codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/NFSDU 06/28/7**
June 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Twenty-eighth Session

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS AT STEP 3

(*Prepared by France*)

Governments and interested international organizations are invited to submit comments or information on the attached document at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Fifteenth Edition)* preferably by email, **to**: Dr Rolf Grossklaus, Director and Professor, Federal Institute for Risk Assessment (BfR), P.O. Box 33 00 13, 14191 Berlin, Germany (fax: +49 1888 529–4965; email: ccnfsdu@bmvel.bund.de), with a copy **to**: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by fax +39-06-5705-4593 or email codex@fao.org **by September 15, 2006.**

BACKGROUND

1. During the 22nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), the delegations of the USA and France, assisted by Denmark and Germany initiated work on the "Scientific Basis of Health Claims" (CX/NFSDU 00/10).

2. During its 24th session, the CCNFSDU considered the request of the Codex Committee on Food Labelling (CCFL) to resume this work on the establishment of scientific criteria relevant for the justification of health claims. It was agreed that the title and the status of this document would be considered later.

3. An electronic drafting group was established under the leadership of the delegation of France and the participation of Brazil, Canada, Denmark, Germany, Hungary, Italy, Japan, Kenya, Malaysia, Netherlands, Russian Federation, South Africa, Sweden, Switzerland, Thailand, United States, EC, CIAA, ISDI, ENCA, IACFO, EFLA, IBFAN, IFT, was requested to prepare a working document, including Proposed Draft Recommendations, for comments at Step 3.

4. Written comments were received before the 25th, 26th and 27th sessions from Argentina, Australia, Bolivia, Brazil, Canada, Denmark, Germany, Indonesia, Kenya, Malaysia, Mexico, New Zealand, Republic of Korea, South Africa, United States, Vietnam, CIAA, CRN, EFLA, IADSA, ICGA

ICGMA, IDF, ILSI and ISDI. Due to time constraints, the Proposed Draft Recommendations could not be discussed in any detail during these sessions. The drafting group was requested by the Committee to consider the written comments received before the 25th and the 26th and revise the document to take them into account.

5. The 27th session of the Committee, held in Bonn, Germany, 21 - 25 November 2005, could not discuss the document CX/NFSDU 05/27/9 in detail, due to time constraints. The Committee agreed to return the Proposed Draft Recommendations to Step 2/3 for redrafting by the Delegation of France in the light of the comments received, for further consideration at the next session.

6. The Committee agreed that further progress, at its next session, required careful consideration of several key issues identified in the comments received from Members and Observers. It was also agreed that a circular letter listing the questions to be addressed would be sent out for comments to be sent to the Delegation of France, before the 31 March 2006.

7. These questions drew on the summary provided by the Delegation of France, in its capacity as chair of the Electronic Drafting Group, on the main issues raised in the written comments submitted, before the 27th session, on the document CX/NFSDU 05/27/9 (July 2005): the scope of the document; the relevance of safety concerns; and the nature of the scientific evidence required according to the type of health claims concerned, including the use of human studies or biomarkers.

8. The circular letter CL 2005/56-NFSDU elicited comments from Argentina, Australia, Bolivia, Brazil, Denmark, Dominican Republic, Mexico, New Zealand, Peru, USA, Venezuela, AESGP, IADSA, ICGA, ICGMA, IDF and NHF.

CODEX DEFINITIONS OF HEALTH CLAIMS

9. The revised *Guidelines for Use of Nutrition and Health Claims*, prepared by the CCFL, have been adopted by the Codex alimentarius Commission, during its 27th session (July 2004)[1]. The Codex alimentarius Commission has considered three types of health claims. Each type is defined as follows:

> **"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*** - 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 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 and 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.

[1] CAC/GL 23-1997, Rev. 1-2004 – The Codex Guidelines for Use of Nutrition Claims were adopted by the Codex Alimentarius Commission at its 22nd Session (1997) and amended at its 24th Session (2001). The Guidelines were revised at its 27th Session (2004) with the insertion of provisions for health claims.

Example:

"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. Food is low in nutrient or substance A."

"A healthful diet rich in nutrient or substance A may reduce the risk of disease B. Food is high in nutrient or substance A."

WHO FRAMEWORK ON "STRENGTH OF SCIENTIFIC EVIDENCE"

10. The WHO *Technical Report on Diet, Nutrition and the Prevention of Chronic Diseases*[2] provided criteria to describe the strength of scientific evidence. They were based on the criteria used by the World Cancer Research Fund, but have been modified by the Expert Consultation to include the results of controlled trials where relevant and available.

