

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 8

CX/FL 01/10

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD LABELLING**

**Twenty-ninth Session
Ottawa, Canada, 1 - 4 May 2001**

**PROPOSED DRAFT RECOMMENDATIONS FOR THE USE OF HEALTH CLAIMS
(ALINORM 01/22, APPENDIX VIII)**

GOVERNMENT COMMENTS AT STEP 3

COMMENTS FROM:

**AUSTRALIA
DENMARK
MALAYSIA
NEW ZEALAND
SPAIN
SWEDEN**

**CONFEDERATION OF THE FOOD & DRINK INDUSTRIES OF THE EU (CIAA)
EUROPEAN FOOD LAW ASSOCIATION (EFLA)
INTERNATIONAL ALLIANCE OF DIETARY FOOD SUPPLEMENT ASSOCIATIONS (IADSA)
INTERNATIONAL DAIRY FEDERATION (IDF)
INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI)**

PROPOSED DRAFT RECOMMENDATIONS FOR THE USE OF HEALTH CLAIMS - (ALINORM 01/22, APPENDIX VIII) - GOVERNMENT COMMENTS AT STEP 3

AUSTRALIA:

The work that was undertaken leading up to and at the 2000 CCFL meeting has been acknowledged and Australia appreciates the opportunity to comment on the Proposed Draft Guidelines For Use of Health and Nutrition Claims. Comments are provided on the guidelines as follows:

Firstly, in line with our previous comments, we would like to suggest that in a preamble to the text, it be acknowledged that these guidelines are for use by those countries that have made a policy decision to permit health claims. It remains a decision of individual countries as to whether they permit health claims or not.

Boxed preamble

The following wording is suggested:

Health claims must be consistent with national **public** health policy. Claims of the type.....

It is not considered necessary to refer specifically to nutrition policy as this should be encompassed by the reference to 'national public health policy'. While the reference to consumer education is appreciated, it is not considered appropriate in the preamble and it is suggested that it be moved to section 7.

Section 1 – supported

Section 2 - definitions

Section 2.2.1

The inclusion of nutrient function claims in the definition of health claims is not supported. Whilst we do support nutrition function claims having to meet many of the same requirements as health claims as set out in section 7, we suggest that this would be better achieved by incorporating these principles in the relevant part of the standard that defines nutrient function claims.

Section 2.2.2 – Enhanced function claims

The following definition is suggested (which is slightly modified from that included in our previous comments):

These claims concern specific beneficial effects of a food or constituent of a food on the physiological, psychological or biological functions other than the role of the nutrient or biologically active substance in the normal growth, development, maintenance and other like functions of the human body.

Section 2.2.3 – Reduction of disease risk claims

As suggested in previous comments, the following definition is proposed:

Claims relating the consumption of a food or food constituent and the reduced risk of developing a disease or health related condition.

Section 7 – Health claims

7.1.1 – supported.

7.1.2 – We suggest that the second sentence “Only health claims that support.....” should be made into a separate point, if used at all. It currently replicates the material included in the boxed preamble to the guidelines.

7.1.3 – supported

7.1.4 – the following wording is suggested:

The claim should be appropriate and realistic: the amount of food to be consumed to obtain the claimed benefit should be appropriate within the context of a normal diet.

7.1.5 – supported

7.1.6 – As suggested above, reference to nutrient function claims in the context of health claims should be removed and included in a separate section of the standard dealing with nutrient function claims.

7.2 – supported

7.3 – supported

7.4 – supported

7.5 – supported

Australia suggests that an additional point be included at 7.6, to refer to the need for health claims to be accompanied by supporting consumer education. We suggest that this be included in place of the reference to the need for consumer education that is currently included in the boxed preamble to the guidelines.

DENMARK:

The opinion of the Danish Government is that the use of health claims should be restrictive and be based on the principle that good dietary habits are important for the reduction of risk factors related to health. Thus, we find it very important to emphasize that if health claims are to be permitted they must be consistent with the national health and/or nutrition policy as stated in the preamble. We also agree to the importance that health claims should be supported by specific consumer education. We think that it should be specified in the preamble that such education should be provided by the national authorities and not just by the food industry. Besides it is important for all claims that the claim must be truthful and not misleading, which should be included in the preamble as well.

We are pleased to see the Nutrient Function Claims (section 2.2.1) removed from Nutrition Claims and incorporated in Health Claims.

In respect to the definition of health claims we are of the opinion that the Enhanced Function Claims (section 2.2.2) are “disguised disease risk claims”, which could easily mislead the consumer. It is due to the fact that it is much simpler to prove an enhanced function or biological activity of a food than to provide the scientific substantiation on the relation between the food and reduction in risk of disease. The latter relation is often not known. However, the consumer could easily interpret the claim to the effect that eating the food will reduce the risk of a disease. We believe that if health claims are to be permitted, they should take the form of Risk Reduction Claims. Therefore, we suggest Enhanced Function Claims to be deleted. However, if such claims should be accepted, we suggest as a requirement that the physiological parameter (biomarker) mentioned in the claim must be valid, meaning that the connection to disease risk reduction must be proven. In that case, we think that the example given with folate is questionable.

