

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**ALINORM 04/27/12**  
**April 2004**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX ALIMENTARIUS COMMISSION**

*Twenty-seventh Session*

*Geneva, Switzerland, 28 June – 3 July 2004*

**REPORT OF THE 36<sup>th</sup> SESSION OF THE  
CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**

*Rotterdam, The Netherlands  
22 - 26 March 2004*

**Note:** This report includes Codex Circular Letter CL 2004/9-FAC

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CX 4/30.2

CL 2004/9-FAC  
April 2004

**TO:** - Codex Contact Points

- Interested International Organizations

**FROM:** Secretary, Codex Alimentarius Commission  
Joint FAO/WHO Food Standards Programme  
Viale delle Terme di Caracalla, 00100 Rome, Italy

**SUBJECT: DISTRIBUTION OF THE REPORT OF THE THIRTY-SIXTH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS (ALINORM 04/27/12)**

The report of the thirty-sixth Session of the Codex Committee on Food Additives and Contaminants will be considered by the 27<sup>th</sup> Session of the Codex Alimentarius Commission (Geneva, Switzerland, 28 June - 3 July 2004).

**PART A: MATTERS FOR ADOPTION BY THE 27<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION**

**DRAFT AND PROPOSED DRAFT STANDARDS AND RELATED TEXTS AT STEPS 8 OR 5/8 OF THE UNIFORM PROCEDURE, RESPECTIVELY**

- 1. Draft Risk Analysis Principles applied by the Codex Committee on Food Additives and Contaminants at Step 8** (para. 39 and Appendix II).
- 2. Draft Food Category System of the Codex General Standard for Food Additives at Step 8** (para. 68 and Appendix V).
- 3. Draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups at Step 8** (para. 125 and Appendix XIV).
- 4. Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts at Step 8** (para. 140 and Appendix XV).
- 5. Draft Code of Practice for the Prevention and Reduction of Lead Contamination in Foods at Step 8** (para. 168 and Appendix XVI).
- 6. Draft and proposed draft Revisions to Table 1 of the Codex General Standard for Food Additives at Steps 8 and 5/8 respectively** (para. 81 and Appendix VI).
- 7. Specifications for the Identity and Purity of Food Additives (Category I) arising from the 61<sup>st</sup> Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at Step 5/8** (para. 99 and Appendix XI)
- 8. Proposed draft Amendments to the International Numbering System for Food Additives at Step 5/8** (para. 103 and Appendix XII).

Governments wishing to propose amendments or to comment on the above texts should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 8 or 5/8) (Codex Alimentarius Commission Procedural Manual, Thirteenth Edition, pages 20 - 22) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; e-mail: [codex@fao.org](mailto:codex@fao.org) (*preferably*)) **no later than 31 May 2004.**

#### **PROPOSED DRAFT STANDARDS AND RELATED TEXTS AT STEP 5 OF THE UNIFORM PROCEDURE**

9. **Proposed draft Maximum Levels for Cadmium - rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; and, other vegetables -** (para. 182 and Appendix XXIII).
10. **Proposed draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts** (para. 143 and Appendix XX).
11. **Proposed draft Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods** (para. 174 and Appendix XXI).
12. **Proposed draft revised Guideline Levels for Radionuclides in Foods for Use in International Trade** (para. 204 and Appendix XXII).

Governments wishing to propose amendments or to comment regarding the implications which the above texts or any provisions thereof may have for their economic interests should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 5) (Codex Alimentarius Commission Procedural Manual, Thirteenth Edition, pages 20 - 22) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; e-mail: [codex@fao.org](mailto:codex@fao.org) (*preferably*)) **no later than 31 May 2004.**

#### **PART B: REQUEST FOR COMMENTS AND INFORMATION**

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 30 September 2004** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: [info@codexalimentarius.nl](mailto:info@codexalimentarius.nl), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: [Codex@fao.org](mailto:Codex@fao.org) (*preferably*)).

13. **Draft (Step 6) and proposed draft (Step 3) Food Additive Provisions in Table 1 of the Codex General Standard for Food Additives** (para. 76 and Appendix IX).
14. **Proposed draft Maximum Level for Total Aflatoxins in Processed and Unprocessed Almonds, Hazelnuts, and Pistachios at Step 3** (para. 155 and Appendix XXV).
15. **Proposed draft Maximum Level for Cadmium in Molluscs (including Cephalopods) at Step 3** (para. 182 and Appendix XXIII).
16. **Maximum Levels for 3-MCPD (Chloropropanol) in Acid-hydrolyzed Vegetable Proteins (acid-HVPs) and Acid-HVP containing Products** (para. 193).
17. **Food Additives considered by the 61<sup>st</sup> JECFA Meeting in the context of the Codex General Standard for Food Additives - INS 961 Neotame and INS 1203 Polyvinyl alcohol (PVA) -** (para. 21 and Appendix XXVI).
18. **International Numbering System (INS) for Food Additives** (proposals for additions and/or amendments).
19. **Deoxynivalenol (DON) Contamination in Cereals** (para. 158).
20. **Mycotoxin Contamination in Sorghum** (para. 160).

21. **Provisional List of Main Internationally Traded Fish Species - including proposals for maximum levels for lead in different fish species - (para. 164 and Appendix XIX).**
22. **Priority List of Food Additives, Contaminants, and Naturally Occurring Toxicants proposed for evaluation by JECFA (paras. 78, 211, and Appendix XXVII).**

## SUMMARY AND CONCLUSIONS

The thirty-sixth Session of the Codex Committee on Food Additives and Contaminants reached the following conclusions:

### **MATTERS FOR ADOPTION/CONSIDERATION BY THE 27<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION:**

#### **Draft and Proposed draft Standards and Related Texts at Steps 8 or 5/8 of the Uniform Procedure, Respectively**

The Committee forwarded:

- the draft Risk Analysis Principles applied by the Codex Committee on Food Additives and Contaminants to the Commission, through the Codex Committee on General Principles, for final adoption at Step 8 (para. 39 and Appendix II);
- the draft Food Category System of the Codex General Standard for Food Additives to the Commission for final adoption at Step 8 (para. 68 and Appendix V);
- the draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups to the Commission, through the Codex Committee on General Principles, for final adoption at Step 8 (para. 129 and Appendix XIV);
- the draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts to the Commission for final adoption at Step 8 (para. 140 and Appendix XV);
- the draft Code of Practice for the Prevention and Reduction of Lead Contamination in Foods to the Commission for final adoption at Step 8 (para. 168 and Appendix XVI);
- draft and proposed draft revisions to Table 1 of the Codex General Standard for Food Additives to the Commission for final adoption at Step 8 and 5/8 (with recommendation to omit Steps 6 and 7) (para. 81 and Appendix VI);
- Specifications for the Identity and Purity of Food Additives (Category I) arising from the 61<sup>st</sup> JECFA Meeting to the Commission for final adoption at Step 5/8 (with recommendation to omit Steps 6 and 7) (para. 99 and Appendix XI); and,
- proposed draft amendments to the International Numbering System (INS) of Food Additives to the Commission for final adoption at Step 5/8 (with recommendation to omit Steps 6 and 7) (para. 103 and Appendix XII).

#### **Proposed Draft Standards and Related Texts at Step 5 of the Uniform Procedure**

The Committee forwarded:

- proposed draft Maximum Levels for Cadmium (rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; and, other vegetables) to the Commission for preliminary adoption at Step 5 (para. 182 and Appendix XXIII);
- proposed draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts to the Commission for preliminary adoption at Step 5 (para. 143 and Appendix XX);
- proposed draft Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods to the Commission for preliminary adoption at Step 5 (para. 174 and Appendix XXI); and,
- proposed draft revised Guideline Levels for Radionuclides in Foods for Use in International Trade to the Commission for preliminary adoption at Step 5 (para. 204 and Appendix XXII).

### **Proposals for New Work**

The Committee agreed to:

- revise the Codex General Standard for Contaminants and Toxins in Foods as new work to be undertaken by the Committee (para. 126);
- develop proposed draft Sampling Plans for Almonds, Brazil Nuts, Hazelnuts and Pistachios as new work to be undertaken by the Committee (para. 149); and,
- establish proposed draft Maximum Levels 3-MCPD (Chloropropanol) in Acid-hydrolyzed Vegetable Proteins (acid-HVPs) and Acid-HVP Containing Products as new work to be undertaken by the Committee (para. 193).

