

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 2

CX/GP 09/25/2

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

Twenty-fifth Session

Paris, France, 30 March – 3 April 2009

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

I. MATTERS ARISING/REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION (CAC30 AND CAC31)

A. Items for Information

Amendments to the Rules of Procedure

The proposed amendments were adopted by the Commission and entered into force following their approval by the Directors-General of FAO and WHO (CAC30²).

Working Principles for Risk Analysis for Food Safety for Application by Governments

The Commission adopted the text as proposed (CAC30³).

Amendments to other Sections of the Procedural Manual

The amendments to the other sections of the Manual were adopted as proposed by CCGP24 (CAC30⁴) and further amendments were adopted by CAC31⁵.

Recommendations from the CCFICS related to the Code of Ethics

The Commission endorsed the recommendations (CAC30⁶).

Implementation of the Joint Evaluation

The Commission acknowledged the remarkable work done by the Committee on General Principles hosted by the Government of France as well as the support so far provided by FAO and WHO in this regard. The Chairperson observed that now the Commission was fully capacitated to efficiently develop international food standards for a decade to come and stand up to new challenges (CAC30⁷).

¹ This document contains: **Part I:** Matters arising/referred from the Codex Alimentarius Commission (30th and 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 07/30/REP, paras. 21-23

³ ALINORM 07/30/REP, paras. 56-60

⁴ ALINORM 07/30/REP, paras. 24-38

⁵ ALINORM 08/31/REP, paras. 11-20

⁶ ALINORM 07/30/REP, para. 194

⁷ ALINORM 07/30/REP, para. 142

B. Items for Action

The concept of “consensus” and its application in Codex (CAC30⁸)

To be discussed under Agenda item 4.

References to the abolished “acceptance” provisions in commodity standards (CAC31⁹)

To be discussed under Agenda item 7.

Participation of Developing Countries in Codex Meetings (CAC31¹⁰)

To be discussed under Agenda item 9.

II. MATTERS REFERRED BY OTHER COMMITTEES

1. Committee on Food Hygiene (CCFH)

Risk analysis policy document for the CCFH¹¹

The CCFH noted the decision of the CAC regarding Activity 2.1 of the Codex Strategic Plan 2008-2013 (Review of consistency of risk analysis principles elaborated by the relevant Codex Committees) and the decision of the previous session of CCFH on the work to elaborate a risk analysis policy document to guide CCFH work, the Committee encouraged the Delegation of India to proceed with this work in order to consider the above document at its next session (2009).

2. Coordinating Committee for Latin America and the Caribbean

Length and content of Codex reports¹²

The Committee decided to request the Committee on General Principles to determine whether the current provision in the *Procedural Manual* under *Point 1 of Rule X – Records and Reports* – and the final paragraph of the Section *Conduct of Meetings – Guidelines on the Conduct of Meetings of the Codex Committees and Ad Hoc Intergovernmental Task Forces* was the same as the recommendation approved by the Commission on the naming of members (*point 1, second indent, paragraph 26 of ALINORM 08/31/3A*) and if it was not, to determine whether both needed to be retained and, if they were the same, that a decision be taken on one of them.

Consensus¹³

The Committee acknowledged the importance of consensus-based decision-making in Codex and agreed that the definition of consensus, as proposed by the Delegation of Paraguay, namely “*consensus is the absence of justified opposition from any member present at the meeting where the decision is taken*” could be proposed at the upcoming session of the Committee on General Principles as a starting point for discussion.

⁸ ALINORM 07/30/REP, paras. 198-200

⁹ ALINORM 08/31/REP, paras. 79-81

¹⁰ ALINORM 08/31/REP, paras. 152-161

¹¹ ALINORM 09/32/13, para. 15

¹² ALINORM 09/32/36, paras. 41 - 48

¹³ ALINORM 09/32/36, paras. 53 - 54

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

Risk Analysis Principles and Guidelines¹⁴

The Committee agreed to forward the Proposed Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for the Special Dietary Uses as amended during the session to the Committee on General Principles (CCGP) for endorsement and to the 32nd Session of the Codex Alimentarius Commission for adoption at Step 8 (see appendix 1)

4. Codex Committee on Pesticide Residues

Risk analysis principles¹⁵

The Committee agreed to request the approval of the Commission for new work on the revision of the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues, which would incorporate the Criteria for the Prioritization Process of Compounds for Evaluation by JMPR and the MRL Periodic Review Procedure. This request was approved by the 31st Session of the Commission.

