codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/NFSDU 08/30/6-Add.1**
October 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
30th Session

Cape Town, South Africa, 3 - 7 November 2008

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS

- ***Comments at Step 3 of the Procedure*** -

Comments from:

BRAZIL
GUATEMALA
UNITED STATES OF AMERICA
EHPM - European Federation of Associations of Health Product Manufacturers
IADSA - International Alliance of Dietary/Food Supplement Associations
ISDI - International Special Dietary Foods Industry
WSRO - World Sugar Research Organisation

BRAZIL

3.1. - Process for the substantiation of health claims:

(a) Identify the criteria for substantiation and other policies for health claims.

Brazil suggests to add at the end of item "a", the following text: "considering the guidelines of the Global strategy on diet, physical activity and health of the World Health Organization as well as the national policies about food and nutrition, when available."

(b) Identify the proposed relationship between the food or food constituent and the health effect.

(c) Identify appropriate measurements for the food or food constituent and the health effect.

Brazil suggests to substitute the expression "food constituent" for "food constituents", considering that more than one food constituent may be involved on a health claim.

12. By taking into account the totality of the available relevant scientific data and by weighing the evidence, the systematic review shall demonstrate the extent to which:

(c) the quantity of the food or food constituent and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet;

Brazil requests a definition for the expression "balanced diet" on item 2 of the document in order to harmonize the understanding among countries. At Brazil, it is used the Food Guide for the Brazilian Population, printed by the Ministry of Health, to guide a balanced diet. (Reference: Brasil. Ministério da Saúde. Guia Alimentar para População Brasileira: promovendo a alimentação saudável. Brasília, 2006, available at http://200.214.130.94/nutricao/documentos/guia_alimentar_conteudo.pdf).

GUATEMALA

Comments from Guatemala			Justification
Page	**Original text**	**Modifications**	
5	**3.1.5(d)** Define and categorize the entirety of the pertinent studies	Place square brackets around the word "entirety": Define and categorize the [entirety] of the pertinent studies	It is necessary to explain how the entirety of the studies should be established.
6	**3.26(a)** ex vivo or in vitro... per se	Put in italics: *ex vivo or in vitro* *per se*	These should be in italics because they are Latin
7	**3.311(a)** …especially an adequate control group,…	Add: ... especially a statistically representative sample, an adequate control group, ...	It is necessary for the sample to be representative to deduce a beneficial property
7	**3.3.13** ...a relation holds which is claimed.	Add: It is recommended that the country make a list of beneficial properties, including the food or ingredient with beneficial effects, requirements, writing and examples of declarations of beneficial properties.	It is necessary to standardize the declarations of permissible beneficial properties.

References:

A Food Labelling Guide. (At: http://www.cfsan.fda.gov/~dms/2lg-xc.html)

Nutritional declarations and declarations of beneficial properties (at: http://europa.eu/scadplus/leg/es/lvb/121306.htm)

UNITED STATES OF AMERICA

I. General Comments

The United States would like to express its appreciation to the Delegation of France for their leadership in chairing an electronic working group to facilitate progress on this agenda item. Below are comments for the Committee's consideration on the latest draft of the proposed draft recommendations. We anticipate we will offer additional comments at the upcoming meeting.

Numbering of Paragraphs.

The United States suggests that the paragraphs be renumbered throughout the document to conform with the rules for numbering Codex texts. For example, for the first section we believe the numbering should be as follows:

1. SCOPE

1.1 These recommendations are intended….

1.2 These recommendations include consideration….

II. Specific Comments

Note: In the comments below, the paragraph numbers refer to those is CX/NFSDU 08/30/6, with the anticipation that the numbering will be changed in the next version. Text proposed to be added is identified in bold; text proposed to be deleted is identified by strikeouts.

2. Definitions. "Food or food constituent refers to ……related substances or components, ingredients…."

> Editorial comment: It would appear that the words "substances" and "components" are redundant in this sentence. Thus, the committee may wish to consider using only one of these terms.

3. SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS

> Comment: We suggest adding the word "Scientific" to the title of Section 3 to clarify the nature of the provisions in this section.

5 (f) "Evaluate the totality of the available **relevant scientific** data, weigh the evidence across studies…"

> Comment: We suggest adding the bolded text above for consistency with the first sentence in para 12 which refers to "the totality of the available relevant scientific data…".