### **Other Matters for Consideration by the Codex Alimentarius Commission**

The Committee agreed to:

- amend certain Sections of the Codex General Standard for Food Additives (para. 80 and Appendix IV);
- amend certain Sections of the Codex General Standard for Contaminants and Toxins in Foods (para. 125 and Appendix XIII);
- revoke some food additive provisions of the Codex General Standard for Food Additives (para. 83 and Appendix VII);
- discontinue work on a number of draft (Step 6) and proposed draft (Step 3) food additive provisions of the Codex General Standard for Food Additives (para. 84 and Appendix VIII);
- discontinue work on the elaboration of a proposed draft Code of Practice for the Safe Use of Active Chlorine pending the outcome of a Joint FAO/WHO Expert Consultation to assess the risk/benefits of the use of active chlorine in food processing upon availability of funds (paras. 91 - 93);
- discontinue work on the establishment of Maximum Levels for Deoxynivalenol (DON) (para. 158);
- request the Commission to endorse recommendations for food contaminant provisions in Codex commodity standards vis-à-vis the Codex General Standard for Contaminants and Toxins in Foods (para. 124); and,
- request the Commission to amend paragraph 4 of the Critical Review vis-à-vis the maintenance of the Codex General Standard for Food Additives, the Codex General Standard for Contaminants and Toxins in Foods, and other related texts developed by the Committee (para. 150).

### **MATTERS OF INTEREST TO THE CODEX ALIMENTARIUS COMMISSION AND/OR CODEX COMMITTEE AND TASK FORCES**

#### **Food Additives**

The Committee agreed to:

- request information on some food additives considered by the 61<sup>st</sup> JECFA Meeting in the context of the Codex General Standard for Food Additives (GSFA) as a result of changes to existing acceptable daily intakes (ADIs) and/or the establishment of new ADIs namely: INS 961 Neotame and INS 1203 Polyvinyl alcohol (para. 21 and Appendix XXVI);
- endorse food additive and processing aid provisions arising from the Codex Committee on Fish and Fishery Products, the *Ad Hoc* Codex Intergovernmental Task Force on Fruit and Vegetable Juices, and the Codex Alimentarius Commission (Codex Standard for Chocolate and Chocolate Products) (paras. 42, 47-49, and Appendix III);

- request the *Ad Hoc* Codex Intergovernmental Task Force on Fruit and Vegetable Juices to clarify whether the technological function of polydimethylsiloxane was linked to a food additive use or a processing aid (para. 48);
- request the *Ad Hoc* Codex Intergovernmental Task Force on Fruit and Vegetable Juices to clarify whether “coconut water” should be regarded as a fruit juice and if so to include this product under Food Category 14.1.2.1 Fruit Juice of the GSFA Food Category System (para. 67);
- reconvene the *ad hoc* Working Group on the Codex General Standard for Food Additives under the Chairmanship of the United States prior to its next Session (para. 52);
- re-install the newly named Electronic Working Group under the Chairmanship of the United States to work through electronic means on a number of draft food additive provisions, to develop a rational and consistent proposal to address the proposed draft, draft, and adopted food additive provisions for phenolic antioxidants of the GSFA, and to present a report for consideration by the Committee well before its next Session (para. 70 and Appendix X);
- establish a working group under the direction of China to elaborate on the working principles agreed to by the Committee for the development of the GSFA and their possible improvements including the relationship between food additive provisions of the GSFA and those of commodity standards for consideration at its next Session (paras. 43, 59, and 60);
- request information on the use of draft (Step 6) and proposed draft (Step 3) food additive provisions to Table 1 of the Codex General Standard for Food Additives for consideration at its next Session (para. 76 and Appendix IX);
- include new proposed uses for food additives submitted in response to CL 2002/44-FAC and CL 2003/34-FAC in Table 1 of the Codex General Standard for Food Additives and to circulate them at Step 3 under a separate Circular Letter for consideration at its next Session (para. 77);
- discontinue the consideration of processing aids in the context of the Codex General Standard for Food Additives and update on a regular basis the Inventory of Processing Aids (IPA) (paras. 87 - 88);
- establish a working group under the direction of United Kingdom to further elaborate on a Discussion Paper on Carriers, including the use of food additives as “nutrient carriers”, for circulation, comments, and consideration at its next Session (para. 89);
- request relevant Codex Committees, including the Codex Committee on Food Hygiene, to: consider safety/benefits issues relevant to uses of active chlorine within their respective purviews, elaborate terms of reference for a possible Joint FAO/WHO Expert Consultation, and pose questions so that the Expert Consultation be comprehensive (para. 92);
- reconvene the *ad hoc* Working Group on Specifications prior to its next Session under the Chairmanship of the United States (para. 97);
- endorse recommendations in relation to new food additives to ensure that these were identified and designated by CCFAC and JECFA according to a common system of terminology (para. 106);
- establish a working group under the direction of the United Kingdom to prepare a document containing proposals on the harmonization of terms used by Codex and JECFA for circulation, comments, and consideration at its next Session (para. 107);
- establish a separate Working Group on the Harmonization of Terms used by Codex and JECFA to meet prior to its next Session to discuss the document produced by the above-mentioned working group and provide advice to the Committee in this respect (para. 107); and,
- entrust the establishment of functional classes that were not currently covered by the Class Names and International Numbering System for Food Additives, e.g. enzymes and propellant gases, to the Working Group on the International Numbering System for consideration at its next Session (para. 108); and,

- establish a working group under the direction of the United States to prepare a Discussion Paper on the Integration of Flavouring Agents in the Codex System for circulation, comments, and consideration at its next Session (para. 215).

### **Contaminants**

The Committee agreed to:

- reconvene the *Ad Hoc* Working Group on Contaminants and Toxins under the Chairmanship of the European Community prior to its next Session (para. 114);
- endorse a number of recommendations in relation to the Codex General Standard for Contaminants and Toxins in Foods (GSCTF) e.g. to include Schedule I in the GSCTF, to exclude of quality-parameters from the GSCTF, to request Codex Committees the inclusion of maximum levels for quality-related parameters under the relevant Section(s) of commodity standards, to coordinate with the Codex Committee on Pesticide Residues the further development of the food categorization system to cover processed foods so that Schedule II can be included in the GSCTF, etc. (paras. 117 - 123); and,
- entrust the elaboration of a document containing an overview of the situation regarding Codex decisions on contaminants and toxins to the Delegations of the Netherlands and Japan for consideration at each Session of the Committee (paras. 118 - 119).

### ***Mycotoxins in Foods and Feeds***

The Committee agreed to:

- reconsider the Maximum Level for Patulin in Apple Juice and Apple Juice Ingredients in Other Beverages at a future Session in the light of the outcome of a re-evaluation to be performed by JECFA in 4 years time and the implementation of the Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients (paras. 130 - 131);
- limit the draft Maximum Level for Ochratoxin A to raw wheat, barley, and rye, retain the draft Maximum Level at Step 7, and place it on the Priority List for Evaluation by JECFA in 2006 (paras. 133, 136 - 137, and Appendices XVII and XXVII)
- request Iran to prepare a revised Discussion Paper on Aflatoxin Contamination in Brazil Nuts for circulation, comments, and consideration at its next Session (para. 148);
- discontinue consideration of methods of analysis for the determination of aflatoxins in tree nuts (para. 151);
- request information on deoxynivalenol (DON) contamination in cereals for consideration at its next Session (para. 158); and,
- request information on mycotoxin contamination in sorghum for consideration at its next Session (para. 160).

