codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/NFSDU 05/27/9-Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS AT STEP 4

- ***Comments at Step 3 –***

Comments from:

ARGENTINA
AUSTRALIA
BOLIVIA
BRAZIL
MEXICO
NEW ZEALAND
REPUBLIK OF KOREA
UNITED STATES OF AMERICA

CIAA - Confédération des industries agro-alimentaires de l'UE
IADSA – International Alliance of Dietary/Food Supplement Associations
ICBA – International Council of Beverages Associations
IFCGA – International Federation of Chewing Gum Associations
ILSI – International Live Sciences Institute
ISDI – International Special Dietary Foods Industries

ARGENTINA

1. PREAMBLE

Paragraph 2
"Claims should be prohibited if they cannot be substantiated."
Argentina suggests adding the term "saludable" after the word "propiedades" (applicable to Spanish version only). Further, we believe that they wording of the phrase in the translation into Spanish is not appropriate, as it places more emphasis on the prohibition than on the need to demonstrate the integrity. Therefore, the wording would be as follows: "Quedan prohibidas aquellas declaraciones de propiedades saludables cuya veracidad no pueda ser probada."

Paragraph 6
"The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities."
Argentina suggests changing the wording so that it is clearer, considering that maintaining a varied and balanced diet should not be modified by the inclusion of foods with health claims.
The proposed drafting is as follows: "The impact of health claims on changes in the eating habits of the target population and consumers and dietary patterns should be monitored, in general, by competent authorities."

2. SCOPE:

Paragraph 1
"The following recommendations are intended for governments, in order to facilitate their own evaluation of health claims, used by the industry."
Argentina proposes the amendment of the text considering the provisions under 7.1.2 of the "Draft Guidelines for Use of Health and Nutrition Claims".
We suggest that the paragraph be drafted as follows: "The following recommendations are intended for governments, in order to facilitate their own evaluation of health claims, those accepted or recognized as acceptable by the competent authorities of the country of sale."

Paragraph 2
"They are only concerned with the nature and the quality of the scientific evidence alleged to support these claims."
We suggest changing the current wording considering that the proposal lays down the general criteria that products should meet (such as maximum level of consumption, item 4.2, paragraph 3).
The proposed wording is as follows:
"They are concerned with the product characteristics alleged to support these claims, with emphasis on the nature and the quality of the scientific evidence."

4.1 IDENTIFICATION AND STABILITY OF THE PRODUCT:

Paragraph 2
"When the claim is about a constituent or the ingredient of a food, evidence shall be provided that the constituent or the ingredient, with the specific function, is present and bioavailable in a quantity and in a form needed to justify the claim throughout the shelf life of the food stored under the conditions indicated on the label."
Argentina suggests replacing "toda la duración" by "vida útil" – which is the appropriate translation considering the internationally used terminology (applicable to Spanish version only).

Paragraph 3
"Scientifically validated analytical methods should be available to verify the quantity or the activity of the constituent in the food."
We propose to change the wording by adding "and if possible (or if appropriate) its bioavailability", given the importance of knowing what percentage of the nutrient (mineral and/or vitamin) is absorbed by the body versus the analytical quantity added to the product, e.g. the bioavailability of the calcium or iron present in a food will depend, among other factors, on the matrix containing them, the type of food, the form of release, etc.
The wording of the paragraph would be as follows:

"Scientifically validated analytical methods should be available to verify the quantity or the activity of the constituent in the food and, if possible, its bioavailability."

4.2 ADDITIONAL SAFETY REQUIREMENTS

We suggest changing the title of this section by replacing the term "etiquetado" by "inocuidad", which is the appropriate translation (applicable to Spanish version only).

Paragraph 3

"The expected level of consumption shall not exceed any relevant internationally recognized level of safe intake (e.g. ADI, if an ADI has been set), for any constituent present in the food."

We suggest changing the paragraph taking into account the fact that safe levels of intake are established by JECFA.

The wording of the paragraph should be as follows:

"Levels of intake should be established in accordance with JECFA criteria given that not always is there agreement on the levels. If they have not been established because they are unknown, health claims regarding the constituent shall not be accepted".

Paragraph 4

"In assessing risk, typically, the exposure (or intake) assessment should be based on an evaluation of the distribution of usual total daily intakes of the substance for the general population, and include consideration of the vulnerable population groups."

In this paragraph we suggest specifying the vulnerable population groups or those at risk, clarifying which is referred to, by adding "(including young children, pregnant women, the aged, celiacs, people with intolerance, etc)" at the end of the paragraph.

Wording proposed:

"In assessing risk, typically, the exposure (or intake) assessment should be based on an evaluation of the distribution of usual total daily intakes of the substance for the general population, and include consideration of the vulnerable population groups (including young children, pregnant women, the aged, celiacs, people with intolerance, etc) ."

Paragraph 5

"The risk from a change in the dietary pattern of the consumer, triggered by the emphasis on the product, resulting in its excessive consumption, leading to nutritional imbalance."

We suggest changing the wording as follows:

"The risk from a change in the dietary pattern eating habits of the consumer, triggered by the emphasis on the product, resulting in its excessive consumption, leading to nutritional imbalance should be assessed."

Paragraph 7

"Cumulative intake risks in a situation where the same constituent is present in several foods.

Simulations to assess the potential risks of excessive consumption shall; as far as possible, be conducted by the appropriate methods."

We suggest amending this paragraph due to its lack of specificity; and the appearance of potential risks owing to excessive consumption should be avoided. We propose that the product should not exceed 50% of the recommended daily intake.

Therefore, we suggest the following wording:

"It is stated that the maximum level of the constituent according to which the functional claim is made, and depending the expected consumption of the food in the target population, shall not exceed 50% of the Recommended Daily Intake if it is a nutrient."

Paragraph 8

"The expected/foreseeable adverse effects on the vulnerable population groups (including infant, young children and pregnant women…) shall be considered."

We suggest specifying the population groups at risk, by adding "(including young children, pregnant women, the aged, celiacs, people with intolerance, etc)" at the end of the paragraph and deleting "infants" form the bracketed phrase. We suggest an assessment of whether this type of products is intended for them

Suggested wording:

"The expected/foreseeable adverse effects on the vulnerable population groups (including young children, pregnant women, the aged, celiacs, people with intolerance, etc) shall be considered."

Paragraph 9
"Where appropriate, other issues may be considered: for instance, the consumption by populations outside the target group, the excessive consumption, the shift of the nutritional balance by the increased consumption of some foods, replacing others, the short-term adverse effects, the introduction of new risky behaviours, …."
We suggest changing the text by adding "Depending on the constituent, where deemed appropriate, a population monitoring programme will be necessary." Factors such as "excessive consumption" and "short-term adverse effects", among others, are issues that shall be considered, rather than remain optional.
Proposed wording:
"Where appropriate, other issues may be considered: for instance, the consumption by populations outside the target group, the excessive consumption, the shift of the nutritional balance by the increased consumption of some foods, replacing others, the short-term adverse effects, the introduction of new risky behaviours, …. Depending on the constituent, where deemed appropriate, a population monitoring programme will be necessary"

5.1 GENERAL REQUIREMENTS:

Paragraph 2
"The scientific quality of a study should be based on several criteria including the study type, study design, study population, outcome measures, data collection (e.g., dietary assessment method), and statistical analysis."
Argentina suggests replacing "dietary assessment" by "assessment of dietary change studies, such as biomarkers or biochemical parameters", in accordance with the definition of biomarkers in 5.2, paragraph 2.
Proposed wording:
"The scientific quality of a study should be based on several criteria including the study type, study design, study population, outcome measures, data collection (e.g., dietary assessment method assessment of dietary change studies, such as biomarkers or biochemical parameters, in accordance with the definition of biomarkers), and statistical analysis."

7. RE-EVALUATION:

Paragraph 1
"Health claims shall be re-evaluated, as soon as new findings are available that affect the underlying science of the nutrient/effect relationship and/or one of the assumption used during the initial evaluation, on the basis of which the use of the claim has been authorised."
The phrase "as soon as (…) are available", which suggests establishing a maximum time frame in which all aspects should be re-evaluated (e.g. 5 years), should be changed.

Paragraph 5
"The expected effects and, if appropriate, its adverse effects, which may appear after a long-term consumption of the food, shall be investigated."
We suggest deleting the words "if appropriate", as they should be assessed previously.

AUSTRALIA

General comment
As noted in response to CX/NFSDU 04/9 in 2004, this document summarises the key issues involved in substantiating health claims on foods and forms a sound basis for further development of recommendations on the scientific basis of health claims. Australia supports the majority of changes made to the document since 2004.

Specific Comments

Preamble
The Preamble combines material drawn from two separate Codex guidelines in the one set of dot points, with reference to the *Codex Guidelines for Use of Nutrition and Health Claims* being presented under the material that relates to the *Codex General Guidelines on Claims*. For clarity purposes it may be better to have a separate set of dot points for each of these documents, or to refer to both of them in the leading sentence.

Some of the material from each of these Guidelines is similar and may not need to be restated (for example, dot points 2 and 5 are very similar in intent).

Scope

Australia notes that the proposed draft recommendations do not provide a great deal of detail and focus primarily on principles to be applied. While this is suitable for member countries that have some experience in this area, there may need to be further detail available for member countries that are not experienced in assessing the scientific basis of health claims.

In addition, it is not only governments who will use these Guidelines (as stated in paragraph 1). Reference to industry use should be included.

Australia notes that the fourth paragraph advises that many of the recommendations also apply to the evaluation of health claims when they are about a food group. However, Australia considers that some of the recommendations may not be feasible in relation to foods or food groups and suggests that, where a different evidence base may be appropriate for a food or food group compared to a food component, this should be identified at the appropriate point of the document. Examples of where this could be done are provided below.

The third paragraph of this section contains a reference to section 2.2. As there is no section 2.2, this should be corrected; presumably it is meant to refer to section 4.2. This paragraph could perhaps be reworded for clarity as:

"The recommendations are limited to the evaluation of the nature and quality of the scientific evidence used to support health claims. They do not encompass the assessment of safety and quality of products, except where considerations of safety are required as a result of exposure to constituents and changes in dietary consumption patterns (see Section 4.2)."

Format

Australia suggests that some consideration be given to the layout of the document to improve readability. For example, section 4.2 be placed after sections 5 and 6, as it is not possible to fully address these safety issues without having first decided whether or not a claim is substantiated and the appropriate foods bearing the claim selected.

It is recommended that the word "shall" be replaced with "should" throughout the document as the latter is less definitive and indicates that recommendations are not mandatory.

There is no reference in the paper as to what the acronym ADI stands for.

Section 4.1 Identification and stability of the product

This section begins by requiring information on "specifications for the product (including the processing method) … as relevant. This product should meet the Codex standards and/or specifications". Australia is not aware that processing method specifications exist, and information on processing method will not always be relevant to the evaluation of a health claim. It would also be useful to clarify what is meant by reference to "origin" in the first dot point. Does it refer to factors such as country of origin, plant or animal origin etc?

If section 4.2 is moved later in the document, a separate section 4.1 is no longer required. The title of section 4 could then become "NATURE OF THE PRODUCT ON WHICH THE CLAIM IS BASED".