6 (c) "The totality of the evidence, including unpublished data where ~~available~~ **appropriate**, should be identified and reviewed,….."

> Comment: We suggest the above edits for clarification. We do not believe the intent is to review all available unpublished data, but only unpublished data assessed to be appropriate and relevant to the substantiation of a health claim.

7 (a) 'Nutrient function' claims may be substantiated based on a generally accepted authoritative statement that has been verified and validated over time."

> Editorial Comment: We suggest adding the word "a" to the above sentence.

7 (b) "**Some** Health claims, such as those involving a relationship between a food category and a health effect, may be substantiated based on observational evidence such as epidemiological studies….."

> Comment: We suggest adding the word "some" to the beginning of this sentence for clarification, and for consistency with the guidance in para 6(a) that: 1) "health claims should primarily be based on evidence provided by well-designed human intervention (clinical) studies", and 2) "Human observational studies are not generally sufficient per se to substantiate a health claim."

10. The relevant data and rationale that the constituent for which the health claim is made is in a form that is available to be used by the human body should be provided where applicable. ~~If absorption is not necessary to produce the claimed effect (eg plant sterols, fibres, lactic acid bacteria), the relevant data and rationale that the constituent reaches the target site are provided.~~ All available data on factors (e.g., forms of the constituent) that could affect the absorption or utilization in the body of the constituent for which the health claim is made should also be provided.

Comment: We do not believe that the second sentence is necessary. The first sentence would encompass all substances that are available to be used by the human body, including those that may not be absorbed but are still used in the gut. In the third sentence, we suggest adding "forms of the constituent" as an example.

NEW para #. Studies may be excluded from further review and would not be included in the relevant scientific data if they do not use appropriate measurements for the food or food constituent and health effect, have major design flaws, or are not applicable to the targeted population for a health claim.

Comment: We propose adding a new paragraph to clarify that studies that have major design flaws or are in other ways not relevant to the review of a particular health claim may be excluded, so that the review of the evidence in paragraph 12 focuses only on relevant studies. We believe this is consistent with the fourth and fifth steps identified in 3.1 (Overview) which are to: 4) Identify and categorise all the relevant studies [emphasis added] and 5) Assess and interpret each relevant study.

12 (b) " …..such as strength, consistency, specificity, does-response, and biological ~~meaningfulness~~ **plausibility** of the relationship."

Comment: **We** suggest referring to "biological plausibility" rather than "biological meaningfulness".

15. "The expected level of consumption ~~shall~~ **should** not exceed relevant upper levels of intake for food constituents."

Comment: We suggest changing "shall" to "should" for consistency with other provisions in Section 4 and in this document.

17. "Health claims should be re-evaluated ~~periodically or~~ following the emergence of significant new evidence….."

Comment: In response to the question from the Delegation of France as to whether the concept of periodic evaluation should be added, we believe that re-evaluation only following the emergence of significant new evidence that has the potential to alter previous conclusions is sufficient.

EHPM - European Federation of Associations of Health Product Manufacturers

The EHPM welcomes the initiative to have further recommendations on the scientific basis for health claims and appreciates the efforts of the French delegation to take into account comments submitted by interested governments and stakeholders. We would like to provide the following comments on the text proposed by the French delegation.

We agree with the approach outlined in the recommendations, and most importantly fully support the need to review the totality of the evidence and to weigh the type of evidence supporting claims. However, we are concerned that some of the concepts and presentation in the draft recommendations are very similar to that used for medicines evaluation and are not as such directly applicable to the area of food and nutrition. In particular, we would question the need to refer to "clinical" intervention studies (section 3.2 paragraph 6 (a)) as the subject is the benefits of foods and food constituents.

Also, we note that the nature and source of the evidence depends on the type of claim. Most of what we already know about diet and human health and several existing health claims cannot be validated

using the highest standard of human intervention studies but can be based on equally valid well designed and comprehensive epidemiological/observational studies.

For example FAO/WHO 2003 experts' report on Diet, Nutrition and the Prevention of Chronic Disease[1] highlighting the importance of the consumption of fruits and vegetables as part of the daily diet is very much based on a convincing body of evidence primarily from observational studies, and therefore any health claims derived from these recommendations should be allowed to use the same source of evidence.