### ***Industrial and Environmental Contaminants in Foods***

The Committee agreed to:

- retain the draft Maximum Level for Lead in Fish at Step 7 and to review the level at its next Session in the light of the result of the evaluation of the 53<sup>rd</sup> JECFA Meeting (1999), a list of the main internationally traded fish species, and comments received in this regard (paras. 164-165 and Appendices XVIII and XIX);
- retain the proposed draft Maximum Level for Tin in Canned Beverages and Canned Foods other than Beverages at Step 4 and to reconsider the levels at a future Session in the light of the result of the 64<sup>th</sup> JECFA re-evaluation in 2005 (para. 171 and Appendix XXIV);



- discontinue the work on developing maximum levels for cadmium in fruits; meat of cattle, pigs, sheep, and poultry; horse meat; herbs, fungi (edible); celeriac; soybeans (dry); and, peanuts as no levels were necessary because these foods were no major contributors to cadmium intake (para. 176);
- request comments at Step 3 on the proposed draft Maximum Level for Cadmium in Molluscs (including Cephalopods) for consideration at its next Session (para. 182 and Appendix XXIII);
- establish a working group under the direction of Germany to revise the proposed draft Code of Practice for Source Directed Measures to reduce Dioxin and Dioxin-like PCB Contamination of Foods for circulation, comments at Step 3, and further consideration at its next Session (para. 185);
- discontinue the consideration of the Position Paper on Dioxins and Dioxin-like PCBs and encourage Codex Members to submit data on dioxins and dioxin-like PCBs in foods to WHO GEMS/Food Database on the understanding that WHO would report back to the Committee on the data submitted within 3 years time with a view to its possible future consideration (paras. 188 - 189);
- establish a working group under the direction of the United Kingdom to prepare an updated Discussion Paper on Chloropropanols with proposals for maximum levels in relevant commodities including acid-HVPs and foods containing acid-HVP for circulation, comments, and consideration at its next Session (para. 194);
- forward terms of reference for the JECFA evaluation on acrylamide in 2005 while establishing a working group under the direction of the United Kingdom and the United States to prepare an updated Discussion Paper on Acrylamide for circulation, comments, and consideration at its next Session (paras. 197-198);
- establish a working group under the direction of Denmark to prepare a Discussion Paper to consider issues related to polycyclic aromatic hydrocarbons (PAH) contamination in foods for circulation, comments, and consideration at its next Session (para. 217); and,
- establish a working group under the direction of the European Community, to prepare a Discussion Paper on the possible revision of the Guideline Level for Methylmercury in Fish including the examination of other possible management options for circulation, comments, and consideration at its next Session (para. 218).

#### **Other General Issues**

#### ***Priority List of Food Additives, Contaminants, and Naturally Occurring Toxicants proposed for Evaluation by JECFA***

The Committee:

- noted that the proposed evaluation of the peroxide value (PV) for instant noodles was not a question of safety and should therefore not be proposed for evaluation by JECFA. Moreover, there were no data proving a positive correlation between peroxide values of foods and food toxicological parameters (para. 209); and,
- agreed to request comments for additions or amendments to the Priority List of Food Additives, Contaminants, and Naturally Occurring Toxicants for Evaluation by JECFA for consideration at its next Session (paras. 78, 211, and Appendix XXVII).

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**REPORT OF THE 36<sup>TH</sup> SESSION OF THE  
CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**

**OPENING OF THE SESSION**

1. Mrs Renee Bergkamp, Director General of the Netherlands Ministry of Agriculture, Nature and Food Quality opened the 36<sup>th</sup> Session of the Codex Committee on Food Additives and Contaminants (CCFAC), which was held in Rotterdam, the Netherlands, from 22-26 March 2004, at the kind invitation of the Government of the Netherlands. The Session was chaired by Ms Annie De Veer of the Netherlands Ministry of Agriculture, Nature and Food Quality. The Session was attended by 283 participants, representing 56 Member Countries, one Member Organization, and 38 International Organizations. The List of Participants is attached to this report as Appendix I.

2. The Delegation of the European Community presented CRD 23 (Annotated Agenda) on the division of competence between the European Community and its Member States according to paragraph 5, Rule II of Procedure of the Codex Alimentarius Commission.

**ADOPTION OF THE AGENDA (Agenda Item 1)<sup>1</sup>**

3. The Committee adopted the Provisional Agenda as proposed. It agreed to discuss the following under Agenda Item 18 "Other Business and Future Work":

- Flavouring agents (request from the United States);
- Polycyclic aromatic hydrocarbons (PAH) contamination (request from Denmark);
- Ochratoxin A in wine (request from the Office International de la Vigne et du Vin - OIV); and,
- Guideline level for methylmercury in fish (request from the 53<sup>rd</sup> Session of the Executive Committee).

4. The Committee agreed to hold Working Groups on the International Numbering System (INS) (Agenda Item 11) and on JECFA Priorities (Agenda Item 17) under the Chairmanship of Finland and the Netherlands, respectively.

**APPOINTMENT OF THE RAPPORTEUR (Agenda Item 2)**

5. The Committee agreed to appoint Dr. Bruce H. Lauer (Canada) as Rapporteur for the Session.

**MATTERS REFERRED/OF INTEREST TO THE COMMITTEE ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 3)<sup>2</sup>**

6. The Committee noted that document CX/FAC 04/36/2, containing matters referred/of interest to the Committee arising from the Codex Alimentarius Commission (CAC) and Other Codex Committees and Task Forces, was divided in two parts. Part I related to matters of interest to the Committee arising from the 26<sup>th</sup> Session of the Codex Alimentarius Commission (July 2003) and other Codex Committees and Task Forces for which the Committee did not need to take any action, while Part II related to matters referred to the Committee by the Codex Alimentarius Commission and other Codex Committees and Task Forces for action. The Committee agreed that issues contained in Part II of the document would be considered under the relevant agenda items as indicated in the working paper.

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<sup>1</sup> CX/FAC 04/36/1; and, comments submitted by OIV (CRD 7); and, Denmark (CRD 20).

<sup>2</sup> CX/FAC 04/36/2.

7. In particular, the Committee noted the following matters concerning Part I: Amendments to the Procedural Manual, the Joint FAO/WHO Evaluation of the Codex Alimentarius and Other FAO and WHO Work on Food Standards, the FAO/WHO Trust Fund for Participation of Developing Countries in Codex Standard Setting Procedures; final adoption of draft standards and related texts at Steps 8, 5/8 and 5 of the Accelerated Procedure; preliminary adoption of proposed draft standards and related texts at Step 5; approval of proposals for new work; and, revision of the footnote to the maximum level for lead in milk. The Committee noted that all proposals put forward by the 34<sup>th</sup> and 35<sup>th</sup> Sessions in regard to final or preliminary adoption of draft and proposed draft standards and related texts, revisions, etc. were adopted/approved by the Commission, with the exception of draft maximum level for ochratoxin A in raw wheat, barley and derived products (returned to Step 6) and proposed draft maximum levels for cadmium in various commodities (returned to Step 3).

8. In addition, the Committee was informed of the decisions of the 53<sup>rd</sup> Session of the Executive Committee<sup>3</sup> (February 2004) concerning: (a) standards management functions, namely the Critical Review and the monitoring of progress of standards development; and, (b) the submission of proposals of new work in the format of a project document as proposed by the 19<sup>th</sup> Session of the Codex Committee on General Principles<sup>4</sup> (November 2003). In this regard, the Committee noted that the procedures related to the maintenance of the General Standard for Food Additives, the General Standard for Contaminants and Toxins in Foods, the Food Category System, and the International Numbering System should follow the procedures established by the Committee and endorsed by the Commission.

#### **SIXTY-FIRST MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 4)**

#### **SUMMARY REPORT OF THE 61<sup>ST</sup> MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (Agenda Item 4a)<sup>5</sup>**

9. The Joint Secretariat to JECFA presented the results of the 61<sup>st</sup> Meeting of the Expert Committee (June 2003) as they were reported in the Summary Report of the Meeting. The Committee evaluated 23 food additives, 7 of them for specifications only and revised the levels for arsenic and heavy metals for an additional 39 additives. Full acceptable daily intakes (ADIs) were allocated to curcumin, diacetyltartaric and fatty acid esters of glycerol (DATEM), neotame, and polyvinyl alcohol.

10. The Expert Committee re-evaluated 6 different annatto extracts and decided to assess their toxicological properties separately and adopted for each product a separate specification. JECFA could not finalize the evaluation of these annatto extracts and was only able to assign temporary ADIs to 4 of the 6 extracts. D-Tagatose also received a temporary ADI. These additives would be discussed at subsequent meetings of JECFA.