In case of Risk Reduction Claims we appreciate the two-part statement where possible. It is, however, not possible to make a health claim about e.g. fruits and vegetables and the connection to reduced risk of heart disease or cancer in this way. Therefore, we propose the wording in section 2.2.3 changed to “**Whenever possible**, the claim must consist of two parts”.

Section 4.1 should be consistent with section 7.1.6 which provides not only for claims for nutrients for which a Nutrient Reference Value (NRV) has been established in the Codex Guidelines on Nutrition Labelling but also for nutrients which are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction. In fact we think that section 7.1.6 should possibly cover not only enhanced function claims but all health claims.

The wording of section 7.1.3 should be amended to: “The claim about a food or food constituent **must** be stated within the context of the total diet.”

We agree with the statement in 7.4 that the impact of health claims on consumers’ eating behaviours and dietary patterns should be monitored.

In section 7.5 the word “minimum” is redundant, as it is always allowed to give further information about a product.

Inclusion of section 7.5.5 is important for safety reasons.

MALAYSIA:

Section 2 Definitions

Malaysia supports the development of guidelines for Nutrition and Health Claims.

We would, however, like to propose the deletion of specific examples given for each of the 3 types of claims, specified under clauses 2.2.1, 2.2.2 and 2.2.3 of the proposed draft, for the following reasons :

- 1) Some examples listed may be misconstrued to be conclusive and proven beyond doubt without the need for scientific evidence.
- 2) The examples now listed may have greater weightage than those that are not listed.
- 3) The examples cited are not exhaustive.
- 4) The conditions for permitting health claims are already stipulated in clause 7.1.

SECTION 7 HEALTH CLAIMS

SECTION 7.1.3

Malaysia proposes to remove the square brackets in section 7.1.3 and adopt the text contained in the brackets, and add the word “daily” to the phrase “total diet”. The section now reads :

The claim about a food constituent should be stated within the context of the total daily diet.

Section 7.2

Malaysia proposes to remove the square brackets in section 7.2 and adopt the text contained in the brackets with the insertion of the word “adverse” before the phrase health-related condition.

Section 7.5

Malaysia proposes to delete the word “minimum” in square brackets and to read as follows :

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

Rationale:

This is to discourage other additional information which may be misleading or imply unsubstantiated claims

Section 7.5.5

Malaysia proposes to remove the square brackets in section 7.5.5 and adopt the text contained in the brackets.

NEW ZEALAND:

New Zealand and Australia are currently reviewing the use of health and related claims on food labels as part of the development of the Joint Australia New Zealand Food Standards Code. New Zealand comments on the proposed draft Codex guidelines for the use of health and nutrition claims reflect consultation undertaken as part of the development of the Joint Food Standards Code. New Zealand has considered the proposed draft Recommendations for the Use of Health and Nutrition Claims and has the following comments to make.

New Zealand supports the inclusion of the word “health” in the title of the proposed guidelines. This more truly reflects the nature of many of the proposed claims, which tend to link a nutrient or component of a food to a health related outcome or condition.

The boxed section on health claims at the beginning of the draft guidelines should be retained and it is recommended that the word “accompanied” be used in reference to the provision of specific consumer education.

New Zealand supports the inclusion of the word “health” in sections 1.1 and 1.2.

New Zealand recommends that the definition of health claim, as contained in section 2.2, be modified to read:

*Health claims means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and ~~health~~ **a disease or health related condition**.*

It is currently proposed for the Joint Australia New Zealand Food Standards Code that nutrient function claims are not considered health claims. This is because there are already a number of nutrient function claims on the Australian and New Zealand markets that meet current regulations. If these were now considered health claims, it would mean that manufacturers would now be required to undergo a robust process of pre market approval for the use of claims even though there is no evidence of harm from the current use of the nutrient function claims. This level of intervention is not considered necessary although any current or future nutrient function claim would continue to be required to be scientifically robust.

New Zealand does not support the inclusion of nutrient function claims as part of health claims.

In the definition of enhanced function claims, New Zealand recommends the inclusion of the effects on psychological functions to reflect the growing number of claims relating to enhanced psychological well-being, mental alertness or other similar claims. The definition would therefore read:

*These claims concern specific beneficial effects of the consumption of foods and their constituents in the context of the total diet on the physiological, **psychological or biological functions** but do not include nutrient function claims. Such claims relate to a positive contribution to health, **or a health related condition** or to the improvement of a function or to modifying or preserving health.*

New Zealand supports the inclusion of examples, which may aid in the user friendliness and interpretation of the guidelines.

New Zealand supports the definition of reduction of disease risk claims, and recommends that the wording in the square brackets “ or health related condition” be included in the definition.

Again, New Zealand supports the provision of examples of reduction of disease risk claims, which may aid in the appropriate interpretation of the guidelines.

New Zealand supports the square brackets in section 7.1.1 that states that scientific substantiation of health claims should be reviewed as new knowledge becomes available. This is essential to ensure that food regulations remain up to date and scientifically robust.

