

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 2

**CX/NFSDU 07/29/2
September 2007**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

29th Session,

Bad Neuenahr-Ahrweiler, Germany

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

A. GENERAL DECISIONS OF THE 30TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Rome, Italy, 2 – 7 July 2007)

1. The Commission **adopted** a number of amendments to the Rules of Procedure and other amendments to the Procedural Manual and took other decisions including re-activation of the Codex Committee on Natural Mineral Waters. The Commission also adopted 44 new or revised Codex standards or related texts elaborated by the Codex Committees and Task Forces. A complete list of these texts and details of their consideration could be found in ALINORM 07/30/REP which is available from: <http://www.codexalimentarius.net>

B. DECISIONS OF THE 30TH 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

Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants¹ (ALINORM 07/30/REP., paras 62-65)

3. The Delegation of Côte d'Ivoire indicated that the reference to good hygienic practice and other provisions in Section 9.5 "Information for Use" did not provide sufficiently detailed guidance for safe preparation and use of powdered infant formula and proposed to reference the recently published WHO/FAO *Guidelines on the Safe Preparation, Storage and Handling of Powdered Infant Formula*, which provided useful information for customers on safe handling and use of powdered infant formula and which had not been available during finalization of the Standard by the Committee on Nutrition and Foods for Special Dietary Uses. The Representative of WHO proposed, instead, to make a reference, in the Section on Hygiene, to the WHO/FAO *Guidelines* in order to better protect infants. These proposals were supported by the Delegation of Singapore and several other delegations and observers.

4. Several other delegations and one observer pointed out that the standard had been under revision during a very long period of time, that the current text had been agreed by consensus at the last session of the CCNFSDU and that introduction of the reference to the WHO/FAO *Guidelines* might open some technical issues which should be dealt with by the Committee. It was noted that the Committee on Food Hygiene has

¹ ALINORM 07/30/26, Appendix II.

been revising the Code of Hygienic Practice for Powdered Infant Formula for Infants and Young Children and that the WHO/FAO Guidelines could be fully taken into account in the revision of the Code.

5. After some discussion, the Commission agreed to **adopt** the Standard at Step 8 as proposed by the CCNFSDU with some editorial changes in Spanish and deletion of the reference to arginine in Annex I containing the list of essential amino acids, with the understanding that the section on methods of analysis would be reviewed by the next session of the CCNFSDU with a view to its submission to CCMAS for endorsement.

6. The Commission also **agreed** to request the Committee on Food Hygiene to take into account the WHO/FAO *Guidelines on the Safe Preparation, Storage and Handling of Powdered Infant Formula* when revising the Code of Hygienic Practice for Powdered Infant formula for Infants and Young Children and to invite the CCNFSDU to review the Section on Hygiene of the adopted Standard once the above Code had been finalized by the CCFH.

7. The Committee therefore is invited to **review** the section on methods of analysis with a view to its submission to CCMAS for endorsement (see Section 10. Methods of Analysis and Sampling, Appendix II of ALINORM 07/30/26 which is available from <http://www.codexalimentarius.net>)

8. Comments from the last 28th session of the Codex Committee on Methods of Analysis and Sampling on the above Section 10 see below (Part C, paras 27-34).

STANDARDS CONSIDERED AT STEP 5

Advisory Lists of the Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children)² (ALINORM 07/30/REP., para. 80)

9. The Commission **adopted** the Proposed Draft Standards and Related Texts at Step 5 submitted by its subsidiary bodies as presented in Appendix V to ALINORM 07/30/REP, including the above text elaborated by the CCNFSDU, and advanced them to Step 6. The Commission noted that technical comments raised during the session would be referred to the relevant Committees for their consideration. The Commission encouraged members and observers that have submitted comments in writing or orally at the session to submit these comments at Step 6 of the Procedure.

ELABORATION OF NEW STANDARDS AND RELATED TEXTS

10. The Commission **approved** the elaboration of new standards and related texts as summarized in Appendix VII to ALINORM 07/30/REP, including the Establishment and Application of Risk Analysis Principles by the Committee on Nutrition and Foods for Special Dietary Uses proposed by the CCNFSDU. This matter will be considered on Agenda Item 7.

