codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 9 **CX/NFSDU 03/9**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
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Proposed Draft Recommendations on the Scientific Basis of Health Claims

Prepared by the Delegation of France with assistance from Brazil, Canada, Germany, Hungary, Italy, Japan, Kenya, Netherlands, Russian Federation, South Africa, Sweden, Switzerland, Thailand, United States, EC, CIAA, ISDI, ENCA, IACFO, EFLA, IBFAN, IFT

Governments and interested international organizations are invited to submit comments or information on the attached proposed Draft Recommendations 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, Twelfth Edition,* pages 19-20) **to**: Dr. Rolf Grossklaus, Chairman of the Committee, Bundesinstitut für Risikobewertung (BfR), P.O. Box 33 00 13, 14191 Berlin, Germany (Fax: +49 1888 412 – 3715; Email: ccnfsdu@bfr.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 October 1, 2003.**

Background

During the 22nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), the delegation 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).

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.

The delegation of France, with the participation of Brazil, Canada, Germany, Hungary, Italy, Japan, Kenya, 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.

The following working document has been drafted, using the report presented at the 22nd session of the CCNFSDU and the comments from the delegations of Brazil, Canada, Denmark, Japan, The Netherlands, CIAA, ISDI.

This draft is closely related to the current work of the Codex Committee on Food Labelling, such as the Proposed Draft Guidelines for use of health and nutrition claims (§ 93, Appendix VII, ALINORM 03/22), but does not anticipate the conclusions of the Committe on Food Labelling on this matter.

These recommendations are intended to specify the requirements for the scientific justification of health claims and put no constraint on the outcome of the work on definitions of health claims by the CCFL. However, see Appendix 2, for these definitions.

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

Appendix 1

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

1 PREAMBLE :

The Codex General Guidelines On Claims (CAC/GL 1-1979 (Rev. 1-1991)) already states 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.
- Health claims should be forbidden if they cannot be justified.

In addition, , health claims should be consistent with national nutrition policy and support that policy[1].

The following recommendations are intented for governments, in order to facilitate their own evaluation of health claims, used by the industry. They may also be used as a reference by the industry, to prepare the evidentiary dossier constituted in order to support the claims.

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 evaluation of the safety and the quality of the products, for which other provisions are relevant, although it is recalled that definite requirements on these matters have to be met.

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

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

2.1 Identifcation and stability of the food, the substance or the ingredient :

- Information on the origin, the nature, the chemical composition, the processing, the specifications of the product on which the health claim is based, shall be provided.
- When the claim is about a constituent of a food, evidence shall be provided that the constituent, 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.
- Validated analytical methods should be available to check the quantity or the activity of the constituent in the food.
- A new evaluation is necessary in case of any change affecting the characteristics of the product in such a way as to put into question the claimed effect.

2.2 Safety of the product:

- The food safety is provided for by Codex Standards or existing national legislations. In addition to the usual risk assessment :
  - The known interactions between the product, on which the claim is based, with other products shall be mentioned.

[1] See ALINORM 03/22 Appendix VII

- The requirement that the expected level of consumption shall be not lead to the ADI (or, if no ADI has been set, any level known to be safe on the basis of the scientific evidence used during the evaluation of the claim), be exceeded, shall be met.

The nutritional safety shall also be taken into account during the evaluation of health claims. The evaluation shall address the risk from a change in the behaviour of the consumer, triggered by the emphasis on the product. The population, or the sub-population targeted by the product, shall be indentified. The selection of this population shall be consistent with the effects alleged by the claim. Where appropriate, various issues can 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, allergies, the introduction of new risky behaviours, ….

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

3 SCIENTIFIC REQUIREMENTS ABOUT THE CLAIM EFFECT :

3.1 GENERAL REQUIREMENTS :

A high level of quality of the scientific justification for the claimed effects is obligatory for using any health claim. It seems evident that the level of scientific justification must be sufficient to support the claimed effect but that the substantiation requirements may differ depending on whether the health claim is for disease risk reduction or enhanced function.

The scientific evidence includes studies results, either already published in scientific litterature, or conducted by the applicant in order to substantiate the alleged claim. In both cases, the studies used shall be consistent with generally accepted scientific procedures and principles.

3.2 NATURE OF THE SCIENTIFIC EVIDENCE ON THE CLAIMED EFFECT :

The claim linking the consumption of the food, the substance or the ingredient and the enhancement of a function, the maintenance or the improvement of a state related to health or the reduction of a disease risk shall be supported by scientific evidence along one or several of the folllowing approaches :

- experimental *in vitro* and/or *in vivo* studies,
- epidemiological or clinical studies on humans ; clinical interventional studies should comply with the requirements established by ethical committees and should substantiate the change in a relevant indicator.

A relevant indicator is a well-defined biological, physiological, clinical or epidemiological indicator which is modulated by the ingestion of the food or the food ingredient and for which there exists a general 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. The magnitude of the variation of this indicator, determined under the effect of ingestion of the product or ingredient, must present (in addition to the statistical significance) a biological, physiological, clinical or epidemiological significance recognised by the scientific community.

Generally, the evidence shall be provided by studies on humans, and, if a sub-population is specifically targeted, on this group (including the higher consumers of the product). When the claim is about the enhancement of a function, studies on humans may be limited, if animal experimental

models or *in vitro* are relevant or sufficiently close to human metabolism. Experiments on animals or *in vitro* studies shall often be required to explain the mechanisms involved precisely enough.

In addition,

- The trials shall include large enough population on a long enough timescale with the relevant dose, in the context of the usual diet of the population under study.
- The amount of the substance or the ingredient added to the food shall be determined according to the following criteria :
    - The toxicological evaluation : The added amount shall not expose the consumer to health risks.
    - The consumption surveys documenting adverse effects : Cumulative intake risks in a situation where the same substance is present in several foods. Simulations to assess the potential risks of excessive consumption may be conducted by the appropriate methods.
    - The amount necessary to produce the alleged effect.
- Statistical analysis of the data must be conducted with methods accepted for such studies by the scientific community : controlled studies, reference groups, statistical analysis…

3.3 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.

4 EVALUATION OF THE SCIENTIFC PROOFS, USED TO JUSTIFY A CLAIM

The evidentiary dossier constituted in order to support the claims must be evaluated scientifically by a group of qualified experts.

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

- shall take all the available scientific data into account.
- shall follow state of art norms of scientific methodology.

5 PERIODIC RE-EVALUATION:

Health claims shall be re-evaluated periodically. With this aim in view :

- Fundamental studies or clinical 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 real 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, the adverse effects which may appear after a long-term consumption of the food shall be investigated.

Appendix 2

Draft definitions currently considered by CCFL

Health claims (ALINORM 03/22A - Appendix IV) :

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."

Appendix 3

Références

FAO/OMS -Codex Alimentarius - CCFL- ALINORM 03/22 (Annexe VII)

FAO/OMS -Codex Alimentarius-CCNFSDU- ALINORM 03/26 A (sections 4 à 6)

FAO/OMS -Codex Alimentarius -CCNFSDU -CX/NFSDU 00/10- Mai 2000

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

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 ans dietary supplements.