CONVINCING EVIDENCE. Evidence based on epidemiological studies showing consistent associations between exposure and disease, with little or no evidence to the contrary. The available evidence is based on a substantial number of studies including prospective observational studies and where relevant, randomized controlled trials of sufficient size, duration and quality showing consistent effects. The association should be biologically plausible.

PROBABLE EVIDENCE. Evidence based on epidemiological studies showing fairly consistent associations between exposure and disease, but where there are perceived shortcomings in the available evidence or some evidence to the contrary, which precludes a more definite judgement. Shortcomings in the evidence may be any of the following: insufficient duration of trials (or studies); insufficient trials (or studies) available; inadequate sample sizes; incomplete follow-up. Laboratory evidence is usually supportive. Again, the association should be biologically plausible.

POSSIBLE EVIDENCE. Evidence based mainly on findings from case-- control and cross-sectional studies. Insufficient randomized controlled trials, observational studies or non-randomized controlled trials are available. Evidence based on non-epidemiological studies, such as clinical and laboratory investigations, is supportive. More trials are required to support the tentative associations, which should also be biologically plausible.

[2] WHO Technical Report Series n° 916 (2004) – pp. 53-54.

INSUFFICIENT EVIDENCE. Evidence based on findings of a few studies which are suggestive, but are insufficient to establish an association between exposure and disease. Limited or no evidence is available from randomized controlled trials. More well designed research is required to support the tentative associations."

ILSI CRITERIA FOR THE SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS[3]

11. Recently, the International life Sciences Institute (ILSI) *Consensus on criteria* has been published and recommended the following criteria for the substantiation of health claims:

1) The food or food component to which the claimed effect is attributed should be characterised.

2) Substantiation of a claim should be based on human data, primarily from intervention studies the design of which should include the following considerations:

(a) Study groups that are representative of the target group.

(b) Appropriate controls.

(c) An adequate duration of exposure and follow up to demonstrate the intended effect.

(d) Characterisation of the study groups' background diet and other relevant aspects of lifestyle.

(e) An amount of the food or food component consistent with its intended pattern of consumption.

(f) The influence of the food matrix and dietary context on the functional effect of the component.

(g) Monitoring of subjects' compliance concerning intake of food or food component under test.

(h) The statistical power to test the hypothesis.

(i) When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers.

3) Markers should be:

– biologically valid in that they have a known relationship to the final outcome and their variability within the target population is known;

– methodologically valid with respect to their analytical characteristics.

4) Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consistent with the claim to be supported.

[3] International Life Sciences Institute (ILSI) – PASSCLAIM (PROCESS FOR THE ASSESSMENT OF SCIENTIFIC SUPPORT FOR CLAIMS ON FOODS) – Consensus on Criteria, Eur J Nutr (2005) [Suppl 1] 44 : I/5–I/30. http://passclaim.ilsi.org/

5) A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence.

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

THE SCOPE OF THE PROPOSED DRAFT RECOMMENDATIONS:

Nature of the health claims in the scope:

12. The Circular Letter CL 2005/56-NFSDU requested to consider further whether the Recommendations were only required for the three types of health claims, listed in Guidelines on the Use of Nutrition Claims adopted by Codex (CAC/GL 23-1997 Rev. 2001, 2004).

13. Responses to this circular letter confirmed that the scope of the Proposed Draft Recommendations should not be expanded beyond what already adopted Codex Guidelines required. The Committee should stay focused on the elaboration of a concise set of principles.

Procedural or organisational issues

14. The last session of the Committee noted that some written comments proposed to expand the scope to cover authorization procedures, but agreed that such procedures were the responsibility of national authorities. The Committee confirmed that the Proposed Draft Recommendations were intended to address the nature of the scientific evidence required to substantiate claims, in accordance with the mandate given by the Commission when new work had been approved. (ALINORM 06/29/26 – para. 142)

15. The Circular Letter CL 2005/56-NFSDU requested further comments on this issue, as to pre-market approval of health claim and on how responsibilities are shared between competent authorities and industry in the provision and updating of scientific evidence.

16. Generally speaking, responses to this circular letter confirmed that procedural or organisational issues should be left for national competent authorities to decide upon and that they were beyond the scope of this work.

