codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/NFSDU 07/29/6-Add. 1[1]**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
28th Session

Chiang Mai, Thailand, 30 October - 3 November 2006

PROPOSED DRAFT RECOMMENDATIONS OF THE SCIENTIFIC BASIS OF HEALTH CLAIMS AT STEP 4[1]

- Comments at Step 3 of the Procedure -

Comments from:
ARGENTINA - 1 -
ARGENTINA - 2 -
AUSTRALIA
BOLIVIA
BRAZIL
GUATEMALA
KENYA
NEW ZEALAND
UNITED STATES OF AMERICA

CIAA - Confederation of the food and drink industries of the EU
IADSA – International Allicance of Dietary/Food Supplement Associations
ISDI - International Special Dietary Foods Industries
WSRO – World Sugar Resaerch Organisation

[1] Previously published as CX/NFSDU 06/28/7-Add.1. The 28th Session of the CCNFSDU agreed to retain the Proposed Draft Recommendations at Step 4 for further consideration at the next session (ALINORM 07/30/26, para.134).

ARGENTINA - 1 -

Appendix 2
PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS: RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS

2. SCOPE:
As regards this paragraph: "These Recommendations are intended for governments, in order to facilitate their own evaluation of health claims, used by the industry.", Argentina proposes to amend the wording as it believes the provisions under paragraph 7.1.2 of the Guidelines for Use of Health and Nutrition Claims are appropriate: "Any health claim must be accepted by or be acceptable to the competent authorities of the country where the product is sold."

The paragraph would therefore be redrafted as follows:
"These Recommendations are intended for governments, in order to facilitate their own evaluation of health claims, ~~used by the industry~~ those accepted by or be acceptable to the competent authorities of the country where the product is sold.

Regarding this paragraph: "They only address the nature and the quality of the scientific evidence supporting these claims.", Argentina proposes to change the wording, as the proposed draft sets out the general criteria that products should meet (e.g. the maximum level of consumption). The wording would be as follows:

"They ~~only~~ address ~~the nature and the quality of the scientific evidence~~ the characteristics of the products for presentation supporting these claims, focusing on the nature and quality of the scientific evidence"

4. EVALUATION OF SCIENTIFIC EVIDENCE, USED TO SUPPORT A HEALTH CLAIM:
4.2. SPECIAL CASES:
As regards the third bullet point of this item: "'Nutrient function' claims may be substantiated based on generally accepted authoritative information that has been verified and validated over time.", Argentina proposes to delete the word "generally" and replace the term "authoritative" with "scientific"; as the phrase "accepted scientific" better conveys the idea of the text, and the term "authoritative" (or, at least, the Spanish word "autoritativa") is not commonly used in this type of documents. The deletion of the term "generally" is proposed because it would indicate that there may be specific declarations that may not necessarily be justified in this manner. The new wording would be as follows:
"'Nutrient function' claims may be substantiated based on ~~generally~~ accepted scientific ~~authoritative~~ information that has been verified and validated over time."

4.3. SCOPE OF THE EVIDENCE:
4.3.2. Specific safety concerns (Inquietudes específicas relativas a la inocuidad)

Argentina proposes to change the word ~~Inquietudes~~" with "Requisitos", in the heading of this section in the Spanish version of the document, to better reflect the contents of this section. The heading would be redrafted as follows:

4.3.2 REQUISITOS ESPECÍFICOS RELATIVOS A LA INOCUIDAD

Argentina suggests that a new paragraph be added below this paragraph: "The expected level of consumption shall not exceed any relevant upper level of intake for food
constituents.", considering that safe intake levels are established by the JECFA. The new wording would be as follows:

"Intake levels should be established according to JECFA criteria. If these have not been established, because they are not known, no claims about the component shall be accepted."

As regards this paragraph: "The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population and, where relevant, those for vulnerable population groups. It should account for the possibility of cumulative intake, when the same constituent is present in several foods, and for nutritional imbalance due to changes in dietary patterns in response to consumers' information laying emphasis on the food property.", Argentina suggests that this paragraph provide more detail on vulnerable population groups, specifying which they are, by adding a bracketed phrase (including young children, pregnant women, the aged, celiacs, people with food intolerance), after the phrase "where relevant, those for vulnerable population groups". The resulting wording would be:

"The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population and, where relevant, those for vulnerable population groups (including young children, pregnant women, the aged, celiacs, people with food intolerance). It should account for the possibility of cumulative intake, when the same constituent is present in several foods, and for nutritional imbalance due to changes in dietary patterns in response to consumers' information laying emphasis on the food property."

ARGENTINA - 2 -

Errata
In item 2, SCOPE, of the Spanish version of our comments, the words ""(…) 7.1.2 del 'Proyecto de Directrices para el Uso de Declaraciones Nutricionales y Saludables': '…Cualquier declaración de propiedades debe ser aceptada por las autoridades competentes del país donde se vende…'" should be replaced with "7.1.2 de las 'Directrices para el Uso de Declaraciones Nutricionales y Saludables': '…Cualquier declaración de propiedades debe ser aceptada o reconocida como aceptable por las autoridades competentes del país donde se vende el producto..."

AUSTRALIA

Australia supports the development of an Annex to the *Guidelines for use of nutrition and health claims* (The Guidelines) as an appropriate vehicle to contain recommendations on the substantiation of health claims. This first draft of the proposed Annex provides a sound basis for further discussion and refinement.

A Australia's response to request for comment on selected paragraphs of agenda paper

Scope

Para 20 –Australia considers that claims about specifically characterised diets such as 'a diet rich in fruit and vegetables' should be within the scope of a health claim. (The term 'specifically characterised diet' is preferred to 'whole diet'). While there might not be international trade in diets, paragraph 7.4.6 of The Guidelines require foods labelled with health claims to describe how foods/constituents fit within the context of a total diet. Therefore reference to diets in food labelling is anticipated by The Guidelines.

Para 23 - Australia considers that a 'specifically characterised diet' as a more precise description of an exposure, which can be differentiated from general advice about healthy diets including from dietary guidelines (Section 8 of The Guidelines).

Australia's experience in examining the evidence for a protective effect of fruit and vegetables against coronary heart disease has led us to conclude that the evidence does not unequivocally point to the fruit and vegetables directly conferring protection. Rather, that the characteristics of *a diet* rich in fruit and vegetables convincingly confers protection against heart disease. Therefore the possibility exists for a diet of a

particular characteristic being the exposure rather than a food (or group of foods) alone. The definition of disease risk reduction claims in The Guidelines allow for this by referring to 'in the context of the total diet'.

Safety considerations
Para 26 - Australia considers that Governments would need to apply a risk analysis approach to determine whether assessment of potential risks associated with foods labelled with a health claim would result in additional risk management measures being taken. Such an approach to risk analysis does not need to be detailed in these Recommendations, although it is noted that some risk management measures such as ineligibility for carrying a particular health claim, or additional advisory statements alerting vulnerable groups are already described in Paragraphs 7.2, 7.4.4 and 7.4.5 of The Guidelines.

Step-by-Step process
Para 32 - Australia strongly supports the inclusion of a Step-by-Step process for substantiation of health claims by national competent authorities. This aspect of the Recommendations should be used as its basic structure (after definitions) with each step in the process being elaborated by more specific and appropriate guidance. We note that some of this guidance is already contained in other sections of the Annex.