Either in this section or in the current section 5.1, it may be worthwhile including some text to indicate that the product identified in section 4.1 is the same product that is the subject of the evidence examined in section 5. If the product is not the same, an assessment should be made of whether or not it is appropriate to extrapolate the evidence to this product.

Section 4.2 Additional safety requirements

As already noted, it is recommended that this section be placed after the current section 6. It is also suggested that the section could be divided into two – one part relating to food safety and the other to nutritional considerations.

In the first dot point, for clarity it could be reworded as:

"Where a constituent or ingredient is added to a food, the amount of the constituent or ingredient should not expose the consumer to health risks."

Australia suggests that, in the second dot point, the word "mentions" be replaced with "adequately assessed".

The third dot point should indicate that this applies only in the case of a food constituent, not a food or group of foods.

Australia queries whether or not the 4th dot point relates to safety assessment or to efficacy assessment. This point may need to be reworded to clarify its intent. If it is intended to refer to a consideration of the potential exposure of the target population as well as of the general population, then it could be incorporated into dot point 4 as follows:

"In assessing risk, the exposure (or intake) should be assessed by evaluating usual total daily intakes of the substance in the general population, in the product's target population and in any potentially vulnerable population groups."
The 5th and 6th dot points could be rewritten for clarity as one dot point as follows:
"The nutritional safety shall also be considered when evaluating health claims, taking into account:

- the risk from a change in the behaviour of the consumer, that could be triggered by the emphasis on the product;
- the population or subpopulation that is the target of the claim and the consistency of the population or subpopulation with the effects alleged by the claim; and
- any other relevant considerations."

The last paragraph in section 4.2 seems to have been covered by previous dot points within this section.

Section 5.1 General requirements
At the end of the third paragraph it may be worthwhile to stress that relevant evidence includes evidence that supports the proposed claim, evidence that contradicts it and evidence that is equivocal. This is mentioned later in section 6 but inclusion earlier in the document may help to reinforce the concept.
It may also be worthwhile to state at the end of this section that evidence needs to be assessed on a case-by-case basis and requires the application of scientific judgement.

Section 5.2 Nature of the scientific evidence on the claimed effect
Australia recommends that it be stated explicitly in this section that evidence derived from studies of humans is required, regardless of whether the claim is a risk reduction or other health claim. Australia does not consider that *in vitro* and animal studies are sufficient, on their own, to substantiate a health claim.
In the fourth dot point, it is suggested that the words "up-to-date" be inserted before "consensus reports".
Australia suggests that the four evidence types identified in dot points be re-ordered to put the highest level (clinical interventional studies) first, then epidemiological evidence.

Section 5.2.1 General requirements
Australia suggests that the introductory sentence should state "In order to provide statistically significant results that are relevant to a population:" as it is not only statistical significance that is important when assessing evidence. The evidence should determine that the outcome is relevant clinically or on a population health basis. Rewording of this sentence would then support the retention of the second dot point.
Reference to 'dose' should be replaced with a term such as 'intake' or 'amount', as dose is a term associated with therapeutic products rather than foods.
The third dot point has no relevance to whether or not a result is statistically significant. It should perhaps be placed in the section relating to safety considerations. In addition, it may be necessary to clarify what is meant by the term 'habitual consumers'.

Section 5.2.2 Specific requirements
As noted earlier, Australia considers that there are times where specific evidence requirements for claims based on foods or diets may need to be different to those for components of foods. For foods and diets, it is less likely that there will be human intervention trials available to support a claim, particularly blinded, placebo-controlled studies, due to the difficulty of undertaking such studies with whole foods or diets. It would therefore be worthwhile to provide more detail on requirements for claims based on foods or diets. For example, observational evidence is likely to be much more relevant in this case and reference should be made to the different strength of evidence that is provided by different types of observational studies (e.g. prospective cohort studies generally provide stronger evidence than case control or ecological studies).
Australia notes that the advice, under "Other types of health claims" that, if a sub-population is specifically targeted, there should be evidence derived from studies of that sub-population, is equally relevant to reduction of disease risk claims.
As noted earlier, Australia does not believe that animal or *in vitro* studies are sufficient on their own, or as the primary evidence base to substantiate health claims in the absence of limited human evidence, as is implied under the heading "Other types of health claim".
In general, Australia believes that more detail should be provided on the different substantiation requirements for "nutrient function", "other function" and "reduction of disease risk". For example, it may be worthwhile to point out for "nutrient function" and "other function" claims that consensus reports and evidence-based dietary guidelines (as identified in section 5.2) may be particularly relevant for these claims.

Section 5.3 Relevance of the evidence at population level
The meaning of this section is unclear. If it is assumed that this section refers to the need for an assessment of potential dietary intakes of the product across the population, the following text could be considered: "Consideration should be given as to whether or not the amount of a product required in order to achieve the identified health outcome, could be consumed among populations outside the setting of an intervention trial. As part of this process, an exposure assessment should be undertaken to evaluate the distribution of usual total daily intakes of the substance for the general population and for any specific target groups for the product."

Section 6 Evaluation of the total body of scientific evidence used to support a health claim
It is suggested that a dot point be included in this section that an assessment should be made of the strength of evidence supporting a relationship (convincing, probable etc). It is further suggested that the definitions used by the World Health Organisation[1] may be appropriate. Australia considers this is necessary to provide clear guidance on the overall standard of evidence required to support claims.
Under the proposed nutrition and health claims standard for Australia and New Zealand, claims that do not refer to a biomarker or a serious disease (essentially those claims that are "nutrient function" or "other function" claims), will not require regulatory agency pre-approval. We suggest that scope for this approach be outlined in the recommendations.

Section 7 Re-evaluation
Australia supports the concept that the evidence associated with a health claim on a food be re-evaluated after a certain period of time (possibly every 5 – 10 years) or following the emergence of significant new evidence. However we question the suggestion that claims be re-evaluated "as soon as new findings are available" as this is unlikely to be feasible due to the frequency with which new evidence emerges, and may be unnecessary if the new evidence is unlikely to change the claim.
Australia also queries the need for the second dot point in this section as it implies that the regulatory agency should conduct such studies rather than industry.

Suggested additional material
The document should also indicate that it will usually be necessary to identify the circumstances under which a claim is substantiated, as part of the evaluation process. For example it may be necessary, based on the evidence evaluated, to identify the specific foods for which a claim is relevant, or the specific chemical form of a constituent or the minimum levels of a constituent in foods before a particular claim can be substantiated.

BOLIVIA

In addition to the comments on the text, BOLIVIA asks for clarification of the following points:

2. SCOPE - no reference to section 2.2

6. EVALUATION OF THE TOTAL BODY OF SCIENTIFIC EVIDENCE, USED TO SUPPORT A HEALTH CLAIM;
- □ What type of risk analysis does this refer to?
- □ What is meant by "state-of-art ..."?

APPENDIX 1

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS at Step 3

1. PREAMBLE:

The Codex General Guidelines on Claims (CAC/GL 1-1979 (Rev. 1-1991)) states, notably, that:

[1] World Health Organization 2003, *Diet, nutrition and the prevention of chronic diseases*, Report of a Joint WHO/FAO Expert Consultation, WHO Technical Report Series No. 916, WHO, Geneva.

- □ No food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect[2].
- □ Claims should be prohibited if they cannot be substantiated[3].
- □ In addition, the Codex Guidelines for Use of Nutrition and Health Claims[4] state that:
- □ Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable.
- □ Health claims should be supported by **QUALIFIED SOURCES WHICH PRESENT** a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education.
- □ The impact of health claims on consumers' eating behaviors and dietary patterns should be monitored, in general, by competent authorities.
- □ Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.

7. RE-EVALUATION:

HEALTH CLAIMS SHALL BE RE-EVALUATED SCIENTIFICALLY BY A GROUP OF QUALIFIED EXPERTS, RECOGNISED BY COMPETENT AUTHORITIES.

Health claims shall be re-evaluated, as soon as new findings are available that affect the underlying science of the nutrient/effect relationship and/or one of the assumptions used during the initial evaluation, on the basis of which the use of the claim has been authorized. With this aim in view:

- □ A new evaluation is necessary in case of any change affecting the characteristics of the food likely to influence the claimed effect.
- □ Studies shall be conducted to increase the knowledge on the benefit for health of the food, the substance or the ingredient.
- □ The consumption of the products, bearing a health claim, shall be monitored **BY THE COMPETENT AUTHORITY** in order to evaluate the actual levels of consumption and ensure that the pattern of consumption, as it is documented, is appropriate to provide the expected benefit, specifically for the population group targeted by the claim.
- □ The expected effects and, if appropriate, its adverse effects, which may appear after a long-term consumption of the food, shall be investigated.
- □ **SHOULD ADVERSE EFFECTS BE DETECTED, CORRESPONDING WARNINGS HAVE TO BE DISSEMINATED ON A LARGE SCALE AND IN A CONTROLLED WAY THROUGH THE MECANISMS OF THE COMPETENT AUTHORITY.**

BRAZIL

3. DEFINITION:

Hereinafter, the word "product" covers a food, a food group, a constituent of a food (nutrients, other constituents), on which the health claim is based.

Comments: We suggest standardization of the terms used in the whole document text.

4. NATURE OF THE EVIDENCE PROVIDED ON THE CHARACTERISTICS OF THE PRODUCT, ON WHICH THE CLAIM IS BASED:

4.1 IDENTIFICATION AND STABILITY OF THE PRODUCT

Comments: we suggest including after "including the processing method…" the reference to "contaminants analyses"

Justification: this inclusion is necessary since the level of contaminants on food, product or constituent can be modified regarding the origin or processing method on above levels of established safe limits.

[2] See CAC/GL 1-1979 (Rev. 1-1991) – Section 1 "SCOPE & GENERAL PRINCIPLES" § 1.2.4

[3] See CAC/GL 1-1979 (Rev. 1 – 1991) – Section 3 "PROHIBITED CLAIMS"

[4] See ALINORM 94/27/22 Appendix II, PREAMBLE

4.2 ADDITIONAL SAFETY REQUIREMENTS:
Comments: to include the term "taken into consideration" on the sentence below which will have the following writing "The known interactions between the constituent or ingredient, on which the claim is based, with other constituents shall be *taken into consideration* and mentioned".
Justification: the inclusion of this term intends to assure that this interaction may be considered in all steps of the product safety analyses.
Comments: we suggest changing the sentence: "Simulations to assess the potential risks of excessive consumption shall; as far as possible, be conducted by the appropriate methods" for "*Whenever possible*, simulations to assess the potential risks of excessive consumption shall be conducted by the appropriate methods"
Justification: it isn't that the appropriate methods must not be applied as far as possible, but the simulations done throughout these methods.

5.2 NATURE OF THE SCIENTIFIC EVIDENCE ON THE CLAIMED EFFECT:
Comments: to change the second item for: "Observational or correlation epidemiological studies in humans".
Justification: Since there are two kinds of epidemiological studies, the observational and the intervention we suggest the text correction.
Comments: to add in the third item the word "human" after interventional.
Comments: to change in the fourth item the word "all" for "any".

MEXICO

In the preamble, we propose modifying the second bullet - "Claims should be prohibited if they cannot be substantiated" - as follows: "Claims must be substantiated in order to be admissible".

Last bullet of section 4.1:
We propose adding, at the end of the sentence, the wording "according to applicable Codex Standards".

NEW ZEALAND

As a general comment we recommend replacing the word "shall" with "should" as this reflects the guideline status of the document.