Terminology – definitions

17. Before the last session of the Committee, written comments pointed out that health claims were used in a broad range of cases: diet/food group/food/food component/substance added to the food. They noted that the different substantiation standards might apply to different cases. It appeared that if the maximum breadth of coverage were maintained, the complexity of the paper could be greatly increased.

18. Moreover, it was pointed out that the terminology, used in the Proposed Draft Recommendations, was not entirely consistent; some Members and Observers provided suggestions for improvement in this regard.

19. The Circular Letter CL 2005/56-NFSDU requested further comments on this issue, namely: (1) whether to restrict the scope of the Recommendations to health claims applied to food/food component/substance added to a food and exclude health claims applied to whole diets; and (2) how adequate were various terms, suggested in some written comments, in order to ensure overall consistency of the new draft.

20. On the first topic, although one Observer pointed out that, except for products which were the sole source of nutrition and thus comprised the “diet” of an individual, a health claim for a diet was beyond the scope of these Proposed Draft Recommendations since 1) there was no international trade in diets, 2) the Codex alimentarius Commission was established to address standards,

guidelines and recommendations for foods, and 3) national governments would deal with authoritative guidelines/recommendations on diets[4], all the other answers to the circular letter did not support any restriction of the scope, by excluding health claims applied to whole diets from consideration. The response to the second question should take this view into account.

21. On the second topic, all Members and Observers which have expressed their views on this matter, did not support the use of the word "product", as this word would denote, at least in English, "something that is produced and sold in large quantities, often as a result of a manufacturing process".

22. Various alternative proposals were put forward: "food or food component"; "food constituent" instead of "food component" (because this language was used in the *Codex Guidelines for Use of Nutrition and Health Claims*); "substance" (as more appropriate to refer to either a food or food constituent that was the subject of a health claim; this word was used in the *Codex Guidelines* and in the Codex Procedural Manual definition of "food"[5]); "property of a food" (as a term to cover energy, nutrients, biologically active substances or components, ingredients, and any other feature or constituent of a food on which the health claim is based).

23. Only the third proposal seemed to encompass the case the whole diet, as the diet itself might be assigned a common property of some of the individual foods making it up. Extensive use of this phrase has been made during the revision of the Proposed Draft Recommendations.

THE RELEVANCE OF SAFETY CONCERNS:

24. All Members, having commented in writing before the last session of the Committee, recognised, although some Observers did not, that the Scope of the Recommendations should cover both scientific of health claim and additional safety concerns, raised by the use of such claims on food.

25. The Committee noted a proposal to make the safety requirements mandatory, however several Delegations and Observers pointed out that all foods placed on the market should be safe and that food safety as such should not be addressed in the Proposed Draft Recommendations. The Committee recalled that food safety was addressed in other Codex texts and confirmed that the purpose of the Proposed Draft Recommendations was to address the issues related to the scientific substantiation of health claims, and only the safety issues directly related to the claims required specific consideration. (ALINORM 06/29/26 – para. 143)

26. The responses to the circular letter have confirmed the agreement on this approach. This section of the Proposed Draft Recommendations has been revised to ensure that only safety issues directly related to the claims were included. Full use has been made of the numerous suggestions for new detailed wordings during the revision of this section.

THE USE OF BIOMARKERS

27. Some Members, having commented in writing before the last session of the Committee, have suggested a basic scheme as broadly applicable; it is made up of three steps: (1) define a physiological or behavioural endpoint (biomarker); (2) define an enhanced component of the diet and (3) monitor the relation between the two.

[4] e.g., Dietary Guidelines for All Australians 2003, Guia Alimentar Para A População Brasileira 2005, Dietary Guidelines for Americans 2005.

[5] "Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs." (Procedural Manual – 15th Edition – p. 42)

28. The Committee noted that the need for human studies and the use of biomarkers would need further consideration but could not discuss these issues in detail at this stage. (ALINORM 06/29/26 – para. 144). The circular letter CL 2005/56-NFSDU requested to consider whether this approach is used as the main basis of the Recommendations.

29. The responses to the circular letter presented a variety of views: Some supported the basic scheme as proposed. Some suggested amendments to the language used in the circular letter (for instance, replacing “endpoint” by “health effect” or “monitor” by “characterise”). Others pointed out that it was not always possible to define a fully validated and predictive biomarker or endpoint, or that the suggested scheme was too narrow to be consistent with the scope of the Proposed Draft Recommendations and disagreed with the inclusion of this scheme in the Proposed Draft Recommendations. Others agreed that some general scheme could be establish and put forward their own proposals.