Strength of evidence
Para 39 – Australia supports articulation of a specific standard/strength/grade of evidence in these Recommendations rather than requiring jurisdictions to make their own determination. Such an approach would contribute to a similar global standard of supporting evidence for health claims appearing on foods traded internationally. The WHO framework quoted in paragraph 10 of the agenda paper provides a good starting point from which to forge consensus on an agreed strength of evidence. Australia supports establishing the standard of evidence at the level of 'convincing'. Australia's modification of the 'convincing' standard of evidence, shown in the footnote to paragraph 38 of the agenda paper, is offered for consideration since it resulted from attempts to directly apply the WHO standards of evidence to a health claims context.
Re-evaluation of health claims
Para 43 - Australia agrees that health claims should be reviewed after a certain timeframe or as soon as new knowledge calls into question the scientific validity underpinning the claim. We acknowledge that industry should not be required to continue to research the beneficial health effects of a food or constituent for a claim that already has been authorised, however future reviews should not be precluded since new evidence on benefit and adverse effects might arise from other sources.

Title and status of the Proposed Draft Recommendations
Para 48 – While Australia agrees that the Recommendations should be read in conjunction with the *General guidelines on claims* and The Guidelines, we believe that a preamble containing the current text is redundant because these considerations are either self evident or reference to the relevant text is included within the body of The Guidelines.

Para 49 – Australia supports the development of an Annex to The Guidelines as an appropriate vehicle to contain Recommendations on the substantiation of health claims. The amendment of the title to this effect is also supported.

B Australia's comments on proposed draft Annex

1 Preamble

Australia believes that a preamble containing the current text is redundant. Paragraph 1.3 of the *Guidelines for use of nutrition and health claims* (The Guidelines*)* states that they are supplementary to the *General guidelines on claims.* Also, the reference to The Guidelines is unnecessary because the Annex is proposed to serve as an attachment to these very same Guidelines.

2 Scope

The following points are suggested as relevant to the Scope section:

These Recommendations are intended for directed to governments, in order to facilitate their own evaluation of for application in substantiating health claims, used by industry in food labelling, and advertising where appropriate, in their jurisdiction.

These Recommendations apply to health claims as defined in these Guidelines and consider the following three types of health claims: nutrient function claims, other function claims, and disease reduction claims.

These Recommendations outline the process for evaluation of the scientific evidence in support of health claims.

These Recommendations do not apply to patterns of eating as recommended in national dietary guidelines or to the use of 'healthy diets' (Section 8).

3 Definition

Australia agrees that a term like 'property of a food' should be developed to define the exposure variable in the diet disease relationship. However as drafted, the proposed definition applies only to reduction of disease risk claims and other function claims; its current scope is too broad for application to nutrient function claims. The exposure variable for nutrient function claims is confined by paragraph 7.1.5 of The Guidelines to essential nutrients having an established Nutrient Reference Value or to those nutrients mentioned in national dietary guidelines.

It might be useful to define 'property' within the context of each type of health claim. Since Australia supports a broad definition of 'property' that includes diets, and groups of foods, the simple term 'property' is preferred over 'property of a food' and these considerations are reflected in the examples given below.

For the purposes of a:

Nutrient function claim, 'property' is defined by paragraph 7.1.5 of The Guidelines as essential nutrients having an established Nutrient Reference Value or those nutrients mentioned in national dietary guidelines.

Other function claim, 'property' refers to either a specifically characterised diet; an individual food or group of foods; or constituents of foods that include biologically active substances and food ingredients.

Reduction of Disease Risk claim, 'property' refers to either a specifically characterised diet; an individual food or group of foods; or constituents of foods that include those nutrients permitted to be the subject of a nutrient function claim, biologically active substances and food ingredients.

Consideration also should be given to defining 'health effect' side of the relationship drawn from existing definitions in The Guidelines since the health effect or endpoint varies according to the type of health claim.

For example, for the purposes of a:

Nutrient function claim, 'health effect' refers to the physiological role of the nutrient in growth, development and normal functions of the body.

Other function claim, 'health effect' refers to specific beneficial effects on normal functions or biological activities of the body.

Reduction of Disease Risk claim, 'health effect' refers to reduced risk of developing a disease or health-related condition.

4 Evaluation of scientific evidence used to support a health claim

This section should be structured according to the Step-by-Step process with provision of additional guidance under each of the steps. A separate section should follow detailing a simplified substantiation process for nutrient function claims (as currently given in the last 2 paragraphs of Section 5).

4.1 Nature and quality of the evidence

The section on nature and quality of the evidence could be captured under Steps 3 and 4. This section should be divided into nature of evidence and quality of evidence.

Nature of evidence: Consistent with Australia's support for a wide range of exposure variables, the evidence base should include observational studies. Australia does not regard observational evidence as a special case (Section 4.2), rather that it is complementary to human intervention trials for certain types of health effect particularly those related to disease reduction. The 2nd dash point of section 4.2 in relation to observational evidence should be transferred to Section 4.1. We support the statements made about animal models and *in vitro* studies.

The second dash point has been applied to intervention trials only and relates to the strength of acceptable evidence consistent with the WHO grade of 'convincing'. Australia supports nominating a strength of evidence such as 'convincing' under Step 1 to ensure similar standards are applied to the evidence base in support of claims on foods that are traded internationally. The third dash point refers to the totality of the evidence and should be discussed under Step 5.

Quality of the evidence: This section could be expanded to include criteria relating to: study type, study design, study population, characterisation of the 'property', outcome measures, data collection and statistical analysis as documented in previously submitted comments to this agenda item.

4.2 Special cases

This section is not needed if an alternate simplified substantiation process is outlined for nutrient function claims (as currently given in the last 2 paragraphs of section 5).

4.3 Scope of the evidence

The intent of Section 4.3.1 should be incorporated into elaboration of Step 2.

4.3.2 Specific safety concerns

Consideration of safety concerns is separate from consideration of the totality of evidence to substantiate a health claim. It relates to paragraph 7.2 in The Guidelines that refers to decisions on the eligibility of foods to carry the health claim, as well as to paragraphs 7.4.4 and 7.4.5 on advice to vulnerable groups and possible maximum safe levels of intake of the food or constituent. Governments should apply a risk analysis approach to determine whether safety considerations would restrict the range of foods that are eligible to carry the claim under Step 7 (see next section). It is not necessary to detail the safety considerations in this Annex as jurisdictions would apply their own approach to risk analysis.

5 Step-by-step process

Australia regards the inclusion of a Step-by-Step process as an essential component of the Recommendations. However, it might be useful to divide Step 6 into two:

- Step 6 Assessment of the totality of evidence according to selected standard of evidence for substantiation; and
- Step 7 Determining the circumstances under which the claim is substantiated for the target population.

Assessment of the totality of the evidence will indicate the overall circumstances associated with the food or with the population studied that must be in place for the claimed relationship to be substantiated. Factors to

consider under Step 7 are the relevance of the property of the food to the population's diet, including when the component is administered in a particular food matrix. A particular consumption amount may also be necessary before the claim can be substantiated. Also, relationships may have been substantiated only for particular population groups, characterized by factors such as age (e.g. studies may have included only those over the age of 45 years), gender (e.g. women only), lifestyle (e.g. in association with an exercise regime), health status (e.g. only those with elevated blood pressure) and ethnicity (e.g. Caucasians only).

