

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3

CX/FAC 03/2
January 2003

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-fifth Session

Arusha, Tanzania, 17 - 21 March 2003

MATTERS REFERRED FROM THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

A. MATTERS ARISING FROM THE 50TH SESSION OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION (Rome, 26 – 28 June 2002)

Preparation of the Medium-Term Plan for 2003-2007

1. The Revised Draft Medium-Term Plan and comments received in response to Circular Letter CL 2001/26-EXEC were considered at the Executive Committee.¹ The Executive Committee noted that Regional Committees would have to opportunity to contribute to the development of the Medium-Term Plan, and that it would be subsequently considered by the next regular sessions of the Executive Committee and the Codex Alimentarius Commission. The Executive Committee noted that as a result of the Codex Evaluation, further changes might be required to the Medium-Term Plan and that this would have to be addressed prior to its finalization. It encouraged Regional Coordinating Committees to provide further input to the development of the Medium-Term Plan in view of its importance for Codex work.

2. The Executive Committee agreed that the Draft Medium-Term Plan should be revised by the Secretariat in the light of the comments made at the session, preferably by the end of July 2002. It would be circulated for consideration by the Regional Committees, as already agreed by the Commission, and for further consideration by the next (regular) session of the Executive Committee (to be held in June 2003). The Executive Committee re-emphasized that the Plan should be flexible enough to allow the introduction of new activities during its operational period.

Consideration of Proposed Draft Standards and Related Texts at Step 5

3. The Executive Committee considered the Proposed Draft Standards and Related Texts that had been submitted for preliminary adoption at Step 5². All of the texts submitted by the CCFAC for consideration were adopted at Step 5 and advanced to Step 6, as follows:

- Proposed Draft Revisions to the International Numbering System for Food Additives (Mineral Oil – INS 905) (ALINORM 03/12, Appendix VII). This subject will be considered under Agenda Item 12a, document CX/FAC 03/15.
- Proposed Draft Code of Practice for the Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages (ALINORM 03/12, Appendix XI). This subject will be considered under Agenda Item 15a, document CX/FAC 03/20.

¹ ALINORM 03/3A, paras. 32-61.

² ALINORM 03/3A, paras. 69-80 and Appendix II.

- Proposed Draft Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, Including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes (ALINORM 03/12, Appendix XII). This subject will be considered under Agenda Item 15c, document CX/FAC 03/22.

Consideration of New Work Proposals at Step 1 of the Procedure

4. The Executive Committee considered proposals submitted by the CCFAC for new work at Step 1 of the Procedure. In addition, the Executive Committee made specific comments on some of the proposals as indicated below.³

Guideline Levels for Radionuclides in Foods for Long-Term Use and Revision or Amendments to the Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989)

5. The Executive Committee decided not to approve the elaboration of the above documents on Guideline levels at this stage and referred them to the CCFAC for consideration of these items together with further input from the International Atomic Energy Agency regarding the Scope of the work. This subject will be considered under Agenda Item 10(b), document CX/FAC 03/13.

Proposed Draft Code of Practice for the Prevention and Reduction of Aflatoxins in Tree Nuts

6. Approved. The Executive Committee amended the title of the proposed Code to make sure that it was not limited to the reduction but also covered “prevention” of aflatoxins in tree nuts. This subject will be considered under Agenda Item 15(e), document CX/FAC 03/24.

Proposed Draft Code of Practice for the Prevention and Reduction of Lead in Food

7. Approved. This subject will be considered under Agenda Item 16(c), document CX/FAC 03/28.

Proposals for the Discontinuation of Work

8. The Executive Committee approved⁴ the proposals submitted by the CCFAC to discontinue previously approved work items, as follows:

- Proposed Draft Maximum Levels for Lead in Bivalve Molluscs and Crustaceans (ALINORM 03/12, para. 130).
- Proposed Draft Maximum Levels for Cadmium in Crustaceans, Liver and Kidney (ALINORM 03/12, para. 142).

