codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/NFSDU 05/27/9**
July 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Twenty-seventh Session

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

(*Prepared by a drafting group led 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, Fourteenth 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 August 31, 2005.**

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, drafted a working document on the "Scientific Basis of Health Claims" (CX/NFSDU 00/10).
2. During its 24th session, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) considered the request of the Codex Committee on Food Labelling on resuming 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 delegation of France, with 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 draft a working document, including a Proposed Draft Recommendations, for comments at Step 3.
4. Written comments were received before the 25th session from Malaysia, Germany, New Zealand, Vietnam, CRN, ICGMA, IDF, ILSI. Due to time constraints, the proposed draft could not be discussed in any detail during the session. The drafting group was requested by the Committee to revise the document.

5. This new version has been drafted, using the reports of the 22nd and 25th sessions of the CCNFSDU and the comments made available before the 25th session of CCNFSDU. The revised text was circulated by e-mail to all drafting group's members and was commented upon by Germany and Malaysia.

6. At its 26th session (November 2004), although the Committee did not discuss this agenda item, due to time constraints, it requested the drafting group led by France to consider the written comments received before this session and to revise the proposed draft Recommendations, for further consideration during the next session of this Committee (November 2005). The delegation of the USA joined the drafting group at this stage.[1]

7. The revised text was circulated by e-mail to all drafting group's members and was commented upon by Denmark and the USA.

8. The Proposed Draft Recommendations are in Appendix 1. A reference list is provided in Appendix 3.

9. The Guidelines on nutritional and health claims, prepared by the CCFL, have been adopted by the Codex Alimentarius Commission, during its 27th session (July 2004). The definitions of health claims established by the CCFL are reproduced in Appendix 2.

RECOMMENDATIONS TO THE COMMITTEE :

10. In the earlier phase of elaboration, the electronic working group interpreted its mandate as involving the drafting 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.

11. Therefore, as this Committee acted on the request of the CCFL, the drafting group produced a text that could be easily trimmed to fit original query. This would avoid the need for an independent request to the Codex Alimentarius Commission for the permission to undertake new work on this issue.

12. During the latest round of revision, one member suggested that the text be construed as Guidelines for the evaluation for the scientific evaluation of health claims, describing the process to be followed. This is a different approach; and it would entail serious changes in the structure and the content of the proposed draft.

13. Moreover, it seems to exceed the current mandate of the electronic working group and, also, that of this Committee on this issue.

14. If the CCNFSDU favours this alternative approach, it should forward a request to the Codex Alimentarius Commission to be allowed to undertake a new work, on the basis of a project document to be prepared by this Committee[2].

15. During the discussion, at this session, the Committee may wish to consider:

    - The status and the title of these proposed draft recommendations, which have been left undecided up to now.
    - The content of the revised proposed draft Recommendations, presented in Appendix 1.

[1] See ALINORM ALINORM 05/28/26 – para. 136

[2] see Procedures for the elaboration of Codex standards and related texts – Procedural Manual 14th Edition –p. 20

APPENDIX 1

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

1. PREAMBLE:

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

- No food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect[3].
- Claims should be prohibited if they cannot be substantiated[4].
- In addition, the Codex Guidelines for Use of Nutrition and Health Claims[5] state that:
- Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable.
- Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education.
- The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities.
- Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.

2. SCOPE:

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

They are only concerned with the nature and the quality of the scientific evidence alleged to support these claims.

They are not intended for the complete evaluation of the safety and the quality of the products, for which other provisions are relevant as laid out by Codex Standards and Guidelines or general rules of existing national legislations, although it is recalled that definite requirements on these matters have to be met and that it does not preclude additional safety requirements (see section 2.2).

Many of these recommendations also apply to the evaluation of health claims when they are about a food group.

