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**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Thirthieth Session

Cape Town, South Africa
3 – 7 November 2008

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

(Prepared by France with the assistance of Australia, Canada, Costa-Rica, Denmark, Germany, Mexico, United States of America and the observers from IADSA, ICGA, IDF-FIL, IFT)

Governments and interested international organizations are invited to submit comments or information on the attached document at Step 3 (see Appendix 2) 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, Seventeenth 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@bmelv.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 17 Ocober 2008.**

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. The Item remained on the Agenda of subsequent session of the Committee. However, due to time constraints, the 25th, 26th and 27th, 28th sessions of the Committee were unable to consider earlier versions of the Proposed Draft Recommendations, in any detail.

4. The 27th session of the Committee, held in Bonn, Germany, 21 - 25 November 2005, agreed that further progress, at its next session, required careful consideration of several key issues identified in

the comments received from Members and Observers. 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 circular letter CL 2005/56-NFSDU was issued by the Codex secretariat to request comments on this topic. The working document CX/NFSDU 06/28/7[1] summarized the comments received.

5. Again, due to time constraints, the 28th session of the Committee could not consider this issue in detail and agreed to hold at step 4 the proposed draft Guideline (in Annex 2 of the document CX/NFSDU 06/28/7), until its next session.

6. At its 29th session[2], the Committee was able to consider this item at some length and agreed to return the Proposed Draft Recommendations to Step 2/3 for redrafting by the electronic working group led by France, on the basis of a general discussion on the main sections in the document and further comments, for consideration at the next session.

7. The French delegation gratefully acknowledges the inputs received from Australia, Canada, Costa-Rica, Denmark, Germany, Mexico, United States of America and the observers from IADSA (International Alliance of Dietary/Food Supplements Association), ICGA (International Chewing Gum Association), IDF-FIL (International Dairy Federation), IFT (Institute of Food Technologists), as all have been of great importance for putting together this revised proposed draft Recommendation.

PROGRESS MADE AT THE LAST SESSION OF THE COMMITTEE

8. The Committee agreed that the Proposed Draft Recommendations, when finalized would be included as an Annex in the Guidelines for Use of Nutrition and Health Claims and that no additional reference to other Codex texts would be required as the recommendations would be part of the Guidelines. The Committee also agreed that the purpose of the Recommendations was to define the scientific basis of health claims and that other issues concerning health claims were addressed in the adopted Guidelines, which were not under consideration. It was emphasised that, while the Recommendations could provide more useful information, the main issue to be addressed was the standard of evidence required to substantiate claims.

9. The Committee agreed to retain the current paragraph on food safety with an editorial amendment for clarification purposes.

10. Noting that biologically active substances were not defined, the Committee agreed that this term should be replaced by “related substances or components”. It was also agreed to replace “whole diets” with “categories of foods” as claims on whole diets were excluded. It was suggested that the phrase “properties of food" be replaced by the language of the Guidelines for Use of Nutrition and Health Claims “food or food constituent” throughout the text.

11. At this stage, the Committee recognized that it was not possible to complete the review of the text section by section in view of the issues raised in the discussion

PROCEEDINGS OF THE ELECTRONIC WORKING GROUP

12. The French delegation has revised the draft proposed Recommendations on the basis of the discussion during the last session of the Committee and all the comments submitted by the participants to the electronic working group. The first two Sections (1.- Scope and 3.- Definitions) have been amended to take into account the agreement during the last session of the Committee. The rest of the text has been reorganized to highlight the various steps during the process of

[1] Republished as document CX/NFSDU 07/29/6 before the 29th session of the Committee.
[2] ALINORM 08/31/26 – para. 79-97.

substantiating a health claim (Section 3), the specific food safety concerns (Section 4., with no substantive change) and the re-evaluation (Section 5).

13. On section 3.- Substantiation of health claims, specifically, readability has been improved by presenting first the various steps in the substantiation process, by identifying more clearly the criteria applicable, then by separating the general criteria (in para. 6) from the criteria applicable only in more specific situations (in para. 7) and last, by spelling out the methodological requirements about the evidence to be provided.

14. At this point in the development of the Draft Proposed Recommendations, the Electronic Working Group has largely agreed on the wording of Section 1.- Scope, Section 2.- Definitions, Section 3.1.- Process of the substantiation of health claims, Section 3.2.- Criteria for the substantiation of health claims and Section 4.- Specific safety concerns.