11. The Expert Committee discussed quillaia extracts and decided to distinguish between a Type 1 product which was the extract that was previously evaluated by JECFA and a Type 2 extract with a higher content of the active saponin principles. For quillaia Type 1, the full ADI was re-established; for quillaia Type 2, an ADI could not be established due to missing information about the quantitative and qualitative composition of the product.

12. The Expert Committee evaluated 144 flavours in 7 different groups applying the decision tree approach developed by JECFA. All of them were considered to be of no safety concern at current levels of intake. For an additional 101 flavours, specifications were elaborated.

13. The Expert Committee also evaluated a water treatment agent (sodium dichloroisocyanurate NaDCC) and a nutritional source of iron (ferrous glycinate). However, neither of these substances were food additives and, therefore, were not up for discussion at the present Session of CCFAC.

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<sup>3</sup> ALINORM 04/27/3, paras. 16 – 20.

<sup>4</sup> ALINORM 04/27/33, Appendix III.

<sup>5</sup> Report available online at the Joint Secretariat's web pages at FAO [http://www.fao.org/es/ESN/jecfa/index\\_en.stm](http://www.fao.org/es/ESN/jecfa/index_en.stm) and WHO <http://www.who.int/pcs/jecfa/jecfa.htm>. Information paper by FAO/WHO (CRD 25).



14. For cadmium, the Expert Committee considered a number of new studies, addressing mainly the dose/response or dose/effect relationships of cadmium exposure and the effects on the kidney. The new data did not provide a sufficient basis for revising the provisional tolerable weekly intake (PTWI), therefore, the PTWI of 7 µg/kg of BW was maintained. Regarding the dietary intake of cadmium, new information from a number of countries was considered. National intake estimates and estimates based on the GEMS/Food regional diets resulted in an estimated cadmium intake of approximately 40-60% of the PTWI. Major dietary sources for cadmium were rice, wheat, starchy roots and tubers, molluscs, and vegetables other than leafy vegetables.

15. In the case of methylmercury (MeHg), the Expert Committee considered a variety of new data from human studies and confirmed that neurodevelopmental effects in children resulting from exposure to MeHg *in utero* was the most sensitive adverse health outcome. The Committee identified a maternal hair mercury level that resulted in no appreciable negative effect in the offspring. From this hair-mercury level, a tolerable intake levels was derived by conversion of the hair to a blood mercury level and relating the blood mercury levels to dietary intake levels. With the application of factors to account for uncertainty in these conversion steps, a PTWI of 1.6 µg/kg bw was derived. The Committee concluded that the previous intake assessment was still valid. For most populations, fish was the only significant source of methyl mercury.

16. The Joint Secretariat drew the attention of the Committee to the *Report of the FAO/WHO Workshop on the Provision of Scientific Advice to Codex and Member States* as presented in CRD 25 which contained the Executive Summary and the Recommendations prepared by a recently held Expert Workshop that discussed upon a request of FAO and WHO, possible improvements of the work of the several scientific expert bodies that provide advice on matters of food safety to Codex Alimentarius. Since one of these bodies was JECFA, Members of the Committee were asked to consider the outcome of the workshop. The full report, which was available at the websites of FAO and WHO, would be discussed at the next Session of the CAC (early July 2004).

17. Finally, the Joint Secretariat informed the Committee that the next two Meetings of JECFA would be dedicated to questions raised by CCFAC. The 63<sup>rd</sup> Meeting in June 2004 would deal with glycyrrhizic acid and food additives, whereas the 64<sup>th</sup> Meeting in February 2005 would discuss contaminants only. The calls for data for both Meetings were available on the Expert Committee's web pages. Member countries were asked to submit data on the substances that were on the agenda of these Meetings. As a matter of urgency, data for stevioside were requested for the Meeting in June 2004.

#### **ACTION REQUIRED AS A RESULT OF CHANGES IN THE ADI STATUS AND OTHER TOXICOLOGICAL RECOMMENDATIONS (Agenda Item 4b)<sup>6</sup>**

18. The Committee noted actions required by CCFAC as a result of changes to existing ADIs and/or the establishment of new ADIs for food additives, or other toxicological recommendations for contaminants, as recommended by the 61<sup>st</sup> JECFA Meeting.

19. The Committee agreed that no action was required with respect to the 6 annatto extracts, D-Tagatose and quillaia extract Type 2 due to their pending evaluation by JECFA (see para. 10).

20. The Committee noted that the Working Group on the International Numbering System had clarified the situation of D-Tagatose in relation to its INS number and had assigned INS numbers to it and to Polyvinyl alcohol (PVA) (see para. 101).

21. The Committee endorsed the recommendations of the *ad hoc* Working Group on the GFSA in this respect (see Appendix XXVI).

#### **DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS (Agenda Item 5)<sup>7</sup>**

22. The Committee noted that the 26<sup>th</sup> Session of the Codex Alimentarius Commission adopted at Step 5 and advanced to Step 6 the proposed draft Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants as proposed by the 35<sup>th</sup> Session of the Committee<sup>8</sup>.

<sup>6</sup> CX/FAC 04/36/3; and, comments submitted by Brazil (CRD 27).

<sup>7</sup> ALINORM 03/12A Appendix IV; CX/FAC 04/36/2-Part II; CL 2003/33-FAC; and, comments submitted by Brazil, Japan, Mexico, and Spain (CX/FAC 04/36/4); and, India (CRD 24).

23. The Committee also noted that the 26<sup>th</sup> Codex Alimentarius Commission adopted Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, while requesting the relevant Codex Committees to develop or complete specific guidelines on risk analysis in their respective areas, for inclusion in the Procedural Manual. The Committee further noted that these texts would be submitted to the Codex Committee on General Principles in order to ensure coordination of work and consistency with overarching Working Principles<sup>9</sup>.

24. The Committee discussed the draft Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants as follows:

Paragraph (d)

25. The Committee agreed to replace the term “Member States” by “Members” in this paragraph and throughout the document.

Paragraph (g)

26. The Committee recognized the need to define the term “safety assessment” which had no clear definition in Codex. In noting that the Joint FAO/WHO Project to Update the Principles and Methods for Risk Assessment of Chemicals in Foods would provide a definition of the term “safety assessment”, it agreed on the need to keep consistency in the definition of this term. However, the Committee acknowledged that it should establish its risk analysis principles as soon as possible in view of their importance for the Committee’s work and the recommendation of the Commission. Therefore, as an interim measure, the Committee decided to insert a footnote containing the definition for “safety assessment” that appeared in the original Discussion Paper<sup>10</sup>, with the clear understanding that it would be replaced when the new definition from JECFA became available.

27. The Committee clarified that safety assessment was a component of risk assessment by replacing the word “or” by “including” as follows: “...*risk assessment* ~~or~~ **including** *safety assessment of food additives*...”.

Paragraph (k)

28. The Committee noted the request to add a footnote to “other legitimate factors” to make reference to the “Statement of Principles Concerning the Role of Science in the Codex Decision Making-Process and the Extent to which Other Factors are Taken Into Account” as laid down in the Codex Alimentarius Commission Procedural Manual. However, the Committee felt that this was unnecessary, since these principles were to be incorporated in the Procedural Manual. In this connection, the Committee agreed that it was more appropriate to refer to “risk assessment and other legitimate factors”, as risk assessment inherently included the concept of “quantitative” and “safety assessment” and, therefore, the reference to “quantitative” and “sufficient safety assessment” were deleted from this paragraph.

Paragraph (m)

29. The Committee agreed to replace the term “safety evaluation” by “safety assessment” as it was the appropriate term used in the context of JECFA and applied this amendment throughout the text.

Paragraph (n)

30. The Committee agreed to modify the latter part of the second statement to include appropriate sampling plans and analytical methods as adopted by Codex. The revised text also reflected that when establishing maximum levels for contaminants and toxins in foods, analytical capabilities of developing countries should be taken into consideration.

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<sup>8</sup> ALINORM 03/12A, para. 28 and ALINORM 03/41, Appendix VI.