6 Re-evaluation

The first and last sentences in this section are contradictory. In view of Australia's support for regular review, we believe that the last sentence should be deleted.

C Other comments

Biomarkers

Australia notes that the Committee previously considered that the use of biomarkers would need further consideration (paragraph 28, agenda paper). Australia considers that the definition of all three types of health claim could accommodate well-established biomarker endpoints as the health effect.

We support text such as that provided by the United States in relation to biomarkers.

Biomarkers might be used as an indicator or predictor of a disease or health-related condition or as an indicator of a body function. A relevant biomarker would be a well-defined and validated biological, physiological, clinical or epidemiological indicator for which there is agreement among the qualified scientific community on the relationship between the biomarker and the disease.

BOLIVIA

3. DEFINITION:
Hereinafter, the phrase "property of a food" ~~or the term "'property"~~ is used to cover energy, nutrients, biologically active substances or components, ingredients~~, and any other feature~~ or constituents of a food on which the health claim is based. This language may also be applied, where relevant, to a whole diet, as the diet itself may be assigned a common property of some of the individual foods making it up. (Translator's note: In the Spanish version "~~constituyen "~~ should be replaced by [componen]).

Justification
We suggest deleting the cancelled wording in order to clarify the interpretation of the definition.

4.2. SPECIAL CASES:
Although a high quality of scientific evidence should always be maintained, substantiation may take into account specific situations, such as:

- Health claims bearing on fully recognized functions of nutrients ~~and for~~ published in clinical studies in the scientific literature.
- ~~The totality of evidence may only comprise observational evidence, particularly for health claims involving a diet/food group/whole food - health effect relationships~~
  [The scientific basis of health claims may comprise observational evidence, particularly for health claims involving a diet/food group/whole food - health effect relationship]

Justification

Bolivia requests that the use of observational evidence be an additional instrument complementing the criteria laid down in 4.1 and that evidence should not be sufficient to substantiate the approval of a health claim. Therefore, a new wording is proposed.

– 'Nutrient function' claims may be substantiated based on generally accepted ~~authoritative~~ [authorized] information that has been verified and validated over time.

6. RE-EVALUATION:
Health claims should be re-evaluated, after a ~~certain~~ period of ~~time~~ 5 years ~~(possibly every 5-10 years)~~ or following the emergence of significant new evidence that has the potential to alter previous conclusions about the food - health relationship. In view of the frequency with which new evidence might emerge, a review may be unnecessary if the new evidence is unlikely to change the claim. ~~Health claims should be re-evaluated only if new evidence calls into question the scientific validity underpinning the claim.~~

Justification
We believe that a health claim re-evaluation period should be laid down in the standard and we accept the proposed period of 5 years.

We request that the last sentence of the paragraph be deleted, as it contradicts the spirit of the text according to which health claims are to be re-evaluated at regular intervals.

BRAZIL

1. PREAMBLE
No comments

2. SCOPE
No comments

V. CX/NFSDU 06/28/7 – Proposed Draft Recommendations on the Scientific Basis of Health Claims

3. DEFINITION:
Hereinafter, the phrase “property of a food” or the term “’property” are used to cover energy, nutrients, biologically active substances or components, ingredients, and any other feature or constituent of a food on which the health claim is based. This language may also be applied, where relevant, to a whole diet, as the diet itself may be assigned a common property of some of the individual foods making it up.

Observations: The phrase “This language may also be applied, where relevant, to a whole diet, as the diet itself may be assigned a common property of some of the individual foods making it up” needs to be more clear, considering that the proposal of the current document is to be an annex to the document CAC/GL 23-1997, Rev. 1-2004 - Codex Guidelines for the use of nutritional and health claim, which in its scope it deals with the use of the declarations of health property in the label and advertising material.
In the item 2.2 of the same document, the definition of declaration of health properties does not make reference to total diet of the population, but to the food or the specific food constituent.
A health claim about the total diet in the label of a specific product can take the consumer to a equivocation, confusion or mistake, because a food separately does not contemplate all the requirements for a healthful feeding. So, we request to clarify in which context the use of a claim on total diet applies in the scope of this norm.
To exemplify, it would be possible to use a claim about a Mediterranean diet in the label or advertising material of a olive oil, once these food compound these diet? This question needs to be clarified.

4. EVALUATION OF SCIENTIFIC EVIDENCE, USED TO SUPPORT A HEALTH CLAIM:

4.1. NATURE AND QUALITY OF THE EVIDENCE:
The following criteria should be applied:
– All health claims should be based on evidence provided by well-designed human intervention (clinical) studies. Animal model studies, and in vitro studies, ~~etc~~… may be provided as supporting knowledge base for the property–health effect relationship but should never be considered as sufficient per se to substantiate any type of health claim.
– Evidence based on human intervention (clinical) studies should demonstrate a consistent association between the property and the health effect, with little or no evidence to the contrary.
– The totality of the evidence should be reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous
or unclear.

Proposal: Brazil proposes to change the word “etc” to “and other kinds of studies”, in view of the maintenance of writing style of the Codex Alimentarius documents.

4.2. SPECIAL CASES:
Although high quality of scientific evidence should always be maintained, substantiation may take into account specific situations, such as:
– Health claims bearing on fully recognized functions of nutrients and for which reports on clinical studies have been published in the scientific literature.
– The totality of evidence may only comprise observational evidence, particularly for health claims involving a diet/food group/whole food – health effect relationships.
– ‘Nutrient function’ claims may be substantiated based on generally accepted authoritative information that has been verified and validated over time.

Observations: Brazil requests clarifications about the paragraph "The totality of evidence may only comprise evidence, particularly will be health claims involving diet/food group/whole food - health effect relationships", in view of the same comments already cited in item 3 and the fact of when the studies already had proven the beneficial relation among some types of diet and the health of the population.

5. STEP-BY-STEP PROCESS
It is possible to broadly outline a process for substantiation of health claims by national competent authorities that takes into account the general principles for substantiation. Such a process would typically include the following steps:
1. Identify the standard of evidence for substantiation and other policies for health claims.
2. Identify the proposed relationship between the food property, and the health endpoint for
a health claim.
3. Identify appropriate measurements for the property and the health endpoint.
4. Identify and categorise all the evidence.
5. Assess and interpret the evidence, study-by-study.
6. Evaluate the totality of the evidence across studies and determining if, and circumstances, a claimed relationship is substantiated.

Observations: Brazil instituted a Technician-scientific Commission of Advising in Foods with Functional Properties Claims, formed by academy members with knowing in the area, which subsidizes the governmental body in the evaluation of the scientific studies directed by the private sector. We noted that the functional properties and or health claims when evaluated by specialists of the academic area with the governmental body confers exemption and greater scientific severity in its analysis.

In order to substantiate a ‘reduction of disease risk’ claim, which offers the highest ‘degree of promise’ in the Codex Guidelines, a rigorous step-by-step evaluation of the available evidence should be required according to the outline given above.