Preamble and Scope:
The Preamble refers to other Codex Guidelines that are relevant to these recommendations and while this is important information, in its current form it tends to confuse the reader as to the actual purpose and focus of the recommendations. We believe that this section is unnecessary in the recommendations. Some of the information in the preamble could be reworded and be included in the Scope.
We propose a modification to the proposed wording in the Scope to reflect that the potential audience and usefulness of the recommendations may be broader than governments alone:
The following recommendations are intended to assist in the evaluation of health claims used by industry
We propose the following or similar wording for the rest of the Scope:
These recommendations provide guidance for the evaluation of all health claims in food labelling and, where required by authorities having jurisdiction, in advertising.
Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable.
These recommendations should be read in conjunction with the Codex General Guidelines on Claims and the Codex Guidelines for Health and Nutrition Claims.

These recommendations outline the key principles for consideration in the evaluation of health claims but focus on the nature and quality of scientific evidence submitted in support of the claims.

Definition:
We believe that the recommendations would benefit from including the definition of "health claim" from the Codex Guidelines for Health and Nutrition Claims within the definitions section.
We also recommend that the Definition section should be more specific in particular to distinguish between a food, food group and a constituent of a food.

A food or food group should refer to a group of product in its final form as a result of combining ingredients. A constituent of a food refers to those nutrients that are contained within the food or food group in its final form. This distinction should be made clear in order to make a better assessment of the strength of evidence and so that it can be determined whether studies should be conducted on the product as a food or food group or on the constituent of the food.

Additional Safety Requirements
Warning labels should be considered in conjunction with the safety assessment and implications for vulnerable populations viewed in light of the safety assessment.

General Requirements
This section needs to clearly outline that the relevant evidence refers 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.

Nature of the Scientific Evidence of the Claimed Effect
New Zealand supports that evidence from human studies be required as the evidence to support a claimed effect, regardless of whether the claim is a risk reduction or other health claim

Evaluation of the total body of scientific evidence used to support a health claim
New Zealand supports recommendations relating health claims that are not considered as biomarker or serious disease claims ie function claims that in New Zealand and Australia will not require agency pre-approval.

Re evaluation
New Zealand supports the concept of re-evaluation of health claims after a period of time but the practicalities of re-evaluation on the basis of new or as soon as new findings emerge is not a realistic approach.

REPUBLIK OF KOREA

Title
This proposed draft recommendations was prepared in order to establish the scientific criteria for the substantiation of health claims and accordingly the contexts focused mostly on efficacy rather than safety and quality at the request of CCFL. Therefore, the Republic of Korea agrees that the current title of these proposed draft recommendations is appropriate. We believe, however, that the "Guidelines for the Evaluation of the Scientific Evidence on Health Claims", which cover every detailed issue on safety, efficacy, and quality all together on the basis of this and other related documents, needs to be established later.

3. Definition
In Sections 4 and 5, the texts seem to apply not only "a constituent" but also "an ingredient". The Republic of Korea considers that the term of "an ingredient" should be inserted in definition as follows:
Hereinafter, the word "product" covers a food, a food group, a constituent or an ingredient of a food.

4. Nature of the evidence provided on the characteristics of the product, on which the claim is based
The Republic of Korea is in favor of the format of the section 4 and 5. Identification and safety issues (Section 4) shall take precedence over efficacy issues (Section 5).

4.2 Additional safety requirements:
The Republic of Korea proposes to replace "ADI" with "UL" in dot 3. The term "ADI" has not been extensively used in nutrient risk assessment.

5.2 Nature of the scientific evidence on the claimed effect:
The Republic of Korea considers that it is not always possible to identify a mechanism. For instance, although there is a significant scientific agreement on the role of soy protein in reducing the risk of coronary heart disease (CHD), exact action mechanisms cannot not be explained. Therefore we suggest inserting the term "as relevant" at the end of second paragraph as follows:

The biochemical and physiological mechanisms explaining the beneficial effect on health are either elucidated or explicable with a sufficient degree of certainty in the current state of knowledge, as relevant.

5.2.2 Specific requirement

The Republic of Korea understands that this section is intended to specify the requirements for the scientific justification of health claims and to be used in conjunction with the Health Claims document by the Codex Committee on Food Labeling in Appendix 2. Therefore we agree that the requirements for the scientific justification of "reduction of disease risk claims" should be introduced separately with that of other types of health claim. Similarly, there is a need to split "other types of health claim" into "other function claims" and "nutrient function claims" in order to be consistent with the work of CCFL.

The Republic of Korea also supports the idea that reduction of disease risk claims shall be based on a hierarchy of evidence, in which human intervention studies are valued highest and other observational epidemiological studies, animal model studies, and in vitro studies are considered as supportive evidences.

In addition, we suggest including another idea that reduction of disease risk claims shall be based on the significant scientific agreement (SSA) among qualified experts by scientific training and experience to evaluate them.

As for nutrient function claims, we consider that it should be applied to the nutrients only which have their own RDAs and shall be substantiated on a broad "generally accepted base" such as current university-level nutrition texts.

Therefore, the Republic of Korea suggests revising this section as follows:

Reduction of disease risk claims shall primarily be based on human intervention studies, having valid design for showing a persistent effect of the food or food ingredient. A well-designed randomized, placebo-controlled clinical trial represents the highest level of evidence to support a health claim. Observational epidemiological studies generally provide evidence that is supportive of an association. Animal model studies, and in vitro studies may be provided as supporting knowledge base for the hypothesis but shall never be considered as sufficient *per se* to substantiate a health claim. Also the reduction of disease risk claim should be validated by the consensus of a significant scientific agreement (SSA) among qualified experts by scientific training and experience to evaluate them.

Other function claims should be based preferably, on the evidence provided by studies of humans, and, if a sub-population is specifically targeted, of this group (including the consumers whose intake of the product is the highest). However, studies of humans may be limited, if animal experimental models or in vitro studies are relevant or sufficiently close to human metabolism.

Nutrient function claims should be applied to the nutrients which have their own RDAs and be based on current, university-level nutrition texts as a possible source of evidence.

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

The United States would like to thank the French delegation for preparing this latest revision of the “Proposed Draft Recommendations on the Scientific Basis of Health Claims”. We are pleased that some progress has been made on this document, and offer additional comments we hope will contribute to further progress. In these comments, we have drawn on our country’s experience with health claims over the past decade, while striving to identify those principles in the evaluation of the scientific basis for health claims that are likely to be universal.

Objectives

We agree with the objective of this document in the preamble, that is:

“The following recommendations are intended for governments, in order to facilitate their own evaluation of health claims, used by industry”.

We further note the provision in the Codex *Guidelines for Use of Nutrition and Health Claims* that:

“Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable.”

Accordingly, throughout the document we generally propose to change “shall” to “should” or “may”, and to use other wording in lieu of “requirements”.

Framework for Health claims to be Addressed

The preamble refers to both the Codex *General Guidelines on Claims* and the Codex *Guidelines for Use of Nutrition and Health Claims*. We agree that these recommendations should generally be consistent with the provisions in these guidelines, and acknowledge differences in how countries define health claims. Accordingly, we recommend that the scope section of this document clarify that these recommendations mainly focus on health claims as defined by Codex (i.e., claims about a relationship between a food or constituent of that food and health), and consider three types of claims (i.e., "reduction of disease risk claims", "nutrient function claims", and "other function claims").

Definitions

We agree with the inclusion of the Codex definitions for the different types of health claims in an appendix to this document, and also suggest that it be referenced in the Definition section.

We further agree it may be helpful for the Committee to consider additional definitions for this document as needed to distinguish between: 1) "a food/food constituent that is the subject of a health claim (or alternatively, a food/food constituent on which a claim is based") and 2) the food(s) that would bear the health claim (which would be influenced by a government's regulatory framework for qualifying and/or disqualifying conditions for eligibility to use a health claim [5]

The latest draft defines "product" to "cover a food, a food group, a constituent of a food (nutrients, other constituents), on which the health claim is based", but other terms such as "substance" are also used. In these recommendations, we believe that "substance" may be a more appropriate term to refer to either a food or food constituent that is the subject of a health claim according to the Codex *Guidelines for Use of Nutrition and Health Claims*. This appears consistent with the Codex Procedural Manual which defines "food" as "any substance which…", and which refers to other food constituents as substances. Accordingly, we recommend revisions to this document to distinguish between the substance that is the subject of the health claim and food(s) that would bear the health claim, and to promote consistency in use of terminology.

Section 5: Scientific Evidence to Support Health Claims

In the attached table, we offer suggestions for grouping related concepts and organizing existing text (as well as new text) in this section under the following headings:

5. SCIENTIFIC EVIDENCE TO SUPPORT HEALTH CLAIMS

- 5.1 Substantiation Standard and Other National Policies for Health Claims
- 5.2 Identification of the Proposed Relationship for a Health Claim
- 5.3 Identification of Appropriate Measurements
  - 5.3.1 Measurement of the Substance
  - 5.3.2 Measurement of Health Endpoints: Disease, Health-Related Condition, or Body Function
- 5.4 Nature, Quality, and Relevance of the Scientific Evidence
  - 5.4.1 Nature of the Scientific Evidence
  - 5.4.2 Quality and Relevance of the Scientific Evidence
- 5.5 Evaluation of the Total Body of Scientific Evidence

II. SPECIFIC COMMENTS

Our proposed revisions are noted in the attached table with rationale.

[5] See Section 7.2, Codex Guidelines for Use of Nutrition and Health Claims. ALINORM 04/27/22 Appendix III

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Note: With the exception of headings, new proposed text is identified below with bolded text. Proposed deletions are identified with strikeouts.	Propose change "shall" to "should" generally throughout document (See rationale in general comments)
Proposed Draft Recommendations on the Scientific Basis **OF HEALTH CLAIMS at Step 3**	Editorial comment: Change "states" to "state"
1. PREAMBLE The Codex General Guidelines On Claims (CAC/GL 1-1979 (Rev. 1-1991)) state~~s~~, notably, that :	Should footnote 1 refer to "§ 1.2" rather than "§ 1.2.4"?
❑ No food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect[6]. ❑ ❑ Claims should be prohibited if they cannot be substantiated[7]. ❑	- Removed indentation - Suggest clarify that bullets below are referring only to the preamble since this document will likely refer to other parts of these guidelines.
In addition, the **preamble to the** Codex Guidelines for Use of Nutrition and Health Claims[8] state**s** that: □ Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. □ Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. □ The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities.	Propose change "Scope" to "Scope and Objectives"
□ Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited. **2. SCOPE AND OBJECTIVES**	Suggest adding this text to clarify and provide an overview of the types of claims that are the main focus of this document.
These recommendations apply to health claims as defined in the Codex 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 constituent of that food and health").[9] They consider the following three types of health claims: "reduction of disease risk claims" "nutrient function claims", and "other function claims".[10]	-Moved this sentence to follow related sentence above. - Suggest add "with regard to" and the sentence in the first bullet to clarify the scope of the recommendations in this document.