¹⁴ ALINORM 09/32/26, para. 82 and appendix IV (reproduced as appendix 1 to this document)

¹⁵ ALINORM 08/31/24, paras. 129-134

Appendix 1

DRAFT NUTRITIONAL RISK ANALYSIS PRINCIPLES AND GUIDELINES FOR APPLICATION TO THE WORK OF THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**(At Step 8 of the Procedure)****SECTION 1 – BACKGROUND**

1. The *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (hereafter cited as “Working Principles”) has established general guidance on risk analysis to Codex Alimentarius. These Working Principles were adopted in 2003 and published in this Procedural Manual.
2. The objective of the Working Principles is “to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations so that food safety and health aspects of Codex standards and related texts are based on risk analysis”. By its reference to health aspects in addition to food safety, the objective provides clearer direction for risk analysis to apply to nutritional matters that are within the mandate of the Codex Alimentarius Commission and its subsidiary bodies.
3. The Nutritional Risk Analysis Principles are established to guide the Codex Alimentarius Commission and its subsidiary bodies - primarily but not exclusively the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) - in applying nutritional risk analysis to their work. This guidance may be used for the work of other Committees since CCNFSDU is also mandated, in accordance with its 4th term of reference, “to consider, amend if necessary, and endorse provisions on nutritional aspects” of foods including those resulting from application of nutritional risk analysis that are developed by other Codex subsidiary bodies.

SECTION 2 – INTRODUCTION

4. Codex nutritional risk analysis addresses nutrients¹⁶ and related substances¹⁷ and the risk to health from their inadequate and/or excessive intake. Nutritional risk analysis applies the same general approach as traditional food safety risk analysis to consideration of excessive intakes of nutrients and related substances. However, unlike many constituents of food that are the subject of traditional food safety risk analysis (such as food additives, chemical (pesticide and veterinary drug) residues, microbiological pathogens, contaminants and allergens) nutrients and related substances are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health. Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes.
5. The *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses* presented in this document (hereafter cited as “Nutritional Risk Analysis Principles”) are subsidiary to and should be read in conjunction with the Working Principles.
6. These Nutritional Risk Analysis Principles are framed within the three-component structure of the Working Principles, but with an added initial step to formally recognize Problem Formulation as an important preliminary risk management activity.

¹⁶ **Nutrient** is defined by Codex *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) to mean: any substance normally consumed as a constituent of food:

- (a) which provides energy; or
- (b) which is needed for growth and development and maintenance of healthy life; or
- (c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.

¹⁷ **A related substance** is a constituent of food (other than a nutrient) that has a favourable physiological effect.

SECTION 3 – SCOPE AND APPLICATION

7. Nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, and the predicted reduction in risk from proposed management strategies. In situations that address inadequate intakes, such a reduction in risk through addressing the inadequacy might be referred to as a nutritional benefit.
8. The food constituents of primary interest in nutritional risk analysis are inherent components of food and/or intentionally added to food and are identified as:
 - nutrients that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; and/or
 - related substances that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at lower intake.
9. When favourable effects of the nutrient or related substance of primary interest are being assessed, consideration should be given to whether the food matrix could increase the risk of an adverse health effect.
10. Where appropriate, the application of quantitative nutritional risk assessment may guide decision making on quantitative content provisions for nutrients and related substances in certain Codex texts.
11. Nutritional risk assessment should be as quantitative as possible, although a qualitative risk-based approach drawing on the principles of nutritional risk analysis could assist the development of Codex texts in such situations as:
 - formulating general principles related to nutritional composition (e.g. principles for the addition of nutrients to foods);
 - formulating general principles for assessing or managing risks related to foods for which a nutrition or health claim has been requested;
 - managing risks by labelling advice in relation to consumption of foods of certain nutrient-related¹⁸ composition, including foods for special dietary use; and
 - advising on risk-risk analysis (e.g. risk associated with a significantly reduced or entirely avoided consumption of a nutritious, staple food in response to a dietary hazard such as a contaminant present in that food).

