



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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Agenda Item 2

CX/NFSDU 10/32/2

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty second Session

Crowne Plaza Hotel, Santiago, Chile

1 – 5 November 2010

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES

A. GENERAL DECISIONS OF THE 33RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Geneva, Switzerland, 5 – 9 July 2010)

1. The Commission adopted several amendments to the Procedural Manual and also adopted 38 new or revised Codex standards or related texts elaborated by the Codex Committees and Task Forces. It also approved a number of new work proposals and proposals for discontinuation of work. A complete list of these texts and details of their consideration could be found in ALINORM 10/33/REP which is available from: <http://www.codexalimentarius.net>.

B. DECISIONS OF THE 33RD SESSION OF THE COMMISSION RELATED TO THE WORK OF THE COMMITTEE

2. The following texts considered and adopted by the Commission have direct relation to the work of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

STANDARDS CONSIDERED AT STEP 8

3. The Commission adopted the Draft Standards and Related Texts submitted by its subsidiary bodies at Step 8 (including those submitted at Step 5 with a recommendation to omit Steps 6 and 7), as well as other standards and related texts submitted for adoption, as presented in Appendix III to ALINORM 10/33/REP.

DRAFT STANDARDS CONSIDERED AT STEP 5

4. The Commission adopted at Step 5 the Proposed Draft Standards and Related Texts submitted by its subsidiary bodies, as presented in Appendix IV to ALINORM 10/33/REP, and advanced them to Step 6. The following paragraphs provide additional information on the comments made and the decisions taken on certain items.

***General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Population*¹**

5. The Delegation of South Africa expressed the view that proposed levels of NRVs were too low, especially having regard to the prevention of chronic diseases and malnutrition and that as a result nutrient content claims would be made for a wider range of foods but would not benefit consumers, and therefore the determination of suitable levels of NRVs should be left for national authorities to decide on the basis of nutrient profiling. One observer, while supporting the views expressed by the above delegation, was of the view that the definition of upper level of intake also should be clarified before proceeding with adoption of this document at Step 5.

¹ ALINORM 10/33/REP, paras 67, 68

6. Some delegations recalled that this document addressed general principles for NRVs, not specific nutrients and supported its adoption. After a short discussion, the Commission adopted the General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Population at Step 5 and encouraged all interested members and observers to resubmit their technical comments to the Committee.

ELABORATION OF NEW STANDARDS AND RELATED TEXTS

7. The Commission approved the elaboration of new standards and related texts summarized in Appendix VI to ALINORM 10/33/REP. The following paragraphs provide additional information on comments made and decisions taken on the following items.

Establishment of Nutrient Reference Values (NRVs) for Nutrients Associated with Risk of Diet-Related Non-communicable Diseases for the General Population²

8. The Delegation of Malaysia pointed out that the science for developing NRVs for nutrients associated with risk of non-communicable diseases was still inconclusive at this time. Malaysia was of the view that Codex should focus on the revision of NRVs for vitamins and minerals because these had wider application for the general population and there were more sound scientific data to allow their establishment. The Delegation also drew the attention of the Commission to the fact that only a few countries were making use of the existing set of NRVs for labelling purposes and that most national legislations were using their own RDA or RDI for nutrition labelling purposes, and therefore strongly opposed the proposed new work in this area.

9. The Representative of WHO drew the attention of the Commission to the fact that the proposed new work on "Establishing NRVs for Nutrients associated with risk of diet-related NCDs" was one of the proposed Actions intended for CCNFSDU and the CCFL in the Draft Action Plan for implementing the WHO Global Strategy on Diet, Physical Activity and Health which was developed at the request of the 28th Session of the Commission in 2005 and that both the CCFL and CCNFSDU had discussed extensively each of these proposed actions during the last years. The Representative pointed out that the proposed new work was timely, given the increasing availability of scientific evidence on nutrients associated with risk of diet-related NCDs during the last decade, including the most recent Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition in 2008. The Representative indicated that there was clear agreement among the experts on the strength of evidence on the associations of different types of fats and fatty acids and various diet-related NCDs, for example and that the only inconclusive outcome of the discussions among the experts was the issues related to total fat. WHO had therefore initiated the process of undertaking a systematic review of the effects of total fat intake on obesity and other diet-related NCDs in February 2010 through the new WHO guideline development process with a view to provide further scientific evidence for developing a clear guideline on the effect of total fat intake on diet-related NCDs. The Representative indicated that the outcomes of this systematic review are expected to become available later this year and stressed that the work was very timely given the on-going work being carried out by WHO in developing guiding principles and framework of nutrient profiling.

