Article 1.2 of the Scope of the Regulation includes the same type of wording as point 1.2 of the Draft Codex Guidelines for use of Health and Nutrition Claims:
"*The regulation shall apply without prejudice to specific provisions concerning foods for particular nutritional uses laid down in Community legislation*"

[1] Regulation of the European Parliament and Council on Nutrition, Functional and health Claims –draft EU Commission Proposal 2002, SANCO/1832/02

which means that the Regulation on claims applies to foods for infants and young children without prejudice to the specific Directives regulating these types of products.

Provisions ensuring that claims for foods for special dietary uses are properly used, have already been detailed in Section 3.1 of Codex STAN 146-1985 (Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses). This section states that these foods may not be "*described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect*".

Finally, IDACE believes that **CCFL shall not adopt provisions on claims specific to foods for infants and young children** until CCNFSDU has discussed this matter in detail. Indeed, CCNFSDU is the relevant Committee to best determine how the Standards on foods for infants and young children should be elaborated.

INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI):

The International Life Sciences Institute (ILSI) submitted comments on this subject to the Codex Committee on Food Labelling (CCFL) meetings in 1998, 1999 and 2001. In the present document, we are expanding on these previous comments.

As part of the European Commission Concerted Action on Functional Food Science in Europe (FUFOSE), ILSI Europe facilitated a consensus among 70 European experts from academia, industry, regulatory agencies, and consumer groups regarding the science base for functional foods. The results of this Concerted Action are published in the British Journal of Nutrition (see references 1,2). The consensus is fully in accordance with the two Codex types of claims, 'other function claims' and 'reduction of disease risk claims' (see annex).

As a follow-up to this Concerted Action, ILSI Europe is carrying out a project on the "Process for the Assessment of Scientific Support for Claims on Foods and Food Ingredients" for the European Commission. Reports of the first task groups were recently published (see reference 3).

As part of this project, a review of claim definitions concluded the following to scientifically clarify the definitions of the two types of function claims:

A nutrient function claim promotes the role of a nutrient in its broadest understanding in growth, development and normal physiological functions of the body, e.g., calcium aids in the development of strong bones and teeth. These claims are based on well-established and generally accepted scientific criteria.

An enhanced [other-according to Codex terminology**] function claim** refers to specific beneficial effects of foods and food components on physiological, and psychological, cognitive functions or biological activities, but does not include nutrient function claims. Beneficial health effects of nutrients (where an additional function is identified or claimed, i.e., beyond its generally accepted nutritional effect), ingredients, and non-nutritive substances are included under the definition of food components. Examples of enhanced function:

- An additional function of a listed nutrient (usually at a higher level of intake)

- A function of a food component (e.g., an ingredient that has cholesterol- lowering, calcium absorption-stimulating, prebiotic effects)
- A specific physical or chemical property of the food or food components (e.g., low glycaemic index due to specific structural or starch properties)

The term "enhanced function" is therefore more descriptive of the concept.

In the last CCFL Session, the term 'psychological' in relation to enhanced function claims was put into brackets. The science describing the effect of nutrients (macronutrients, micronutrients and non-nutritive compounds) on brain function is well documented in the ILSI Europe publication of the FUFOSE project (see reference 1, Bellisle et al; p 173-193) and the International Symposium proceedings (see reference 4). This published work demonstrates that nutrient interventions on brain function and related physiological functions can be measured and validated using this science and methodology.

Thus, "brain functions" is a more comprehensive term and more scientifically appropriate than "psychological" or "behavioural" functions.

References

1) Bellisle F, Diplock AT, Hornstra G, Koletzko B, Roberfroid M, Salminen S and Saris WHM (1998) Functional Food Science in Europe. *British Journal of Nutrition*, Vol 80, Suppl 1, p 1-193.
2) Diplock AT, Aggett PJ, Ashwell M, Bornet F, Fern EB, Roberfroid M (1999) Scientific Concepts of Functional Foods in Europe: Consensus Document. *British Journal of Nutrition*, Vol 81, Suppl 1, p 1-27.
3) Asp N-G, Cummings JH, Mensink RP, Prentice A, Richardson DP, Saris WHM (in press) PASSCLAIM – Process for the Assessment of Scientific Support for Claims on Foods – Phase One: Preparing the Way. *European Journal of Nutrition*.
4) Saris WHM, Verschuren PM, Harris S (2002) Supplement Functional Foods: Scientific and Global Perspectives. *British Journal of Nutrition*, Vol 88, p 123-235

Annex: Extract from Reference 1

Type A. 'Enhanced function' claims
These claims concern specific beneficial effects of nutrients and non-nutrients on physiological, psychological functions or biological activities beyond their established role in growth, development, and other normal functions of the body. This type of claim is also similar to a 'structure/function' claim used in the United States.