Although stringent standards of scientific evidence should always be maintained, substantiation may be achieved through simplified processes for categories of claims with a lower ‘degree of promise’.

Observations: Brazil requests that the two paragraphs above are re-written to facilitate its interpretations or that the term ‘degree of promise' is defined for this norm.

One could also use consensus reports or evidence-based dietary guidelines, providing that these reports/guidelines are: prepared by an authoritative body; meet high scientific standards; are relevant to the claim; are relevant to the population in question; and are up-to-date.

Proposal: Brazil suggests to add to the end of the last paragraph the recommendation of that the functional properties and or health claims must come followed of a phrase aiming at to clarify the consumer that the product by itself is not responsible for all the benefits proportionate by a healthful feeding.

Brazil adopts the following phrase: the claim phrase approved followed of ‘…, since associated to an balanced feeding and healthful life habits.

6. RE-EVALUATION:
Health claims should be re-evaluated, after a certain period of time ~~(possibly every 5-10 years)~~ or following the emergence of significant new evidence that has the potential to alter previous conclusions about the food - health relationship. In view of the frequency with which new evidence might emerge, a review may be unnecessary if the new evidence is unlikely to change the claim.
Health claims should be re-evaluated only if new evidence calls into question the scientific validity underpinning the claim.

Justification: Brazil proposes to exclude the text above between parentheses “(possibly every 5-10 years)”, because the definition of the stated period must be in charge of each country.

GUATEMALA

Comments of Guatemala				Justification
Document in English		Document in Spanish		
Page	Text	Page	Text	
14 4.1	(clinical) studies must be changed by: published clinical studies in prestige journals and/or scientific magazines	13 Point 4.1 (first paragraph)	*Modify the wording "por estudios (clínicos)"* **so that it reads** *"por estudios clínicos publicados en revistas científicas de prestigio".*	If the studies on which health claims are based have already been published this fact underpins their validity and reliability.
NA	NA	13 Point 4.1 (third paragraph)	**Replace** the word "alega" **by** "declara" so that the paragraph reads as follows: "Debe someterse a revisión la totalidad de la evidencia, incluyendo: la evidencia que respalda el efecto que se declara; la evidencia que contradice el efecto que se declara; y la evidencia ambigua o poco clara".	The word "declara" is more understandable for semantic reasons.
NA	NA	14 Point 4.2	Add the word "que" after: "a propósito de las" so that the paragraph reads as follows: "Declaraciones de propiedades saludables que se refieren a funciones de nutrientes plenamente reconocidas a propósito de las **que** ya se han publicado estudios clínicos en la literatura científica."	Language and grammar
NA	NA	14 4.2	Change the word "autoritativa" into: "autorizada por un organismo competente".	In order to make clear what is meant and for linguistic and semantic reasons.
NA	NA	15 Point 5 – number 6	Replace the word "alega" **by** "declara"	For semantic reasons; "declara" is more understandable".
14	To change: "degree of promise" by "degree of certainty"	15 Point 5	Modify the wording "grado de promesa" into "grado de certeza".	It is not possible to promise that a disease risk be reduced. We are of the opinion that for reasons of subjectivity and interpretation of the sentence "degree of promise" should be replaced by "degree of certainty".

KENYA

4.2 SPECIAL CASES:
Although high quality of scientific evidence should always be maintained, substantiation may take into account specific situations, such as:
- Health claims bearing on fully recognized functions of nutrients and for which reports on clinical studies have been published in the scientific literature.

_Kenya proposes to modify the statement as follows; the totality of evidence may only comprise observational evidence, particularly for health claims involving a diet/food group/whole food - health effect relationships, over generations.

NEW ZEALAND

New Zealand continues to support the inclusion of health claims that apply to whole diets in the scope of these recommendations.

New Zealand supports the use of the term 'property of a food' as a term to cover energy, nutrients, biologically active substances or components, ingredients, and any other feature or constituent of a food on which the health claim is based. We feel this term is more encompassing than the term 'food or food constituent'. 'Property of a food' as defined in this drafting would cover claims such as glycemic index claims which we feel would not be covered by the term 'food or food constituent'.

We note the term 'biologically active substance' does not appear to be defined by Codex and recommend a definition is given for this term if it is to be used in the definition of 'property of a food'.

New Zealand agrees with the approach taken at this drafting to ensure only safety issues directly related to claims be included in the scope of these recommendations. We reiterate our suggestion in comments on CL2005/56-NFSDU that the use of warning labels be considered in conjunction with the safety assessment and the implications for vulnerable populations viewed in light of the safety assessment.

New Zealand is supportive of the step-by-step process for substantiation of health claims and the revised recommendations proposed in the current drafting. We agree evidence for all health claims should be substantiated using studies on humans and that other types of evidence only be used in support of the evidence provided by studies on humans and that relevant evidence should refer to the totality of evidence including evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.

New Zealand supports adding the proposed draft recommendations as an appendix , at the end of the current Guidelines for Use of Nutrition and Health Claims and the change in the title of the Proposed Draft Recommendations in line with this.

New Zealand comments on the Proposed Draft Annex to the Codex Guidelines for Use of Nutrition and Health Claims: Recommendations on the Scientific Basis of Health Claims are as follows:

1. Preamble
New Zealand agrees with the change in drafting to reference other relevant Codex guidelines rather than restating large parts of relevant guidelines in these recommendations.

2. Scope

New Zealand agrees with the scope proposed in CX/NFSDU 06/28/7. We suggest the word 'in' needs to replace the word 'by' in the second line of the last paragraph. Thus the sentence would then read "They are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out in other Codex Standards and Guidelines…"

3. Definitions
New Zealand does not believe the term 'biologically active substance is defined in Codex. We believe that if this term is to form part of the definition of 'property of a food' that this term must itself also be defined. In the Australia New Zealand Food Standards Code biologically active substance is defined as 'a substance, other than a nutrient, with which health effects are associated'.

We suggest the wording of the last sentence be changed to read "This language may also be applied, where relevant, to a whole diet, as the diet itself may be assigned a common property of some of the individual foods comprising the diet".

4. Evaluation of Scientific Evidence, Used to Support a Health Claim:

4.1 Nature and Quality of the Evidence
New Zealand agrees with the change in wording from 'shall' to 'should' in this drafting as it more accurately reflects the status of the document as recommendations.

4.3 Scope of the Evidence

4.3.2 Specific Safety Concerns
We suggest changing the words 'other constituents' in the first sentence of this section to the words 'other factors'. We also recommend that the words 'and the risk managed to acceptable levels' be added to the end of the first sentence. This sentence would then read, "When the claim is about a food constituent, the amount should not expose the consumer to health risks and the known interactions between the constituent and other factors should be considered and the risk managed to acceptable levels".

This would capture interactions between a food constituent and other factors e.g. medications, rather than just food constituent : food constituent interactions. In New Zealand we have recently had a situation where a constituent added to a food to give a health benefit has been found to nullify the effect of a common medication and thus pose a serious risk to those people taking that medication and also consuming the product. We feel it is important that such interactions are captured by these recommendations.

5. Step by Step Process
New Zealand is supportive of the step by step process outlined in the current drafting.

In step 2 we recommend replacing the term 'health endpoint' with the term 'health effect' to maintain consistency in drafting of these recommendations.