3. DEFINITION:

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

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

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

[5] See ALINORM 04/27/22 Appendix III, PREAMBLE

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

4.1 IDENTIFICATION AND STABILITY OF THE PRODUCT:

- Information on the origin, nature, composition, and other specifications (including the processing method) of the product(s) that are proposed to bear the health claim, shall be provided, as relevant. This product should meet the Codex standards and/or specifications, if it is covered by existing Codex texts.
- When the claim is about a constituent or the ingredient of a food, evidence shall be provided that the constituent or the ingredient, with the specific function, is present and bioavailable in a quantity and in a form needed to justify the claim throughout the shelf life of the food stored under the conditions indicated on the label.
- Scientifically validated analytical methods should be available to verify the quantity or the activity of the constituent in the food.

4.2 ADDITIONAL SAFETY REQUIREMENTS:

In addition to the usual risk assessment :

- In case of addition of a constituent or ingredient in the food, the amount shall not expose the consumer to health risks.
- The known interactions between the constituent or ingredient, on which the claim is based, with other constituents shall be mentioned.
- The expected level of consumption shall not exceed any relevant internationally recognised level of safe intake (e.g. ADI, if an ADI has been set), for any constituent present in the food.
- In assessing risk, typically, the exposure (or intake) assessment should be based on an evaluation of the distribution of usual total daily intakes of the substance for the general population[6] [7], and include consideration of the vulnerable population groups.
- The risk from a change in the dietary pattern of the consumer, triggered by the emphasis on the product, resulting in its excessive consumption, leading to nutritional imbalance.
- The population, or the sub-population targeted by the product (target group), shall be identified. The selection of this population shall be consistent with the effects alleged by the claim.
- Cumulative intake risks in a situation where the same constituent is present in several foods. Simulations to assess the potential risks of excessive consumption shall; as far as possible, be conducted by the appropriate methods.
- The expected/foreseeable adverse effects on the vulnerable population groups (including infant, young children and pregnant women…) shall be considered.

Where appropriate, other issues may be considered : for instance, the consumption by populations outside the target group, the excessive consumption, the shift of the nutritional balance by the increased consumption of some foods, replacing others, the short-term adverse effects, , the introduction of new risky behaviours, ….

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[6] 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.

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

5. SCIENTIFIC REQUIREMENTS ABOUT THE CLAIMED EFFECT:

5.1 GENERAL REQUIREMENTS:

A high level of quality of the scientific justification for the claimed effects is obligatory for using any health claim. The level of scientific justification shall be sufficient to support the claimed effect; but that the substantiation requirements may differ depending whether the health purported claim is a "nutrient-function" claim, an "other-function" claim or a "reduction-of-disease-risk" claim.

The scientific quality of a study should be based on several criteria including the study type, study design, study population, outcome measures, data collection (e.g., dietary assessment method), and statistical analysis.

All relevant scientific evidence for the evaluation of a health claim should be identified. These include studies that use appropriate measurements, that do not have significant study design flaws, and that are applicable to the targeted population for a health claim.

The trials should be designed to test for an association of interest (e.g., by manipulating the intake level of the substance while controlling for other factors that can affect the health endpoint).

Statistical analysis of the data shall be conducted with methods recognised as appropriate for such studies by the scientific community to ensure good experimental design (including an appropriate time span), the appropriateness of tests applied and proper interpretation of "statistical significance", i.e. assess both statistical and biological significance.

The scientific evidence shall be derived from study results, either already published in scientific literature, or conducted by the applicant in order to substantiate the alleged claim. The scientific study design shall be consistent with generally accepted scientific procedures and principles.

5.2 NATURE OF THE SCIENTIFIC EVIDENCE ON THE CLAIMED EFFECT:

The proposed relationship between product and health endpoint (e.g., disease, health condition, or body function) should be identified. Appropriate measurement, of both the substance and health endpoint is a key factor in the review of data for health claims. Biomarkers may be used as an indicator or predictor of such a relationship.

A relevant biomarker is a well-defined biological, physiological, clinical or epidemiological indicator which is modulated by the ingestion of the food or the food constituent or ingredient and for which there is agreement among the qualified international scientific community on the relation between the modulation of this indicator and the state of health of the population in which it is measured. The biochemical and physiological mechanisms explaining the beneficial effect on health are either elucidated or explicable with a sufficient degree of certainty in the current state of knowledge.