Type B. 'Reduction of disease-risk' claims
Claims for reduction of disease-risk relate to the consumption of a food or food component that might help reduce the risk of a specific disease or condition because of specific nutrients or non-nutrients contained within it. These claims correspond to those referred to as 'health claims' in the United States.

INTERNATIONAL SOFT DRINKS COUNCIL (ISDC):

The International Soft Drinks Council (ISDC) is a non-governmental organization representing the worldwide soft drinks industry. ISDC is pleased to provide comments on the draft Codex *Guidelines for the Use of Health and Nutrition Claims*.

Preamble

ISDC supports removing the references to national health policies in the preamble as they are contradictory to the goals of international harmonization. We suggest deleting the preamble box.

1.4

ISDC supports the recommendation of the Executive Committee that the scope and application of the guidelines be extended to cover children. We do not see any justification to exclude nutrition or health claims from foods intended for children. We support deletion of section 1.4.

2.1.2

We suggest adding **"as much as"** in the examples given. This type of a claim is used for example for calcium enriched products (e.g., "contains as much calcium as milk").

2.2.2

ISDC recommends removing the brackets around "other" and "psychological".

6.1

Although we understand that the section on comparative claims may not be under discussion, we believe it does not address comparisons made between products that are not "different versions of the same food or similar foods", such as calcium fortified juices and milk, or comparisons made between nutrient levels in different products, e.g., calcium. We believe use of the term "as much as" needs to be clarified.

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI):

- The phrase **"Food for Special Medical Purposes" should be deleted from section 1.2**. They are, by definition, Foods for Special Dietary Uses.

- **Section 1.4 of the Scope is redundant and should be deleted.**

If claims are appropriate, truthful, not misleading, and scientifically substantiated, for this specific group of the population, there is no reason to prohibit them. They provide important information about the product.

The Scope section would then read:

1. **SCOPE**

   1.1. These guidelines relate to the use of nutrition and health claims in food labeling.

   1.2. These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses ~~and Foods for Special Medical Purposes~~ .

   1.3. These guidelines are intended to supplement the Codex General Guidelines on Claims and do not supersede any prohibition contained therein.

   1.4. ~~[~~Nutrition~~]~~ ~~and Health claims are not permitted for foods for infants and young children unless specifically provided for in relevant Codex standards.~~

REMINDER

Foods for Special Dietary Uses are clearly defined in the General Standard for the labeling of and claims for prepackaged foods for special dietary uses (CODEX STAN 146-1985):

> "Foods for special dietary uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physiological condition and/or disease and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary food exist."

As part of foods for special dietary uses, commodity standards already exist on the following products:

- Infant formula (CODEX STAN 72-1981
- Canned baby foods (CODEX STAN 73-1981)
- Processed cereal-based foods for infants and children (CODE STAN 74-1981)
- Follow-up formula (CODEX STAN 156-1987)
- Foods with low sodium content (CODEX STAN 53-1981)
- Gluten-free foods (CODEX STAN 118-1981)
- Labelling of and claims for foods for special medical purposes (CODEX STAN 180-1991)
- Formula foods for use in weight control diets (CODEX STAN 181-1991)
- Formula foods for use in very low energy diets for weight reduction (CODEX STAN 203-1995)

RATIONAL

Foods for Special Medical Purposes are Foods for Special Dietary Uses and should therefore be deleted from section 1.2. In the same way, provisions described in Section 1.4 are already addressed in Section 1.2 since foods for infants and young children are also Foods for Special Dietary Uses, Section 1.4 should therefore be deleted.

Moreover, if claims on foods for infants and young children are appropriate, truthful, not misleading, and scientifically substantiated, there is no reason to prohibit them. Nutrition and health claims, being true statements/information regarding the dietary properties of the foods, provide important information to parents.

Several countries already allow certain health and nutrition claims in labelling of foods for infants and young children.

Provisions ensuring that claims for foods for special dietary uses are properly used, have already been detailed in Section 3.1 of Codex STAN 146-1985 (Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses). This section states that these foods may not be "*described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect*".

Finally, ISDI believes that **CCFL should not adopt provisions on claims specific to foods for infants and young children** until CCNFSDU has discussed this matter in detail. Indeed, CCNFSDU is the relevant Committee to best determine how the Standards on foods for infants and young children should be elaborated.