codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 2 **CX/FL 09/37/2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
Thirty-seventh Session
Calgary, Canada, 4 - 8 May 2009

MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES [1]

I. MATTERS ARISING/REFERRED FROM THE 31st SESSION OF THE CODEX ALIMENTARIUS COMMISSION

A. Items for Information

Amendment to the General Standard for the Labelling of Prepackaged Foods: Quantitative Declaration of Ingredients
Amendment to the Guidelines for Use of Nutrition and Health Claims (Definition of Advertising)
Amendment to the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods: Annex 1 (inclusion of ethylene)

The Commission adopted the amendments.[2]

Amendment to the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999) – Rotenone
Revision of the Guidelines on Nutrition Labelling (CAC/GL 2-1985) – Implementation of the Global Strategy for Diet, Physical Activity and Health

The Commission approved new work on these items. [3]

Review of the Codex Committee Structure and Mandates of Codex Committees and Task Forces (Proposal 10 - Tasks related to nutrition)

The Commission agreed that the tasks related to nutrition were adequately addressed in the current structure of Codex through the Committee on Nutrition and Foods for Special Dietary Uses and, where appropriate, the Committee on Food Labelling, and that there was no need for another subsidiary body such as a Task Force. [4]

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[1] This document contains: **Part I**: Matters arising/referred from the 31st Session of the Codex Alimentarius Commission (31th Session) either of specific interest to the Committee for information (A) or for action (B). **Part II**: Matters referred from other Codex Committees and Task Forces that require specific action by the Committee. The Codex Secretariat will report verbally on matters of horizontal nature as appropriate to the discussion of the Committee.
[2] ALINORM 08/31/REP, para 21 and Appendix VII
[3] ALINORM 08/31/REP, para 92 and Appendix X
[4] ALINORM 08/31/REP, para 162

B. Items for Action

None.

II. MATTERS REFERRED BY OTHER COMMITTEES

1. Codex Committee on Nutrition and Foods for Special Dietary Uses

Definition of Fibre[5]

The Committee agreed to forward the amended Draft Table (Provisions on Dietary Fibre) including the definition on dietary fibre to the CCFL for information.

Proposed Draft Annex on Recommendations on the Scientific Substantiation of Health Claims to the Codex Guidelines for Use of Nutrition and Health Claims[6]

The Committee agreed to forward the proposed draft Annex to the Committee on Food Labelling for information.

2. Committee on Food Additives (CCFA)

Revision of the Codex Class Names and International Numbering System (CAC/GL 36-1989)[7]

The 31st Session of the Commission adopted the revision of the Codex Class Names and International Numbering System (CAC/GL 36-1989). The revised text includes in Section 2 a revised list of technological functions that is different from the technological functions listed in CODEX STAN 1-1985 for labelling purposes. The CCFL has been kept informed of the revision of CAC/GL 36-1989 but it did not take any action at its last session waiting for the finalisation of the text by the CCFA and adoption by the Commission.

[5] ALINORM 09/32/26, para. 48 and Appendix II (reproduced as Appendix 1 to this document)

[6] ALINORM 09/32/26, para. 102 and Appendix V (reproduced as Appendix 2 to this document)

[7] ALINORM 08/31/12, para. 147; ALINORM 08/31/22, para. 15; CAC/GL 36-1989 (Section 2)

APPENDIX 1

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B) DIETARY FIBRE
(At Step 8 of the Procedure)

COMPONENT	CLAIM	CONDITIONS
B.		**NOT LESS THAN**
Dietary Fibre	Source	3 g per 100 g* or 1.5 g per 100 kcal or 10 % of daily reference value per serving**
	High	6 g per 100 g* or 3 g per 100 kcal or 20 % of daily reference value per serving**

* Conditions for nutrient content claims for dietary fibre in liquid foods to be determined at national level.

** Serving size and daily reference value to be determined at national level.

Definition:

Dietary fibre means carbohydrate polymers[8] with ten or more monomeric units[9] , which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities

Methods of Analysis for Dietary Fibre
→ To be agreed.