Matters Arising from Codex Committees

9. The Executive Committee noted⁵ that the CCFAC had agreed to develop *Proposed Risk Assessment Policy Statement for the Application of Risk Analysis Principles to the Standard Setting Activities of the CCFAC in Conjunction with risk Assessments Performed by the JECFA* and that this followed the recommendation of the 22nd Session of the Commission for Codex Committees to develop their risk analysis policies. The Executive Committee noted that this text would be developed in the Step Procedure, and would be ultimately incorporated into the Procedural Manual, to be read in conjunction with the general principles for risk analysis in Codex, currently under development. The Executive Committee recommended that the Committee give consideration to a simplification of the title and to some rewording of the text in order to make its application more general, since scientific advice might be required from other bodies than JECFA, especially concerning radionuclides.

³ ALINORM 03/3A, paras. 64-67 and Appendix III.

⁴ ALINORM 03/3A, para. 68 and Appendix IV.

⁵ ALINORM 03/3A, para. 89.

B. MATTERS ARISING FROM OTHER CODEX COMMITTEES

Draft Revised Codex Standard for Cream and Prepared Creams (Step 8)

10. As a result of the work of a drafting group that met during the 5th Session of the Codex Committee on Milk and Milk Products (April 2002), the Committee agreed in principle with the inclusion of a generic table based on food additive functional classes and food product categories. In this regard, the Table proposed by the IDF was simplified to reflect the food additive functional classes and food categories contained in the revised Standard. The Committee also noted the importance of including a specific list of food additives and their respective maximum use levels in the Standard and therefore, agreed to maintain the list of food additives as previously endorsed by the CCFAC.⁶

11. The Committee forwarded the draft revised Standard for Cream and Prepared Creams to the 25th Session of the Codex Alimentarius Commission for final adoption at Step 8. The Committee also noted that since the food additives had already been previously endorsed by the Codex Committee on Food Additives and Contaminants, their reconsideration was not necessary. However, the Codex Secretariat agreed to inform the CCFAC of the new CCMMP procedure regarding the use of the generic table of food additives.⁷ This subject will be considered under Agenda Item 6, document CX/FAC 03/5.

12. The 5th Session of the CCMMP noted that contaminants could also include other sources of contamination in addition to heavy metals (e.g., radionuclides). In this regard, the Committee agreed that Sections 5.1 (Heavy Metals) and 5.2 (Pesticide Residues) should be combined and simplified to read that “The products covered by this Standard shall comply with the maximum limits for contaminants and the maximum residue limits for pesticides and veterinary drugs established by the Codex Alimentarius Commission”. The Committee also applied this decision to the draft Revised Codex Standard for Fermented Milk Products and the draft Revised Codex Standard for Whey Powders.⁸

Draft Revised Codex Standard for Fermented Milks (Step 8)

13. In consideration of its previous discussions on the food additive provisions in the draft revised Codex Standard for Cream and Prepared Creams, the 5th Session of the CCMMP agreed with the inclusion of a generic table based on food additive functional classes and food product categories. In this regard, the functional classes of “anticaking agents” and “firming agents” were removed from the table, as these additives were only used in the separately packaged composite non-dairy components (e.g., cereals) accompanying the product.

14. In addition, the use of stabilizers and thickeners was added to the category of plain fermented milks, with the qualification that their use was restricted to reconstituted and recombined products only and if permitted by national legislation in the country of sale to the final consumer. In view of the ongoing revision of food category system within the context of the General Standard for Food Additives, the Committee also decided to totally remove the footnote references to specific food categories from the table.

15. It was noted that the Codex Committee on Food Additives and Contaminants had not endorsed the new listing of specific food additives and their corresponding use levels as proposed in the Standard. In view of the difficulties in deciding on specific additives and their corresponding use levels at the current meeting, the Committee decided to separate out the proposed listing for the time being.⁹ This subject will be considered under Agenda Item 6, document CX/FAC 03/5.

Draft Revised Codex Standard for Whey Powders (Step 8)

16. The 5th Session of the CCMMP noted that the list of additives was already approved by 33rd CCFAC. However, the proposed maximum level of 100 mg/kg for benzoyl peroxide (INS 928) was not endorsed by the CCFAC because the 55th Session of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) did not establish an acceptable daily intake for the compound. The 55th JECFA recommended an acceptable level of treatment of 0-40 mg/kg for flour, and noted that it could draw no conclusions in regard to the

⁶ ALINORM 03/11, para. 29

⁷ ALINORM 03/11, para. 36 and Appendix II

⁸ ALINORM 03/11, paras. 30, 56 and 71, respectively.