30. Obviously, the views expressed on this topic were closely linked to the approach taken on the nature of the scientific evidence and could not be addressed in isolation from it.

31. Furthermore, two Members pointed out that these Proposed Draft Recommendations’ usefulness to governments would be enhanced if the common steps and logical sequence in evaluating health claims were identified. And, furthermore, that the rigorousness of the step-by-step evaluation of the available evidence might be linked to the ‘degree of promise’ of the claim to be substantiated.

32. This suggestion has been taken up in a new Section, describing, in very broad outline, a step-by-step process that might facilitate the consideration of health claims by national competent authorities.

THE NATURE AND THE STATUS OF THE SCIENTIFIC EVIDENCE:

33. All Members and Observers, having submitted written comments before the last session of the Committee, noted that three types of health claims were allowed and highlighted the issues relating to the type of scientific evidence, which might differ according to the claim concerned. (ALINORM 06/29/26 – para. 144). They agreed that there were "grades of [scientific] evidence" and that the nature of available scientific evidence varied with different types of claims. All Members required "significant scientific consensus" (SSA). However, some Observers pointed out the importance of acknowledging "emerging science".

34. All Members stressed that health claims should be substantiated using studies on humans (preferably, clinical studies); other types of evidence may be only used in support of the evidence provided by studies on humans.

35. The circular letter called upon Codex Members and Observers for their views on (1) the approach suggested in the Proposed Draft Recommendations for the use of scientific evidence and (2) whether the emphasis on human studies was appropriate for all types of health claims.

36. On these issues, it was clear that the approach presented in the Proposed Draft Recommendations submitted to the last session of the Committee was not supported by most responses to the circular letter.

37. All Members and some Observers concurred that:

    (1) Different substantiation standards should not be applied to different cases.

    (2) All health claims should be based on evidence provided by human intervention (clinical) studies, irrespective of whether the health claim is applied to the whole diet, food group, food or a property of the food.

(3) Animal model studies, and *in vitro* studies, etc… might be provided as supporting knowledge base for the hypothesis but should never be considered as sufficient *per se* to substantiate any type of health claim.

(4) Data had to show a consistent association between intake and the improvement of the function and or reduction of the disease risk, with few or no data that demonstrate the opposite.

(5) Relevant evidence should refer to the totality of evidence including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.

(6) A 'convincing' standard of evidence (or significant scientific agreement) was needed to offer reasonable certainty that any health claim would be unlikely to be contradicted in the future by new evidence.

38. However, some Members also pointed out that such a high level of substantiation might not be necessary or achievable in some situations:

(1) The above definition of a 'convincing strength of evidence' should be amended[6] to allow for the possibility of the totality of evidence comprising observational evidence only, as this could be particularly relevant for diet/food group/whole food – health relationships.

(2) 'Nutrient function' claims may be substantiated based on generally accepted authoritative information that has been verified and validated over time. One could also use consensus reports or evidence-based dietary guidelines, providing that these reports/guidelines are: prepared by an authoritative body; meet high scientific standards; are relevant to the claim; are relevant to the population in question; and are up-to-date.

(3) New clinical studies should be provided for substantiating innovative health claims but not for health claims bearing on fully recognized functions of nutrients and for which reports on clinical studies have been published in the scientific literature.

39. The relevant section of Proposed Draft Recommendations has been revised to take into account the new approach supported by Members, in their responses to the circular letter: First, a general statement presenting the recommended criterion of the substantiation of all health should follow; and then a list of instances, as identified by Members in their comments, where stringency could be relaxed.

40. In addition, some Observers expressed their support for:

(1) The need to accommodate emerging science and to identify characteristics of research that gave a high probability of predicting future confirmation by new science for a particular diet and health relationship, as the public could benefit by enabling earlier application of such evolving knowledge.

(2) A system of grading of evidence (published or not, peer-reviewed or not) that reflected the strength of the evidence, the degree of certainty, or the balance of probabilities that the weight of the evidence supporting a claim between a property of a food and a health benefit and that the claim is truthful, accurate and not misleading. Were listed in these comments, molecular studies (published, peer reviewed research), cellular studies (published, peer

[6] The following language was suggested: "***Convincing evidence*** *– There are consistent associations between the diet, food or food constituent and the health effect, with little or no evidence to the contrary. There should be a substantial number of human studies of acceptable quality, preferably including both observational and experimental studies and preferably conducted in different population groups. Any intake-response relationships should be supportive of a causal relationship and the relationship should be biologically plausible. Supporting evidence sources should be consistent with the findings of human evidence.*"

reviewed research), animal studies (published, peer reviewed research), controlled clinical studies (published, peer reviewed research), uncontrolled clinical studies (published, peer reviewed research), epidemiological studies (published, peer reviewed research), meta-analyses (published, peer reviewed research), government, university or other reports (published or unpublished), case reports (published or unpublished), commercial data (conference proceedings or unpublished).