[6] See CAC/GL 1-1979 (Rev. 1-1991) -- Section 1 -"SCOPE & GENERAL PRINCIPLES" § 1.2 ~~.4~~

[7] See CAC/GL 1-1979 (Rev. 1-1991) -- Section 3 - "PROHIBITED CLAIMS" § 3.3

[8] See ALINORM 04/27/22 Appendix III, Section 1- PREAMBLE

[9] See ALINORM 04/27/22 Appendix III, Section 1- DEFINITIONS § 2.2

[10] See ALINORM 04/27/22 Appendix III, Section 1- DEFINITIONS § 2.2.3 § 2.2.1, § 2.2.2

[11] 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.

[12] 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 Novermber 2000. p.4

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Many of these recommendations also apply to the evaluation of health claims when they are about a food group. The following recommendations are intended for governments, in order to facilitate their own evaluation of health claims, used by the industry**, with regard to:** ❑ **the nature of the evidence provided on the characteristics of the food or food constituent on which the claim is based, and additional risk assessment criteria useful in the evaluation of health claims.** ❑ ~~They are concerned with~~ the nature and the quality of the scientific evidence [~~alleged~~] to support these claims. They are not intended for the complete evaluation of the safety and the quality of the products, for which other provisions are relevant as laid out by Codex Standards and Guidelines or general rules of existing national legislations, although it is recalled that definite requirements on these matters have to be met and that it does not preclude additional safety considerations (see section [#]). **3. DEFINITIONS** **Appendix [#] identifies Codex definitions pertaining to health claims.** ~~Hereinafter, the word "product" covers a food, a food group, a constituent of a food (nutrients, other constituents), on which the health claim is based.~~ **In addition, for the purpose of these recommendations, hereinafter the word:** **"Substance" generally refers to the [specific] food or food constituent (nutrients, ingredients, other constituents) that is the subject of the health claim.** ***4. NATURE OF THE EVIDENCE PROVIDED ON THE CHARACTERISTICS OF THE ~~PRODUCT~~ SUBSTANCE~~. ON WHICH THE CLAIM IS BASED~~ AND ADDITIONAL RISK ASSESSMENT CRITERIA USEFUL IN THE EVALUATION OF HEALTH CLAIMS:***	-This bullet reflects proposed revised wording of the heading for Sec. 4. -Propose a second bullet for this text and to delete "alleged" -Suggest make "definition" plural. -Propose refer to Codex definitions in Appendix. - We believe that "substance" is a more appropriate term to refer to either a food or food constituent that may be the subject of a health claim according to the Codex Guidelines for Use of Nutrition and Health Claims. A definition of "substance" would also help clarify and promote consistency in use of this term throughout this document. -Propose change "product" to "substance" and delete "on which the claim is based" since latter phrase appears unnecessary with above proposed definition. - Propose add "Additional Risk Assessment Criteria Useful in the Evaluation of Health Claims" to this heading to encompass nature of bullets in second part of Section 4 (i.e. 4.2). -Propose change "product" to "substance" - Propose delete "including processing method". It is unclear how this is relevant to the

[13] National authorities may also have a regulatory framework that prohibits health claims on foods that contain nutrients or other constituents in amounts that increase the risk of disease or an adverse health-related condition. (See Codex Guidelines for Use of Nutrition and Health Claims (ALINORM 04/27/22 Appendix III, Section 7.2),

[14] See ALINORM 04/27/22 Appendix III, Section 1- PREAMBLE

[15] ALINORM 04/27/22 – Appendix III & ALINORM 04/27/41 – para. 51

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4.1 IDENTIFICATION AND STABILITY OF THE ~~PRODUCT~~ SUBSTANCE:	evaluation of health claims, and if relevant, it would be covered by "other specifications".
❑ Information on the origin, nature, composition, and other specifications ~~(including the processing method)~~ of the **food or food constituent on which the claim is based should** ~~product(s) that are proposed to bear the health claim shall~~ be provided, as relevant. ~~The product shall meet the Codex standards and/or specifications, if it is covered by existing Codex texts.~~	- Propose change "shall" to "should". - Propose other minor edits in 2nd and 3rd bullets to simplify language (e.g., "ingredients" is identified as an example of a food constituent in the proposed definition of "substance").
❑ When the claim is about a **food** constituent ~~or the ingredient of a food~~, evidence ~~shall~~ **should** be provided that the constituent [~~or the ingredient~~], with the specific function, is present and bioavailable in a quantity and in a form needed to justify the claim throughout the shelf life of the food stored under the conditions indicated on the label.	
❑ Scientifically validated analytical methods should be available to verify the quantity or the activity of the **food** constituent ~~in the food~~.	- Propose change "Additional Safety Requirements" to "Additional Risk Assessment Criteria Useful in the Evaluation of Health Claims". We believe this heading is more consistent with the nature of the bullets in this section.
4.2 ADDITIONAL ~~SAFETY REQUIREMENTS~~ RISK ASSESSMENT CRITERIA USEFUL IN THE EVALUATION OF HEALTH CLAIMS:	
In addition to the usual risk assessment:	-Propose edits to be consistent with wording of second bullet in 4.1 and the bullet below, and to clarify that that this is referring to the food constituent that is the subject of a health claim.
❑ ~~In case of addition of a constituent or ingredient in the food,~~ **When a claim is about a food constituent, t**he amount ~~shall~~ **should** not expose the consumer to health risks.	
❑ **When the claim is about a food constituent,** the known interactions between the constituent ~~or ingredient, on which the claim is based,~~ with other constituents ~~shall~~ **should** be ~~mentioned~~.**considered.**	Moved this bullet (with suggested edits) to related text in last bullet which addresses the potential increase in consumption of foods bearing health claims.
~~❑ The expected level of consumption shall not exceed any relevant internationally recognised level of safe intake (e.g., ADI, if an ADI has been set), for any constituent present in the food.~~	
❑ In assessing risk, typically the exposure (or intake) assessment should be based on an evaluation of the distribution of usual total daily intakes of the substance for the general population[11] [12], and include consideration of ~~the~~ vulnerable population groups **(including infants, young children and pregnant women).** Cumulative intake risks ~~in~~ **result from** a situation where ~~the same~~ **a** constituent is present in several foods**, in food supplements, and/or in the case of minerals, in water.**. Simulations **may be used** to assess the potential risks of excessive consumption, **and should** ~~shall; as far as possible,~~ be conducted by the appropriate methods.	- Combined 2 separate bullets related to estimating total exposure (or intake) of the substance into one bullet. -Propose identify examples of vulnerable groups here to eliminate the need for a separate bullet below and reduce redundancy.
❑ The risk from a change in the dietary pattern of the consumer, triggered by the emphasis on the ~~product~~**food(s) that would bear the health claim should be considered. In addition to evaluating potential risk from excessive intake of the substance on which the health claim is based**, **the evaluation may also consider potential risk of** ~~resulting in its excessive consumption, leading to a~~ nutritional imbalance **and excessive intake of other food constituent(s) and food energy.**[13] The ~~expected~~	Propose edits to address additional risk assessment considerations with the potential for increased consumption of foods bearing health claims. We prefer wording to refer to consideration of science-based upper levels of intake for food

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~~level of consumption~~ **evaluation** ~~shall not exceed~~ **should consider, as** ~~any~~ relevant, **science-based** ~~internationally recognised~~ **upper** level**s** of ~~safe~~ intake ~~(e.g., ADI, if an ADI has been set),~~ for ~~any~~ **food** constituent**s.** ~~present in the food.~~ ~~❑ The population, or the sub-population targeted by the product (target group), shall be identified. The selection of this population shall be consistent with the effects of the claim.~~ ~~❑ Cumulative intake risks in a situation where the same constituent is present in several foods. Simulations to assess the potential risk of excessive consumption shall; as far as possible, be conducted by the appropriate methods.~~ ~~❑ The expected/foreseeable adverse effects on the vulnerable population groups (including infants, young children and pregnant women…) shall be considered.~~ ~~Where appropriate, other issues may be considered. : for instance, the consumption by populations outside the target group, the excessive consumption, the shift of the nutritional balance by the increased consumption of some foods, replacing others, the short-term adverse effects, , the introduction of new risky behaviours,… .~~	constituents, as relevant. Moved first sentence (with proposed edits) to Sec. 5 (scientific evidence to support health claims). The need for studies to be applicable to the targeted population for a health claim is also addressed in Sec. 5. Moved these two sentences (with proposed edits) to the bullet above which addresses estimation of total exposure (or intake) of the substance. Propose delete this bullet because it appears redundant with the above bullet on methods for assessing risk, especially if the examples of vulnerable groups are provided. Propose delete this text. It appears redundant with above bullets and/or is not specific. ***NOTE: BELOW ARE SUGGESTED REVISIONS FOR SECTIONS 5 AND 6 (INCLUDING SOME ADDITIONAL TEXT AND REORGANIZING OF EXISTING TEXT) WE PROPOSE TO FOCUS ON GENERAL PRINCIPLES IN THE REVIEW OF SCIENTIFIC EVIDENCE TO SUPPORT HEALTH CLAIMS, AND TO GROUP RELATED CONCEPTS. FOR THIS SECTION WE IDENTIFY NEW TEXT IN BOLD (EXCEPT FOR HEADINGS), AND SHOW SOME BUT NOT ALL CHANGES TO THE EXISTING TEXT.*** -Propose change "Scientific Requirements about the Claimed Effect" to "Scientific Evidence to Support Health Claims" - Propose new text to provide a guide to the topics to be covered in this section (as reflected in proposed section subheadings).

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5. SCIENTIFIC ~~REQUIREMENTS ABOUT THE CLAIMED EFFECT~~ EVIDENCE TO SUPPORT HEALTH CLAIMS	Propose move most of the existing text under 5.1 (General Requirements) to these subheadings.
The review of the scientific evidence to support a health claim typically includes the following: o **Identification of the substantiation standard and other national policies for health claims** o **Identification of the proposed relationship for a health claim** o **Identification of appropriate measurements** o **Nature, quality, and relevance of the scientific evidence** o **Evaluation of the total body of evidence**	New subheading - Propose replace first sentence with bolded text in second paragraph below to be consistent with the wording for substantiation of health claims in the Codex Guidelines on the Use of Nutrition and Health Claims.
5.1 SUBSTANTIATION STANDARD AND OTHER NATIONAL POLICIES FOR HEALTH CLAIMS ~~A high level of quality of the scientific justification for the claimed effects is obligatory for using any health claim. The level of scientific justification shall be sufficient to support the claimed effect; but that the substantiation requirements may differ depending whether the health purported claim is a "nutrient-function" claim, and "other-function" claim or a "reduction-of disease risk" claim.~~	- Propose replace second sentence with bolded text in first paragraph below, to among other things, identify initial considerations in governments' review of the scientific evidence for health claims.
National policies should be identified that are applicable the review of the scientific evidence for a health claim. These include the definition of a health claim (e.g., the scope of health endpoints that are included), the substantiation standard (e.g., "significant scientific agreement", "weight of the evidence"), and general requirements for a food to be eligible for a health claim.	New subheading -Moved 1st sentence from 5.2 -Moved 2nd sentence from 4.2
Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, and provide truthful and non-misleading information[14].	Propose new text
5.2 IDENTIFICATION OF THE PROPOSED RELATIONSHIP FOR A HEALTH CLAIM	Propose new subheading and section to focus on appropriate measurements
The proposed relationship between ~~product~~ **the substance** and health endpoint (e.g., disease, health-**related** condition, or body function) should **first** be identified. The population, or the sub-population targeted by the ~~product (target group)~~ **claim** ~~shall~~ **should also** be identified.	Moved sentence from 5.2
This preliminary assessment may serve as a basis for identifying prohibited health claims (e.g., if the claim is about treatment of a disease), and for selecting studies to evaluate a health claim.	Propose new text
5.3 IDENTIFICATION OF APPROPRIATE MEASUREMENTS	
Appropriate measurement, of both the substance and health endpoint is a key factor in the review of data for health claims.	New subheading
5.3.1 <u>Measurement of the Substance</u> **Identifying the effect of the substance that is the subject of a health**	Propose new text