SECTION 4 – DEFINITIONS

12. The *Definitions of Risk Analysis Terms Related to Food Safety* in this Procedural Manual provide suitable generic definitions of risk analysis, risk assessment, risk management, risk communication and risk assessment policy. When applied in a nutritional risk analysis context, these high-level risk analysis terms should be prefaced by 'nutritional' and their existing definitions appropriately adapted by replacement of relevant existing terms and definitions with those listed below.
13. However, other *Definitions of Risk Analysis Terms Related to Food Safety* have been modified to reference inadequate intake as a nutritional risk factor. Some new terms also have been defined to provide further clarity. The modified or newly developed subsidiary definitions are as follows:

Nutritional risk – A function of the probability of an adverse health effect associated with inadequate or excessive intake of a nutrient or related substance and the severity of that effect, consequential to a nutrient-related hazard(s) in food.

¹⁸ For the purpose of these Nutritional Risk Analysis Principles, the descriptive term 'nutrient-related' refers to one or more nutrients and/or related substances, as the case may be.

Adverse health effect¹⁹ – A change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.

Nutrient-related hazard – A nutrient or related substance in food that has the potential to cause an adverse health effect depending on inadequate or excessive level of intake.

Nutrient-related hazard identification – The identification of a nutrient-related hazard in a particular food or group of foods.

Nutrient-related hazard characterization – The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with a nutrient-related hazard.

Dose response assessment – The determination of the relationship between the magnitude of intake of (or exposure to) (i.e. dose) a nutrient or related substance and the severity and/or frequency of associated adverse health effects (i.e. response).

Upper level of intake – the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

Highest observed intake – the highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects have been identified.

Intake (Exposure) assessment – The qualitative and/or quantitative evaluation of the likely intake of a nutrient or related substance from food as well as intake from other relevant sources such as food supplements.

Nutrient-related risk characterization – The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on nutrient-related hazard identification, nutrient-related hazard characterization and intake assessment.

Bioavailability²⁰ – The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host-related intestinal and systemic factors.

Homeostatic mechanism – A mechanism effected through a system of controls activated by negative feedback that allow the maintenance of normal body functions in the presence of a variable nutrition environment.

SECTION 5 – PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

14. Nutritional risk analysis comprises three components: risk assessment, risk management and risk communication. Particular emphasis is given to an initial step of Problem Formulation as a key preliminary risk management activity.

PRELIMINARY NUTRITIONAL RISK MANAGEMENT ACTIVITIES

15. Preliminary nutritional risk management activities should have regard to the particular sections in the Working Principles titled General Aspects of Risk Analysis, and Risk Assessment Policy.

Nutritional Problem Formulation

16. Nutritional Problem Formulation is necessary to identify the purpose of a nutritional risk assessment and is a key component of preliminary nutritional risk management activity because it fosters interactions

¹⁹ *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*. Report of a joint FAO/WHO technical workshop 2005, WHO, 2006.

²⁰ Gibson R.S. The role of diet- and host-related factors in nutrient bioavailability and thus in nutrient-based dietary requirement estimates. *Food and Nutrition Bulletin* 2007;28 (suppl): S77-100.

between risk managers and risk assessors to help ensure common understanding of the problem and the purpose of the risk assessment.

17. Such considerations should include whether a nutritional risk assessment is needed and if so:

- the priority it should be accorded;
- who should conduct and be involved in the nutritional risk assessment, nutritional risk management and nutritional risk communication processes;
- the need for development of nutritional risk assessment policy;
- how the nutritional risk assessment will provide the information necessary to support the nutritional risk management decision;
- whether data are available to embark on an evaluation of nutritional risks;
- what level of resources are available; and
- the timeline for completing the assessment.