So while it is important to use human intervention studies, when available, as a source of evidence of a cause-effect relationship, where these are not available, other type of evidence such as epidemiological/observational, history of use, animal or in vitro studies should be used and their respective strengths/weaknesses for supporting a claim should be assessed.

We therefore believe there is need to substantially amend the current wording of the text to clarify the need to assess and weigh all evidence available using nutritional science concepts and approaches before it can be forwarded to the next step.

In particular, on the basis of the above comments, we believe that section 3.2 should re-arranged and re-worded as follows:

"3.2 Criteria for the substantiation of health claims:

6. The following criteria are applicable to the three types of health claims as defined in section 2.2 of the Guidelines for use of nutrition and health claims:

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

(b) A high quality of scientific evidence should always be maintained. The evidence should be presented according to a hierarchy of study designs reflecting the relative strength of evidence that may be obtained from different types of sources.

(c) The totality of the available evidence should demonstrate a consistent association between the food or food constituent and the health effect.

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

(a) Where possible, health claims should primarily be based on evidence provided by well-designed human studies. Human intervention studies have greater weight than observational studies to determine the extent of a causal relationship. The scientific validity of an individual study depends on the appropriateness of the study type and on the quality of its design, execution and analysis, including statistical interpretation.

(b) Animal model studies, ex vivo or in vivo data may be provided as support for the knowledge base (e.g. mechanism of action) for the relationship between the food or food constituent and the health effect, but cannot be considered as sufficient per se to substantiate any type of health claim.

(c) Sources of scientific evidence may include generally accepted authoritative statements that have been verified and validated over time, or well documented history of use. Evidence-based dietary guidelines prepared or endorsed by an authoritative body and meeting high scientific standards may also be used

[1] WHO Technical Report Series 196 (2003)

IADSA - International Alliance of Dietary/Food Supplement Associations

The International Alliance of Dietary/Food Supplement Associations (IADSA) welcomes the revised draft of the proposed recommendations and acknowledges the efforts of the French delegation to take into account the various points raised by ourselves and other interested organisations.

IADSA has the following observations on the proposed draft and stresses the need to change significantly the text in Section 3.2.

3. SUBSTANTIATION OF HEALTH CLAIMS

3.1 Process for the substantiation of health claims:

Bullet points (a) to (d):

While IADSA agrees with the text regarding points (a), (b), and (c), it considers that the text in point (d) needs to be consistent with (f), and therefore IADSA proposes to replace the word 'studies' with "evidence" as follows: "Identify and categorise all the relevant evidence".

IADSA agrees that a health claim must be based on a systematic and objective compilation of all the available scientific evidence. This evidence-based approach needs to include the different sources and nature of the evidence and take into account all relevant studies including human intervention studies, human observational studies, animal studies and in vitro studies as well as other pertinent evidence from consensus reports, evidence-based dietary guidelines and history of use.

Bullet point (e):

IADSA agrees that individual studies should be evaluated for rigour of design, appropriateness of methods and procedures, reliability of measures of intakes and outcomes, and sufficient statistical power etc. It is important to note that the relationship between a food or food constituent and a claimed beneficial effect can be demonstrated by a number of different types of studies and designs. Methodological soundness overrides any hierarchy in studies on humans, given that validity depends not only on the appropriateness of the study type, but also on the quality of the design, execution and analysis.

Bullet point (f):

IADSA proposes to delete the words 'across studies'.

The statement in (f) should be consistent with Section 3.3 (paragraph 12), and the IADSA proposes that text remains a follows: "Evaluate the totality of the available data, weigh the evidence and determine if, and under what circumstances, a claimed relationship is substantiated".

This statement reflects the sources and nature of the evidence to include other pertinent evidence from authoritative statements, consensus reports, evidence-based dietary guidelines etc.

3.2 Criteria for the substantiation of health claims:

Paragraph 6, bullet point (a):

IADSA proposes to delete the word '(clinical)' as the subject is the benefits of foods and food constituents.