<sup>9</sup> ALINORM 03/41, para.147.

<sup>10</sup> CX/FAC 02/4, footnote 21.

Paragraph (o)

31. The Committee agreed that with regard to contaminants, the correct term was “maximum levels” as opposed to “maximum limits” and agreed to be consistent in using this term throughout the text. Also the Committee agreed to replace the acronym “ML” by the term “maximum level” wherever the former occurred.

32. The Committee noted the concern expressed by the Delegation of India that JECFA, as the body with scientific expertise, should take responsibility to recommend maximum levels to the Committee and considered the proposals to amend paragraphs (o) and (p) to this effect. The Committee noted that it was an established practice for CCFAC to decide maximum levels based on the outcome of JECFA’s risk assessment and that the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius clearly distinguished that the responsibility for providing advice on risk management laid with the Codex Alimentarius Commission and its subsidiary bodies (risk managers) while the responsibility for risk assessment laid primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).

33. In this connection, it was pointed out that since the procedure laid down in the document reflected the standing practice of CCFAC in setting maximum levels, it would not be appropriate at this stage to introduce amendments leading to major changes in the approach followed by CCFAC in this respect. As a result, the Committee agreed to leave the relevant paragraphs unchanged.

Paragraph (q)

34. The Committee agreed to change the term “any non-science-based considerations” by “other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade” for consistency with paragraph (k).

Paragraph (cc)

35. The Committee agreed to delete the first part of the first sentence of this paragraph since its content did not comprise a criterion for JECFA to perform risk assessment.

Paragraph (ii)

36. The Committee recognized that “general risk analysis in Codex and CCFAC” referred to the adopted Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and to the actual document under discussion (Risk Analysis Principles applied by CCFAC) and, therefore, it agreed to make explicit reference to these documents in the paragraph.

Paragraphs (gg) and (kk)

37. The Committee noted that paragraph (gg) related to risk assessment performed by JECFA at the request of CCFAC while paragraph (kk) related to risk assessment performed by JECFA as part of its own working priorities.

Figure 1

38. After some discussion about the original intend of figure 1, which was to facilitate a common understanding of the roles of the CAC, CCFAC and JECFA on the risk analysis process, the Committee agreed that the figure had served its purpose and decided to delete it.

**Status of the draft Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants**

39. The Committee forwarded the draft Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants to the Codex Alimentarius Commission, through the Codex Committee on General Principles, for final adoption at Step 8 (see Appendix II) and inclusion in the Procedural Manual.

**ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES AND PROCESSING AIDS IN CODEX STANDARDS (Agenda Item 6)<sup>11</sup>**

40. In accordance with the section concerning the relations between Commodity Committees and General Committees of the Codex Alimentarius Commission Procedural Manual, the Committee considered the endorsement of food additive and processing aid provisions arising from the Codex Committee on Fish and Fishery Products (CCFFP), the *Ad Hoc* Codex Intergovernmental Task Force on Fruit and Vegetable Juices (TFFVJ), and the Codex Alimentarius Commission.

**Draft Codex Standard for Salted Atlantic Herring and Salted Sprat**

41. The Committee noted that at its 35<sup>th</sup> Session (March 2003) it endorsed food additive provisions, including propyl gallate (INS 310), in the draft Codex Standard for Salted Atlantic Herring and Salted Sprat. The Committee also noted that the 26<sup>th</sup> Session of the Codex Committee on Fish and Fishery Products (October 2003) agreed to delete this additive from the endorsed list of permitted additives as its use was not technologically justified in salted Atlantic herring and salted sprat.

42. The Committee decided not to endorse the deletion of propyl gallate from the draft Standard for Salted Atlantic Herring and Salted Sprat and decided to request further clarification from the Codex Committee on Fish and Fishery Products on this request, in particular, as to its technological justification. The Committee noted that the use of sorbates (INS 200 – 203), but not propyl gallate, were listed as antioxidants in this commodity Standard (see Appendix III).

43. The Committee noted that this request was part of a broader request that the CCFFP had forwarded to it. In that request, the CCFFP recognized that this product belonged to a food category identified in the General Standard for Food Additives (GSFA) as “09.2.5 smoked, dried, fermented, and/or salted fish, including molluscs, crustaceans and echinoderms” that allowed the use of food additives e.g. propyl gallate and fast green colour (INS 143) which were not permitted under the Codex Standard for Salted Atlantic Herring and Salted Sprat. Therefore, the CCFFP agreed to seek the advice of CCFAC to address the situation where a food additive was allowed in a food category of the GSFA but was not allowed in a particular product within that food category. The Committee agreed that this request should be taken up in the Working Group that would analyse the relationship between food additive provisions of the GSFA and those of the commodity standards in order to assure consistency throughout the Codex system (see para. 59).

**Draft Codex General Standard for Fruit Juices and Nectars*****Food Additives***

44. The Committee endorsed food additive provisions in the draft Codex General Standard for Fruit Juices and Nectars with the following amendments:

**Footnote 2**

45. The Committee agreed to refer to “consumer” as opposed to “customer” to ensure that the maximum levels apply to the product as consumed.

**Footnote 4**

46. The Committee had an exchange of views on the need to keep Footnote 4 as only additives which were technologically justified were included in the GSFA. The Committee noted that the use of sulphites applied to specific cases such as fruit juices/nectars in bulk dispensers or to prevent oxidation in certain tropical fruit juices/nectars when no other more suitable technological means were available. The Committee further noted that the use of sulphites was subject to national legislation of the importing country. In view of this, the Committee amended Footnote 4 to limit the use of sulphites to fruit juices/nectars in bulk dispensers and to certain tropical fruit juices/nectars.

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<sup>11</sup> CX/FAC 04/36/5 and CX/FAC 04/36/2-Part II.

47. The Committee agreed that, as a result of the above discussion, the current food additive provisions in the GSFA in Food Categories 14.1.2.1, 14.1.2.3, 14.1.3.1 and 14.1.3.3 would be removed and the provisions endorsed by CCFAAC would be entered into the revised GSFA (see paras. 83-84 and Appendix III). Consequently, the *Ad Hoc* Codex Intergovernmental Task Force on Fruit and Vegetable Juices should remove the list of food additives from the draft Codex General Standard for Fruit Juices and Nectars and replace it with the following text: “Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Categories 14.1.2.1 (Fruit juice), 14.1.2.3 (Concentrates for fruit juice), 13.1.3.1 (Fruit nectar) and 14.1.3.3 (Concentrates for fruit nectar) may be used in foods subject to this Standard”.

### ***Processing Aids***

48. The Committee endorsed processing aid provisions in the draft Codex General Standard for Fruit Juices and Nectars with the exception of polydimethylsiloxane. The Committee agreed to request further clarification about whether the technological function of this compound was linked to a food additive use or a processing aid. In addition, the Committee agreed that the column on Maximum Levels referred to levels of use and not to the residual level of the compound in the final product. Consequently, a maximum level of “GMP” was inserted for those compounds for which no levels were indicated (see Appendix III).

### **Codex Standard for Chocolate and Chocolate Products**

49. The Committee agreed with the request of the 26<sup>th</sup> Session of the Codex Alimentarius Commission to amend the level of carnauba wax (INS 903) for Food Category “05.1.4 Cocoa and Chocolate Products” to 500 mg/kg instead of the GMP level in the GSFA<sup>12</sup> (see para. 82 and Appendix III).

## **CONSIDERATION OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 7)**

### **REPORT OF THE *AD HOC* WORKING GROUP ON THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 7a)<sup>13</sup>**

50. The 35<sup>th</sup> Session of the CCFAAC decided to reconvene the *ad hoc* Working Group on the Codex General Standard for Food Additives prior to its 36<sup>th</sup> Session under the Chairmanship of the United States<sup>14</sup>. Dr Dennis Keefe (United States) chaired this meeting of the *ad hoc* Working Group and Dr Yukiko Yamada (Japan) acted as vice-chair. Ms Iona Pratt (Ireland) and Mr Najib Layachi (Morocco) served as rapporteurs.

51. The Chairperson of the *ad hoc* Working Group briefly summarized its discussions and proposed several general recommendations for endorsement by the Committee.