New Zealand supports the inclusion of text in section 7.1.2 which states that the health claims must be accepted by competent authorities. The statement that health claims must support national health policy and goals is also supported.

New Zealand supports the inclusion of section 7.1.3 in square brackets which refers to the claim being stated within the context of a healthy diet.

New Zealand supports section 7.1.5, but in New Zealand, reference to “free from” must be consistent with fair trading law. This means that ‘free from’ means no detectable level of the constituent being claimed.

New Zealand supports Section 7.1.6, but notes that footnote 13 is not accurate: the text is not identical to section 7.3 of the Codex Guidelines for Use of Nutrition Claims (CAC/GL 23-1997). It is almost identical to section 7.1 of that Guideline.

New Zealand supports inclusion of the term “or health related condition” in section 7.2.

New Zealand supports section 7.3.

Section 7.4 is an ideal rather than achievable for most countries. The ability to monitor the effects of health claims alone on dietary patterns is extremely difficult and resource intensive.

New Zealand supports the inclusion of the minimum information as outlined in section 7.5, except for section 7.5.5, as it is highly unlikely if there is potential risk of over consumption of a nutrient that it would meet appropriate criteria for a health claim.

New Zealand does not support all of the conditions outlined in the table of conditions for nutrient contents. There are proposed criteria for “fat free”, “saturated fat free”, “cholesterol free” and “sugar free”. All of these criteria are inconsistent with fair trading law in New Zealand, which requires that nutrition claims of “free from” should have no detectable amounts of the claimed nutrient.

SPAIN:

General comment:

Spain is of the opinion that no joint guidelines for use of Health Claims and Nutrition Claims should be drafted. At this time, it would be much better to keep the recommendations for use of nutrition claims separate from health claims, because the former are defined and set out in the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev 1 (1993)). For this reason we propose eliminating from the draft document all references that allude to nutrition labelling.

Specific comments:

On the title of the draft document:

For the reasons expressed above, in order to separate nutrition claims from health claims, we propose the following title: “Proposed Draft Guidelines for Use of Health Claims”.

The preamble:

We propose eliminating the first box, since it only refers to nutrition claims.

In the second box, 3rd line, of the options appearing in square brackets, we prefer the term “supported”, because we believe that health claims must be supported simultaneously by educational programs directed at consumers.

On Section 1. Scope:

The references to “nutrition claims” should be eliminated, given that now there need only be reference to health claims.

On Section 2. Definitions:

- Item 2.1 “Nutrition claim” should be eliminated, given that this is from the definitions already set out in the Codex Guidelines on Nutrition Labelling.
- For Item 2.2.2 “Enhanced Function Claims”, we propose the following definition to improve the wording of the text:

“Enhanced Function Claims: These claims concern have to do with beneficial effects from the consumption of foods and their constituents, within the context of the total diet, on physiological functions or biological activities. They may include nutrient function claims as well.
- We propose eliminating item 2.2.3 which appears in square brackets, because we feel that, on food labelling, there should not appear any generic allegations of disease risk reduction due to food consumption, because any given recommendations to population groups with special health conditions are best made in an individual way by medical professionals.

On Sections 3, 4, 5, 6 and the box appearing in the annex:

Because these refer to nutrition labelling, we propose they be eliminated.

On Section 7. Health claims:

- Because we are in agreement with the content between square brackets appearing in items 7.1.1 and 7.1.3, we propose removing the square brackets.
- In Item 7.3, first line, where it reads: “Health claims must be able to be fulfilled:...”, we propose changing it to read: “Health claims must be able to be proven:...”.
- In Item 7.4, where it reads: “...should be monitored and...”, it should read: “...must be controlled and...”.
- In Item 7.5, first line, where it reads “...should appear on the label or labelling of...”, it should read: “...should appear on the label and publicity of...”.
- In Item 7.5.5, first line, where it reads “Maximum safe intake of...”, it should read: “Maximum consumption of...” and the square brackets should be eliminated.

SWEDEN:

In reply to the proposal for health claims in Codex CL 2000/16-FL Sweden would like to make the following comments.

GENERAL COMMENTS

For the purpose of consistency

- all conditions for the use of health claims should be concentrated in p. 7.
- all examples should be concentrated in a new table.

COMMENTS IN DETAIL

INTRODUCTORY STATEMENT (IN THE BOX BEFORE DEFINITIONS)

The word *supplemented* is preferred instead of [accompanied/supported].

2.2.1 Nutrient Function Claims

These claims are always generic. The two-step-principle is well suited for these kinds of claims.

The examples should be removed to a new table.

2.2.2 Enhanced Function Claims

The wording ‘in the context of the total diet’ is a condition for the use of health claims and should therefore only appear in p. 7.1.3.

The square brackets should be removed and the wording ‘or to a condition linked to health’ be retained.

The examples should be removed to a new table.

2.3 Reduction of Disease Risk Claims

The wording ‘in the context of the total diet’ is a condition for the use of health claims and should therefore only appear in p. 7.1.3.

The square brackets should be removed and the wording ‘or health-related condition’ be retained.