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claim is an important consideration in the evaluation of a health claim. Without evidence that the specific substance *per se* is responsible for the benefit, the relationship between the substance and a disease, health-related condition or body function cannot be established. **In determining whether a substance that is the subject of a health claim has been measured appropriately, it is important to critically evaluate the method of assessment of dietary intake.**	Moved text on biomarkers from Sec. 5.2 and revised to shorten, bring in concept of validation, and provide an example.
5.3.2 <u>Measurement of Health Endpoints: Disease, Health-Related Condition, or Body Function</u>	Revised 5.2 heading
The disease state, health-related condition or specific body function that is affected by the substance should be identified. **Biomarkers may 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 is 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 one of the three health endpoints (e.g., LDL-cholesterol concentration is a relevant biomarker for coronary heart disease).**	Moved text from 5.1 to this new 5.4 with suggested edits to provide an introductory paragraph to this section. New subheading
5.4 NATURE, QUALITY, AND RELEVANCE OF THE SCIENTIFIC EVIDENCE	-Propose delete this sentence.
The scientific evidence ~~shall~~ **should** be derived from study results, either already published in scientific literature, or conducted by the applicant in order to substantiate the alleged claim. All relevant scientific evidence for the evaluation of a health claim should be identified. These include studies that use appropriate measurements **for the health claim being evaluated**, that do not have significant study design flaws, and that are applicable to the targeted population for a health claim.	-Reordered bullets to begin w/ interventional studies and follow organization of discussion below.
5.4.1 <u>Nature of the Scientific Evidence</u>	Slightly revised paragraph under 5.2.2 to apply to both "reduction of disease risk" and "body function" claims, because we believe that the statements apply to both.
~~As appropriate, supporting scientific evidence along one or more of the following approaches shall be used.~~ Possible types of scientific evidence include: ❑ human interventional studies complying with the requirements established by ethical committees. ❑ epidemiological or observational studies of humans ; ❑ *In vitro* studies and animal studies, ~~❑~~ All other pertinent evidence, such as consensus reports and evidence-based dietary guidelines.	Propose add this text to address last bullet in new 5.4.1
~~Reduction of disease risk claims~~ **Health claims** ~~shall~~ **should** primarily be based on human interventional studies, having a scientifically valid design for showing a persistent effect of the ~~food or food ingredient~~ **substance**. A well-designed randomized, placebo-controlled clinical trial represents the highest level of evidence to support a health claim. Observational epidemiological studies generally provide evidence that is supportive of an association. Animal model studies and *in vitro* studies may be provided as supporting **the** knowledge base for the hypothesis but ~~shall never~~ **should not** be considered as sufficient *per se* to substantiate a health claim. **In addition, some consensus reports or evidence-based dietary guidelines may represent appropriate evidence sources to substantiate health**	Re: comments above, propose delete this separate paragraph for "other types of health claims" (i.e., body function claims). New heading Moved text from 5.1

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claims, provided that these reports/guidelines are prepared by an authoritative body and meet high scientific standards and are relevant to the claim and the population in question.	Moved text from 5.1
~~**Other types of health claim** should be based preferably, on the evidence provided by studies in human, and, if a sub-population is specifically targeted, of this group (including the consumers whose intake of the product is the highest). However, studies of human may be limited, if animal experimental models or *in vitro* studies are relevant or sufficiently close to human metabolism.~~	Moved text from 5.1; propose change "trial" to "study" here for consistent terminology in this section. Moved text from 5.2.1
5.4.2 <u>Quality and Relevance of the Scientific Evidence</u> The scientific quality of a study should be based on several criteria including the study type, study design, study population, outcome measures, data collection (e.g., dietary assessment method), and statistical analysis. **These criteria are also applicable to assessing the relevance of a study. For example:**	Moved text from 5.1
□ The scientific study design should be consistent with generally accepted scientific procedures and principles.	Moved this bullet (w/ a few suggested edits) to the section on review of the total body of evidence.
❑ The ~~trials~~ **study** should be designed to test for ~~an~~ **the** association of interest (e.g., by manipulating the intake level of the substance while controlling for other factors that can affect the health endpoint).	
❑ The ~~trials~~ **study** ~~shall~~ **should** include **a** large enough population ~~on~~ **for** a long enough time scale with the relevant dose, in the context of the usual diet of the population under study.	Propose revise to clarify meaning or delete.
□ Statistical analysis of the data ~~shall~~ **should** be conducted with methods recognised as appropriate for such studies by the scientific community to ensure good experimental design (including an appropriate time span), the appropriateness of tests applied and proper interpretation of "statistical significance", i.e. assess both statistical and biological significance.	Retained title but changed numbering to reflect a subheading under Sec. 5
~~□ The trials shall demonstrate that the claimed effect can be achieved by consuming a reasonable amount of the product as a part of the diet.~~	
~~**5.3 RELEVANCE OF THE EVIDENCE AT POPULATION LEVEL:** It shall be required to check that the benefit documented by experimental studies is still present at the level of the target population (general population or sub-group), preferably by simulations based on consumption data.~~	
5.5 EVALUATION OF THE TOTAL BODY OF SCIENTIFIC EVIDENCE, USED TO SUPPORT A HEALTH CLAIM	-Propose new text. 3rd sentence was moved from Sec. 5.2.1
The total body of evidence provided to support the claims, ~~shall~~ **should** be evaluated scientifically by a group of qualified experts, recognised by competent authorities. Their evaluation of the scientific evidence should be consistent with scientific principles and, specifically :	(Changed "…shall demonstrate that the claimed effect" to "…may also address whether the claimed effect")
❑ ~~Shall~~ **Should** take all the available scientific data into account. Compiling the evidence should be done in a balanced and unbiased way to ensure that all relevant data, both positive and negative, have been	New text

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included in the documentation. ❑ ~~Shall~~ **Should** follow the state-of-art norms of scientific methodology. **In evaluating the strength of the scientific evidence, consideration should be given to the type, quantity and quality of relevant studies; and consistency and reproducibility of results. The evaluation should also consider the amount of the substance necessary to justify the claim, and whether there are any health risks at these levels.** The evaluation may also address whether the claimed effect can be achieved by consuming a reasonable amount of the product(s) as a part of the daily diet. **Based on this evaluation, a government can determine whether the evidence meets its substantiation standard(s) and other requirements for a health claim.** **~~7~~ 6. RE-EVALUATION** Health claims ~~shall~~ **should** be re-evaluated, as soon as new findings are available that affect the underlying science of the ~~nutrient/effect~~ **substance/health endpoint** relationship and/or one of the assumptions used during the initial evaluation, on the basis of which the use of the claim has been authorised. With this aim in view: ❑ ~~A new evaluation is necessary in case of any change affecting the characteristics of the food likely to influence the claimed effect.~~ ❑ Studies ~~shall~~ **should** be conducted to increase the knowledge on the benefit for health of the ~~food,~~ the substance ~~or the ingredient.~~ ❑ The consumption of the ~~product(s)~~ **food(s)**, bearing a health claim, ~~shall~~ **may** be monitored in order to evaluate **whether** the actual levels of consumption~~, as it is documented, is appropriate to~~ provide the expected benefit~~, specifically~~ for the population group**(s)** targeted by the claim. ❑ The expected **beneficial** effects and, if appropriate, ~~its~~ adverse effects, which may appear after ~~a~~ long-term consumption of the [food**(s) bearing a health claim**] ~~shall be investigated~~ **should be considered**. APPENDIX 2 CODEX Definitions IN CODEX GUiDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS ADOPTED AT THE 27th session of the Codex alimentarius Commission (Geneva July 2004)[15] ***2. 2* Health claim** means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following: **2.2.1 *Nutrient Function Claims*** - a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body. **Example:** "Nutrient A (naming a physiological role of nutrient A in the body in the	Propose delete this bullet. We believe this is inherent in setting criteria for foods to be eligible to bear a health claim. The proposed definition of substance would include food, ingredients, and other food constituents that are the subject of health claims. Is the intent of this sentence to address long-term consumption of the food(s) that would bear the health claim? Suggested edits reflect wording in the Codex Guidelines for Use of

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maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A." **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 on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health. **Examples:** "Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A." **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, to the reduced risk of developing a disease or health-related condition. Risk reduction 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. **Examples:** " A healthful diet low in nutrient or substance A may reduce the risk of disease ~~B~~ **D**. Food **X** is low in nutrient or substance A" " A healthful diet rich in nutrient or substance A may reduce the risk of disease ~~B~~ **D**. Food **X** is high in nutrient or substance A"	Nutrition and Health Claims.

CIAA - Confédération des industries agro-alimentaires de l'UE

CIAA proposed changes	Justification
General remarks CIAA recommends replacing the word "shall" with "should" throughout the document.	This document is a Recommendation and not a Standard.
1. PREAMBLE: ~~Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.~~	Those claims are already prohibited and therefore, the provision is redundant.
• ~~Health claims shall be consistent with national health policy, including nutrition policy, and support such policies where applicable~~.	Delete this bullet point. These guidelines are intended primarily to foster a level playing field in international trade. Since national health policy and nutrition policy are essentially parochial, they have no place in these guidelines.
2. SCOPE: The following recommendations are intended both for governments, in order to facilitate their evaluation of health claims, ~~used by the industry,~~ and for industry, to help assure that health claims have an appropriate and sufficiently scientific basis.	Self-explanatory

They are only concerned with the nature and the quality of the scientific evidence ~~alleged~~ used to support these claims.	Clarification
They are not intended for the ~~complete~~ evaluation of the safety and quality of the products, for which other provisions are relevant as laid out by Codex Standards and Guidelines or general rules of existing national legislations~~, although it is recalled that definite requirements on these matters have to be met and that it does not preclude additional safety requirements (see section 2.2)~~. Many of these recommendations also apply to the evaluation of health claims when they are about a food group.	Clarification
4. NATURE OF THE EVIDENCE PROVIDED ON THE CHARACTERISTICS OF THE PRODUCT, ON WHICH THE CLAIM IS BASED: **4.1 IDENTIFICATION AND STABILITY OF THE PRODUCT:** ❑ Information on the origin, nature, composition, ~~and other specifications (including the processing method)~~ of the product on which the health claim is based, ~~shall~~ should be provided. This product should meet the Codex standards and/or specifications, if it is covered by existing Codex texts.	<u>Clarify</u> the meaning of "origin", is it country, or source? **Processing methods represent confidential and proprietary information. They are of little, or no, relevance to the claim. As well, there are no processing methods defined within Codex.**
~~❑ Scientifically validated analytical methods shall be available to check the quantity or the activity of the constituent in the food.~~	The methodology used in substantiating a claim should be presented as part the science-based evidence. Consideration of the methodology should, therefore be part of the overall scientific evaluation process. **Furthermore, where a single food company develops a new product, validated methodology may not be available at the time the claim is presented for evaluation.**
4.2 ADDITIONAL SAFETY REQUIREMENTS: In addition to the usual risk assessment: • In case of addition of a constituent or ingredient in the food, the amount recommended to be eaten ~~shall~~ should not	<u>Rephrase</u> to clarify what is meant by the "usual risk assessment". Add "recommended to be eaten". Industry cannot monitor consumption.