18. Specific information to be gathered for nutritional problem formulation may include:

- a detailed inventory of prior knowledge;
- identification of the (sub)populations to be the focus for the risk assessment, geographical areas or consumer settings to be covered;
- relevant source(s) of intake ; and
- the health endpoints to be considered.

NUTRITIONAL RISK ASSESSMENT

19. The risk assessment section of the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk assessment. Additional nutritional risk assessment principles to consider within the Codex framework are identified below.

Nutrient-Related Hazard Identification and Hazard Characterization

20. These two steps are often globally relevant because they are based on available scientific and medical literature that contribute data from diverse population groups. This global relevance for characterization of hazard does not, however, preclude the possibility of a (sub)population-specific hazard.
21. Nutritional risk assessment should take into consideration the nutrient-related hazard(s) posed by both inadequate and excessive intakes. This may include consideration of hazard(s) posed by excessive intakes of accompanying risk-increasing nutrients in the food vehicle(s) under consideration.
22. Nutrient-related hazard identification and characterization should recognize current methodological differences in assessment of nutritional risk of inadequate and excessive intakes, and scientific advances in these methodologies.
23. Nutrient-related hazard characterization should take into account homeostatic mechanisms for essential nutrients, and limitations in the capacity for homeostatic adaptations. It may also take into account bioavailability including factors affecting the bioavailability of nutrients and related substances such as different chemical forms.
24. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to adequacy include measures of average requirement. Some globally applicable nutrient reference standards for average requirement have been published by FAO/WHO. Official regional and national nutrient reference standards are also available and have been periodically updated to reflect scientific advances. These are more likely to relate to nutrients than to related substances.

25. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to excessive intakes include upper levels of intake. Some globally applicable reference standards of upper level of intake have been published by FAO/WHO. In addition, the establishment of international upper levels of intake and highest observed intake that build on recommendations may be considered in the future. Some periodically-updated nutrient reference standards are available from regional and national authorities. For some related substances, such standards developed from a systematic review of the evidence are available only in the peer-reviewed scientific literature.
26. The assessment of inadequate and excessive levels of intake of particular nutrients and related substances should take into account the availability of all such scientifically determined reference sources, as appropriate. When using such reference standards for nutrient and related substances in nutritional risk assessment, the basis for their derivation should be explicitly described.

Nutrient-Related Intake Assessment and Risk Characterization

27. These two steps are generally specific to the (sub)population(s) under consideration for risk assessment. The populations relevant to Codex consideration are populations at large in Codex member countries or particular subpopulation groups in these countries defined according to physiological parameters such as age or state of health.
28. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements⁶, and in the case of certain minerals, water. It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed.

NUTRITIONAL RISK MANAGEMENT

29. The risk management section of the *Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk management. Additional nutritional risk management principles to consider within the Codex framework are identified below.
30. Nutritional risk management can be effected through quantitative measures or qualitative guidance elaborated in Codex texts. Such risk management could involve decisions about nutrient composition, consideration of the suitability of foods containing risk-increasing nutrients for certain purposes or (sub) populations, labelling advice intended to mitigate nutritional risks to public health, and formulation of relevant general principles.

Nutritional risk management decisions should take into account their impact on dietary patterns and consumer behaviour. Such information should be supported by relevant research.

31. Nutritional risk assessment policy should be articulated as appropriate for the selected risk assessor prior to the conduct of the nutritional risk assessment.

NUTRITIONAL RISK COMMUNICATION

32. The risk communication section of the *Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* is generally applicable to nutritional risk communication.

SECTION 6 – SELECTION OF RISK ASSESSOR BY CCNFSU

⁶ Codex *Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55 – 2005) define food supplements as sources in concentrated forms of those nutrients or related substances alone or in combinations, marketed in forms such as capsules, tablets, powders solution, etc., that are designed to be taken in measured small unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of nutrients or related substances from the diet.

-
33. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This acknowledgement however, does not preclude the possible consideration of recommendations arising from other internationally recognised expert bodies, as approved by the Commission.
 34. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk assessment policy to provide guidance to the risk assessor. These parameters should be established by CCNFSDU.