⁹ ALINORM 03/11, paras. 52-54 and Appendix III.

acceptability of other proposed uses for benzoyl peroxide because information on toxicity and intake was not available.

17. The Committee agreed in principle that bleaching agents were required in the manufacture of whey powders and in view of the latest decision of the CCFAC, decided to maintain the maximum level of 100 mg/kg for benzoyl peroxide in square brackets, pending a final determination as to its status by JECFA and the CCFAC. It was understood that the square bracketed entry would be removed by the Commission at the time of adoption if a final determination as to its inclusion had not been made. The Committee decided that hydrogen peroxide should not be included as it was considered to be a processing aid.¹⁰ This subject will be considered under Agenda Item 6, document CX/FAC 03/5.

18. The 5th Session of the CCMMP was informed that the 33rd Session of the CCFAC did not endorse the proposed draft maximum level of 1 mg/kg for lead (ALINORM 01/12A, para. 102). The CCFAC agreed that in view of the adoption of a maximum level for lead in milk, there was no need for specific levels for lead in milk products. The CCMMP therefore agreed with the CCFAC determination and deleted the specific maximum level of 1 mg/kg for lead.

Draft Standard for Salted Atlantic Herring and Salted Sprats (Step 6)

19. The 25th Session of the Codex Committee on Fish and Fishery Products (June 2002) noted that Fast Green FCF was already included in the General Standard for Food Additives (GSFA) in food category 9.2.5 “Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms” but agreed to delete this additive from the present Draft Standard as it was not used in salted Atlantic herring and salted sprats. In reply to a question on propyl gallate, the Committee recalled that it had been endorsed by the Committee on Food Additives and Contaminants and adopted in the GSFA with a level of 100 mg/kg.¹¹ This subject will be considered under Agenda Item 6, document CX/FAC 03/5.

Methods of Analysis for Dioxins and PCBs

20. At the 24th Session of the Codex Committee on Methods of Analysis and Sampling (November 2002), the Delegation of Germany informed the Committee that the document on the determination of dioxins and PCBs had not been prepared as there were no proposals received from Member Governments before this Session. The Committee agreed that a Circular Letter would request Member Governments and interested international organizations to submit their proposals for the determination of dioxins and PCBs to Germany who would prepare a paper for consideration at the next session of the Committee.¹² This subject will be considered under Agenda Item 16(g), document CX/FAC 03/32.

Methods of Analysis for Food Additives and Contaminants

21. The 24th Session of the CCMAS endorsed¹³ the methods for additives and contaminants corresponding to specific provisions under consideration or included in adopted standards. Method EN 12955:1999-07 was endorsed as it applies to the sum of aflatoxins in peanuts, for which a maximum level has been established¹⁴. The Committee recalled that several methods had been endorsed earlier for aflatoxins and they were included in the Table for reference. After some discussion on the need for amendments to the type of the current methods, it was agreed to retain AOAC 991.31 for total aflatoxins in raw peanuts as Type II and to endorse EN 12955:1999-07 as Type III.

22. The Committee agreed to delete the method for aflatoxin in maize that had been endorsed earlier as there was no maximum level for aflatoxin in maize.

23. The Committee, recalling that methods for cyclamate and saccharin had been endorsed earlier¹⁵, considered whether changes were required to the endorsement status. It was agreed to retain NMKL 122(1997) for saccharin in beverages and sweets as Type II and to endorse EN 12856: 1999-04 for saccharin

¹⁰ ALINORM 03/11, para. 67- 69 and Appendix IV.

¹¹ ALINORM 03/18, para. 32 and Appendix IV.

¹² ALINORM 03/23, para. 5

¹³ ALINORM 03/23, paras. 64-66 and Appendix VI.

¹⁴ CODEX STAN 209-1999: 15 µg/kg for total aflatoxins in peanuts intended for further processing

¹⁵ ALINORM 97/23A, Appendix V

in all foods as Type III. As regards cyclamates, the Committee endorsed EN 12857:1999-04 as Type II and retained the current NMKL method 123 (1998) as Type III. The methods proposed for nitrates/nitrites in meat products were temporarily endorsed pending final publication of the validation results.