The two-step-principle is also a condition for the use of health claims and should therefore be removed to p. 7.

Thus the definition should get the following wording: *Reduction of disease risk claims* - Claims relating the consumption of a food or food constituent to the reduced risk of developing a disease or health-related condition. Reduction of disease risk means significantly altering a major risk factor(s) for a disease or health-related condition. 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.’

The examples should be removed to a new table.

7.1 Health Claims should be permitted provided that the following conditions are met:

7.1.1

The word *accepted* is preferred instead of *acceptable*.

The square brackets should be removed and the wording ‘and the scientific substantiation should be reviewed as new knowledge becomes available’ be retained.

7.1.3

The square brackets should be removed and the wording ‘The claim about a food or food constituent should be stated within the context of the total diet.’ be retained. (See p. 2.2.2 and p. 2.2.3).

7.2

The square brackets should be removed and the wording ‘or a health-related condition’ be retained.

7.5

The word *minimum* should be deleted.

7.5.5

The square brackets should be removed and the wording ‘Maximum safe intake of the food where necessary.’ be retained.

7.5.6

The meaning of ‘full nutrition labeling’ is unclear. Maybe it is possible to make a cross-reference to p. 3 in these draft guidelines and relevant parts of Section 3 of the Codex Guidelines of Nutrition Labelling.

New 7.6

A new p. 7.6 should be inserted. This should be the rest of p. 2.2.3, which are conditions for the use of health claims. A new p. 7.6 should read as follows: ‘Reduction of disease risk claims 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.’

The examples should be removed to a new table.

Table of Conditions for Nutrient Contents

The component *sodium* is missing.

A new table

A new table with all examples should be inserted.

Different types of claims subject to the conditions in these guidelines

The purpose of these examples is only to illustrate the differences between different types of health and nutrition claims. Special conditions for use of these claims are found in the guidelines.

COMPONENT	TYPE OF CLAIM	CLAIM
Calcium	Nutrient content claim	Food A is a source of calcium
	Comparative claim	Food A contains x % more calcium than...
	Nutrient function claim	Calcium aids in the development of strong bones and teeth. Food A is a source of/rich in calcium.
	Enhanced function claim	Calcium may help to improve bone density. Food A is a source of/rich in calcium.
	Reduction of disease risk claim	Sufficient calcium intake may reduce the risk of osteoporosis in later life. Food A is high in calcium.
Iron	Nutrient content claim	Food B is a source of iron
	Comparative claim	Food B contains increased contents of iron
	Nutrient function claim	Iron is a factor in red blood cell formation. Food B is a source of/rich in iron.
	Enhanced function claim	A good iron status may promote endurance. Food B is a source of/rich in iron.
	Reduction of disease risk claim	Iron deficiency is common among women, but

		good dietary habits can reduce the risk for iron deficiency. B is an important source of the type of iron that is readily absorbed by the body.
Folic acid	Nutrient content claim	Food C is a source of folic acid
	Comparative claim	Food C contains x % more folic acid than...
	Nutrient function claim	Folic acid contributes to the normal growth of the fetus. Food C contains folic acid
	Enhanced function claim	Folate may help to normalise plasma homocysteine levels. Food C is a source of/rich in folic acid.
	Reduction of disease risk claim	Folate may reduce a woman's risk of having a child with neural tube defects. Food C is high in folate.

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 of a balanced regulatory framework.
2. The aim of health 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.
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 recommendations on health claims currently at step 3 of the procedure provide the basis for a good framework for the use of health claims. As they currently stand, the recommendations 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 recommendations 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 provision of accurate and scientifically grounded information.
7. A list of authorised claims should however be avoided in as much as this could discourage food manufacturers from researching and developing innovative products with health benefits. A list will also be difficult to agree at international level.
8. CIAA wishes to recall that Codex standards should establish general principles and should therefore be concise and precise in order to be recognised world-wide for their vital role in protecting the consumer and facilitating international trade.