We suggest step 4 is reworded to read "Identify and classify all the evidence for the proposed relationship".

We suggest the last paragraph could be reworded as follows "Consensus reports or evidence based dietary guidelines could also be used providing that these reports /guidelines are:…" for consistency in tone.

6. Re-evaluation
New Zealand is supportive of the approach taken to re-evaluation in the current drafting. We recommend the term 'food property' replaces the term 'food' and that the term 'health relationship' be changed to 'health effect' to maintain consistency in the drafting of these recommendations.

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

The United States would like to thank the French delegation for preparing this latest revision of the draft recommendations. We are pleased that some progress has been made on this document, and offer additional comments that we hope will contribute to further progress.

Scope and Nature of Recommendations.
The United States agrees that these recommendations should be read in conjunction with the *Codex General Guidelines on Claim*s and the Codex *Guidelines for Use of Nutrition and Health Claims.* Accordingly, we support France's proposal to place these recommendations as an Annex to the Codex *Guidelines for Use of Nutrition and Health Claims.*

Moreover, to enhance these recommendations' usefulness to governments, we support France's proposal that these guidelines focus on elaborating a concise set of principles, and on identifying the common steps and logical sequence in substantiating health claims that are identified in Section 5 (Step-By-Step Process). Accordingly, in the attached table, we offer a few suggestions for grouping related concepts and organizing existing text (as well as new text) in Section 4 under the following headings:

4. EVALUATION OF SCIENTIFIC EVIDENCE USED TO SUPPORT A HEALTH CLAIM
4.1 Nature, Quality, and Scope of the Evidence
4.2 Evaluation of the Total Body of Relevant Evidence
4.3 Special Cases

In the June 2006 revised text, some specificity on the criteria for evaluating studies has been eliminated. We regard some of this information as valuable to make the document useful to governments. These proposed additions are noted in the attached table.

Terminology
To be consistent with the definition of a health claim in the Codex *Guidelines for Use of Nutrition and Health Claims*, we support the use of the phrase "food or food constituent" when referring to the substance of a proposed health claim in lieu of defining new phrases such as "property of a food" or "property" . We do not believe that the latter phrases have the same meaning as a "food or food constituent", and thus are not consistent with the Codex definition of a health claim.

It appears that part of the rationale for proposing new terms is in response to one or more comments that proposed to extend health claims to "whole diets". Consequently, we believe that it may be helpful to clarify in the Scope section that while these recommendations apply to health claims as defined in Section 2 of the *Guidelines for Use of Nutrition and Health Claim*s (i.e., "any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health"), such health claims should take into account how the food or food constituent fits within the context of the total diet (Sec. 2.2.2, 2.2.3 and 7.4.6).

Specifically, the *Guidelines for Use of Nutrition and Health Claims* address the need to consider the total diet context in health claim language in the following provisions:

2.2.2 Other Function Claims- These claims concern specific beneficial effects of the consumption of foods or their constituents, in the *context of the total diet* (emphasis added) on normal functions or biological activities of the body….

2.2.3 Reduction of disease risk claims- Claims relating the consumption of a food or food constituent, in the *context of the total diet* (emphasis added), to the reduced risk of developing a disease or health-related condition.

Example:
"A healthful diet low in nutrient or substance A may reduced the risk of disease D. Food X is low in nutrient or substance A."
"A healthful diet high in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A."

7.4. The following information should appear on the label or labeling of the food bearing health claims:
….
7.4.6 How the food or food constituent fits within the *context of the total diet* (emphasis added).

In summary, we believe that already adopted Codex provisions identify a food or food constituent as the subject of a health claim, but also provide for truthful and non-misleading health claim language that takes into account the context of the total diet.

II. SPECIFIC COMMENTS
Please refer to the attached table.

U.S. SPECIFIC COMMENTS: PROPOSAL FOR REVISED TEXT	Nature of Proposed Revision and Rationale
Note: Bolded text identifies proposed text to be added, with the exception of headings in which shaded text identifies proposed text to be added. Proposed deletions are identified with strikeouts.	
PROPOSED DRAFT ANNEX TO THE *CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS:* RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS (Appendix 2)	We support the proposal that these recommendations be an Annex to the guidelines.
1. PREAMBLE: This Annex should be read in conjunction with the *Codex General Guidelines on Claims* (CAC/GL 1-1979 (Rev. 1-1991)) and the Codex *Guidelines for ~~the~~ Use of Nutritional and Health Claims* (CAC/GL 23-1997, Rev. 1-2004).	Propose minor edits to title
2. SCOPE: These Recommendations are intended for governments, in order to facilitate their own evaluation of health claims, used by the industry. They apply to health claims as defined in Sec 2.2 of the *Guidelines for Use of Nutrition and Health Claims* (i.e., "any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health"). Such health claims should take into account how the food or food constituent fits within the context of the total diet (Sec. 2.2.2, 2.2.3 and 7.4.6). They ~~only~~ address the nature and the quality of the scientific evidence supporting these claims. They include consideration of safety in the evaluation of proposed health claims, but are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Codex Standards and Guidelines or general rules of existing national	Propose clarify that the scope is consistent with the Codex definition of health claim (i.e., claims about a food or food constituent), but that such claims should also take into account the context of the total diet. (Refer to examples in 2.2.3) Propose delete "only" given that they also include safety considerations (see next sentence). Propose add text to encompass

U.S. SPECIFIC COMMENTS: PROPOSAL FOR REVISED TEXT	Nature of Proposed Revision and Rationale
legislations.~~, although~~ However, it is recalled that definite requirements on these matters have to be met and that they do not preclude consideration of specific food safety concerns (see section ~~4.3.2~~ 3).	section on safety considerations. Propose renumber section on safety considerations (see rationale below).
~~3. DEFINITION:~~ ~~Hereinafter, the phrase "property of a food" or the term "'property" are used to cover energy, nutrients, biologically active substances or components, ingredients, and any other feature or constituent of a food on which the health claim is based. This language may also be applied, where relevant, to a whole diet, as the diet itself may be assigned a common property of some of the individual foods making it up.~~	Propose delete this definition section and instead add the bolded text in the second paragraph of Section 2 (Scope) above for consistency with the health claim provisions and terminology in the Codex *Guidelines for Use of Nutrition and Health Claims.*
~~4.3.2.~~ 3. SPECIFIC SAFETY CONCERNS When the claim is about a food or food constituent, the amount should not expose the consumer to health risks and the known interactions between the constituent and other constituents should be considered. The expected level of consumption shall not exceed ~~any~~ relevant upper levels of intake for food constituents. The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population[2] [3] and, where relevant, those for vulnerable population groups. It should account for the possibility of cumulative intake from all dietary sources,~~ when the same constituent is present in several foods~~, and ~~for~~ of nutritional imbalance due to changes in dietary patterns in response to consumers' information laying emphasis on the food or food constituent ~~property~~.	Propose move and renumber Sec. 4.3.2 in June 2006 draft in order to separate safety-related principles from principles for substantiating a proposed claim about a food/food constituent and a beneficial health effect. Propose add "food" Propose edit for clarification. Propose edits for clarification. Propose add "food constitutent"
4. EVALUATION OF SCIENTIFIC EVIDENCE, USED TO SUPPORT A HEALTH CLAIM: After identifying national policies for health claims, the following principles apply to the evaluation of the scientific evidence for a proposed health claim.	 Propose add introductory sentence to refer to the need to first identify national policies

[2] Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Washington, D.C. National Academy Press, 1996. p.8.