THE RE-EVALUATION OF HEALTH CLAIMS:

41. All Members, having commented in writing prior to the last session of the Committee, recognised the need to re-evaluate health claims. There was some disagreement on how such a requirement might be framed to be practicable (reassessment at regular intervals was not supported) and not too onerous (as every new studies published might not add significant new findings). The circular letter CL 2005/56-NFSDU requested further comments on this issue.

42. In their responses to the circular letter, all Members and several Observers supported the concept of the re-evaluation of a health claim, after a certain period of time (possibly every 5-10 years) or following the emergence of significant new evidence that has the potential to alter previous conclusions about the food - health relationship. But they also noted the practical difficulties to be overcome. They pointed out that a review "each time as new knowledge became available" was not feasible due to the frequency with which new evidence emerged, and that a review might be unnecessary if the new evidence was unlikely to change the claim. Health claims should be re-evaluated only if new evidence calls into question the scientific validity underpinning the claim.

43. The relevant section of Proposed Draft Recommendations has been revised to take into account these views.

44. In addition, one Observer noted that a standard of evidence "identical" to the one used to evaluate the claim in the first place, should also apply to proposals to re-evaluate such claims.

45. Some Observers expressed the view that companies should not be required to continue to conduct studies on a claim that has already met the scientific criteria to permit its use. In addition, monitoring consumption levels and patterns should not be required since this issue would have already been addressed in the initial evaluation of the health claim.

TITLE AND STATUS OF THE PROPOSED DRAFT RECOMMENDATIONS

46. In the earlier phase of elaboration, the electronic working group interpreted its mandate as involving the establishment of criteria for the evaluation of (or basic requirements for) the scientific evidence adduced by applicants to substantiate health claims. This approach was consistent with the work on the establishment of Guidelines for nutrition and health claims, developed in parallel by the Codex Committee on Food labelling and already adopted by the Codex alimentarius Commission.

47. Several comments have been made on the Preamble of the Proposed Draft Recommendations to point out that it was unnecessary to reproduce large amount of adopted text and that the relationship of the Proposed Draft Recommendations with the revised *Guidelines for Use of Nutrition and Health Claims* and the *Codex General Guidelines on Claims (CAC-GL 1-1979 – REV 1-1991)*[7] needed some clarification.

[7] The Codex General Guidelines on Claims was adopted by the Codex Alimentarius Commission at its 13th Session, 1979. A revised version of the Codex General Guidelines on Claims was adopted by the 19th Session of the Commission in 1991. It has been sent to all Member Nations and Associate Members of FAO and WHO as an advisory text, and it is for individual governments to decide what use they wish to make of the Guidelines.

48. To take these comments into account, the Preamble of the Proposed Revised Recommendations has been revised to state that they should be read in conjunction with others relevant Codex adopted texts, including the two Guidelines referred to above.

49. It is recommended that the Proposed Draft Recommendations should be added, as an Appendix, at the end of the current *Guidelines for Use of Nutrition and Health Claims*. The title of the Proposed Draft Recommendations has been amended to this effect.

50. An updated list of references is provided in Appendix 1. This list is for information only and is not part of the Proposed Draft Recommendations.

RECOMMENDATIONS TO THE COMMITTEE:

51. The Proposed Draft Recommendations are in Appendix 2. During the discussion, at the 28th session, the Committee may wish to consider:

    ♦ The suggestions in para. 20, 23, 26, 32, 39, 43, 48 and 49, based on the comments received in response to the circular letter CL 2005/56-NFSDU.

    ♦ The content of the revised Proposed Draft Recommendations, presented in Appendix 2, with the view of forwarding them for adoption at step 5 to the next session of the Codex alimentarius Commission.

Appendix 1

REFERENCES

FAO/WHO – Codex Alimentarius – Codex General Guidelines on Claims (CAC-GL 1-1979 – Rev. 1-1991)

FAO/WHO – Codex Alimentarius – Codex Guidelines for the use of nutritional and health claims (CAC/GL 23-1997, Rev. 1-2004)

FAO/WHO – Safety aspects of genetically modified foods of plant origin. Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, Geneva, 29 May - 2 June 2000.