10. The Commission noted that the Committee on Nutrition and Foods for Special Dietary Uses and the CCEXEC had recommended to initiate work in this area and, after a short discussion, approved new work on the Establishment of Nutrient Reference Values (NRVs) for Nutrients Associated with Risk of Diet-Related Non-communicable Diseases for the General Population, with the reservation expressed by the Delegation of Malaysia.

C. MATTERS ARISING FROM OTHER CODEX COMMITTEES AND TASK FORCES

64th SESSION OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION (CCEXEC)

² ALINORM 10/33/REP, paras 80 – 82

Study on the Speed of the Codex Standard-Setting Process³

11. The Representative of the FAO said that FAO and WHO were in the process of installing a mechanism with a structure similar to JEMRA in order to give scientific advice to the CCNFSDU. In some cases in the past the missing structure for scientific advice on issues related to nutrition and foods for special dietary uses had led to delays in the work of the CCNFSDU.

12. The Committee noted extensive use of pre-session and electronic working groups by the CCNFSDU.

38th SESSION OF THE CODEX COMMITTEE ON FOOD LABELLING (CCFL)***Matters referred by the Codex Committee on Nutrition & Foods for Special Dietary Uses (CCNFSDU)***⁴

13. The Committee noted that the CCNFSDU had agreed to recommend to the CCFL to establish a definition for the term “nutrient reference values” and had proposed as a basis for discussion the following draft definition: “*Nutrient reference values are a set of numerical values established and used for purposes of nutrition labelling*”. The CCNFSDU had also proposed to extend this definition to include the basis on which NRVs are determined by adding “and are based on scientific data on nutrient requirements” and “and/or nutrient levels associated with risk of diet-related noncommunicable diseases” but that the CCNFSDU did not reach agreement on this point.

14. The Committee agreed that there was a need for a definition of NRVs and several delegations indicated support for the wording proposed by the CCNFSDU.

15. The Delegations of Canada, the United States and the European Union offered to prepare a draft project document requesting new work on a definition for nutrient reference values, for discussion under agenda item 12.

Proposal for New Work on a Definition for Nutrient Reference Values (NRVs)⁵

16. In view of its earlier agreement to develop a definition for nutrient reference values (NRVs) in response to a request from the Committee on Nutrition and Foods for Special Dietary Uses (see Agenda Item 2), the Committee considered the proposed Project Document presented in CRD 20 and made a few editorial amendments.

17. The Committee agreed to initiate new work on a definition for NRVs as proposed in the project document (Appendix XII). Subject to approval by the Commission, the Committee agreed that comments would be requested through a circular letter on the proposed text provided by the CCNFSDU (CX/CF 10/38/2) and that the Delegation of Canada would provide a proposed draft definition for consideration by the next session based on these comments.

Discussion Paper on Labelling Provisions dealing with the Food Ingredients Identified in the Global Strategy on Diet, Physical Activity and Health⁶

18. The delegation of Canada noted that the CCFL had asked that the CCNFSDU look at establishing conditions for claims for use for labelling relating to salt, trans-fatty acids and added sugars.

19. The delegation recalled that the CCNFSDU had considered that there was merit in establishing claims in relation to salt but there was no clear agreement for claims for added sugars and trans-fatty acids. CCNFSDU requested the CCFL to identify the specific claims that are of interest and then CCNFSDU would be in a position to develop the corresponding conditions for those claims.

20. The Committee debated as to how to reply to the question of the CCNFSDU. The issue of whether to request CCNFSDU to look into criteria for claims on trans-fatty acids was discussed.

³ ALINORM 10/33/3A, paras 111, 112

⁴ ALINORM 10/33/22, paras 11 – 13

⁵ ALINORM 10/33/22, paras 190 – 191

⁶ ALINORM 10/33/22, paras 105 - 111

Several delegations said that this would not be appropriate as the Committee had not started new work on claims for trans-fatty acids and they did not support such work, as there might be regional differences.

21. It was suggested that such work could be included in the project document and the terms of reference of the working groups previously established.

22. After some discussion, the Committee agreed to request from the Commission new work on considering the addition of nutrient content claims in relation to trans-fatty acids (see Appendix V) and to discuss this work in the working groups previously established (see paras. 96 - 97). There was no consensus to start work on claims on the absence of trans-fatty acids and it was agreed that this would be reconsidered in light of the outcome of the working groups.

23. Some delegations noted that section 3.2.1.4 of the *Guidelines on nutrition labelling* allows for additional declaration of nutrients addressing those that should be limited in the diet as well as those with inadequate intakes.

24. In the discussion it had been mentioned that there seemed to be an editorial error in the use of the footnote 3 in the table of conditions for nutrient contents in the *Guidelines on Nutrition and Health Claims* (CAC/GL 23-1997). The footnote should in fact apply to all four claims related to saturated fats and cholesterol. The Committee agreed to propose to the Commission to amend the table as indicated in Appendix VI in the framework of editorial changes to Codex standards and related texts.