II. DETAILED COMMENTS:

CODEX PROPOSED DRAFT	CIAA COMMENTS
<p>Box: Health claims must be consistent with national health policy including nutrition policy, and support such policies. Health claims should be [accompanied/supported] by specific consumer education. Claims of the type described in Section 3.4 of the Codex General Guidelines on Claims are prohibited.</p>	<p>To be replaced by: <i>“Health claims should be made only when there is sufficient scientific evidence of a contribution to good dietary practice.”</i> This box could potentially create barriers to trade and should be removed.</p>
<p>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 the following:</p>	
<p>2.2.2 Enhanced 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 functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health [or to a condition linked to health] or to the improvement of a function or to modifying or preserving health.</p> <p>Examples: [“Certain non-digestible oligo-saccharides improve the growth of specific bacterial flora in the gut”]. “Folate can help reduce plasma homocysteine levels”]</p>	<p>Remove: <i>“in the context of the total diet”</i>. CIAA agrees with the principle but considers that this provision should be laid down under “conditions for use”. Include after physiological: <i>“or psychological”</i>.</p> <p>Examples: “Certain non-digestible oligo-saccharides improve the growth of specific bacterial flora in the gut. <i>Product X contains...</i>” <i>“Margarine Y helps to reduce cholesterol levels”</i>.</p>
<p>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 that might help reduce the risk of a specific disease or condition]. The claim must consist of two parts:</p> <ol style="list-style-type: none"> 1) Information on an accepted diet-health relationship; followed by 2) Information o the composition of the product relevant to the relationship <p>Risk reduction means significantly altering a major risk factor(s) for a disease [or health-related condition]. Disease has 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.</p> <p>(Examples: “Iron can help reduce the risk of anaemia. Food A is a high source of iron.”; “A diet low in saturated fat may reduce the risk of heart disease. Food B is low in saturated fat”; “Folate may reduce a woman’s risk of having a child with neutral tube defects. Food C is high in folate.” “Sufficient calcium intake may reduce the risk of osteoporosis in later life. Food D is high in calcium.”</p>	<p>Remove: <i>“in the context of the total diet”</i>.</p> <p>To be replaced by: “It is recommended that the claim consists of two parts”. The reference to an “accepted” diet-health relationship gives room for diverse national interpretation and should not be a precondition for making a claim. If a claim is validated for a product, it should be possible to make the claim as such, e.g. <i>“Fermented milk X helps to reduce the risk of intestine infections”</i></p> <p>Examples: <i>“Margarine Y helps to reduce the risk of CVD”</i>.</p>
<p>7.1 Health claims should be permitted provided that the following conditions are met:</p>	
<p>7.1.1 Health claims must be based on relevant scientific</p>	

	substantiation and the level of proof must be sufficient to substantiate the type of claimed effect as recognised by generally acceptable scientific 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. Only health claims that support national health policy and goals should be allowed.	To be removed or to be replaced by: <i>“Health claims should be made only when there is sufficient scientific evidence of a contribution to good dietary practice.”</i>
7.1.3	The claim about a food constituent should be stated within the context of the total diet.	To be replaced by: <i>Health claims should only be made for a food as part of a total dietary pattern.</i>
7.1.4	The claimed benefit should arise from the consumption of a reasonable quantity of a food in the context of a normal diet.	To be replaced by: <i>The claimed benefit should arise from the consumption of a reasonable quantity of <u>the food or food constituent</u> in the context of a normal diet.</i>
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 appropriate, 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 recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim.	
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 in amounts that increase the risk of disease [or a 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.	First sentence and last five words of second sentence to be removed. 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 valid method to quantify the food constituent that forms the basis of the claim.	To be removed. This should be included in the scientific substantiation.
7.4	The impact of health claims on consumers’ eating behaviours and dietary patterns should be monitored.	To be removed. This is a matter for national competent authorities.
7.5	The following [minimum] 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.	

7.5.2	Information on the target group, if appropriate.	
7.5.3	Information on how to use the food to obtain the claimed benefit, if 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	Full nutrition labelling	Remove: Nutrition labelling should depend on the nature of the claims.

EUROPEAN FOOD LAW ASSOCIATION (EFLA):

GENERAL REMARKS

The European Food Law Association (EFLA) enrolls professionals working in all branches of the food sector, including officials in National or European administrations, consultants, lawyers and executives from the industry or trade. EFLA welcomes the work carried out by Codex in relation to the use of health claims. The initiative to tackle the issue of health claims (including risk reduction claims) is one that reflects developments in nutrition science and can make a positive contribution towards a better consumer understanding of food. At the same time, EFLA is concerned that sufficient legal clarity is brought to the text to avoid unnecessary biases and ambiguities and to make it a practical and useful reference point for international trade and that the recommendations remain consistent with the general principles of Codex Alimentarius and already agreed standards on this issue.

SPECIFIC COMMENTS

Opening box (and 7.1.4)

While EFLA understands the concerns that lie behind the creation of the statement, namely that health claims may cause changes in consumption that could detract from what countries would consider balanced diets, EFLA believes that this paragraph needs be removed as:

1. Its inclusion is in contradiction with one of the principle goals of Codex, that is to remove restrictions to international trade. This box could potentially create new national barriers to trade as national policies may not be based on sound science, may be vague and ambiguous or may not be defined precisely at all.
2. The statement would require a comprehensive understanding of what these individual national nutrition/health policies are. It is highly unlikely that such clarity can be achieved ever on national level, and certainly not internationally. Legal certainty is likely to be at stake.
3. In order to justify the argument that a single claim not is in conflict or consistent with nutritional policy it would be necessary to prove,
 - a. that the health claim would not increase consumption of that product
 - b. and that increased consumption would not significantly alter the total diet
 - c. and that total diet would not conflict with a specific nutrition goal
 - d. and that that nutrition goal was, either explicitly or implicitly, part of national nutrition/health policy.

EFLA does not believe that such a prove is possible and fears that this paragraph would therefore be open to discriminatory or arbitrary interpretation. As an organisation engaged in the practical implications of the law, EFLA states that the box and paragraph 7.1.4 formulated as such would simply not be workable.