The basic principles of the scientific substantiation of health claims are 'to take into account the totality of the available data and to weigh the evidence'. The nature and source of the evidence depends on the type of claim. Well designed, executed and analysed human intervention studies, such as well-designed, randomised controlled trials (RCTs), human observational studies and other sources of evidence can be used as appropriate. Human intervention studies can provide the most persuasive evidence of efficacy in human subjects. However, the lack of well-designed RCTs should not disqualify a body of substantiating evidence from other sources. For example, decisions on disease risk reduction need to draw on a much broader spectrum of evidence including epidemiological evidence.

All research approaches, and indeed all studies, are accompanied by inherent limitations, and although reference can be made to a hierarchy of study designs, the relationship between a food or a food

constituent and a health outcome can be demonstrated by a number of different types of studies. The scientific interpretation of the results of RCTs and observational studies need to be addressed intelligently and sensitively on a case-by-case basis. Each kind of study provides a different kind of evidence. Clearly, an RCT carried out over a relatively short period of time (weeks or months) will answer completely different questions compared with a prospective observational study that may be carried out over several years. For disease risk reduction claims, reliance primarily on human intervention studies and a relatively small number of validated, surrogate biomarkers is not realistic or scientifically sound. The demonstration of a diet and disease risk reduction in a 'healthy' baseline population using RCTs is extremely rare for pragmatic reasons, e.g. blinding of test foods, subject compliance (especially over long trial periods), follow-up, costs etc.

Much of what is already known about diet and human health and several existing health claims cannot be validated using gold-standard human intervention studies. The clinical trial model is only one source of scientific data and is not practical when applied to the reduction of risk of disease in persons generally regarded as 'healthy'. Human observational studies, no matter how robust, cannot establish causality, but their results underpin many international dietary guidelines and several national health claims.

Section 3.3 (paragraph 12) requires assessment of the totality of the available relevant scientific data, the weighing of the evidence and demonstration of the extent to which a cause and effect relationship is established, the extent to which the claimed effect is beneficial for human health etc.

Hence, all the sources and the overall nature of the evidence need to be taken into account and the strength of the evidence needs to be assessed, e.g. 'convincing', 'probable', 'possible' and 'insufficient'.

Paragraph 6, bullet point (b):

IADSA proposes to delete the words 'with little or no evidence to the contrary'.

Most active areas of research result in some positive and negative results. The words to be deleted are redundant when the scientific assessment includes the totality of the available data and weighing of the evidence.

IADSA suggests that the statement should read as follows: "Evidence based on human studies should demonstrate a consistent association between the food or food constituent and the health effect'.

IADSA strongly recommends that Section 3.2, paragraphs 6 and 7 be rewritten and proposes the following text:

"3.2 Criteria for the substantiation of health claims:

6. The following criteria are applicable to the three types of health claims as defined in section 2.2 of the Guidelines for use of nutrition and health claims:

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

(e) A high quality of scientific evidence should always be maintained. The evidence should be presented according to a hierarchy of study designs reflecting the relative strength of evidence that may be obtained from different types of studies.

(f) The totality of the available evidence should demonstrate a consistent association between the food or food constituent and the health effect.

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

(d) Where possible, health claims should primarily be based on evidence provided by well-designed human studies. Human intervention studies have greater weight than observational studies to determine the extent of a causal relationship. The scientific validity of an individual study depends on the appropriateness of the study type and on the quality of its design, execution and analysis, including statistical interpretation.

(e) Animal model studies, ex vivo or in vivo data may be provided as support for the knowledge base (e.g. mechanism of action) for the relationship between the food or food constituent and the health effect, but cannot be considered as sufficient per se to substantiate any type of health claim.

(f) Sources of scientific evidence may include generally accepted authoritative statements that have been verified and validated over time. Evidence-based dietary guidelines prepared or endorsed by an authoritative body and meeting high scientific standards may also be used."

3.3 Consideration of the evidence:

IADSA commends the overall text in section 3.3.

Regarding paragraph 8, it is important that Codex has included a statement that if a claimed health effect can be measured directly, these measures (i.e. a true outcome or event) are equal to or better than surrogate biomarkers. In some cases where true outcomes cannot be measured, relevant validated biomarkers may need to be used.

However, concerning paragraph 9, IADSA is pointing out again that in many cases data on absorption, bioavailability, bioaccessibility of a food or food constituent may not always be available.