26th SESSION OF THE CODEX COMMITTEE ON GENERAL PRINCIPLES (CCGP)

***Review of the Risk Analysis Policies of Codex Committees*⁷**

general aspects

The Committee agreed that risk analysis policies developed by Codex committees were generally consistent with the *Working Principles for Risk Analysis*, which complied with the mandate given to the Committee under Activity 2.1. The Committee also agreed to forward the review presented in CL 2010/1-GP to the committees concerned for their consideration and review of their risk analysis policies, which would initiate Activity 2.2 of the Strategic Plan. The relevant section of the CL is attached in the **Annex**.

definition of “hazard”

25. The Observer from CRN pointed out that the definition of hazard in the Procedural Manual, referring to an “agent” was different from the definitions used in authoritative scientific documents relating to nutrient risk assessment, which referred to “effect” and therefore proposed to insert the following footnote to the definition of “hazard” in the Procedural Manual: “*This definition of hazard as an agent differs from the definition as an effect in many of the authoritative scientific references cited by several Codex committees in their documents on risk analysis. This difference should not be interpreted as producing any conflict in the interpretation or application of the Working Principles of Risk Analysis.*”

26. Some delegations expressed the view that the current definition of “hazard” was consistent with the definition of nutrient-related hazard and that there was no need to revise it or to include an additional footnote. Another delegation proposed an amendment to the present definition, and it was also suggested to refer this proposal to the CCNFSDU as it was mainly related to nutritional risk assessment.

27. The Committee could not reach a conclusion on this proposal at this stage and in view of the general relevance of the “hazard” definition, agreed to forward the above proposal to the committees concerned (CCFA, CCCF, CCRVDF, CCPR, CCNFSDU, CCFH) for advice and to consider this question further at its next session, taking into account the views of these Committees.

42nd SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES (CCFA)

⁷ ALINORM 10/33/33, paras 56 – 58

Food Additive Provisions in the Codex Standard for Infant Formula and Formulas for Special Medical Purposes (CODEX STAN 72-1981)⁸

28. The Committee noted that the CCNFSDU was still waiting for an advice on a number of food additive provisions forwarded by the 28th Session of the CCNFSDU to the CCFA and accepted the kind offer of the delegation of Switzerland to review what issues were still pending for advice to the CCNFSDU and to prepare a discussion paper containing proposals on how to address these issues.

29. One observer pointed out the importance of this work for some African countries and expressed willingness to provide available information on gum Arabic (INS 414).

31st SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING (CCMAS)

Endorsement of Methods of Analysis Provisions in Codex Standards⁹

30. The report of the Working Group was presented by its Chair, Dr Roger Wood (United Kingdom). The Committee considered the methods proposed for endorsement and in addition to editorial changes made the amendments and recommendations presented below.

Methods for Dietary Fibre¹⁰

31. Following the adoption of the provisions for dietary fibre in the Table of Conditions for Claims in the *Guidelines for Use of Nutrition and Health Claims*, the Committee on Nutrition and Foods for Special Dietary Uses finalised the methods of analysis for dietary fibre at its last session (2009).

32. The Committee noted that the working group had discussed extensively the methods proposed for the determination of dietary fibre but could not reach a conclusion on the suitability of several methods and on their type and had agreed that some interested delegations would prepare a revised list to clarify the commodities covered and the components of dietary fibre determined by the proposed methods.

33. The Delegation of the United States and the Observer from AOCS informed the Committee that the revised Table in CRD 21 took into account the characteristics of several AOAC and AAAC methods.

34. The Committee noted that most of these methods were empirical and that some of them might be overlapping, and therefore agreed that they could be endorsed as Type IV in order to make them available as Codex methods and asked the CCNFSDU to define their scope more precisely. It was agreed that further endorsement of these methods would be considered when such clarification became available, as some of them might be suitable as Type I methods.

35. The Committee also made some specific amendments and comments to the list of methods, as follows. It was proposed to amend the title of the first group of methods to reflect that they measure the higher molecular weight fraction of dietary fibre based on solubility and not on the number of monomeric units. However the current title was retained, taking into account the definition of dietary fibre.

36. For the first two methods in the list, it was agreed to clarify which component of dietary fibre was determined under the “provisions”. Although a proposal was made to amend the description of the commodity to refer to specific foods studied in collaborative studies, it was recalled that the definition of dietary fibre applied to all foods. The general term “all foods” was therefore retained, with an additional description of the products concerned in some cases. It was also recalled that according to footnote 1, users should consult the description of each method for the food matrices concerned.