2.2

The first option should be included with the removal of the brackets. EFLA is concerned that there may be different interpretations of 'disease' and would therefore propose the inclusion of a 'disease' definition.

2.2.1

Internationally recognised definitions for function claims and risk reduction claims have already been developed by the International Life Sciences Institute (ILSI). For the sake of consistency, the **enhanced function claim** should therefore be replaced by:

"These claims concern specific beneficial effects of nutrients and non-nutrients on physiological and psychological functions or biological functions beyond their established role in growth, development and other normal functions of the body."

2.2.2

It has been noted that in the last CCFL session it was proposed to delete the term "psychological" in relation to enhanced function claims as some delegations raised concern that psychological functions could not be properly substantiated

While this is certainly a legitimate concern, EFLA would like to point out that paragraph 7.2.1 of the proposed draft recommendation already provides that any claim has to be based on scientific substantiation satisfying the requirements of the competent authority of the country where the product is sold. Therefore, if a psychological claim cannot be substantiated objectively, a producer would not be allowed to make such a claim according to the substantiation requirements of the proposed draft recommendations

There are, however, many psychological functions that can be measured objectively and reliably and there is scientific consensus that psychological functions such as, for instance, mental performance can be beneficially effected by foods and food components.

Such functions are important in a wide variety of every day activities such as the work environment and car driving. Many psychological functions can be measured objectively, reliably and validly by standardised test systems supported by modern computer technology and the assessment is comparable to the measurement of physiological functions or basic biological states and activities.

To exclude psychological functions such as cognitive or mental performance from the definition of enhanced function claims would be arbitrary and have the effect that claims referring to physiological and biological activities would be harmonised in the Codex system while psychological claims would be left unregulated. This would leave out important psychological functions such as attention, awareness, learning, memory, orientation, perception and recognition.

Furthermore, the border between psychological functions and biological activities such as stress, activation or alertness is blurred and considerable overlap exists. To include biological activities, but to omit psychological functions would amount to an artificial division which would be contrary to any harmonisation efforts.

In the same line of reasoning EFLA wants to underline that health claims should be allowed for all foods, provided the appropriate scientific substantiation is available.

We therefore recommend that enhanced function claims should be defined as follows:

"These claims concern specific beneficial effects of the consumption of foods and their constituents on physiological or psychological (in event: cognitive or mental) functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health or to a condition linked to health or the improvement of a function or to modifying or preserving health."

7.1.2

This clause should be deleted. It is irrelevant. If a health claim should encourage excessive consumption of certain food stuffs or certain substances, i.e. if excessive consumption of a specific food would be a concern such concern should be addressed through adequate labelling.

7.1.5.

If the concern of over-consumption is adequately addressed under 7.1.2, this paragraph is unnecessary. Moreover, as under 7.1.4., the inclusion of unqualified relationships between food and diet make objective application of the paragraph practically impossible and could therefore lead to discriminatory judgements. At least, the following should be added

".....such contribution being of significance to general human health and or well being"

7.2.1 (and 7.3.1.)

To avoid diverse national interpretations and resulting barriers to trade, the reference for scientific substantiation should be the requirements of the Codex guidelines to be adopted by the CCNFSDU. It should be sufficient that a claim is based on internationally accepted science. If national requirements are the reference, than it should be clearly stated that these national requirements have to take into account international scientific findings and research.

7.3.3

No constituent should be present in a food for general consumption in an amount that would increase risk of a disease or health-related condition. This, however, is a food safety question and does not need to be included here and should be deleted. At least, the reference to a " health-related condition" should be changed into " negative health-related condition".

INTERNATIONAL ALLIANCE OF DIETARY FOOD SUPPLEMENT ASSOCIATIONS (IADSA):

GENERAL COMMENTS

IADSA, the International Alliance of Dietary/Food Supplement Associations, considers the proposed draft Codex recommendations on health claims to provide the basis for a good framework for health claims. The recognition that foods and food constituents play an important role in relation to specific diseases; that 'prevention' and 'risk reduction' are correctly treated as separate concepts; and the commitment to the provision of accurate and scientifically based information to consumers, are all of major importance.

However, IADSA is concerned about some of the wordings in the text and would like to make the following specific comments.