11. The Commission noted that project documents submitted to the 59th Session of the Executive Committee contained information that, while respecting the overall format as set out in the Procedural Manual, varied significantly in terms of quantity and quality, and therefore, endorsed the recommendation of the Executive Committee to encourage Codex committees, task forces and Codex Members to prepare future project documents according to the format set out in the current revision of the Procedural Manual and provide sufficiently detailed, relevant information with particular regard to the evidence-based assessment against each of all the Criteria for the Establishment of Work Priorities³.

STRATEGIC PLAN 2008-2013 OF THE CODEX ALIMENTARIUS COMMISSION⁴

12. The Commission adopted the Strategic Plan 2008-2013. In view of this, the Committee is invited to review all the Activities presented in Part 2 Programme Areas and Planned Activities 2008-20013 relevant to its work (see below) and report back to the Commission on the outcome of its consideration.

² ALINORM 07/30/26, para. 130 and Appendix V.

³ ALINORM 07/30/3, para. 46

⁴ ALINORM 07/30/REP paras 131-138 and Appendix IX.

Goal 1 “Promoting Sound Regulatory Frameworks**1.1 : Review and develop Codex standards and related texts for food safety**

Description: Review and develop Codex standards and related texts for food safety, taking into account scientific and technological developments, to ensure that they: emphasize a horizontal approach; employ an approach to food safety that is based on risk and that addresses the entire food chain; and reflect global variations so as to avoid being more trade restrictive than necessary, while respecting the basic objectives of the CAC, taking into consideration the technical and economic implications for all members as well as the special needs of developing countries including infrastructure, resources and technical and legal capabilities.

Timeline : Continuing

Responsible parties: CCFH, CCFA, CCCF, CCPR, CCRVDF, CCNFSDU, relevant Task Forces and Commodity Committees

13. Output/Measurable indicators: Standards related texts adopted at respective steps.

Goal 2 “Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis”.**2.2 Review risk analysis principles developed by relevant Codex Committees**

Description: Review risk analysis principles developed by relevant Codex Committees in the light of the experience gained when all relevant Codex Committees have elaborated risk assessment policies pertaining to their area of work, these policies having been adopted by the CAC.

As these risk assessment policies play a pivotal role in the interaction between risk managers and risk assessors, communication between these two parties should be further improved, where appropriate. The result of such a review may be revised documents on risk analysis principles for adoption by the Commission. The review should also take into account the outcome of the activities described under 2.1 and 2.3.

Timeline: Completion by 2013

Responsible parties: CAC, CCEXEC, CCFA, CCCF, CCPR, CCRVDF, CCFH, CCNFSDU

14. Output/Measurable indicators: Report by relevant Committees of completed review, taking into account the review of the Activities 2.1 and 2.3.

2.3 Enhance communication among relevant Codex subsidiary bodies and the FAO/WHO scientific expert bodies

Description: Enhance communication between the risk managers and risk assessors in accordance with paragraph 38 of the Working Principle for Risk Analysis for Application in the Framework of the Codex Alimentarius.

Timeline: Ongoing

Responsible parties: CCFA, CCCF, CCPR, CCRVDF, CCFH, CCNFSDU

15. Output/Measurable indicators: Incorporated into report as required in Activity 2.2.

2.5 Encourage countries to channel their requests for scientific advice to FAO / WHO through the CAC
Description: Encourage countries to channel their requests through the CAC in order to make the best use of the limited resources available at FAO and WHO for the provision of scientific advice. Encourage FAO and WHO to inform the CCEXEC and the CAC of all requests on provision of scientific advice on food safety received from member countries.
Timeline: Continuing
Responsible parties: CAC, CCEXEC, all subsidiary bodies

Goal 3 “Strengthening Codex Work-Management Capabilities”

3.3 Develop committee-specific decision making and priority setting criteria
Description: Develop committee-specific decision-making and priority-setting criteria and use these criteria for management of work. Implement and review criteria where necessary.
Timeline: Completion of decision making and priority setting criteria by 2008. Review of criteria, beginning in 2008.
Responsible parties: All General Subject Committees and some other subsidiary bodies as appropriate

16. Output/Measurable indicators: Committee-specific decision-making and priority-setting criteria. Confirmed review of criteria beginning in 2008.