[8] When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis : Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysacchrides, these associated substances may provide additional beneficial effects (pending adoption of Section on Methods of Analysis and Sampling).

[9] Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

APPENDIX 2

DRAFT ANNEX TO THE *CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS*: RECOMMENDATIONS ON THE SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS[10]

(at Step 5/8 of the Procedure)

1. SCOPE

1.1 These Recommendations are intended to assist competent national authorities 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.

1.2 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:

2.1 Food or food constituent refers to energy, nutrients, related substances, ingredients, and any other feature of a food, a whole food, or a category of foods on which the health claim is based. The category of food is included in the definition because the category itself may be assigned a common property of some of the individual foods making it up.

2.2 Health effect refers to a health outcome as defined in sections 2.2.1 to 2.2.3 of the Guidelines.

3. Scientific SUBSTANTIATION OF HEALTH CLAIMS

3.1. PROCESS FOR THE SUBSTANTIATION OF HEALTH CLAIMS

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

(a) Identify the proposed relationship between the food or food constituent and the health effect;

(b) Identify appropriate valid measurements for the food or food constituent and for the health effect;

(c) Identify and categorise all the relevant scientific data;

(d) Assess the quality of and interpret each relevant scientific study;

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

[10] Note: This document is intended as an annex to the *Codex Guidelines for the Use of Nutrition and Health Claims* (CAC/GL 23-1997, Rev. 1-2004) and should be read in conjunction with the Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)

3.2. CRITERIA FOR THE SUBSTANTIATION OF HEALTH CLAIMS

3.2.1 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 studies. Human observational studies are not generally sufficient *per se* to substantiate a health claim but where relevant they may contribute to the totality of evidence. 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) The totality of the evidence, including unpublished data where appropriate, 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.

(c) 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.

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

(a) 'Nutrient function' claims may be substantiated based on generally accepted authoritative statements by recognised expert scientific bodies that have been verified and validated over time.

(b) Some Health claims, such as those involving a relationship between a food category and a health effect, may be substantiated based on observational evidence such as epidemiological studies. Such studies should provide a consistent body of evidence from a number of well-designed studies. Evidence-based dietary guidelines and authoritative statements prepared or endorsed by a competent authoritative body and meeting the same high scientific standards may also be used.

3.3. CONSIDERATION OF THE EVIDENCE

3.3.1 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).

3.3.2 The scientific data should provide adequate characterization of the food or food constituent considered as responsible for the health effect. 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.

3.3.3 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 or mediates the effect are provided. All available data on factors (e.g. forms of the constituents) that could affect the absorption or utilisation in the body of the constituent for which the health claim is made should also be provided.

3.3.4 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) (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.

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

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

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

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

(e) 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 as relevant for the target population for which the claim is intended;

(f) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

3.3.7 Based on this evaluation and the substantiation criteria, competent national authorities can determine if, and under what circumstances, a claimed relationship is substantiated.

4. SPECIFIC SAFETY CONCERNS

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

4.2 The expected level of consumption should not exceed relevant upper levels of intake for food constituents.

4.3 The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population[11,12] 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

Health claims should be re-evaluated. Competent national authorities should re-evaluate health claims either 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.

[11] 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.

[12] 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.