expose the consumer to health risks.	
• The known interactions between the constituent or ingredient, on which the claim is based, with other constituents ~~shall~~ should be ~~mentioned~~ adequately assessed.	
• The expected level of consumption ~~shall~~ should not exceed ~~any relevant internationally recognized level of~~ scientifically based safe intake level ~~(e.g. ADI, if an ADI has been set),~~ for any constituent present in the food.	Safe intake levels are determined on a case by case basis using risk assessment approach as described in Codex framework.
• In assessing risk, typically, the exposure (or intake) assessment should be based on an evaluation of the distribution of usual total daily intakes of the substance for the general population or intended subpopulation, and include consideration of the vulnerable population groups.	In certain cases, a product may only be intended for a specific subpopulation.
• The ~~expected/foreseeable~~ potential adverse effects on the vulnerable population groups (including infants, young children and pregnant women…) ~~shall~~ should be considered.	Adverse effects are not always guaranteed.
• The risk from a change in the ~~dietary pattern~~ behaviour of the consumer, that could be triggered by the emphasis on the product~~,~~. ~~resulting in its excessive consumption, leading to nutritional imbalance~~.	Clarification
• ~~The population, or the sub-population targeted by the product (target group), shall be identified~~. The ~~selection of this~~ population or subpopulation that is the target of the claim and the consistency of the population or subpopulation ~~shall~~ should be consistent with the effects alleged by the claim.	
• The ~~C~~cumulative intake risks ~~in a situation~~ where the ~~same~~ constituent that is the subject of the claim is present in several foods. Simulations, using appropriate methods, should be carried out to assess the potential risks arising from ~~of~~ excessive consumption. ~~shall; as far as possible, be conducted by the appropriate methods~~.	
• The ~~expected/foreseeable~~ potential adverse effects on ~~the~~ vulnerable population groups (including infant, young children and pregnant women…) ~~shall~~ should be considered.	
• The trials ~~shall~~ should demonstrate that the product bearing the health claim ~~shall~~ should not have negative nutritional and health	Add this additional bullet point taken from 5.2.1 (General requirements) and rephrase for clarity.

impacts at recommended levels of intake ~~of~~ short-term and habitual consumers.	
5. SCIENTIFIC REQUIREMENTS ABOUT THE CLAIMED EFFECT: **5.1 GENERAL REQUIREMENTS**: ~~A high level of quality of the scientific justification for the claimed effects is obligatory for using any health claim~~ The use of any health claim should be based on sound science. The level of scientific justification ~~shall~~ should be sufficient to support the claimed effect; but that the substantiation requirements may differ depending on whether the health claim is a "nutrient function" claim, an "other function" claim or a "reduction of disease risk" claim.	Clarification
The scientific evidence ~~shall~~ should be derived from study results, either already published in scientific literature, or conducted by the applicant in order to substantiate the alleged claim. The scientific study design ~~shall~~ should be consistent with generally accepted scientific procedures and principles. The weight given to statistical vs. biological importance should be judged on a case-by-case basis.	In general, when making health claims related to broad population groups, biological relevance and statistical significance should both be taken into consideration. However, the weight given to each should be judged on a case-by-case basis, depending on the parameter being evaluated and the overall health claim.
5.2 NATURE OF THE SCIENTIFIC EVIDENCE ON THE CLAIMED EFFECT: The proposed relationship between product and health endpoint (eg. Disease, health condition, or body function) should be identified. Appropriate measurement of both the substance and health endpoint is a key factor in the review of data for health claims. Biomarkers may be used as an indicator or predictor of such a relationship, provided that the relevance of the biomarkers cited are justified to the same standard of scientific rigour. A relevant biomarker is a well-defined biological, physiological, clinical or epidemiological indicator which is modulated by the ingestion of the food or the food constituent or ingredient and for which there is agreement among the qualified international scientific community on the relation between the modulation of this indicator and the state of health of the population in which it is measured. The biochemical and physiological mechanisms explaining the beneficial effect on health are either elucidated or explicable with a sufficient degree of certainty in the current state of knowledge.	Redundant (see the paragraph below)

As appropriate, supporting scientific evidence along one or several of the following approaches ~~shall~~ should be used. Possible types of scientific evidence include: ❑ In vitro studies and animal studies; ❑ Epidemiological or observational studies of humans; ❑ Clinical (human) interventional studies complying with the requirements established by ethical committees; ❑ All other pertinent evidence, such as consensus reports and evidence-based dietary guidelines.	
5.2.1 General requirements: In order to provide statistically significant results, ❑ the trials ~~shall~~ should include ~~large enough~~ statistically valid population on an ~~long enough~~ appropriate timescale with the relevant dose, in the context of the usual diet of the population under study. ❑ The trials ~~shall~~ should demonstrate that the claimed effect can be achieved by consuming a reasonable amount of the product as a part of the daily diet, as recommended by the manufacturer. ~~❑ The trials shall demonstrate that the product bearing the health claim shall not have negative nutritional and health impacts at recommended levels of intake of habitual consumers.~~	Rephrase for clarity. The final bullet point should be moved to Additional Safety Requirements (4.2).
5.2.2 Specific requirements: Other types of health claims, such as nutrient function claims or other function claims, should be based, preferably, on the evidence provided by studies of humans, and, if a sub-population is specifically targeted, of this group (including the consumers whose intake of the product is the highest). However, studies of humans may be limited, -if animal experimental models or in vitro studies are relevant or sufficiently close to human metabolism.	Clarification
~~5.3 RELEVANCE OF THE EVIDENCE AT POPULATION LEVEL:~~ ~~It shall be required to check that the benefit documented by experimental studies is still present at the level of the target population (general population or sub-group), preferably by simulations based on consumption data~~	Submission of scientific evidence for the efficacy of a health claim should include simulated evidence, e.g., consumption estimates showing the benefit that would be expected by the target population. Statement of this requirement is redundant with section 3.1.

6. EVALUATION OF THE TOTAL BODY OF SCIENTIFIC EVIDENCE, USED TO SUPPOER A HEALTH CLAIM: The total body of evidence provided to support the claims ~~shall~~ should be evaluated scientifically by a group of qualified experts, recognized by competent authorities. Their evaluation of the scientific evidence shall be consistent with the scientific principles of risk assessment~~analysis~~.	Risk analysis involves various steps including Risk Assessment, Risk Management and Risk Communication. Only the risk assessment part is relevant here
7. RE-EVALUATION: Health claims ~~shall~~ should be re-evaluated, as soon as new findings are available that affect the underlying science of the nutrient/effect relationship and/or one of the assumptions used during the initial evaluation, on the basis of which the use of the claim has been authorised. With this aim in view: ❑ A new evaluation is necessary in case of any change affecting the characteristics of the food likely to influence the claimed effect. ❑ ~~Studies shall be conducted to increase the knowledge on the benefit for health of the food, the substance or the ingredient.~~ ❑ ~~The consumption of the products, bearing a health claim, shall be monitored in order to evaluate the actual levels of consumption and ensure that the pattern of consumption, as it is documented, is appropriate to provide the expected benefit, specifically for the population group targeted by the claim.~~ ❑ ~~The expected effects and, if appropriate, its adverse effects, which may appear after a long-term consumption of the food, shall be investigated.~~	<u>Delete</u> the four bullet points. <u>Rationale:</u> The first paragraph sufficiently addresses the aim of the section. In addition, in reference to the first point, it should be left to the governments to decide whether there is enough new evidence to necessitate a new evaluation. In relation to the third bullet point, industry cannot ensure compliance with recommendations for intake.

IADSA – International Alliance of Dietary/Food Supplement Associations

1. PREAMBLE
Two issues should be emphasised and included in the preamble:
- Second bullet point
In relation to this provision of the Codex General Guidelines on Claims and linked to it, the following sentence should be included at the end of the preamble:
"Claims should be prohibited if they cannot be substantiated by (generally) accepted scientific knowledge. Any claim should be scientifically substantiated by taking into account the totality of the available data and by weighing the evidence."
Rationale: *The substantiating evidence should be proportionate to the claim and take into account the totality of the available data. The term 'generally accepted scientific knowledge' needs to acknowledge emerging science as well as well established, consensus science. The addition of 'generally accepted*

scientific knowledge' should allow the claim to reflect the nature of the evidence when it is in the public health interest and is relevant to the health of individuals.
The World Health Organisation (WHO) and the World Cancer Research Fund (WRCF) use four grades of evidence: convincing, probable, possible and insufficient. Codex needs to include the concept of grades of evidence with appropriate qualifying language and/or graphical representations to reflect the strength of the evidence, the degree of certainty, or the balance of probabilities that the weight of the evidence between a food or a food component and a health benefit is truthful, accurate and not misleading.
IADSA agrees that health claims should only be authorised after scientific assessment of the highest possible standard and supports the need to accommodate emerging science and to develop a system, depending on the state of the science and history of use, that stimulates academic research, product innovation and the use of sound nutrition communications in a way that consumers can understand and trust.

- Fourth bullet point
In relation to this provision of the Codex General Guidelines on Claims and linked to it, the following sentence should be added at the end of the preamble:
"Health claims should be relevant to the health of individuals and the intended consumers."
Rationale: *There are an increasing number of scientific reports of the effects of foods and food components on body functions and health. There are concerns that a focus only on national health and nutrition policies will exclude several areas of health benefit that may not be set out specifically in national policy. Examples include the scientific research on bone health and osteoporosis, digestive health, eye function, physical and mental performance including cognitive performance, particularly in ageing populations where their social and economic impact is significant. Thus it should be constantly borne in mind that ensuring the health of individuals is the primary motive of bodies reviewing or regulating health claims.*
Substantiated health claims should be used in a wider range of areas of nutritional and health benefit to reflect the scientific research efforts.

2. SCOPE
- Second paragraph
The word 'alleged' should be deleted and replaced with the word 'used' reading there as follows:
"They are only concerned with the nature and the quality of the scientific evidence <u>used</u> to support these claims."
Rationale: *The verb 'alleged' in English is sometimes used in a derogatory context when a low opinion is being expressed. The current phraseology and use of the word 'alleged' appear to present the concept of a health claim being speculative, crude, suspicious and vague.*
The objective is to promote research and product innovation based on a scientific evaluation of the highest possible standard.

3. DEFINITION
Replace the word 'product' by the phrase 'food and food components' throughout the text. Perhaps it would be better to delete the definition section and use the following text under Section 2, Scope.
"Health claims can relate either to a food group, a food or a component of a food (nutrients, ingredients, other constituents)."
Rationale: *The word 'product' is inappropriate in the context of this draft. The Collins Cobuild English dictionary describes a 'product' as something that is produced and sold in large quantities, often as a result of a manufacturing process. Therefore the word 'product' is replaced by the phrase 'food and food components' throughout the text.*

4. NATURE OF THE EVIDENCE PROVIDED ON THE CHARATERISTICS OF THE PRODUCT, ON WHICH CLAIM IS BASED:

4.1 IDENTIFICATION AND STABILITY OF THE PRODUCT
Section 4.1
- First bullet point
Replace the word 'product' with 'food or food component'. This bullet point would therefore read as follows (new words underlined):
"Information on the origin, nature, composition, and other specifications (including processing method) of the <u>food or food component(s)</u> that are proposed to bear the health claim, shall be provided, as relevant. This food or food component should meet the Codex standards and/or specifications, if it is covered by existing Codex texts."