Regarding paragraph 12 point (b), dose response curves are common for medicines where study designs can be strictly controlled but for essential nutrients and other substances with nutritional or physiological effects it is much more difficult to undertake dose response human studies because of other confounding nutritional and lifestyle factors. IADSA proposes to add the words "where/when appropriate" after the words 'dose-response' in the brackets. The sentence would then read as follows:

"(b) a cause and effect relationship is established between consumption of the food or food constituent and the claimed effect in humans (such as the strength, consistency, specificity, dose-response where/when appropriate, and biological meaningfulness of the relationship);"

ISDI - International Special Dietary Foods Industry

We commend the work undertaken to date by the electronic Working Group chaired by France. Codex's work on nutrition and health claims has global importance, as there is growing interest in nutrition and health. Research indicates that consumers value foods that provide health benefits[i] and find function claims on labels, which link nutrients and health benefits to be particularly useful.[ii] We believe the development of recommendations for the scientific basis of health claims is also important with regard to the mandate of Codex to protect consumer health and encourage fair trade. Such substantiation criteria would provide assurance that claims are truthful, robust, and not misleading.

Section 3.1 – Systematic Review of the Scientific Evidence: Overview

Bullet (b) under Paragraph 5 states that one of the steps needed for the systematic review of the scientific evidence for health claims is to "identify the proposed relationship between the food or food constituent and the health effect." We would like to clarify that under this requirement, a separate, complete submission would not be expected for each nutrient when one submission would more appropriately support claims resulting from a product for which a blend of nutrients/ingredients synergistically provides the effect of multiple nutrients. For example, we believe one should be able to submit one substantiation dossier for "calcium and vitamin D and bone health" versus one each for calcium and vitamin D. Other examples of claims resulting from multiple nutrients/ingredients would be some sports performance foods, or perhaps a food for special medical purpose to support wound healing, for which the product was clinically studied for its effect and the product contained several nutrients or compounds designed to achieve the effect.

Bullet (f) under Paragraph 5 states the evaluation of the totality of the evidence across studies is needed to substantiate a claim. We are concerned this terminology may be interpreted too broadly, and suggest wording such as: "Evaluate the evidence, provided as a balance of the relevant studies and determine if…" For example, it would be very difficult to provide all of the extensive data available to

satisfy the requirement for "the totality of evidence" for health claim relationships such as calcium, vitamin D and bone health.

We also believe that, for body function claims and some health condition claims, one should not have to identify and categorize *all* relevant studies or assess and interpret each relevant study. This is referred to under section 3.2.7 with the statement "nutrient function claims may be substantiated based on generally accepted authoritative statement[s]…" We would like to clarify that the *Draft Recommendations'* definition of body function and nutrient function claims are the same. Different types of claims will require different levels of substantiation and different formats, as handled in the European Union via article 13 and article 14 definitions.

Section 3.2 – Criteria for Substantiating a Health Claim

Bullet (a) under Paragraph 6 notes "health claims should primarily be based on evidence provided by well-designed human intervention (clinical) studies." We believe that in some situations, this paragraph is more relevant for disease reduction claims than for body function and health condition claims, for which the provisions in section 3.2.7 should again be emphasized.

The ISDI agrees with the U.S. delegation's position as articulated in its preliminary draft positions for CCNFSDU 30, which state the Draft Recommendations should "focus on the systematic review of evidence for the three categories of health claims as defined by Codex, and that the same principles for the review of the scientific evidence generally apply to all three categories."[iii] We are concerned that, as the Draft Recommendations are currently written, the same level of substantiation may be required for function claims (both nutrient function and "other function") and for reduction of disease risk claims. We believe that different criteria should be required for reduction of disease risk claims, as compared to function claims, which describe normal physiologic functions. Reduction of disease risk claims should require a greater assurance, because the consequence to health of either insufficient or changing information is greatest. Substantiation criteria for such claims should be based on "significant scientific agreement," based on the totality of evidence that utilizes all types of evidence including randomized intervention trials but emphasizes the highest quality types of evidence and insures that the information is generally known and generally agreed upon. Nutrient function and other function claims should ideally be based on randomized clinical trials but could be based on data from animal studies conducted in an appropriate number of species, observational human studies or generally accepted statements by authoritative bodies.