[3] European Commission, Scientific Committee on Food. Guidelines of the Scientific Committee on Food for the Development of Tolerable Upper Intake Levels for Vitamins and Minerals. SCF/CS/NUT/UPPLEV/11 Final. 28 November 2000. p.4

U.S. SPECIFIC COMMENTS: PROPOSAL FOR REVISED TEXT	Nature of Proposed Revision and Rationale
	for health claims consistent with Step 1 in Section 5 and with introductory text to the *Guidelines for Use of Nutrition and Health Claims*, and to clarify that this section focuses on *principles* for substantiating health claims.
4.1 NATURE ~~AND~~ QUALITY, AND SCOPE OF THE EVIDENCE The following criteria should be applied in identifying, categorizing, and evaluating relevant studies: – The scientific ~~evidence~~ studies should provide adequate characterization of the ~~property of~~ relationship between the food or food constituent ~~to which~~ and the health effect. ~~is attributed and should ensure that the study groups are representative of the target group.~~ Relevant studies include those that use appropriate measurements for the food or food constituent and health endpoint, that do not have significant study design flaws, and that are applicable to the targeted population for a health claim. Appropriate measurements for a health endpoint may include relevant validated biomarkers such as blood LDL-cholesterol for coronary heart disease. – ~~4.1~~ The totality of the evidence should be identified and reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear. – ~~All~~ Health claims should primarily be based on evidence provided by well-designed human intervention (clinical) studies. A well-designed randomized, placebo-controlled clinical trial may demonstrate a causal relationship between a food or food constituent and health endpoint. Observational studies provide information about an association, but not causation. Animal model studies~~,~~ and in vitro studies~~, etc…~~ may be provided as supporting the knowledge base for the ~~property~~ food or food constituent–health effect relationship but should ~~never~~ not be considered as sufficient per se to substantiate any type of health claim. – The methodological quality of each type of study should be assessed, including study design and statistical analysis. For example, human intervention studies ~~: It~~ should include an appropriate control group, characterize the ~~target~~ study groups' background diet and other relevant aspects of lifestyle, ~~the intake~~	Propose slight revision to heading for 4.1 in June 2006 draft to encompass Steps 3 and 4 in Section 5, and to encompass and expand on the principles in 4.1 and 4.3.1 in the June 2006 draft. Propose edits consistent with Steps 4 and 5 in Section 5. Propose move 1st sentence from 4.3.1 in June 2006 draft and slightly revise. Propose add text to address considerations in identifying relevant evidence, such as the importance of identifying appropriate measurements for both the food/food constituent and health endpoint (including validated biomarkers). Propose move this bullet from section 4.1 in June 2006 draft here and slightly revise so that it addresses the identification of relevant scientific evidence to review. -Propose add "primarily" to first sentence for clarification. -Propose additional text to include observational studies and further distinguish between different types of human studies. Propose slight revision to this sentence.

U.S. SPECIFIC COMMENTS: PROPOSAL FOR REVISED TEXT	Nature of Proposed Revision and Rationale
~~consistent with its intended pattern of consumption~~, ~~the~~ be of an adequate duration.~~ of exposure,~~ and assess the influence of the food matrix and total dietary context on the ~~property~~ health effect. Statistical analysis of the data should be conducted with methods recognized as appropriate for such studies by the scientfiic community and with proper interpretation of "statistical significance".	Propose reinsert principle from previous July 2005 draft to address the assessment of the quality of studies, consistent with the scope of this section. -Propose move text from 4.3.1 in June 2006 draft here with these revisions. Propose reinsert principle pertaining to statistical analysis from July 2005 draft.
4.2 EVALUATION OF THE TOTAL BODY OF RELEVANT EVIDENCE In evaluating the strength of the evidence, consideration should be given to the type, quantity and quality of relevant human studies, and consistency and reproducibility of results. For example: – ~~4.1~~Evidence based on human intervention (clinical) studies should demonstrate a consistent association between the food or food constituent ~~property~~ and the health effect, with little or no evidence to the contrary. Based on this evaluation, a government can determine if, and under what circumstances, a claimed relationship is substantiated, and if so, assess truthful and non-misleading language for the claim.	Propose new subheading to address principles in evaluating the strength of the total body of scientific evidence. This is consistent with Step 6 in Section 5 and with a separate section on this topic that was proposed in the July 2005 draft. -Propose add this principle to provide overview of key considerations in evaluating the strength of the total evidence. -Propose move this bullet from Section 4.1 in June 2006 draft here (with slight revision) since it appears to address evaluation of the strength of the totality of evidence. -Propose new sentence for additional context consistent with Step 6 in Section 5.
~~4.2~~ 4.3 SPECIAL CASES: Although a high quality of scientific evidence should always be maintained, substantiation may take into account specific situations, such as: ~~– Health claims bearing on fully recognized functions of nutrients and for which reports on clinical studies have been published in the scientific literature.~~ – The totality of evidence may only comprise observational evidence, ~~particularly for health claims involving a diet/food group/whole~~	Propose renumber and move Section 4.2 in June 2006 draft here so that it follows discussion of the main principles in evaluating the scientific evidence for health claims (i.e, after Steps 1 through 6 in Section 5). Propose delete this bullet or reword. It appears similar to the next to last bullet on "nutrient function claims"

U.S. SPECIFIC COMMENTS: PROPOSAL FOR REVISED TEXT	Nature of Proposed Revision and Rationale
~~food – health effect relationships.~~ – 'Nutrient function' claims may be substantiated based on generally accepted authoritative information that has been verified and validated over time. – ~~5.~~ One could also use consensus reports or evidence-based dietary guidelines, providing these reports/guidelines are: prepared by an authoritative body, meet high scientific standards; are relevant to the claim; are relevant to the population in question; and are up-to-date.	Propose delete reference to diet/food group/whole food given these recommendations focus on claims about a food or food constituent. Propose include the entire text in last paragraph in Section 5 in June 2006 draft here, although we agree that it is also appropriate to briefly refer to this process in Section 5.
5. STEP-BY-STEP PROCESS It is possible to broadly outline a process for substantiation of health claims by national competent authorities that takes into account the general principles for substantiation. Such a process would typically include the following steps: 1. Identify the standard of evidence for substantiation and other national policies for health claims. 2. Identify the proposed relationship between the food or food constituent ~~property~~ and the health endpoint for a health claim. 3. Identify appropriate measurements for the food or food constituent ~~property~~ and the health endpoint. 4. Identify and categorise all the relevant ~~evidence~~ studies. 5. Assess and interpret ~~the evidence, study by study~~ each relevant study. 6. Evaluate the totality of the evidence across human studies and determine~~ing~~ if, and under what circumstances, a claimed relationship is substantiated. ~~In order to substantiate a 'reduction of disease risk' claim, which offers~~	Propose add "national" to be consistent with the provisions in the Codex *Guidelines for Use of Nutrition and Health Claims* which state in the preamble that "Health claims should be consistent with national health policy, including nutrition policy and support such policies where applicable." Propose add "or food constituent" for consistency in terminology with the Codex *Guidelines for Use of Nutrition and Health Claims.* Propose edits for consistency in terminology. Propose edits to Steps 4 and 5 for clarification and consistency with the principles proposed in Section 4.1.