- Second bullet point
Amend as follows (new words underlined):
"Wherever possible, when a claim is made about a food or food component with a specific function, evidence shall be provided that the food or food component is present and bioavailable in a quantity and in a form needed to justify the claim throughout the shelf-life of the food or food component when stored under the conditions indicated on the label."
- Third bullet point
Add the words 'where possible' at the beginning of the sentence reading then as follows (new words underlined):
"Wherever possible, scientifically validated analytical methods should be available to verify the quantity or the activity of the component in the food."
Rationale: *The PASSCLAIM criterion 1 (Aggett et al. 2005) state, "The food or food components to which the claimed effect is attributed should be characterised". However, it is not always possible to know exactly what the bioactive components are, e.g. plant components in fruits and vegetables, wholegrains etc where there may be a combination of bioactives, some identified, others not. A strict requirement for bioavailability will, in many cases, be impossible to achieve.*
Similarly, in many cases, scientifically validated analytical methods may not be available to verify the quantity or the activity of the food component. Hence, the addition of 'wherever possible' is appropriate.

4.2 ADDITIONAL SAFETY REQUIREMENTS

The current draft should be solely deal with scientific substantiation. Additional work on the safety/nutritional safety is being carried out by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) Working Group on Risk Analysis led by Australia.
The text should be modified to be in keeping with the PASSCLAIM 'principles of nutritional safety'.
Add the following words to the introductory sentence 'where appropriate, the following aspects could be addressed'. The sentence would then read as follows (new words underlined):
"In addition to the usual risk assessment, where appropriate, the following aspects could be addressed".
- Second bullet point
Replace the words 'shall be mentioned' by 'shall be included'. This bullet point would therefore read as follows (new words underlined):
"The known interactions between the constituent or ingredient, on which the claim is based, with other constituents shall be included."
- Third bullet point
The text refers only to ADI. As the safe upper levels —SUL, UL etc— are already being set, they should also be included in this sentence.
- Fifth bullet point
Amend as follows:
"Foods with health claims have the potential to influence dietary habits (patterns). The extent of use of a food or food component is important, and health claims that could encourage high levels of consumption should not be made for any substances where there is evidence that excessive intakes of the food or food component could have adverse effects."
- Sixth bullet point
Replace the word 'product' by 'food or food component'. Amend the second sentence of this bullet point by replacing the words, "with the effects alleged by the claim" by "the claimed effects". This bullet point would therefore read as follows (new words underlined):
"The population, or the sub-population targeted by the food or food component (target group), shall be identified. The selection of this population shall be consistent with the claim effects."
Delete at the end the last paragraph of this section as it is vague and meaningless, and it is covered already in previous parts and it open to misinterpretation.

5. SCIENTIFIC REQUIREMENTS ABOUT THE CLAIMED EFFECT:

5.1 GENERAL REQUIREMENTS
- First paragraph
Delete the word 'purported' especially as the whole section refers to the use of high-quality science to justify a claim. In English this word is formal and implies an element of doubt, i.e. it has negative connotations rather like 'alleged'.
Add the following words to the paragraph: "The substantiating evidence should be proportionate to the claim and take into account the totality of the available data and by weighing of the evidence".

- Second and Third paragraphs
Amend this two paragraphs becoming it into one that it would read as follows:
"All relevant scientific evidence for the evaluation of a health claim should be identified. Individual studies should be evaluated for rigor of design, appropriateness of target population methods and procedures, reliability of measures of intake and outcome, sufficient statistical power, strength of conclusions and comprehensiveness of reporting".
- Sixth paragraph
Delete the word 'alleged' and amend the first sentence of this paragraph as follows:
"The evidence shall be derived from generally accepted scientific knowledge either already published in scientific literature or conducted by the applicant in order to substantiate the claim."
Delete the second sentence on study design as it is already covered by the previous points.

5.2 NATURE OF THE SCIENTIFIC EVIDENCE ON THE CLAIMED EFFECT
- Second paragraph
Replace 'food constituent or ingredient' with 'food or food component'.
The second sentence concerning the biochemical and physiological mechanisms should start with the words, 'Where possible'.
Rationale: *Many nutritional health claims to date are based on epidemiological/observational studies in the first place and the elucidation of the actual mechanism(s) may take years or never be fully explained. Often there are several theories on how a particular food category, food or food component works to promote health.*
- Third paragraph
Amend as follows:
"A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence. Possible sources of scientific knowledge and data include*:*
- In vitro studies and animal studies
- Epidemiological or observational studies of humans
- Clinical (human) intervention studies etc.
- All other pertinent evidence, such as consensus reports, authoritative statements, evidence-based dietary guidelines, history of use, traditional use and other reasonable evidence.

5.2.1
- First bullet point
Replace 'dose' by 'amount', as this text refers to foods and food components.
5.2.2
- Reduction of disease risk claims
Disease states take years to develop and most disease risk reduction claims are based on observational/epidemiological evidence. To state that these claims shall be based primarily on human intervention studies that are relatively short term is unachievable and does not reflect current scientific knowledge. Animal models and *in vitro* studies provide knowledge of underlying biological mechanisms. This paragraph should be improved and re-drafted to reflect the above-mentioned concerns.

5.3 RELEVANCE OF THE EVIDENCE AT POPULATION LEVEL
Replace 'shall' by 'may'.
Rationale: *Although observation of the consumers is important, especially if the foods or food components are targeted at particular population groups or sub-groups, this requirement is too restrictive.*

6. EVALUATION OF THE TOTAL BODY OF SCIENTIFIC EVIDENCE USED TO SUPPORT A HEALTH CLAIM
Add the following words at the beginning of this section:
"A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence".
Rationale: *This statement will allow the development of the concept of 'grades of evidence' and the use of appropriate qualifying language or graphical representations (gold, silver and bronze) to reflect the emerging science and using the classifications 'convincing', 'probable' and 'possible'.*

7. RE-EVALUATION
This section requires fundamental discussion to ensure that the goals and means to achieve them are meaningful and practical.
This section needs considerable redrafting. The scope refers only to 'nutrient/effect relationship', not to 'foods and food components'. There is confusion in the use of terminology throughout the text. The final

point refers to 'its adverse effects'. Apart from grammatical errors, the word 'its' should be replaced by 'any'.
APPENDIX 2
It should be made clear in the text that, in many cases, there is an observation of a reduction of risk of disease without demonstrating an effect on a risk factor. The PASSCLAIM initiative has highlighted the fact that there are relatively few fully validated biomarkers.
Consumer research shows that consumers cannot distinguish between the terminologies 'reduction of risk of disease' and 'reduction of a disease risk factor'.
REFERENCES
Ad the following references:

1. Aggett, PJ *et al.* (2005) Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM): consensus on criteria. *European Journal of Nutrition* 44 (1): 1–30.
2. Richardson, DP (2005) The scientific substantiation of health claims with particular reference to the grading of evidence. *European Journal of Nutrition* 44 (5): 319–324.
3. World Cancer Research Fund/American Institute for Cancer Research (1997) Food, Nutrition and the Prevention of Cancer: a Global Perspective. Washington D.C.
4. World Health Organisation (2004) Diet, Nutrition and the Prevention of Chronic Diseases: Report of a Joint FAO/WHO Expert Consultation. Geneva: WHO Technical Report Series 916.

ICBA - International Council of Beverages Associations

General remarks

We suggest replacing the word "shall" with "should" throughout the document to follow the general Codex practice. We suggest considering giving more guidance on the requirements for scientific substantiation based on the three types of claims mentioned in Appendix 2 of the document. The level of data and regulatory requirements generally differ based on the level of the claim.

Title
We suggest considering replacing the word "basis" with "substantiation" so that the title would read "Proposed Draft Recommendations for the Scientific Substantiation of Health Claims" to better reflect the scope of the draft Recommendations and paragraph 7.1.1 of the Guidelines for Use of Nutrition and Health Claims.

2. Scope
In the first paragraph, we suggest adding a footnote after "health claim" to provide a reference to the definition of "health claim" in section 2.2 of the Codex Guidelines for the Use of Nutrition and Health Claims (that now is Appendix 2 of the document CX/NFSDU 05/27/9).
In the fourth paragraph, we suggest adding "when appropriate" after "a food group." The draft recommendations may not be always appropriate for the evaluation of health claims intended for a food group.

3. Definition
We suggest adding "unless otherwise specified" in the end of the sentence to make a difference between a food group and a food or a constituent of a food when appropriate.

4 Nature of the Evidence Provided on the Characteristics of the Product on which the Claim is Based
The title does not reflect the section 4.2 (Additional Safety Requirements) and we suggest either revising the title to include "and Safety" after "the Characteristics" or moving the section 4.2 elsewhere in the document as a separate section or deleting it from the document since it does not -directly relate to the scope of the document.

4.1. Identification and Stability of the Product
We suggest amending "(including the processing method)" by adding "when relevant to the claim" after the word "method." Information about the processing method should be requested only when it is directly relevant to the claim to avoid unnecessary disclosure of proprietary information.

4.2 Additional Safety Requirements
In the fourth bullet, we suggest adding "or intended subpopulation" after "the general population" since in certain cases a product may only intended for a specific subpopulation.

5.1 General Requirements
We suggest making it more clear that the level of substantiation may differ depending on the nature or level of the claim, i.e., more data would be necessary to substantiate a "reduction-of-disease risk" claim than a "nutrient-function" or "other function" claim.

5.2.2 Nature of the Scientific Evidence on the Claimed Effect
We support the approach taken to differentiate the evidence necessary to support different types of health claims but consider it could be further clarified. In the second paragraph, we suggest adding for clarity "(nutrient function claims or other function claims)" after "Other types of health claim". We believe that health claims for humans should be based on the evidence provided primarily by studies in humans and suggest deleting the word "preferably" from the first sentence. We suggest revising the second sentence the following: "Animal experimental models or *in vitro* studies that are relevant to humans may be used to support limited human evidence to substantiate a claim." We also suggest adding in the end a sentence "Scientific consensus reports and evidence-based dietary guidelines may be used to substantiate nutrient function or other health claims."

6. Evaluation of the Total Body of Scientific Evidence Used to Support a Health Claim
While we generally support the recommendation that the total body of scientific evidence of certain types of health claims should be evaluated scientifically, we are concerned that the requirement to get an opinion of a group of qualified experts might be interpreted as a requirement for pre-market authorization of any kind of health claims for each product. This seems overly restrictive and not a general regulatory practice, especially considering other than reduction of disease risk claims. We suggest that the opinion of a group of qualified experts should only be necessary only for certain types of claims such as disease-risk reduction claims.

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7. Re-Evaluation
The recommendations (bullets) in this section seem overly ambitious and we suggest a careful consideration of the need for such specific recommendations. Specifically, we are concerned that the first bullet might be interpreted as a requirement for systematic new evaluations that would be resource intensive. It should be left to the governments to decide if there is enough new evidence that would necessitate a new evaluation. We also question the need for the second bullet that is a general request to conduct studies "to increase the knowledge on the benefit for health of the food, the substance or the ingredient."