FAO/WHO – Codex Alimentarius (2003) – Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 4 – 2004)

Conseil de l'Europe – Lignes directrices sur la justification scientifique des allégations santé des aliments fonctionnels -Accord Partiel dans le domaine de la santé publique

CIAA – Code of Practice on the use of Health claims CIAA, CIAA Document MIN/066/9E Final, Brussels, Belgium, http://www.ciaa.be

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

US Department of Health and Human Services-Food and Drug Administration – US guidance for Industry -Significant Scientific Agreement in the review of health claims for conventional foods and dietary supplements. -- US FDA, Washington DC, http://vm.cfsan.fda.gov/~dms/ssaguide.html

Food and Nutrition Board, Institute of Medicine, National Academy of Sciences (1996) – Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Washington, D.C. National Academy Press, 1996

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Aggett PJ, Antoine JM, Asp N-G *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.

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.

Richardson DP, Affertsholt T, Asp N-G *et al.* (2003) – PASSCLAIM – Synthesis and review of existing processes. *European Journal of Nutrition* **42** (Suppl 1): 96–111.

World Cancer Research Fund/American Institute for Cancer Research (1997) – Food, Nutrition and the Prevention of Cancer: a Global Perspective. Washington D.C.

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.

Appendix 2

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

1. PREAMBLE:

This Annex should be read in conjunction with the *Codex General Guidelines on Claims* (CAC/GL 1-1979 (Rev. 1-1991)) and the *Codex Guidelines for the use of nutritional and health claims* (CAC/GL 23-1997, Rev. 1-2004).

2. SCOPE:

These Recommendations are intended for governments, in order to facilitate their own evaluation of health claims, used by the industry.

They only address the nature and the quality of the scientific evidence supporting these claims.

They are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Codex Standards and Guidelines or general rules of existing national legislations, although it is recalled that definite requirements on these matters have to be met and that they do not preclude consideration of specific food safety concerns (see section 4.3.2).

3. DEFINITION:

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

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

4.1. NATURE AND QUALITY OF THE EVIDENCE:

The following criteria should be applied:

– All health claims should be based on evidence provided by well-designed human intervention (clinical) studies. Animal model studies, and *in vitro* studies, etc… may be provided as supporting knowledge base for the property–health effect relationship but should never be considered as sufficient *per se* to substantiate any type of health claim.

– Evidence based on human intervention (clinical) studies should demonstrate a consistent association between the property and the health effect, with little or no evidence to the contrary.

– The totality of the evidence should be reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.

4.2. SPECIAL CASES:

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

– Health claims bearing on fully recognized functions of nutrients and for which reports on clinical studies have been published in the scientific literature.

– The totality of evidence may only comprise observational evidence, particularly for health claims involving a diet/food group/whole food – health effect relationships.

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

4.3. SCOPE OF THE EVIDENCE:

4.3.1. Identification of the property – health effect relationship

The scientific evidence should provide adequate characterization of the property of the food to which the health effect is attributed and should ensure that study groups are representative of the target group.

It should characterise the target groups' background diet and other relevant aspects of lifestyle, the intake consistent with its intended pattern of consumption, the adequate duration of exposure, the influence of the matrix and dietary context on the property.

4.3.2. Specific safety concerns

When the claim is about a food constituent, the amount should not expose the consumer to health risks and the known interactions between the constituent and other constituents should be considered.

The expected level of consumption shall not exceed any relevant upper level of intake for food constituents.

The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population[8,9] and, where relevant, those for vulnerable population groups. It should account for the possibility of cumulative intake, when the same constituent is present in several foods, and for nutritional imbalance due to changes in dietary patterns in response to consumers' information laying emphasis on the food property.

5. STEP-BY-STEP PROCESS

It is possible to broadly outline a process for substantiation of health claims by national competent authorities that takes into account the general principles for substantiation. Such a process would typically include the following steps:

1. Identify the standard of evidence for substantiation and other policies for health claims.

[8] 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.

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

2. Identify the proposed relationship between the food property, and the health endpoint for a health claim.

3. Identify appropriate measurements for the property and the health endpoint.

4. Identify and categorise all the evidence.

5. Assess and interpret the evidence, study-by-study.

6. Evaluate the totality of the evidence across studies and determining if, and under what circumstances, a claimed relationship is substantiated.

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

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

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

6. RE-EVALUATION:

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