APPENDIX 3

CAC/GL 36-1989

SECTION 2 – TABLE OF FUNCTIONAL CLASSES, DEFINITIONS AND TECHNOLOGICAL PURPOSES

FUNCTIONAL CLASSES	DEFINITION	TECHNOLOGICAL PURPOSE
1. Acidity regulator	A food additive, which controls the acidity or alkalinity of a food.	acidity regulator, acid, acidifier, alkali, base, buffer, buffering agent, pH adjusting agent
2. Anticaking agent	A food additive, which reduces the tendency of components of food to adhere to one another.	anticaking agent, anti-stick agent, drying agent, dusting agent
3. Antifoaming agent	A food additive, which prevents or reduces foaming.	antifoaming agent, defoaming agent
4. Antioxidant	A food additive, which prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	antioxidant, antioxidant synergist, antibrowning agent
5. Bleaching agent	A food additive (non-flour use) used to decolourize food. Bleaching agents do not include pigments.	bleaching agent
6. Bulking agent	A food additive, which contributes to the bulk of a food without contributing significantly to its available energy value.	bulking agent, filler
7. Carbonating agent	A food additive used to provide carbonation in a food.	carbonating agent
8. Carrier	A food additive used to dissolve, dilute, disperse or otherwise physically modify a food additive or nutrient without altering its function (and without exerting any technological effect itself) in order to facilitate its handling, application or use of the food additive or nutrient.	carrier, carrier solvent, nutrient carrier, diluent for other food additives, encapsulating agent
9. Colour	A food additive, which adds or restores colour in a food.	colour, decorative pigment, surface colourant
10. Colour retention agent	A food additive, which stabilizes, retains or intensifies the colour of a food.	colour retention agent, colour fixative, colour stabilizer, colour adjunct
11. Emulsifier	A food additive, which forms or maintains a uniform emulsion of two or more phases in a food.	emulsifier, plasticizer, dispersing agent, surface active agent, crystallization inhibitor, density adjustment (flavouring oils in beverages), suspension agent, clouding agent
12. Emulsifying salt	A food additive, which, in the manufacture of processed food, rearranges proteins in order to prevent fat separation.	emulsifying salt, melding salt
13. Firming agent	A food additive, which makes or keeps tissues of fruit or vegetables firm and crisp, or interacts with gelling agents to produce	firming agent

FUNCTIONAL CLASSES	DEFINITION	TECHNOLOGICAL PURPOSE
	or strengthen a gel.	
14. Flavour enhancer	A food additive, which enhances the existing taste and/or odour of a food.	flavour enhancer, flavour synergist
15. Flour treatment agent	A food additive, which is added to flour or dough to improve its baking quality or colour.	flour treatment agent, flour bleaching agent, flour improver, dough conditioner, dough strengthening agent
16. Foaming agent	A food additive, which makes it possible to form or maintain a uniform dispersion of a gaseous phase in a liquid or solid food.	foaming agent, whipping agent, aerating agent
17. Gelling agent	A food additive, which gives a food texture through formation of a gel.	gelling agent
18. Glazing agent	A food additive, which when applied to the external surface of a food, imparts a shiny appearance or provides a protective coating.	glazing agent, sealing agent, coating agent, surface-finishing agent, polishing agent, film-forming agent
19. Humectant	A food additive, which prevents food from drying out by counteracting the effect of a dry atmosphere.	humectant, moisture-retention agent**,** wetting agent
20. Packaging gas	A food additive gas, which is introduced into a container before, during or after filling with food with the intention to protect the food, for example, from oxidation or spoilage.	packaging gas
21. Preservative	A food additive, which prolongs the shelf-life of a food by protecting against deterioration caused by microorganisms.	preservative, antimicrobial preservative, antimycotic agent, bacteriophage control agent, fungistatic agent, antimould and antirope agent, antimicrobial synergist
22. Propellant	A food additive gas, which expels a food from a container.	propellant
23. Raising agent	A food additive or a combination of food additives, which liberate(s) gas and thereby increase(s**)** the volume of a dough or batter.	raising agent
24. Sequestrant	A food additive, which controls the availability of a cation.	sequestrant
25. Stabilizer	A food additive, which makes it possible to maintain a uniform dispersion of two or more components.	stabilizer, foam stabilizer, colloidal stabilizer, emulsion stabilizer
26. Sweetener	A food additive (other than a mono- or disaccharide sugar), which imparts a sweet taste to a food.	sweetener, intense sweetener, bulk sweetener
27. Thickener	A food additive, which increases the viscosity of a food.	thickener, bodying agent, binder, texturizing agent