The U.S. delegation can provide guidance to Codex on the appropriate criteria and review process for function claims (defined as "structure function claims" in the U.S.) since the U.S. Food and Drug Administration (FDA) has different requirements for this category of claims and for reduction of risk claims (defined as "health claims" in the U.S.). In the U.S., "truthful, non-misleading" structure function claims may be made for all foods without prior approval by the Food and Drug Administration (FDA); however, the manufacturer is responsible for ensuring accuracy[iv]. In contrast, health claims defined in the U.S. as reduction of disease risk claims are permitted only if they have been authorized by an FDA finding that there is "significant scientific agreement" to support the claim. The U.S. could supplement the reference to the FDA's guidance on the review of health claims with guidance on the review of structure function claims. The inclusion of this information in the Codex Guidelines would assist national authorities in developing appropriate review procedures for the three categories of health claims as defined by Codex.

The use of different requirements for the different categories of claims is recognized in Paragraph 7 of Section 3.2. We suggest that this concept is more explicitly stated at the beginning of the *Draft Recommendations* so that it is clear that different criteria and/or review processes may be used for function claims. A separate section on the substantiation criteria for these claims could be included along with the criteria for reduction of disease claims already specified in paragraph 6 of the *Draft Recommendations*. Although stringent standards of scientific evidence should always be maintained, substantiation may be achieved through simplified processes for categories of claims related to normal physiologic function. We are concerned that an overly restrictive review process for function claims will deny consumers access to important information about foods that contain nutrients that may be beneficial to normal physiologic function and discourage product innovation by manufacturers.

Section 3.3 – Comprehensive Review of the Scientific Data

Paragraph 9 states "the scientific data should provide adequate characterization of the food or food constituent considered as responsible for the health effect, including the analytical methods applied. Where applicable, the characterization includes a summary of the studies undertaken on production conditions, batch-to-batch variability, analytical procedures, results and conclusions of the stability studies, and the conclusions with respect to storage conditions and shelf-life." We believe such information should be collected by any manufacturer wishing to use a given claim, in order to ensure that the food constituent considered responsible for the health effect is present at levels associated with the claimed effect and is stable over the shelf-life of their specific product. However, such information should not be required as part of the scientific data necessary to substantiate the more general relationship between a food or food constituent and a health effect, *per se*. National authorities set Good Manufacturing Practices to ensure that foods are manufactured safely and that nutrient/ingredient label claims are met. In addition, in the case of novel food ingredients, such data are included in submissions required to assure safety and bioavailability of a food component before it is used in a food. Furthermore, the food constituent that is the subject of the claim may appropriately be used in a variety of food matrices. For these reasons, we believe such information should not be a component of Codex guidance for evaluating a health claim.

Paragraph 12(c) includes the phrase "as part of a balanced diet." To accommodate those diets that meet special needs and health conditions, we suggest a phrase such as "and/or a special diet required for a specific disease or condition" be added.

WSRO - World Sugar Research Organisation

WSRO welcomes clarification of the process for the substantiation of Health Claims and commends the excellent draft produced by the e-working group led by France (as shown in Appendix 2 to the paper) as a substantial step towards a final text.

However, WSRO respectfully submits the following comments as a contribution towards the discussions to take place at the Thirtieth Session of the Committee to take place in Cape Town, South Africa on 3-7 November 2008.

1. In answer to the question posed in paragraph 15 (page 3 last bullet point) as to whether it is desirable that any guidelines should be re-evaluated periodically or only when new relevant scientific evidence has emerged, WSRO would support regular review. The reason for this position is that the guidelines may benefit from review not only when new evidence is available but also when evidence that has been in existence for many years is re-evaluated by fresh thinking.

   A recent example is provided by the current debate on the definition of dietary fibre (see CX/NFSDU 08/30/3 pages 2 ff) which has substantial ramifications for health claims relating to fibre. This, most recent, debate arises from the proposal of the WHO/FAO Scientific Update on Carbohydrates and Human Nutrition to restrict the use of the term Dietary Fibre to constituents intrinsic to plant food sources. This proposal did not arise from new scientific evidence but from an objective re-appraisal of evidence that had been available for many years. The authors of the update recognised that all the available evidence that had previously been interpreted to indicate that Dietary Fibre consumption conferred long term health benefits in fact related to diets containing plant foods (fruit, vegetables and grains). In consequence it was deemed impossible to exclude the possibility that some other component of these foods was actually responsible for the benefits traditionally attributed to Dietary Fibre over the last 50 or more years.