U.S. SPECIFIC COMMENTS: PROPOSAL FOR REVISED TEXT	Nature of Proposed Revision and Rationale
~~the highest 'degree of promise' in the Codex Guidelines, a rigorous step-by-step evaluation of the available evidence should be required according to the outline given above.~~ ~~Although stringent standards of scientific evidence should always be maintained, substantiation may be achieved through simplified processes for categories of claims with a lower 'degree of promise'.~~ As described in (*new)* Section 4.3, One could also use consensus reports or evidence-based dietary guidelines in special cases, ~~-~~provid~~inged~~ that specific criteria are met. ~~these reports/guidelines are: prepared by an authoritative body; meet high scientific standards; are relevant to the claim; are relevant to the population in question; and are up-to-date.~~	Propose add "human" to modify studies and change "determining" to "determine". Propose delete these two paragraphs. The intended meaning of "degree of promise" is unclear, as well as how this concept relates to national policies for the substantiation standard(s) for health claims. Propose identify this alternative process here, but describe the principles more fully in the section on "Special Cases" above.
6. RE-EVALUATION: Health claims should be re-evaluated, after a certain period of time (possibly every 5-10 years) or following the emergence of significant new evidence that has the potential to alter previous conclusions about the food or food constituent- health relationship. In view of the frequency with which new evidence might emerge, a review may be unnecessary if the new evidence is unlikely to change the claim. Health claims should be re-evaluated only if new evidence calls into question the scientific validity underpinning the claim.	Propose add "or food constituent".

CIAA - Confederation of the food and drink industries of the EU

CIAA acknowledges the importance to prepare guidelines for the scientific basis of health claims. In this respect, CIAA welcomes the re-drafting of the Recommendation and agrees with the principles of this document.

However, CIAA has a few detailed comments to make:

Human intervention studies

Regarding the scientific substantiation of health claims, we consider appropriate to replace all the references to human intervention (clinical) studies with human studies. CIAA considers that as regards the appropriate studies to substantiate a claim, methodological soundness overrides any hierarchy of studies, given that the scientific validity depends not only on the appropriateness of study type but also on the quality of its design, execution and analysis.

In CIAA's opinion, the sources and nature of evidence may be different, but the scientific standard for the process of substantiation of all health claims should be the same. The substantiation of health claims must be carried out on a case-by-case basis and the degree of substantiation and the sources and nature of the

supporting evidence should be proportionate to the type of health claim and take into account the totality of the available evidence and the weighing of the evidence.

Human studies are accorded greater weight than animal and in vitro studies, and human intervention studies have greater weight than observational studies. However, it is important to include text which states that the substantiation of a health claim can be demonstrated on a case-by-case basis by a number of different sources of evidence and types of studies and designs.

Proportionality
Another important aspect missing in section 4.1. is the issue of proportionality. We suggest the following wording here to be inserted as a new bullet point: "The degree of substantiation and the sources and nature of the evidence should be proportionate to the health benefit as expressed in the claims".

We consider that Sections 4.1. and 4.2. should be re-drafted in order to reflect the ideas indicated above.

IADSA - International Allicance of Dietary/Food Sipplement Associations

BACKGROUND
IADSA finds the background section helpful because it sets out clearly the Codex Definition of Health Claims, describes the WHO framework on strength of scientific evidence and the recently published ILSI PASSCLAIM Consensus on criteria for the scientific substantiation of health claims. These summaries help underpin the Codex Recommendations on the scientific basis of health claims and an evidence-based approach**.**

CONSIDERATION OF THE RESPONSES TO THE CIRCULAR LETTER CL 2005/56-NFSDU

The Scope of the Proposed Draft Recommendations:

- Paragraphs 12 & 13
IADSA supports the focus on the elaboration of a concise set of principles to substantiate the three types of health claims.

- Paragraph 22
Having reviewed the various alternative proposals for wording, IADSA agrees that the expression ‘property of a food’ as defined in paragraph 22 is appropriate. IADSA is pleased that the word ‘product’ has been deleted in line with its recommendation.

The Relevance of Safety Concerns: Paragraphs 24–26

IADSA supports the position adopted by the Committee that food safety as such should not be addressed in the proposed draft recommendations, and that the focus should be on the scientific substantiation of health claims.

The Use of Biomarkers: Paragraphs 27–32

IADSA agrees that the use of biomarkers will need further consideration as it is not always possible to identify and define fully validated and predictive biomarkers or endpoints. This approach is particularly important for disease-risk reduction health claims where relatively short-term human intervention studies using biomarkers cannot be used because the disease endpoints may take years to develop.

The Nature and Status of the Scientific Evidence:

- Paragraph 33
IADSA supports the approach that the concept of grades of scientific evidence is a practical and feasible way of reflecting emerging and consensus science, and that the nature of the available scientific evidence will vary with different types of claim. It is essential that each diet and health relationship is assessed on a case-by-case basis within a framework that acknowledges the importance of emerging science to stimulate research and its application in foods and food supplements with health claims.

- Paragraph 37
(2) IADSA is concerned that the emphasis on all health claims being based on evidence from human intervention studies may not be feasible, especially as many of the original health claims were based on observational studies and epidemiological research.

(3) IADSA agrees that animal models and in vitro studies are generally used to provide supporting evidence such as mechanisms of action. The paragraph states that these kinds of studies should never be considered per se as sufficient to substantiate any type of health claim. However, in many parts of the world, health claims are already being made on the basis of substantial animal-based research. IADSA recommends that further discussion be made with representatives of those countries where such studies are taken into account, and when the wording of the claim reflects the fact that the evidence is based on animal and in vitro studies.

(4), (5) & (6) IADSA supports an approach that reflects the ILSI PASSCLAIM Consensus Criterion number 6 for the scientific substantiation of a health claim to take into account the totality of the available data and by weighing of the evidence.

- Paragraph 38
IADSA reaffirms its position and supports the text set out under points 1, 2 and 3.

- Paragraph 39
The terminology 'where stringency could be relaxed' gives a poor impression of the nature and quality of the evidence on which a health claim could be based. An alternative text is proposed in which sections 4.1 and 4.2 of the proposed draft annex are combined.

- Paragraph 40
IADSA reaffirms the need to accommodate emerging science and for an approach that reviews the weighing of evidence and the balance of probabilities that the beneficial health effect expressed in a claim is truthful, accurate and not misleading.

The Re-evaluation of Health Claims:

- Paragraph 42
IADSA supports the view that health claims should be re-evaluated if and when new evidence calls into question the scientific validity underpinning the claim. The approach must be on a case-by-case basis and a re-evaluation after a set time period of five or ten years could significantly stifle scientific research, its application and communication. The process of scientific discovery evolves over time and it is one in which new data may support and sometimes contradict what is already known.

- Paragraph 45
It is imperative that the use of health claims on foods and food components stimulate, not stifles, academic research and product innovation. For any process of scientific discovery, it is essential to reflect emerging as well as consensus science with the use of appropriately worded claims.