### **Status of the *ad hoc* Working Group on the Codex General Standard for Food Additives**

52. The Committee decided to reconvene the *ad hoc* Working Group on the Codex General Standard for Food Additives prior to its next Session, under the Chairmanship of the United States.

### **PROPOSED DRAFT REVISED PREAMBLE OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 7b)<sup>15</sup>**

53. The Committee noted that the 26<sup>th</sup> Session of the Codex Alimentarius Commission approved the revision of the Preamble as new work for the Committee<sup>16</sup>.

54. The Committee considered some of the recommendations contained in working document CX/FAC 04/36/6, regarding:

<sup>12</sup> ALINORM 03/41, para. 42.

<sup>13</sup> CRD 1.

<sup>14</sup> ALINORM 03/12A, para. 40.

<sup>15</sup> CX/FAC 04/36/6; Report of the *ad hoc* Working Group on the GSFA (CRD1); and, comments submitted by Australia, European Community, Norway, United States, ELC, IFT, IFU, and ISDC (CX/FAC 04/36/6-Add-1); Thailand (CRD 17); and, Canada (CRD 28).

<sup>16</sup> ALINORM 03/12A, para. 47 and ALINORM 03/41-App. VIII.

### **Current Format of the GSFA**

55. The Committee agreed to request the Codex Secretariat to add clarifying language to the text of each page of the adopted GSFA that identified the section of the Standard and to delete Lists A and B (see para. 80).

56. It further agreed to amend Section 1.1 of the Preamble to include a reference to the JECFA website to provide ready access to the most up-to-date information on ADIs and to request JECFA to make an index of food additives available on its website with current information on ADI status, the year of the most recent JECFA review, and the INS number assigned to each additive as appropriate (see para. 80).

### **Definitions and Terminology Used in the GSFA; General Principles for the Use of Food Additives**

57. The Committee considered the recommendation of the *ad hoc* Working Group<sup>13</sup> regarding the establishment of a Working Group to prepare a discussion paper, outlining the working principles that the CCFAC had previously developed during its elaboration of the GSFA, for discussion by the next Session of CCFAC.

58. The Committee recognized that in order to solve the conflicting views and make further progress in the development of the GSFA, it was important to be aware of the previous decisions and to establish a common understanding on the principles governing the GSFA and how they were commonly applied by the Committee. The second step, would be to improve these principles and to ensure consistency of all texts governing the development of the GSFA.

59. The Committee therefore agreed to establish a Working Group with the following terms of reference:

The Working Group shall:

- (a) review the currently-used working principles applied by the Committee when developing the GSFA;
- (b) adapt these working principles with the objective to improve the work, taking into consideration that the development of the GSFA needs to respect the following criteria:
  - (i) the GSFA needs to be consistent with other standards adopted by the Codex Alimentarius Commission;
  - (ii) the entries to the GSFA should be developed in a transparent manner;
  - (iii) the GSFA needs to be developed in a fair and consistent way; and,
  - (iv) the GSFA has been under development for more than 10 years, changes to the working principles should result in an acceleration rather than leading to further delay.
- (c) describe the proposed amended working principles in a separate document that will accompany the GSFA. In a second step, the Working Group is asked to consider where these working principles would require the amendment of other documents adopted by the Commission;
- (d) analyse, as part of this work, the relationship between provisions of the GSFA and those of Commodity Standards and shall propose procedures that will assure consistency among different sections of the Codex Alimentarius that address the use of food additives in standardized foods; and,
- (e) present to the next Session of the Committee a progress report and possibly, depending on the progress made, questions in order to receive further comments.

60. The Committee agreed that the Working Group will be led by China with the assistance of Australia, Brazil, Canada, EC, France, India, Japan, Korea, Morocco, New Zealand, Sweden, Switzerland, Thailand, United States, ELC, ICGMA, IDF, and IFU.

**DRAFT FOOD CATEGORY SYSTEM OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 7c)<sup>17</sup>**

61. The 26<sup>th</sup> Session of the Codex Alimentarius Commission adopted the proposed draft Food Category System of the Codex General Standard for Food Additives at Step 5 and advanced it to Step 6 as proposed by the 35<sup>th</sup> Session of the Committee<sup>18</sup>. In addition, the 35<sup>th</sup> Session of the CCFAC noted that Delegations of the Asian region would develop proposals on the finalization of certain Food Categories for soybean products for consideration at the next Session of the Committee<sup>19</sup>.

62. In addition to the changes recommended by the *ad hoc* Working Group<sup>13</sup> to the Food Category System, the Committee made amendments to the following food categories and descriptors:

- (a) 01.7 Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt);
- (b) 5.2 Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4;
- (c) 7.1.1 Breads and rolls;
- (d) 12.2 Herbs, spices seasonings, and condiments (e.g. seasoning for instant noodles);
- (e) 12.9.1 Soybean milk and 12.9.2 Soybean milk film; and,
- (f) 14.1.2 Fruit and vegetable juices, 14.1.2.1 Fruit juice, and 14.1.2.3 Concentrates for fruit juice.

63. The Committee agreed on the above changes with the understanding that any consequential changes to adopted provisions in the GSFA would be accounted for as editorial matters.

64. The Committee agreed with the recommendation of the *ad hoc* Working Group<sup>13</sup> that use of the terms “filled milk”, “filled condensed milk”, and “filled milk powders” in the descriptors of food categories 01.3, 01.3.2, and 01.5.2 were included with the understanding that they would be aligned with the terms of relevant Codex Standards under development in the Codex Committee on Milk and Milk Products.

65. In recognizing the integral nature of the Food Category System (FCS) and the implications that further revisions would have on the GSFA, the Committee endorsed the recommendation of the *ad hoc* Working Group<sup>13</sup> to develop a more rigorous procedure for future revisions of the FCS.

66. The Committee agreed that all requests for revision of the FCS should be accompanied by a project document, prepared by the Committee or Member, detailing as appropriate:

- (a) The purposes and the scope of the revision;
- (b) Its relevance and timeliness;
- (c) The main aspects to be covered; and,
- (d) An assessment against the *Criteria for the Establishment of Work Priorities*.

67. The Committee endorsed the recommendation of the *ad hoc* Working Group<sup>13</sup> to request the *ad hoc* Codex Intergovernmental Task Force on Fruit and Vegetable Juices to clarify whether coconut water should be included in the draft Codex General Standard for Fruit Juices and Nectars, with the understanding that if coconut water was included, coconut water would be included in Food Category 14.1.2.1.

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<sup>17</sup> ALINORM 03/12A, Appendix II; CX/FAC 04/36/2-Part II; CL 2003/33-FAC; Report of the *ad hoc* Working Group on the GSFA (CRD1); and, comments submitted by Brazil, China, Greece, Spain, United States, and IFU (CX/FAC 04/36/7); IBFAN (CRD 16); Thailand (CRD 17); India (CRD 24); and, Brazil (CRD 27).

<sup>18</sup> ALINORM 03/12A, para. 51 and ALINORM 03/41, Appendix VI.

<sup>19</sup> ALINORM 03/12A, para. 50.

**Status of the draft Food Category System of the Codex General Standard for Food Additives**

68. The Committee forwarded the draft Food Category System of the Codex General Standard for Food Additives to the Codex Alimentarius Commission for final adoption at Step 8 (see Appendix V).

**DRAFT AND PROPOSED DRAFT REVISIONS TO TABLE 1 OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 7d)<sup>20</sup>**

69. The 35<sup>th</sup> Session of the CCFAC noted that in the absence of the data required to implement revisions to Table 1 of the GSFA, additional comments on CL 2002/44-FAC should be requested for consideration at its next Session. The Committee decided to re-install the Quality Control Working Group, under the direction of the United States, to work through electronic means well before the next Session of the Committee<sup>21</sup>.

**Electronic Working Group**

70. The Committee endorsed the recommendation of the *ad hoc* Working Group<sup>13</sup> to re-establish the newly named Electronic Working Group and requested it to provide a report with recommendations to the 37<sup>th</sup> Session of the CCFAC on the draft maximum levels for the food additives listed in Appendix X to this report. The Committee agreed that the report of the Electronic Working Group should also develop a rational and consistent proposal to address the proposed draft, draft, and adopted provisions for phenolic antioxidants (BHA, BHT, TBHQ, and propyl gallate) in the GSFA.