   Similar considerations *mutatis mutandis* may well arise in the future with regard to health effects currently attributed to specific nutrients, foods or food constituents. Indeed some health claims relating to food constituents may be more appropriately attributed to the food matrix itself (for example the anti-caries effect of polyol-containing chewing gum may be at least in part attributable to the chewing gum itself: the act of chewing stimulating salivation).

   For these reasons WSRO recommends that the guidelines should be regularly reviewed to allow new thinking to be applied to revision of the guidelines, as well as any new evidence.

2. Under the Criteria for the substantiation of health claims (page 5 section 3.2 paragraph 6 of Appendix 2) WSRO would suggest the removal of the term "clinical" in paragraph 6 (a).

   Well designed, especially well controlled, intervention studies, conducted in free-living conditions, represent the most persuasive evidence that a claimed health benefit is of sufficient magnitude to make any material difference to health in real life. Studies under clinical conditions have the advantage of reducing the risk of confounding but the disadvantage of over-emphasising a small impact of a food constituent that may be trivial in a real life situation. Both types of study have their place and the guidelines should allow for both to be cited in evidence.

3. In this same section, WSRO strongly supports the comment "Human observational studies are not generally sufficient ***per se*** to substantiate a health claim". However, the intended meaning of this sentence might be better expressed "Human observational studies **alone** are not generally sufficient to substantiate a health claim". Indeed, WSRO would suggest this should be strengthened to read "Human observational studies **alone are insufficient** to substantiate a health claim".
4. The excellent and precise terminology of paragraph 6 is in danger of being diluted by paragraph 7 of Appendix 2. It is not clear what the phrase "verified and validated over time" referring to "generally accepted authoritative statement" in paragraph 7 (a) means. If it means "expert opinion that has been in place unchallenged for many years" then it would represent a substantial weakening of the evidence base required in paragraph 6. The Dietary fibre example cited above should caution against such a weakening of the validation requirements. If it means "expert opinion that has been supported by consistent evidence from good quality controlled intervention trials", then the whole sentence becomes redundant, since the issue has been covered by paragraph 6.
5. Paragraph 7 (b) presents similar problems. If a "health claim… involving a relationship between a food category and a health effect may be substantiated based on observational evidence such as epidemiological studies" then the strict requirements of paragraph 6 are vitiated. Furthermore it is illogical to ask for a lower standard of proof for a food category than for a nutrient or food constituent, since the possibilities of confounding, and errors in intake estimation, in epidemiological studies may be greater for a food category.

   Similarly, the second sentence of paragraph 7(b) is also either a weakening of the standard of evidence to rely on "authority" rather than evidence, or it is a repetition of the conditions set out in paragraph 6.

6. **WSRO would respectfully suggest that the whole of Section 7 (page 6) should be deleted.**
7. The comments on methodological quality of studies in paragraph 11 (page 6) are particularly welcome but could usefully include an additional emphasis on the importance of the **statistical power** of studies.
8. The Section on Specific Safety Concerns (Section 4, page 7), while excellent, might also address the importance of providing **direct evidence of the safety to all likely consumers** of an enhanced intake of any particular food, nutrient of food constituent on which a health claim is to be made. This is particularly relevant when, as in the case of folic acid, the intention of making a claim is to increase consumption above the level likely to be achieved by any normal diet based on un-fortified foods.

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[i] International Food Information Center, 2008 Food & Health Survey: Consumer Attitudes toward Food, Nutrition & Health**.** http://www.ific.org/research/foodandhealthsurvey.cfm

[ii] Asian Food Information Centre, Survey of Consumer Responses to Front-of-pack Nutrition and Health Information in China and Malaysia, September 2007.
http://www.afic.org/2006%20Survey%20of%20Consumer%20Responses%20to%20Front-of-Pack.pdf

[iii] U.S. Draft Positions. Codex Committee on Nutrition and Foods for Special Dietary Uses: 30th Session. As of September 19, 2008.

[iv] CFSAN/Office of Nutrition, Labeling, and Dietary Supplements, Guidance for Industry

A Food Labeling Guide, Chapter VIII. Claims, April 2008.
http://www.cfsan.fda.gov/~dms/2lg-8.html#health