Title and Status of the Proposed Draft Recommendations:
Paragraphs 46–50

IADSA agrees that it is appropriate to add the proposed draft recommendations on the scientific basis of health claims as an Appendix at the end of the current Guidelines for Use of Nutrition and Health Claims.

APPENDIX 1. REFERENCES

Please note that the 7th reference by Richardson et al. (2003) listed in Appendix 1 is repeated further down the list.

APPENDIX 2. PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS: RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS

3. DEFINITIONS
IADSA supports the use and the definition of 'property of a food'.

4. EVALUATION OF SCIENTIFIC EVIDENCE USED TO SUPPORT A HEALTH CLAIM

4.1 & 4.2 NATURE AND QUALITY OF THE EVIDENCE & SPECIAL CASES:

IADSA is concerned that the proposed criterion to have all health claims based on evidence provided by well designed human intervention (clinical) studies is neither feasible nor practical from a scientific point of view. Additionally, in relation to human intervention studies, in IADSA's view the apparent restriction in the draft text to '(clinical)' studies is inappropriate in the context of this proposal because the emphasis throughout is on the review and weighing of the totality of the available evidence. IADSA therefore asks that the references to '(clinical)' in the context of human intervention studies be removed from the text of the draft proposal. Moreover, IADSA considers that the current texts of sections 4.1 and 4.2, and paragraph 39 of the background notes, give the impression that the nature and quality of the scientific evidence from epidemiological studies and other supporting evidence is weaker, and hence the criteria for substantiation of health claims could be less stringent or be relaxed.

In IADSA's opinion, the sources and nature of the evidence may be different, but the scientific standard for the process of substantiation of all health claims should be the same. The substantiation of health claims must be carried out on a case-by-case basis and the degree of substantiation and the sources and nature of the supporting evidence should be proportionate to the type of health claim and take into account the totality of the available evidence and the weighing of the evidence.

Human studies are accorded greater weight than animal and in vitro studies, and human intervention studies have greater weight than observational studies. However, it is important to include text which states that the substantiation of a health claim can be demonstrated on a case-by-case basis by a number of different sources of evidence and types of studies and designs, and that methodological soundness overrides any hierarchy of studies, given that scientific validity depends not only on the appropriateness of study type but also on the quality of its design, execution and analysis.

In Section 4.2, the first and third bullet points both refer to 'fully recognised function of nutrients' and 'generally accepted authorisation information that has been verified and validated over time', respectively. The difference between these two situations is not clear. However, a key point is that, as well as 'nutrient function', there are many other 'other function claims' or claims for 'other substances' (i.e. a substance other than a nutrient that has a nutritional or physiological effect) and that claims for these substances may also be substantiated using generally accepted authoritative information that has been verified and validated over time.

In view of the points described above, IADSA suggests the following combined text to replace Sections 4.1 and 4.2:

"The following criteria should be applied:

- All health claims must be capable of substantiation based on the totality of the available evidence and weighing of the evidence on a case-by-case basis.

- The scientific standard for the process of substantiation of all health claims should be the same, although the sources and nature of the evidence may be different.

- Sources of scientific evidence includes generally accepted authoritative information that has been verified and validated over time, human intervention studies, human observational/epidemiological studies, animal and in vitro studies and traditional knowledge and experience of use.

- Studies on human subjects are accorded greater weight than animal and in vitro studies, which are used to provide supporting evidence for dose-responses, mechanism of action etc. Human intervention studies have greater weight than observational studies. The scientific validity of an individual study depends on the appropriateness of the study type and on the quality of its design, execution and analysis, including statistical interpretation.

- The totality of the evidence should be reviewed including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear. Where there are inconsistencies in the evidence, it is important to establish whether there is a plausible explanation. Selective presentation of evidence depending on whether or not it supports the claim is not acceptable.

- The degree of substantiation and the sources and nature of the evidence should be proportionate to the health benefit as expressed in the claim."

4.3 SCOPE OF THE EVIDENCE:

4.3.1 Identification of the property – health effect relationship

IADSA notes that the text in this section mixes the key point about adequate characterisation of the property of the food with one of the design criteria of the study. Hence, IADSA suggests the following text:

"The property of the food to which the health effect is attributed should be adequately characterised.

The design of the study should include the following: study groups that are representative of the target group, appropriate controls, an adequate duration of exposure, an intake consistent with its intended pattern of consumption, characterisation of the target group's background diet and other relevant aspects of lifestyle and the influence of the food matrix and dietary context of the property."

4.3.2 Specific safety concerns

IADSA suggests that two further references be included in addition to numbers 8 and 9:

"1. FAO/WHO (2006). A model for establishing upper levels of intake for nutrients and related substances. Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment, Geneva, Switzerland, 2–6 May 2005. Published 30 June 2006.

2. Food Standards Agency (2003). Safe Upper Levels for Vitamins and Minerals: Expert Group on Vitamins and Minerals. London: FSA, Aviation House, 125 Kingsway."

5. STEP-BY-STEP PROCESS

- First paragraph

IADSA suggests that on the first step the words 'and other policies' are deleted. The focus should be on the process for the scientific basis of health claims. Hence, the text should read as follows:

"1. Identify the standard of evidence for substantiation of health claims."

6. RE-EVALUATION

IADSA reaffirms its comments on paragraphs 42 and 45 and recommends that the words 'after a certain period of time (possibly every 5–10 years)' are deleted.

ISDI - International Special Dietary Foods Industries

ISDI acknowledges the importance to prepare guidelines for the scientific basis of health claims. The possibility to have a scientific basis for putting health claims on dietetic products is important to provide relevant information to consumers.

In this respect, ISDI appreciates the efforts made in redrafting this recommendation & generally supports the content of this document.

Besides, ISDI believes that valuable information included in the background paper could be added as an addendum to the *"Proposed draft Annex to the Codex Guidelines of nutrition and health claims: Recommendations on the scientific basis of health claims"*.

Such information would be the references to existing papers:

- Richardson DP *et al.* 2003 (PASSCLAIM) 2x
- Aggett PJ *et al.* 2005 (PASSCLAIM)
- US Dept of Health etc.
- Richardson DP 2005
- WHO 2004

WSRO - World Sugar Research Organisation

WSRO support the proposed draft recommendations on the scientific basis of health claims provided there is added rigour in the terminology used in section 4.1 (nature and quality of the evidence) of the document, in order to reinforce the high level of scientific evidence required to substantiate a claim.
It is suggested to replace the sentence
'*Evidence based on human intervention (clinical) studies should demonstrate a consistent association between the property and the health effect, with little or no evidence to the contrary.*'
with
'*Evidence based on human intervention (clinical) studies should demonstrate that the preponderance of evidence shows intake is directly and causally associated with a biologically significant benefit, which outweighs potential negative effects.*'

There is a need to clarify exactly what instances would warrant this high level of substantiation being relaxed in section 4.2 (special cases) of the document.
It is suggested to replace the sentence
'*Although high quality of scientific evidence should always be maintained, substantiation may take into account specific situations*'
with
'*Although high quality of scientific evidence should always be maintained, substantiation may take the following 3 specific situations into account*'

It should also be indicated in the text that observational evidence may be used as evidence <u>only</u> for health claims involving a diet/food group/whole food – health effect relationships.