71. The Committee agreed that the Electronic Working Group would be led by the United States with the assistance of Australia, Brazil, Canada, EC, Japan, Ireland, South Africa, IFAC, and ICGMA.

**Table 1 of the GSFA*****Recommendations for Adoption of draft (at Step 8) and proposed draft (at Step 5/8) Food Additive Provisions***

72. The Committee endorsed the recommendation of the *ad hoc* Working Group<sup>13</sup> to advance to Steps 8 and 5/8 (with recommendation to omit Steps 6 and 7) the draft and proposed draft food additives provisions of Table 1 of the GSFA, contained in Appendix VI to this report, for final adoption by the Commission (see para. 81). The Committee noted the reservation of the Delegations of the EC and Norway regarding the use level of benzoates in Food Category 14.1.4 “Water-based flavoured drinks, including “sport”, “energy”, or “electrolyte” drinks and particulated drinks”.

73. The Committee also agreed to advance to Step 8 for final adoption by the Commission an amendment to the provision for the use of dimethyl dicarbonate (INS 242) in Food Category 14.1.5 “Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa” which would delete the reference to Note 2 (on dry ingredient, dry weight, dry mix or concentrate basis) (see para. 81).

***Recommendations for Revocation of Adopted Food Additive Provisions and for Discontinuation of Draft and Proposed Draft Food Additive Provisions***

74. The Committee noted that for some of the adopted and non-adopted food additive provisions to Table 1 of the GSFA, there were additives for which JECFA had withdrawn ADIs. It also noted that some of the adopted and non-adopted food additive provisions reflected the result of carry-over and needed to be deleted. It further noted the need to take into account the work of some Commodity Committees.

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<sup>20</sup> CX/FAC 04/36/8; ALINORM 03/12, Appendix III; CL 2002/44-FAC; CL 2003/13-FAC; CL 2003/34-FAC; CX/FAC 04/36/2-Part II; Report of the *ad hoc* Working Group on the GSFA (CRD1); and, comments submitted by Australia, Brazil, El Salvador, European Community, Italy, Spain, IFAC, IFU, IPPA, ISDC, ISDI and, OIV (CX/FAC 04/36/9); Malaysia (CRD 15); Thailand (CRD 17); ISC (CRD 19); Norway (CRD 26); Brazil (CRD 27); and, Australia (CRD 30).

<sup>21</sup> ALINORM 03/12A, paras 39 and 53.



75. As a result, the Committee agreed to:

- (a) request the Commission to revoke adopted food additive provisions to Table 1 of the GSFA as contained in Appendix VII. The Committee noted that a decision on polydimethylsiloxane (INS 900a) would be taken in the light of the clarification provided by *ad hoc* Codex Intergovernmental Task force on Fruit and Vegetable Juices about the technological function of this compound (see paras. 47-48 and 83); and,
- (b) discontinue work on draft (Step 6) and proposed draft (Step 3) food additive provisions as listed in Appendix VIII to this report (see paras. 47 and 84).

### ***Request for Information***

#### **Draft (Step 6) and proposed draft (Step 3) Food Additive Provisions in Table 1 of the GSFA**

76. The Committee asked the Codex Secretariat to request information on the use of the draft and proposed draft food additive provisions to Table 1 of the GSFA listed in Appendix IX to this report.

#### **New entries for Food Additive Provisions in Table 1 of the GSFA**

77. The Committee agreed that new proposed uses for food additives submitted in response to CL 2002/44-FAC and CL 2003/34-FAC should be included in the GSFA and circulated for comments at Step 3 under a separate Circular Letter. The Committee accepted the offer of the Delegation of the United States to prepare a revised GSFA with proposed draft, draft, and adopted food additive provisions.

#### **Priority List for JECFA Evaluation**

78. The Committee asked the Codex Secretariat to request information and data on beeswax (INS 901) and candelilla wax (INS 902) that were necessary for JECFA to perform an exposure assessment in relation to the proposed uses in Food Category 14.1.4 “Water-based flavoured drinks, including “sport”, “energy” or “electrolyte” drinks and particulated drinks”, based on adopted provisions in the GSFA (see Appendix XXVII).

79. The Committee took these decisions with the understanding that at its 37<sup>th</sup> Session it would delete these draft and proposed draft provisions, if such information and data were not submitted. In this regard, the Committee noted that the Delegation of Japan was willing to submit information on national consumption data on beeswax and would clarify the use levels of candelilla wax on a final product basis.

### **Status of the Codex General Standard for Food Additives**

#### **Amendment to the GSFA**

80. The Committee forwarded to the Codex Alimentarius Commission the amendments to the General Standard for Food Additives namely: deletion of Lists A and B and addition of a footnote to Section 1.1 of the Preamble (see paras. 55-56 and Appendix IV).

#### **Revisions to Table 1 of the GSFA**

81. The Committee forwarded draft and proposed draft food additive provisions to the Codex Alimentarius Commission for final adoption at Steps 8 and 5/8 (with recommendation to omit Steps 6 and 7) for inclusion in Table 1 of the General Standard for Food Additives (see paras. 72 - 73 and Appendix VI).

82. The Committee forwarded to the Codex Alimentarius Commission an amendment to the maximum level of GMP in the GSFA for carnauba wax (INS 903) for Food Category 05.1.4 “Cocoa and Chocolate Products” which would establish a maximum level of 500 mg/kg (see para. 49 and Appendix VI).

83. The Committee requested the Codex Alimentarius Commission to revoke a number of food additive provisions in Table 1 of the General Standard for Food Additives (see paras. 47, 75 and Appendix VII).

84. The Committee informed the Codex Alimentarius Commission of discontinuation of work on a number of draft and proposed draft food additive provisions listed in Table 1 of the General Standard for Food Additives (see paras. 47, 75 and Appendix VIII).

### **DISCUSSION PAPER ON THE CONSIDERATION OF PROCESSING AIDS AND CARRIERS (Agenda Item 8)<sup>22</sup>**

85. The 35<sup>th</sup> Session of the CCFAC decided that a drafting group under the direction of Switzerland would elaborate a discussion paper on realistic approaches and recommendations on the consideration of processing aids and carriers for circulation, comments, and further discussion at its next Session<sup>23</sup>.

86. The Delegation of Switzerland briefly introduced the document by highlighting the main recommendations on: (a) future consideration of processing aids; (b) inventory of processing aids; and, (c) inclusion of carriers in the GSFA.

#### **Future Consideration of Processing Aids**

87. The Committee recognised that the development of a positive list of processing aids was not a realistic approach to resolving the issue. It acknowledged that provisions for processing aids were already included in commodity standards. It agreed on the need to develop guidelines, for the use of Governments, to address various aspects such as principles for the use of processing aids and their control; advice on Good Manufacturing Practice; information on handling; etc. However, the Committee could not identify a delegation willing to prepare a document dealing with these issues.

#### **Inventory of Processing Aids (IPA)**

88. The Committee, in recognizing the value of the IPA as a useful reference for countries, in particular developing countries, agreed to maintain the IPA for the time being and accepted the offer of the Delegation of New Zealand to prepare an updated version of the IPA for consideration at its next Session. In this regard, it was noted that reference to some enzyme preparations that were recently evaluated by JECFA, should be considered when updating the IPA. It was also noted that the IPA version available on the Codex website needed to be updated.

#### **Inclusion of Carriers in the GSFA**

89. The Committee considered a definition for the term “carrier” in view of the development of a suitable approach for consideration of carriers in the GSFA. In recognizing the difficulty to reach a common understanding on the definition, the Committee agreed that a working group led by the United Kingdom, with the assistance of the EC, Ghana, Switzerland, and the United States would prepare a discussion paper that would address the definition and approaches for the inclusion of carriers in the GSFA, including the use of food additives as “nutrient carriers” as requested by the 25<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)<sup>24</sup> for circulation, comments, and consideration at its next Session.