REVIEW OF CODEX COMMITTEE STRUCTURE AND MANDATES OF CODEX COMMITTEES AND TASK FORCES (ALINORM 07/30/REP, paras 144-156)

17. The Commission considered 11 Proposals as contained in Circular Letter CL 2006/29-CAC. Due to time constraints, the Commission only made decisions regarding Proposal 1 (numbers of meetings), Proposal 2 (number of subsidiary bodies), Proposal 3 (interval of meetings), Proposal 4 (duration of meetings) and Proposal 8 (conversion of regional standards into world-wide standards) and agreed to request the 60th Session of the Executive Committee for further consideration of the other six Proposal⁵.

18. The Committee should draw attention to the Proposals 3 and 4, reproduced below, when discussing the date of its next meeting (Agenda Item 12: Date and Place of the next Session).

- **Proposal 3 (interval of meetings):** The Committee should consider adopting a longer interval with the understanding that a structured, effective inter-session working mechanism should then be put in place in accordance with the Guidelines on Physical Working Groups and on Electronic Working Groups.
- **Proposal 4 (duration of meetings):** The duration of a Codex session should be kept within seven days, including the pre-session meetings of working groups, if any, in order to keep its proceedings well focused, ensure transparency, and facilitate effective participation of the members, with the understanding that certain margin of flexibility should be allowed, depending on the workload of each subsidiary bodies.

WHO Global Strategy on Diet, Physical Activity and Health: actions that could be taken by Codex⁶ (ALINORM 07/30/REP., paras 181-188)

19. The Commission recalled that the background to the consideration of the Global Strategy was as follows. WHA Resolution 57.17 endorsing the Global Strategy requested the Codex Alimentarius Commission “to continue to give full consideration within the framework of its operational mandate, to

⁵ ALINORM 07/30/REP paras 146-161.

⁶ ALINORM 07/30/26, paras. 144-147, ALINORM 07/30/22, paras. 20-64, CAC/30 INF/13 (Progress Report on the Implementation of the WHO Global Strategy on Diet, Physical Activity and Health as related to Codex)

measures which it might take to contribute towards the improvement of health standards of foods consistent with the aims and objectives of the Global Strategy.”

20. The 28th Session of the Commission agreed to ask WHO, in cooperation with FAO, to prepare a document focused on actions that could be taken by Codex including specific proposals for new work for consideration by the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and the Committee on Food Labelling (CCFL).

21. The 29th Session of the Commission considered a progress report on the consideration of the Global Strategy and agreed that WHO and FAO would complete a document containing concrete proposals for possible actions by Codex that would be circulated for comments and consideration by the CCNFSDU and CCFL.

22. The Representative of WHO recalled that the document on the implementation of the Global Strategy contained a series of proposed actions related to nutrition labelling, certain nutrition claims, quantitative declaration of ingredients, modification of standardized foods and production and processing standards regarding nutritional quality and safety of foods. The Representative thanked the members who had provided comments and participated in the work of the two Committees concerned for their active contribution and indicated that WHO and FAO planned to strengthen their interaction with the Committees concerned as regards the implementation of the Global Strategy. The Representative indicated that WHO and FAO would make every effort to inform these Committees of the scientific advice currently being produced by WHO and FAO and of any plans for relevant scientific work which may affect the implementation of the Global Strategy, including the planned FAO/WHO Expert Consultation on Fats and Oils in Human Nutrition.

23. The Representative of FAO expressed his appreciation for the work carried out so far and looked forward to further consideration of the Global Strategy in the relevant Codex Committees, while recalling the ongoing cooperation with WHO in this area.

24. The Delegation of Germany, speaking as Chair of the CCNFSDU, stressed the importance of the Global Strategy to address public health issues related to non communicable diseases and indicated that the Committee had agreed to proceed with the consideration of the revision of the Nutrient Reference Values (NRVs) for vitamins and minerals and to ask the advice of the Committee on Food Labelling concerning the revision and extension of the list of NRVs in the Guidelines for Nutrition Labelling to other nutrients associated with increased and decreased risk of non communicable diseases. The Committee had agreed that if this reply was positive it would consider new work on the revision and extension of the list to relevant nutrients at its next session. The Delegation noted that there was no support in the Committee to initiate work on claims for trans fatty acids and restrictions on saturated and trans fatty acids in the conditions for comparative claims.