SPECIFIC COMMENTS

§	IADSA COMMENTS	Argumentation
Boxed preamble	<p>Health claims must be consistent with national health policy, including nutrition policy, and support such policies. Health claims should be [accompanied/supported] by specific consumer education. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.</p>	<ul style="list-style-type: none"> ▪ IADSA notes that many countries prevent legitimate health claims with significant public health benefits. For example, while the benefit of folic acid for pregnant women is now well established, policies involving supplementation of folic acid are yet to be developed in many areas of the world. In such a case, restricting the claims made about folic acid products may well reflect national policy, but could work against the actual interest of consumers. ▪ Therefore, IADSA requests removal of this preamble as it can work against the actual interest of consumers and is inconsistent with Codex general principles. ▪ If the preamble were to be retained, it should be replaced by the following text: <i>'Health claims must be based on relevant scientific evidence. National authorities may challenge a health claim when the claim is in conflict with such evidence.'</i>
2.2	<p>Health claims means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health <u>or disease</u>. Health claims include the following:</p>	<ul style="list-style-type: none"> ▪ Delete 'suggests, or implies' because the statement must be clear factual and not subject to subjective interpretation. ▪ Add 'or disease' at the end of the first sentence to incorporate risk-reduction claims.
2.2.2	<p>Enhanced 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 <u>and psychological</u> functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health { or to a condition linked to health } or to the improvement of a <u>bodily structure or function</u> or to modifying or preserving health. [Examples: 'Certain non-digestible oligosaccharides improve the growth of specific bacterial flora in the gut.' 'Folate can help reduce plasma homocystiene levels']</p>	<ul style="list-style-type: none"> ▪ Remove 'in the context of the total diet' and retain this under the conditions for use for authorised risk reduction claims (see 7.1.3). ▪ Include 'and psychological' after 'physiological'. ▪ Remove the brackets around 'or a condition linked to health'. ▪ Include 'bodily structure or' before 'function'.
2.2.3	<p>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 that might help reduce the risk of a specific disease or condition]. 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</p> <p>Risk reduction means significantly altering a major risk factor(s) for a disease {or health-related condition }. Disease has</p>	<ul style="list-style-type: none"> ▪ Remove the brackets around the section of the reduction of disease risk claims. ▪ Remove 'in the context of the total diet' and retain this under the conditions for use for risk reduction claims (see 7.1.3) ▪ Remove the brackets around 'or health-related condition that might help reduce the risk of a specific disease or condition' to accommodate risk reduction claims. ▪ Delete the brackets around 'or health related condition'.

	<p>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 or therapy claims.}</p> <p>[Examples: 'Iron can help reduce the risk of anaemia. Food A is a high source of iron.' 'A diet low in saturated fat may reduce the risk of heart disease. Food B is low in saturated fat.' Folate may reduce a woman's risk of having a child with neural tube defects. Food C is high in folate.' Sufficient calcium intake may reduce the risk of osteoporosis in later life. Food D is high in calcium.']</p>	<ul style="list-style-type: none"> ▪ Include 'or therapy' after 'prevention'.
7.1	Health claims should be permitted provided that the following conditions are met:	
7.1.1	<p>Health claims must be based on <u>current</u> relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect as recognised by generally acceptable scientific data</p> <p>[and the scientific substantiation should be reviewed as new knowledge becomes available]</p>	<ul style="list-style-type: none"> ▪ Add 'current' to ensure that scientific substantiation is up to date (such as current Good Manufacturing Practices - cGMP). ▪ Delete 'and the scientific substantiation should be reviewed as new knowledge becomes available.'
7.1.2	<p>Any health claim must be accepted by or be acceptable to the competent authorities of the country where the product is sold. Only health claims that support national health policy and goals should be allowed.</p>	<ul style="list-style-type: none"> ▪ Presenting the same scientific dossiers to different national authorities for consideration is illogical, impractical and expensive for both authorities and industry. Countries should have the right to challenge health claims that they consider are unjustified, but scientific knowledge is sufficiently universal to not require specific national verification as agreed by authoritative international bodies. ▪ In addition, the claim must be based on scientific substantiation satisfying the requirements of the Codex guidelines to be adopted by CCNFSDU. ▪ For the above reasons, and because it is inconsistent with Codex General Principles, this entire point must be deleted.
{7.1.3}	{The claim about a food or food constituent should be stated within the context of the total diet.}	<ul style="list-style-type: none"> ▪ Remove the brackets
7.1.4	The claimed benefit should arise from the consumption of a reasonable quantity of a <u>food or food constituent</u> in the context of a normal diet.	<ul style="list-style-type: none"> ▪ Add 'or food constituent' after food
7.1.5	<p>If the claimed benefit is attributed to a constituent in the food, the food in question should be:</p> <p>(i) - a [<u>significant</u>] or high source of the</p>	<ul style="list-style-type: none"> ▪ Note: 'significant' should be placed in square brackets until defined, either by CCFL, or more appropriately, by CCNFSDU.

	<p>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.</p> <p>Where appropriate, the conditions for nutrient content claims and comparative claims will be used to determine the levels for 'high', 'low', 'reduced', and 'free'.</p>	
7.1.6	<p>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 recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim.</p>	<ul style="list-style-type: none"> ▪ IADSA request the deletion of the entire paragraph. The current Codex Food Labelling Texts, Nutrition Claims, Point 4, already specify this provision and inclusion in a new Health Claims section is therefore redundant.
7.2	<p>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 in amounts that increase the risk of disease [or a 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.</p>	<ul style="list-style-type: none"> ▪ This condition lacks clarity with the danger that it will undermine fair practices in food trade. ▪ The concerns over the relationship between the individual product and the general diet are dealt with in the scientific substantiation (see 7.1.1) and 7.1.4 ▪ This paragraph is redundant and duplicative.
7.3	<p>If the claimed effect is attributed to a constituent of the food, there must be a valid method to quantify the food constituent that forms the basis of the claim.</p>	<ul style="list-style-type: none"> ▪ This paragraph should be removed here and be included in the scientific substantiation.
7.4	<p>The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored.</p>	
7.5	<p>The following [minimum] information should appear on the label or labelling of the food bearing health claims:</p>	
7.5.1	<p>A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.</p>	
7.5.2	<p>Information on the target group, if appropriate</p>	
7.5.4	<p>If appropriate, advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food</p>	
[7.5.5]	<p>[Maximum safe intake of the food where necessary]</p>	<ul style="list-style-type: none"> ▪ This paragraph is redundant (see 7.1.4 and 7.5.4)
7.5.6	<p>Full nutrition labelling</p>	