Requirements for Single Laboratory Validation for Codex Purposes

24. As a result of discussions¹⁶ at the 24th CCMAS on the above subject, the Committee agreed that the following text would be acceptable:

General Criteria for the Acceptance of Single-Laboratory Validated Methods of Analysis

Especially in the case of multi-analyte-multi-substrate methods and new hazards, interlaboratory validated methods may not be available or appropriate. Criteria used to select a method include the General Criteria for the Selection of Methods of Analysis, where appropriate. In addition, the single-laboratory validated methods must fulfil the following criteria:

- i the method is validated according to an internationally recognized protocol (e.g. those referenced in the *Harmonized IUPAC Guidelines for the Single-Laboratory Validation of Methods of Analysis*)
- ii the single-laboratory validated method is embedded in a quality system complying with ISO/IEC 17025

25. However, the Committee could not agree on the modalities of its incorporation into the Procedural Manual. It was recalled that these *General Criteria* had been proposed for inclusion after the *General Criteria for the Selection of Methods of Analysis using the Criteria Approach* and had not been associated with a specific Type of method in earlier discussions. However, some delegations expressed the view that these recommendations could not be included in the Manual as General Criteria, but should be restricted to Type IV methods because Type II and III methods should be collaboratively tested.

26. Other delegations recalled that the purpose of single-laboratory validation was to allow the use of reference methods that would not otherwise be available and that the current requirements for the type of methods would have to be amended accordingly. It was also pointed out that there was no need to apply additional requirements to Type IV methods and that the inclusion of criteria for single-laboratory validation was not relevant if they were not generally applicable.

27. The Committee could not come to a conclusion on an amendment to the Procedural Manual and agreed to inform the Committee on Pesticide Residues, the Committee on Residues of Veterinary Drugs in Foods and the Committee on Food Additives and Contaminants of the above discussion as the use of single-laboratory validation was especially important for their work.

Maximum Level for Chloropropanol

28. At the 13th Session of the FAO/WHO Regional Coordinating Committee for Asia (September 2002), the Committee exchanged views on a proposal from Thailand to seek a support from the Committee on its proposal to set a Maximum Level of 3-MCPD for non-naturally fermented soy sauce at the level of 1 mg/kg. The members expressed diverse opinions on this issue and finally the Committee agreed to forward the matter to the Codex Committee on Food Additives and Contaminants for further deliberation. The Committee also agreed that further data collection on exposure (consumption of soy sauce and levels of 3-MCPD) was necessary. It stressed that an early conclusion on this issue was required due to the importance of the product in the region for both trade and domestic consumption.¹⁷ This subject will be considered under Agenda Item 16(i), document CX/FAC 03/34.

¹⁶ ALINORM 03/23, paras. 101-104.

¹⁷ ALINORM 03/15, para. 14.

Maximum Level of Tin

29. The 13th Session of the CCASIA took note of the request by Thailand to support its position to maintain maximum level of tin to 200 mg/kg for canned beverages and to 250 mg/kg for other canned foods.¹⁸ This subject will be considered under Agenda Item 16(d), document CX/FAC 03/29.

Soybean Products in the Food Category System of General Standard for Food Additives (GSFA)

30. At the 13th Session of CCASIA, the Delegation of China sought support from the Committee to its position to maintain category of soybean products (category 6. 8) in the light of the importance of soybean products as a source of protein in Asian Region and also in order for the Food Category System, FCS to include all soybean products as a separate category. The Delegations of Malaysia and Thailand supported Chinese position to retain category 6.8. The Delegation of Japan also expressed its concern over the treatment of soybean products in the Food Category System and stated that this should be discussed in the next Committee on Food Additives and Contaminants. In this context, Secretariat asked member countries to submit information on the products to the CCFAC for its better understanding on these products.¹⁹ This subject will be considered under Agenda Item 7(c), document CX/FAC 03/7.

¹⁸ ALINORM 03/15, para. 29.

¹⁹ ALINORM 03/15, para. 32.