IFCGA - International Federation of Chewing Gum Associations

4.2 ADDITIONAL SAFETY REQUIREMENTS
IFCGA questions the added value of the section on "Additional Safety Requirements" as such requirements are already covered by other provisions laid out in Codex General Standards and Guidelines. The entire section ought to be deleted. Indeed its inclusion in the current document would clearly conflict with the scope of the Recommendations namely that the latter *"are only concerned with the nature and the quality of the scientific evidence alleged to support claims"*.

5.1 GENERAL REQUIREMENTS
The inclusion of 'that' in the second sentence of the first paragraph seems superfluous and the addition of 'on' is required before 'whether' in the same sentence. Furthermore, the nature of the scientific evidence required should be proportionate to the benefits declared in the claim and their significance in the total diet.
The sentence should thus read: "*The level of scientific justification shall be sufficient to support the claimed effect; but the substantiation requirements may differ depending on whether the health purported claim is a "nutrient-function" claim, an "other-function" claim or a "reduction-of-disease-risk" claim, and shall, in all cases, be proportionate to the nature of the benefits declared in the claim and their significance in the total diet.*"

The use of the term "alleged" in the last paragraph of the section on General Requirements should be deleted as the use of this adjective in relation to "claims" often has a negative connotation.
The sentence should therefore read: *"The scientific evidence shall be derived from study results /.../ in order to substantiate the use of the claim"*.

5.2 NATURE OF THE SCIENTIFIC EVIDENCE OF THE CLAIMED EFFECT
As stated above, the nature of the required scientific evidence for a claim should be proportionate to the benefits declared in the claim and their significance in the total diet. The scientific knowledge on the impact of certain substances/products on the human body should also be considered.
The first sentence in Section 5.2.1 should read:
"*In order to provide statistically significant results, while at the same time remaining consistent with the proportionality requirements,*

- *the trials /…/ habitual consumers".*

6. EVALUATION OF TOTAL BODY OF SCIENTIFIC EVIDENCE USED TO SUPPORT A HEALTH CLAIM
As stated in the first indent of the second paragraph, *all* relevant data, both positive and negative shall be taken into account when compiling the evidence. Nevertheless, it ought to be specified here that if the former outweighs the latter, the health claim should be authorised.

7. RE-EVALUATION
Re-evaluation should be necessary in cases where findings affecting the underlying science of the nutrient/effect relationship and/or one of the assumptions used during the initial evaluation, *only* if such findings are significant and have resulted from scientifically validated analytical methods and have a direct impact on the viability of the health claim or the safety of the product.

ILSI - International Live Sciences Institute

1. The SCOPE of the document mentions that the proposed recommendations are "only concerned with the nature and the quality of the scientific evidence alleged to support these claims." Nevertheless, **point 4.2, Additional Safety Requirements**, includes several comments not related to substantiation of health claims but with safety requirements. These comments are made in bullets 1, 2, 3, 4, 7, and 8. Safety is also referred to in **point 5.2.1, Nature of the Scientific Evidence on the Claimed Effect**, **General Requirements**. Bullet 3 states that "… product … shall not have negative nutritional and health impacts …."
We suggest that safety data be not considered with the data supporting the scientific validity of health claims. We would like to mention that the final PASSCLAIM document states that safety is a prerequisite for all foods (Aggett P.J. *et al*, 2005; full citation provided below).

2. Do the proposed recommendations apply to Nutrient Function claims? Please clarify this in the document.
3. Please replace the reference:
Richardson D. P *et al* (2003) Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM) -- Synthesis and review of existing processes. Eur. J. Nutr. 42 [Supp. 1]; I/96-I:111
With the citation of the final PASSCLAIM publication:
Aggett P.J. *et al* (2005) Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)—Consensus on Criteria. A European Commission Concerted Action Project Coordinated by ILSI Europe. Eur. J. Nutr. 44 [Supp. 1]; 1/3-1/30. Available on-line at:
http://europe.ilsi.org/passclaim/docs/PASSCLAIMConsensusonCriteria.pdf

ISDI - International Special Dietary Foods Industries

CODEX PROPOSAL	ISDI PROPOSAL	RATIONAL
SCOPE The following recommendations are intended for governments, in order to facilitate their own evaluation of health claims, used by the industry.	**SCOPE** The following recommendations are intended for governments, in order to facilitate their ~~own~~ evaluation of health claims, ~~used by the industry~~ **and for industry, to help assure that health claim have an appropriate and**	The sentence should be changed to point out the usefulness of the recommendations to the industry

	sufficient scientific basis.	
They are only concerned with the nature and the quality of the scientific evidence alleged to support these claims.	They are only concerned with the nature and the quality of the scientific evidence ~~alleged~~ **used** to support these claims.	Replace the word “alleged” by “used” for clarity
4.1 IDENTIFICATION, AND STABILITY OF THE PRODUCT: Information on the origin, nature, composition, and other specifications (including the processing method) of the product(s) that are proposed to bear the health claim, shall be provided, as relevant.	**4.1 IDENTIFICATION, AND STABILITY OF THE PRODUCT:** Information on the origin, nature, composition, ~~and other specifications (including the processing method)~~ of the product(s) that are proposed to bear the health claim, shall be provided, as relevant.	 ISDI seeks clarification on the meaning of “origin”, is it country?, source? Delete "and other specifications (including the processing method)". Rationale: Processing methods represent confidential and proprietary information. They are of little, or no, relevance to the claim. As well, there are no processing methods defined within Codex.
Scientifically validated analytical methods should be available to verify the quantity or the activity of the constituent in the food.	~~. Scientifically validated analytical methods should be available to verify the quantity or the activity of the constituent in the food.~~	Delete this section. Rationale: The methodology used in substantiating a claim should be presented as part the science-based evidence. Consideration of the methodology should, therefore be part of the overall scientific evaluation process. Furthermore, where a single food company develops a new product, validated methodology may not be available at the time the claim is presented for evaluation.
4.2 ADDITIONAL SAFETY REQUIREMENTS In case of addition of a constituent or ingredient in the food, the amount should not expose the consumer to health risks	**4.2 ADDITIONAL SAFETY REQUIREMENTS** ~~In case of addition of a constituent or ingredient in the food, the amount should not expose the consumer to health risks~~	 ISDI does not believe this bullet is necessary. This statement applies whether or not a health claim is made.
The expected level of consumption shall not exceed any relevant internationally recognized level of safe intake (e.g. ADI, if an ADI has been set), for any constituent present in the food.	The expected level of consumption shall not exceed ~~any relevant internationally recognized level of~~ **scientifically based** safe intake **level** ~~(e.g. ADI, if an ADI has been set),~~ for any constituent	Delete “relevant internationally recognized” and ”(e.g. ADI, if an ADI has been set)”. Rational: Safe intake levels are determined on a case by case basis using risk assessment

	present in the food.	approach as described in Codex framework.
5.2 NATURE OF THE SCIENTIFIC EVIDENCE ON THE CLAIM EFFECT	**5.2 NATURE OF THE SCIENTIFIC EVIDENCE ON THE CLAIM EFFECT**	
	The weight given to statistical vs. biological importance shall be judged on a case-by-case basis.	Add: new sentence related to biological relevance" vs. "statistical significance". Rationale: In general, when making health claims related to broad population groups, biological relevance and statistical significance should both be taken into consideration. However, the weight given to each should be judged on a case-by-case basis, depending on the parameter being evaluated and the overall health claim.
As appropriate, supporting scientific evidence along one or several of the following approaches shall be used. Possible types of scientific evidence include: ❑ *In vitro* studies ❑ animal studies, ❑ epidemiological or observational studies of humans ; ❑ clinical interventional studies complying with the requirements established by ethical committees. ❑ All other pertinent evidence, such as consensus reports and evidence-based dietary guidelines.	As appropriate, supporting scientific evidence along one or several of the following approaches shall be used. Possible types of scientific evidence include: ❑ *In vitro* studies ❑ animal studies, ❑ epidemiological or observational studies of humans ; ❑ clinical interventional studies complying with the requirements established by ethical committees. All other pertinent evidence, such as consensus reports, **position statements from authoritative organizations (i.e. governmental agencies, NGO's, IGO's)** and evidence-based dietary guidelines.	
5.3 RELEVANCE OF THE EVIDENCE AT POPULATION LEVEL It shall be required to check that the benefit documented by experimental studies is still present at the level of the target	**5.3 RELEVANCE OF THE EVIDENCE AT POPULATION LEVEL** ~~It shall be required to check that the benefit documented by experimental studies is still present at the level of the target~~	Delete this section. Rationale: Submission of scientific evidence for the efficacy of a health claim should include simulated evidence, e.g., consumption

population (general population or sub-group), preferably by simulations based ~~on consumption data~~	~~population (general population or sub-group), preferably by simulations based on consumption data~~	estimates showing the benefit that would be expected by the target population. Statement of this requirement is redundant with section 5.1.
6. EVALUATION of the total body of scientific evidence, used to support a health claim The total body of evidence provided to support the claims, shall be evaluated scientifically by a group of qualified experts, recognized by competent authorities.	**6. EVALUATION of the total body of scientific evidence, used to support a health claim** THE TOTAL BODY OF EVIDENCE PROVIDED TO SUPPORT THE CLAIMS, SHALL BE EVALUATED SCIENTIFICALLY BY A GROUP OF QUALIFIED EXPERTS, **SELECTED BY BOTH THE PETITIONER AND THE GOVERNMENT EVALUATING THE EVIDENCE, AND** RECOGNIZED BY COMPETENT AUTHORITIES.	ISDI believes there needs to be further detail about the "group of qualified experts", namely who selects them (e.g, the petitioner, the government evaluating the evidence).
7. RE-EVALUATION: Health claims shall be re-evaluated , as soon a s new findings are available that affect the underlying science of the nutrient/effect relationship and/or one of the assumption used during the initial evaluation, on the basis of which the use of the claim has been authorised . With this aim in view : ❑ Studies shall be conducted to increase the knowledge on the benefit for health of the food, the substance or the ingredient. ❑ The consumption of the products, bearing a health claim, shall be monitored in order to evaluate the actual levels of consumption and ensure that the pattern of consumption, as it is documented, is appropriate to provide the expected benefit, specifically for the population group targeted by the claim. ❑ The expected effects and, if appropriate, its adverse	**7. RE-EVALUATION**: Health claims shall be re-evaluated , as soon a s new findings are available that affect the underlying science of the nutrient/effect relationship and/or one of the assumption used during the initial evaluation, on the basis of which the use of the claim has been authorised . With this aim in view : ~~❑ Studies shall be conducted to increase the knowledge on the benefit for health of the food, the substance or the ingredient.~~ ~~❑ The consumption of the products, bearing a health claim, shall be monitored in order to evaluate the actual levels of consumption and ensure that the pattern of consumption, as it is documented, is appropriate to provide the expected benefit, specifically for the population group targeted by the claim.~~ ❑ ~~The expected effects and, if appropriate, its adverse~~	Delete the three bullet points. Rationale: The first paragraph sufficiently addresses the aim of the section.

effects, which may appear after a long-term consumption of the food, shall be investigated.	~~effects, which may appear after a long-term consumption of the food, shall be investigated.~~	