25. The Delegation of Canada, speaking as Chair of the Committee on Food Labelling, recalled that the Committee had discussed extensively the proposals for action related to labelling issues, with the following result: there was no support for the amendment of the Purpose of the *Guidelines on Nutrition Labelling*, no conclusion on the need to amend the *Guidelines* to require mandatory nutrient declaration, on the revision of the current list of nutrients that should always be declared, and on the development of additional criteria for nutrient presentation. There was no support to undertake new work on nutrition claims for trans fatty acids. The Committee had agreed with the proposal of the CCNFSDU to revise the list of vitamins and minerals but had not reached a conclusion on the extension of the list to other nutrients. The Delegation further advised that a working group would be held immediately prior to the next session of the Committee in May 2008 to consider all issues relevant to the draft action plan.

26. The Commission **agreed** that it would defer further consideration of the implementation of the Global Strategy to its next session in order to consider the outcome of the Committee on Food Labelling to be held in May 2008.

C. MATTERS ARISING FROM OTHER CODEX COMMITTEES AND TASK FORCES

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Draft Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (ALINORM 07/30/23, paras 81 – 88)

27. The Committee agreed that the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) needed to further consider the proposed methods since many required updating and agreed to refer all methods back to CCNFSDU. In particular the Committee made the following comments:

28. The list included two methods for total dietary fibre and clarification was needed on which of these methods should be used and for what purpose.

29. In general, methods using microbioassay as a principle should be reviewed, as well as the methods for determination of PER, carbohydrates and fat in order to replace them with more modern methods.

30. Clarification was required as to how Vitamin C was expressed and on the differences between the methods proposed for Vitamin K, B12 and B6.

31. It was recommended that the method for sodium and potassium be replaced with the ISO 8070|IDF 119.2007 method (atomic absorption).

32. As regards crude protein, the Committee agreed that the conversion factors included in the method proposed corresponded to the earlier standard and recommended that the CCNFSDU correct the conversion factor for soy protein to 5.71 in the description of the method in order to be consistent with the provision in the revised standard.

Update of other Methods

33. The Committee agreed to update the references to some methods as consequential or related amendments to the update of the methods for fats and oils. It noted that the method for determination of free fatty acids in the Standard for Cocoa Butter (CODEX STAN 86-1981) measured free acidity and allowed for conversion to fatty acids and thus agreed to update the method as Type I.

34. In updating the methods in the Guidelines for Nutrition Labelling, it was noted that AOCS Ce 1h-05 was also available as a validated method for the determination of trans unsaturated fatty acids and agreed to inform the CCNFSDU of this.

CODEX COMMITTEE ON FOOD ADDITIVES

Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (at Step 8)(ALINORM 07/30/12, paras 25-29 and 57-63)

35. The Committee recalled that the Codex Committee on Nutrition and Food for Special Dietary Uses, at its 28th session, agreed to ask this Committee to put forward the following questions to JECFA: to what extent an ADI established by JECFA, whether numerical or not specified, applied to young infants below 12 weeks?; what scientific principles should apply to the evaluation of additives intended for this group of the population?; and whether the establishment of an ADI in itself was sufficient or whether other issues had to be addressed?

36. It was also recalled that the Codex Committee on Nutrition and Food for Special Dietary Uses agreed⁷:

- to forward the food additives in Table 2 as reproduced in CX/FA 07/39/2 (including additives for which suitability for use in sections A and B should be determined) to this Committee for advice on their suitability in the products covered by sections A and B and evaluation by JECFA if required, in light of the advice that would be provided on the general questions mentioned above;

⁷ ALINORM 07/30/26, paras 56-68 and Appendix III.

- To forward the food additives in Table 3 as reproduced in CX/FA 07/39/2 (including additives intended only for Formulas for Special Medical Purposes Intended for Infants) to this Committee for advice on their suitability in the products covered by section B and evaluation by JECFA if required.

37. The Representative of WHO, speaking on behalf of FAO and WHO JECFA Secretariats, recalled that JECFA had considered these questions regarding the applicability of ADIs to children below 12 weeks on several occasions. In particular, at its twenty-first meeting had concluded that, for most food additives, the ADIs allocated were applicable to all children older than 12 weeks⁸. The Representative pointed out JECFA's opinion that food additives should not generally be used in foods for infants and very young children below 12 weeks of age.