15. It would be beneficial that further discussion take place during the Physical working group, established by the last session of the Committee[3] and to be held before the forthcoming session, and during the next plenary itself on some remaining issues Section 3.3.- Consideration of the evidence and Section 5.- Re-evaluation:

    - Para 8 à 11 have been developed specifically to assist governments in their review of available studies in order to assess whether the evidence provided are relevant and whether those studies have been adequately performed (characterization of the 'food or food constituent – health claim' relationship, representativity of the population tested, characterization of the food or the constituent on which the claim is based, bioavailability, methodological and statistical requirements,…).
    - Para 12 & 13 describe the data the evaluation should provide to enable governments to take an informed decision.
    - On para 17, The Committee may wish to consider whether re-evaluation should proceed only when new scientific evidence have emerged or whether the concept of periodic re-evaluation is relevant and should be added.

RECOMMENDATION TO THE COMMITTEE

16. The Committee may wish to consider 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.

[3] See ALINORM 08/31/26 – para. 178.

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

European Commission, Scientific Committee on Food (2000) – Guidelines of the Scientific Committee on Food for the Development of Tolerable Upper Intake Levels for Vitamins and Minerals

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.

European Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council.

Appendix 2

PROPOSED DRAFT ANNEX TO THE *CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS*: RECOMMENDATIONS ON THE SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS[4]

1.- SCOPE:

1. These Recommendations are intended to assist governments in their evaluation of health claims in order to determine their acceptability for use by the industry. The recommendations focus on the criteria for substantiating a health claim and the general principles for the systematic review of the scientific evidence. The criteria and principles apply to the three types of health claims as defined in section 2.2 of the Guidelines for use of nutrition and health claims.

2. These recommendations include consideration of safety in the evaluation of proposed health claims, but are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Codex Standards and Guidelines or general rules of existing national legislations.

2.- DEFINITIONS:

For the purposes of this Annex:

3. **Food or food constituent** refers to energy, nutrients, related 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 categories of food, as the category itself may be assigned a common property of some of the individual foods making it up.

4. **Health effect** refers to a body function, health condition or reduction of disease risk.

3.- SUBSTANTIATION OF HEALTH CLAIMS:

3.1.- Process for the substantiation of health claims:

5. The systematic review of the scientific evidence for health claims by national competent authorities takes into account the general principles for substantiation. Such a process typically includes the following steps:

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

(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.

(d) Identify and categorise all the relevant studies .

(e) Assess the quality of and interpret each relevant study .

(f) Evaluate the totality of the available data, weigh the evidence across studies and determine if, and under what circumstances, a claimed relationship is substantiated.

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) Health claims should primarily be based on evidence provided by well-designed human intervention (clinical) studies. Human observational studies are not generally sufficient *per*

[4] **Note:** This document is intended as an annex to the *Codex Guidelines for the use of nutritional and health claims* (CAC/GL 23-1997, Rev. 1-2004).

se to substantiate a health claim. Animal model studies, *ex vivo* or *in vitro* data may be provided as supporting knowledge base 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.

(b) Evidence based on human studies should demonstrate a consistent association between the food or food constituent and the health effect, with little or no evidence to the contrary.

(c) The totality of the evidence, including unpublished data where available, should be identified and reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.

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

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

(b) 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. 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:

8. The scientific studies considered relevant for the substantiation of health claim are those addressing the relationship between the food or food constituent and the health effect. In case of a claimed health effect that cannot be measured directly, relevant validated biomarkers may be used (e.g. plasma cholesterol concentrations for cardiovascular disease risk).

9. 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.

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 (e.g. 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 that could affect the absorption or utilisation in the body of the constituent for which the health claim is made should also be provided.

11. The methodological quality of each type of study should be assessed, including study design and statistical analysis.

(a) The design of human intervention studies should notably include an appropriate control group, characterize the study groups' background diet and other relevant aspects of lifestyle, be of an adequate duration, take account of the level of consumption of the food or food constituent that can be reasonably achieved in a balanced diet, and assess the influence of the food matrix and total dietary context on the health effect.

(b) Statistical analysis of the data should be conducted with methods recognized as appropriate for such studies by the scientific community and with proper interpretation of "statistical significance".

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:

(a) the claimed effect of the food or food constituent is beneficial for human health;

(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, and biological meaningfulness of the relationship);
(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;
(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

13. Based on this evaluation and the substantiation criteria, a government can determine if, and under what circumstances, a claimed relationship is substantiated.

4.- SPECIFIC SAFETY CONCERNS:

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

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

16. The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population[5,6] and, where relevant, those for vulnerable population groups. It should account for the possibility of cumulative intake from all dietary sources, and of nutritional imbalance due to changes in dietary patterns in response to information to consumers that lays emphasis on the food or food constituent.

5.- RE-EVALUATION:

17. Health claims should be re-evaluated periodically or following the emergence of significant new evidence that has the potential to alter previous conclusions about the relationship between the food or food constituent and the health effect.

[5] 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, 1998. p. 8.
[6] 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