⁸ ALINORM 10/33/12, paras 168 – 169

⁹ ALINORM 10/33/23, Appendix II

¹⁰ ALINORM 10/33/23, paras 71 – 78

37. The Committee discussed the proposal to delete the AOAC 2001.03 method as some delegations considered that it had been replaced by the more recently validated AOAC 2009.01, however the Committee could not come to a conclusion on this question and agreed to ask the CCNFSDU for clarification on the need for this method.

38. The Committee agreed to delete the AAAC Intl 32 06 01 or AOAC 992.16 method as it applies to the same analyte and matrices as AOAC 991.43 and double counts fibre, and the AAAC Intl 32-22- 01 or AOAC 992.28 as they measure the same components as AOAC 995.16, they are not used and kits are no longer available.

Annex**Review of the Risk Analysis Policies of Codex Committees (CL 2010/1-GP) (relevant sections)****General considerations**

Several sets of principles for risk analysis already exist, all of which were developed after the *Working Principles* were adopted. All Committees concerned have developed their risk analysis policies and some of them are still discussing new issues or reviewing their approaches to risk management, which may result in new developments or updates in the near future.

However, this should not prevent the Committee from initiating the review of the current principles for risk analysis in the relevant areas, while recognising that some of the texts under consideration may be amended and reconsidered. The Committee on General Principles may also make some general recommendations to the Committees that are still revising or developing risk analysis policies in order to ensure consistency with the *Working Principles*.

As a general remark, it may be noted that the format of the principles for risk analysis developed by Codex committees does not always follow the structure of the *Working Principles* and the components of risk analysis, but rather a description of the respective responsibilities and tasks carried out by the Committee concerned and the expert committees providing scientific advice.

The Committee on General Principles may consider a general recommendation to the committees concerned to review their documents in order to follow the structure of the *Working Principles* and to proceed according to the components of risk analysis. In several cases there would be no need for substantial amendments but rather for reordering the text.

At the last session of the Committee, it was noted the differences in the documents might be due to the nature of the specific risks considered and that the review should take into account these specificities (such as chemical and microbiological risks as regards food safety, and the application of risk analysis to nutrition issues). However there are also substantial differences in the structure of the risk analysis principles developed to address chemical risks related to additives, contaminants, veterinary drugs and pesticide residues, between them or as compared with the *Working Principles*.

Another general remark is that in several documents on risk analysis, the section on risk assessment policy is missing as a separate section, although several elements of such policy may appear throughout the text. At the last session of the Committee on General Principles, it was pointed out that the establishment of risk assessment policies was essential to the risk analysis process and that several elements should be considered when reviewing risk analysis policies.

While the *Working Principles* address only the components of risk analysis, it may be noted that elements of procedure are also included in various sections of specific documents, which may lead to repetition of texts appearing elsewhere in the Manual, such as the Elaboration Procedure or Criteria for New Work. A general recommendation might be to concentrate only on the risk analysis process and to avoid repeating elements of procedure in risk analysis documents, although that may not always be easy in practice, especially when considering new work related to the prioritisation process.

At the last session, the Committee briefly discussed the provisions presented in the annexes to the risk policy documents, such as data requirements and criteria for prioritisation and it was agreed that they would be taken into account in the review of risk analysis principles. These texts have been considered according to their relevance to risk analysis principles and policies for each specific food safety area.

Nutrition and Foods for Special Dietary Uses

When the *Working Principles* were developed, they were mainly intended to address risk analysis in the context of chemical and microbiological hazards and to ensure food safety. As the Principles are of general application, they were taken into account in the development of the *Nutritional Risk Analysis Principles for Application to the Work of the CCNFSDU*. However, due to the nature of the subject and the addition of health aspects in addition to food safety, it was necessary to introduce several new concepts and definitions that were specifically required to develop the concept of risk analysis as

applied to nutrition. For this reason, a comparison with the *Working Principles* may not be as relevant as in the case of risk analysis principles addressing chemical or microbiological hazards, and only a few remarks are presented below.

The *Nutritional Risk Analysis Principles* generally follow the structure of the *Working Principles* as regards the description of risk assessment and risk management. There are no specific provisions regarding risk communication, only a reference to the corresponding section in the *Working Principles*, and this section might be further developed to take into account the specificities of nutrition risk assessment, if needed.

As regards the order of the sections, the last section *Selection of Risk Assessor by CCNFSDU* includes only two paragraphs which might also be transferred to other sections. Paragraph 33 could be inserted at the beginning of the document, possibly under Section 1 which identifies the risk manager and could also refer to the risk assessor.

Paragraph 34 refers to the request for risk assessment formulated by the CCNFSDU and could be transferred to the section on *Nutritional Problem Formulation* or in *Nutritional Risk Management*, rather than including it at the end of the document.