As appropriate, supporting scientific evidence along one or several of the following approaches shall be used. Possible types of scientific evidence include :

- *In vitro* studies and animal studies,
- Epidemiological or observational studies of humans ;
- Clinical (human) interventional studies complying with the requirements established by ethical committees.
- All other pertinent evidence, such as consensus reports and evidence-based dietary guidelines.

5.2.1 General requirements:

In order to provide statistically significant results,

- the trials shall include large enough population on a long enough time scale with the relevant dose, in the context of the usual diet of the population under study.
- the trials shall demonstrate that the claimed effect can be achieved by consuming a reasonable amount of the product as a part of the daily diet.
- the trials shall demonstrate that the product bearing the health claim shall not have negative nutritional and health impacts at recommended levels of intake of habitual consumers.

5.2.2 Specific requirements:

Reduction of disease risk claims shall primarily be based on human intervention studies, having a scientific valid design for showing a persistent effect of the food or food ingredient. A well-designed randomised, placebo-controlled clinical trial represents the highest level of evidence to support a health claim. Observational epidemiological studies generally provide evidence that is supportive of an association. Animal model studies, and *in vitro* studies may be provided as supporting knowledge base for the hypothesis but shall never be considered as sufficient *per se* to substantiate a health claim.

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

5.3 RELEVANCE OF THE EVIDENCE AT POPULATION LEVEL:

It shall be required to check that the benefit documented by experimental studies is still present at the level of the target population (general population or sub-group), preferably by simulations based on consumption data.

6. EVALUATION OF THE TOTAL BODY OF SCIENTIFIC EVIDENCE, USED TO SUPPORT A HEALTH CLAIM:

The total body of evidence provided to support the claims, shall be evaluated scientifically by a group of qualified experts, recognised by competent authorities.

Their evaluation of the scientific evidence shall be consistent with the scientific principles of risk analysis and, specifically :

- shall take all the available scientific data into account. Compiling the evidence shall be done in a balanced and unbiased way to ensure that all relevant data, both positive and negative, have been included in the documentation.
- shall follow the state-of-art norms of scientific methodology.

7. RE-EVALUATION:

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

- A new evaluation is necessary in case of any change affecting the characteristics of the food likely to influence the claimed effect.
- Studies shall be conducted to increase the knowledge on the benefit for health of the food, the substance or the ingredient.

- The consumption of the products, bearing a health claim, shall be monitored in order to evaluate the actual levels of consumption and ensure that the pattern of consumption, as it is documented, is appropriate to provide the expected benefit, specifically for the population group targeted by the claim.
- The expected effects and, if appropriate, its adverse effects, which may appear after a long-term consumption of the food, shall be investigated.

APPENDIX 2

CODEX DEFINITIONS IN CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS ADOPTED AT THE 27TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION (GENEVA JULY 2004) [8]

2. 2 Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

2.2.1 ***Nutrient Function Claims*** - a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

Example:

"Nutrient A (naming a physiological role of nutrient A in the body in the 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.

Examples: "Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."

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

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

Examples:

"A healthful diet low in nutrient or substance A may reduce the risk of disease B. 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."

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

APPENDIX 3

References

FAO/WHO -Codex Alimentarius - CCFL (2003) - ALINORM 03/22 (Appendix VII)

FAO/WHO -Codex Alimentarius-CCNFSDU (2002) - ALINORM 03/26 A (para. 4 to 6)

FAO/WHO -Codex Alimentarius -CCNFSDU (2000) - CX/NFSDU 00/10- May 2000

FAO/WHO - Codex Alimentarius (2003) - 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) - Draft Guideline for the conduct of Food Safety Assessment of Foods Products Using Recombinant DNA Microorganisms - ALINORM 03/34A (Appendix II)

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 Departement 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. Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Washington, D.C. National Academy Press, 1996. p. 8.

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