38. The Representative also informed the Committee that more detailed guidance on this matter was contained in EHC 70: Principles for the safety assessment of food additives and contaminants in food⁹, which was based on the advice of the FAO/WHO expert meeting on additives in baby food held in 1971 and additional considerations by JECFA. It was pointed out that toxicological studies had not directly covered the developmental period in question. The JECFA Secretariat informed the Committee that JECFA's basic principles for the use of additives in foods intended for children below 12 weeks of age remain valid. Certain food additives had been evaluated applying these principles on a case-by-case basis.

39. The Committee agreed to forward the questions posed by the Codex Committee on Nutrition and Food for Special Dietary Uses to JECFA for consideration. It was agreed by the Committee that it would also be appropriate to request JECFA to perform a detailed specific review of the general question of the applicability of ADIs to children below 12 weeks first, so as to provide the Committee with further guidance on this issue. The Committee also agreed to consider the additives listed in Tables 2 and 3, in light of the JECFA advice on this issue, once it became available, and to inform the Codex Committee on Nutrition and Food for Special Dietary Uses of this decision.

40. The Committee endorsed the food additive provisions in the draft revised Standard, including the introductory text of the Food Additives section of Section A "Infant Formula" with some modifications, proposed by the *ad hoc* physical Working Group on the GSFA, to align the INS numbers and the corresponding food additive names with those of the Class Names and International Numbering System (CAC/GL 36-1989).

41. The Committee did not endorse the provision for carrageenan (INS 407) pending the outcome of the 68th JECFA meeting in June 2007. In this regard, the Committee noted the concern of some delegations over the effects of the time gap which the non endorsement of carrageenan could create given that carrageenan is used in food products in international trade. It further noted that the summary report and the full draft report of the 68th JECFA meeting would only be available in electronic form by end of July/August 2007 and January/February 2008 respectively, after the 30th session of the Codex Alimentarius Commission.

42. The Committee agreed with the recommendation of the *ad hoc* physical Working Group on the GSFA not to endorse the additional introductory text to the Food Additives section of Section B "Formulas for Special Medical Purposes Intended for Infants" because it felt that it was unnecessary.

43. The Committee agreed with the recommendation of the *ad hoc* physical Working Group on GSFA to separate the provision of sodium citrate (INS 331) into sodium dihydrogen citrate (INS 331i) and trisodium citrate (INS 331iii).

44. The Committee agreed to rename "packing gases" to "packaging gases" for consistency with the discussion on the revision of the Class Names and International Numbering System (see Agenda Item 10a).

⁸ WHO Technical Report Series 617: Evaluation of certain food additives, WHO, Geneva 1978.

⁹ Environmental Health Criteria 70: Principles for the safety assessment of food additives and contaminants in food. WHO, Geneva 1987.

Advisory List of Food Additives for Special Nutrient Forms (at Step 5)

45. The Committee endorsed the food additive provisions of the Advisory List with the changes recommended by the *ad hoc* physical Working Group on the GSFA, to add “for vitamin B₁₂ dry rubbing, 0.1% only” to the maximum level for mannitol (INS 421) and to clarify that the acronym PUFA corresponded to polyunsaturated fatty acids.

46. The Committee noted that the 28th session of the Codex Committees on Nutrition and Food for Special Dietary Uses had not reached an agreement regarding the level of uses for gum arabic (INS 414) and had decided to put the two proposed figures [10] and [100] mg/kg in square brackets. Therefore, it did not endorse any value for gum arabic and agreed **to request** the Codex Committees on Nutrition and Food for Special Dietary Uses **to identify** the level of use that was technologically justified and to revise the name of gum arabic to be consistent with the INS.

47. The Committee is therefore invited to reply to the CCFA.

CODEX COMMITTEE ON FOOD LABELLING***Nutrient Reference Values for nutrients that are associated with both increased and decreased risks of noncommunicable diseases (ALINORM 07/30/22, paras 48-53)***

48. The Committee recalled that the Committee on Nutrition and Foods for Special Dietary Uses had agreed to proceed with the consideration of the revision of the NRVs for vitamins and minerals and to ask the Committee on Food Labelling its advice concerning the revision and extension of the list of NRVs in the Guidelines for Nutrition Labelling to other nutrients associated with increased and decreased risk of noncommunicable diseases. The Committee had agreed that if this reply was positive it would consider new work on the revision and extension of the list to relevant nutrients at its next session.

49. The Committee agreed with the proposal of the CCNFSDU to revise the list of vitamins and minerals but did not reach a conclusion on the extension of the list to other nutrients.