INTERNATIONAL DAIRY FEDERATION (IDF):

The IDF welcomes the initiative to set up a legislative framework for recommendations for the use of health claims. In the absence of any internationally recognized legal framework, technical barriers to trade will be encountered whilst introducing functional foods, or foods with proven health benefits that carry health claims on their label into different markets all over the world. Since it has been widely recognized that rapidly increasing

consumer demand resulted in a fast-growing market potential of functional foods all over the world over the past few years, setting-up a legal framework internationally for the use of health claims would be a significant step.

We would like to put forward the following comments for consideration at the forthcoming session of the Codex Committee on Food Labelling.

The health claims recommendations should create an overall legal framework that clearly distinguishes between health claims on normal food products and the medical claims relating to pharmaceutical products. We therefore believe that they are best dealt with by the Codex General Guidelines on Claims.

Codex proposed Draft	IDF Proposed modification	Reasons
<p>Box:</p> <p>Health claims must be consistent with national health policy, including nutrition policy, and support such policies. Health claims should be [accompanied/ supported? ? by specific consumer education. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.</p>	<p>Health claims should not conflict with national health policy, including nutrition policy. Claims of the type described in section 3.4 of the Codex General guidelines on claims are prohibited</p>	<p>Scientific research evolves rapidly but not all national health policies are updated at the same rate. Having this reference in the box could lead to situations in which enough scientific research is available to substantiate the claim, but national health policies are not yet updated, so that the claim can not be made.</p> <p>We agree that it is important that the competent authorities do commit themselves to consumer education in relation to claims. However we wonder if a better place could be found for this statement. In the present position it seems out of context.</p>
<p>In relation to 7.1.6 the footnote 13 says</p> <p>“13 This section is identical to Section 7.3 of the Codex Guidelines for Use of Nutrition Claims (CAC/GL 23-1997)”</p> <p>However the proper Section is Section 7.1.</p>		
<p>7.4 The impact of health claims on consumers’ eating behaviours and dietary patterns should be monitored.</p>		<p>IDF supports the idea that the authorities should monitor consumers’ eating behaviour and dietary patterns on a regular basis. This is to the benefit of all interested parties.</p>
<p>7.5 The following [minimum? ? information should appear on the label or labelling of the food bearing health claims:</p> <p>7.5.1 A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.</p> <p>7.5.2 Information on the target group, if appropriate</p> <p>7.5.3 Information on how to use the food to obtain the claimed benefit, if appropriate</p> <p>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.</p> <p>[7.5.5 Maximum safe 7.5.6 Full nutrition labelling intake of the food where necessary.?</p>		<p>We note that 7.5.6 now mentions “full nutrition labelling”.</p> <p>We take that this is to be understood that nutrition labelling should apply according to the rules in the Codex Guidelines on Nutrition Labelling, and that they should be used <u>if</u> a health claim is made.</p>

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 and 1999. 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 reached 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 2 Codex types of claims, 'enhanced function claims' and 'reduction of disease risk claims' (see annex).

In the last session of the CCFL, it was decided to put the definition of 'disease risk reduction claims' in square brackets. However, the findings of this concerted action clearly demonstrate that *both* types of claims, 'enhanced function' and 'disease risk reduction', as defined in CCFL, can be supported by the available scientific data. It was agreed by the FUFOSE participants that foods and food products for which reduction of disease risk claims are allowed must contain components and/or have properties that affect well-established risk factors for certain diseases. Functional foods must remain foods and they must demonstrate their effects in amounts that can normally be expected to be consumed in the diet. Functional foods must be safe according to all standards of assessing food risk. These decisions should be based on the totality of publicly available scientific evidence. There should be a substantial agreement amongst qualified experts that the claims are supported by evidence.

In the last CCFL Session, the term 'psychological' in relation to enhanced function claims was deleted. The results of FUFOSE support the fact that nutrients and non-nutrients can have demonstrable effects on both physiological functions and on *mental/cognitive performance* (see reference 1), which can be objectively documented, thus supporting the inclusion of this concept in the description of enhanced function claims. Such functions are important elements of health and well-being.

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 MB (1999) **Scientific Concepts of Functional Foods in Europe: Consensus Document. *British Journal of Nutrition*, Vol 81, Suppl 1, p 1-27.**

Annex: Extract from Diplock AT *et al.* (1999)
British Journal of Nutrition, Vol 81, Suppl 1 p 1-27.

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 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.