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<sup>22</sup> CX/FAC 04/36/10; CX/FAC 04/36/2-Part II; and, comments submitted by Australia, Cuba, European Community, Ghana, Norway, Poland, Unites States, AMFEP, CEFIC, ELC, IFU, and IFT (CX/FAC 04/36/10-Add 1); India (CRD 24); and, Brazil (CRD 27).

<sup>23</sup> ALINORM 03/12A, para. 60.

<sup>24</sup> ALINORM 04/27/26, paras. 131-137

**PROPOSED DRAFT CODE OF PRACTICE ON THE SAFE USE OF ACTIVE CHLORINE (Agenda Item 9)<sup>25</sup>**

90. The 35<sup>th</sup> Session of the CCFAC decided to commence work on the development of a Code of Practice for the Safe Use of Active Chlorine and agreed that a working group led by Denmark would prepare a proposed draft Code of Practice for circulation, comments, and further consideration at this Session<sup>26</sup>. The 26<sup>th</sup> Session of the Codex Alimentarius Commission approved the elaboration of the Code of Practice as new work for the Committee with the understanding that recommendations on the safe use of active chlorine would require close collaboration with other Codex Committees, such as the Codex Committee on Food Hygiene<sup>27</sup>.

91. In presenting the document, the Delegation of Denmark pointed out that an evaluation of the technological effects; the efficacy; and, the risk assessment of residues and reaction products of the active chlorine compounds was necessary in order to assess whether the benefits on the microbiological contamination outweigh the possible risks of intake of chlorine and its reaction products. In this regard, the Committee noted that a Joint FAO/WHO Expert Consultation would be a more appropriate forum to carry out this evaluation and assessment, as it could bring together all necessary expertise. It was also stressed that undertaking this consultation would depend upon the availability of financial resources of FAO and WHO.

92. The Committee agreed to request FAO and WHO to convene a Joint Expert Consultation to conduct a comprehensive assessment of use of active chlorine, taking into account both benefits and risks. In recognizing the multiple aspects of the use of active chlorine, the Committee agreed on the need to clearly define the scope of the Expert Consultation. Therefore, it agreed that a working group led by Denmark with the assistance of Australia, Canada, EC, Ireland, Korea, Philippines, United States, and ICGMA would prepare clear terms of reference for the expert consultation for the aspects relevant to the CCFAC for discussion at its next Session. It was also agreed to request relevant Committees, including the Codex Committee on Food Hygiene, to: (a) consider safety/benefit issues relevant to uses of active chlorine within their respective purviews; (b) elaborate terms of reference for the expert consultation within their mandates; and, (c) pose questions so that the Expert Consultation be comprehensive.

**Status of the proposed draft Code of Practice on the Safe Use of Active Chlorine**

93. The Committee decided to discontinue work on the development of a Code of Practice on the Safe Use of Active Chlorine and to inform the Codex Alimentarius Commission accordingly. It was understood that the Committee would consider resuming this work in the light of any recommendation emanating from the proposed Joint FAO/WHO Expert Consultation.

**SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES (Agenda Item 10)**

**REPORT OF THE *AD HOC* WORKING GROUP ON SPECIFICATIONS (Agenda Item 10a)<sup>28</sup>**

94. The 35<sup>th</sup> Session of the CCFAC decided to reconvene the *ad hoc* Working Group on Specifications prior to its current Session under the Chairmanship of the United States. The *ad hoc* Working Group's meeting was chaired by Mr Paul Kuznesof (United States). Mrs H.C. Wallin (Finland) acted as Rapporteur and Mrs I. Meyland (Denmark) as Category Monitor. The recommendations of the *ad hoc* Working Group were considered under Agenda Item 11(b).

95. The *ad hoc* Working Group considered the monographs for Specifications for the Identity and Purity of Food Additives and Flavouring Agents established at the 61<sup>st</sup> Meeting of JECFA and published in Food and Nutrition Paper 52-Addendum 11 (FNP 52-Add.11) along with the comments received on this document. The *ad hoc* Working Group assigned the monographs to categories for use by the full Committee.

96. In addition, the *ad hoc* Working Group considered Principles Governing the Establishment and Revision of Specifications that were discussed by JECFA (published in Section A of FNP 52-Add.11) and provided feedback to the FAO Joint Secretary on some of these matters.

<sup>25</sup> CX/FAC 04/36/11; and, comments submitted by Canada, Cuba, European Community, United States, ICGMA, and ISDC (CX/FC 04/36/11-Add.1); and, India (CRD 24).

<sup>26</sup> ALINORM 03/12A, paras. 67 – 68.

<sup>27</sup> ALINORM 03/41, para. 131 and Appendix VIII.

<sup>28</sup> CRD 2.

### **Status of the *ad hoc* Working Group on Specifications**

97. The Committee decided to reconvene the *ad hoc* Working Group on Specifications prior to its next Session under the Chairmanship of the United States.

### **SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 61<sup>ST</sup> JECFA MEETING (Agenda Item 10b)<sup>29</sup>**

98. The Committee agreed with the following recommendations of the *ad hoc* Working Group<sup>28</sup>:
- (a) to forward for final adoption the Category I Specifications for 13 food additives;
  - (b) to forward for final adoption the Category I Specifications for 225 flavouring agents;
  - (c) to forward for final adoption the updated levels for arsenic and lead, and the deletion of the Heavy Metals (as lead) levels for 33 Specifications; and,
  - (d) to refer back the Category III Specifications for food additives to JECFA for further revisions namely: laccase from *Myceliophora thermophila* expressed in *Aspergillus oryzae* and sucrose esters of fatty acids.

### **Status of the Specifications for the Identity and Purity of Food Additives arising from the 61<sup>ST</sup> JECFA Meeting**

99. The Committee forwarded 13 food additive Specifications, 225 flavouring agent Specifications in Category I and 33 revised Specifications to the Codex Alimentarius Commission for adoption at Step 5/8 (with recommendation to omit Steps 6 and 7) as Codex Advisory Specifications (see Appendix XI).

### **INTERNATIONAL NUMBERING SYSTEM (INS) FOR FOOD ADDITIVES (Agenda Item 11)**

#### **PROPOSALS FOR AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM (INS) (Agenda Item 11a)<sup>30</sup>**

100. The Committee noted that the comments received in response to CL 2003/13-FAC had been discussed by the Working Group on the International Numbering System that was chaired by Mrs H. Wallin (Finland), who presented the recommendations of the Working Group.

#### **REPORT OF THE WORKING GROUP ON THE INTERNATIONAL NUMBERING SYSTEM (Agenda Item 11b)<sup>31</sup>**

101. The Committee agreed to the following recommendations of the Working Group<sup>31</sup>:
- (a) To allow for alternative names for INS entries 466 “Sodium carboxymethyl cellulose/Cellulose gum”; 468 “Cross-linked sodium carboxymethyl cellulose/Cross-linked cellulose gum”; and, 469 “Carboxymethyl cellulose, enzymatically hydrolysed/Cellulose gum, enzymatically hydrolysed”;
  - (b) To assign INS Number 1203 to Polyvinyl alcohol with the following technological functions: coating, binder, sealing agent, and surface-finishing agent;
  - (c) To assign INS Number 426 to Soybean hemicellulose with the following technological functions: emulsifier, thickener, stabilizer, and anti-caking agent;
  - (d) To change INS Number 962 for the sweetener D-Tagatose (which had been allocated at the 35<sup>th</sup> Session of CCFAC) to 963 in order to align the INS and the EU numbers for Acesulfame-aspartame salt; and,

<sup>29</sup> CX/FAC 04/36/12; and, comments submitted by Japan (CX/FAC 04/36/12-Add. 1); and, Brazil (CRD 27).

<sup>30</sup> CL 2003/13-FAC; CX/FAC 04/36/2-Part II; and, comments submitted by IFAC (CX/FAC 04/36/13); and, Brazil (CRD 27).

<sup>31</sup> CRD 4.

- (e) To assign INS Number 962 to Acesulfame-aspartame salt with the technological function of a sweetener.

102. The Committee agreed to request the Codex Secretariat to update the INS list posted on the Codex webpage in a timely manner following each Session of the Codex Alimentarius Commission.

### **Status of the Amendments to the International Numbering System for Food Additives**

103. The Committee forwarded the proposed draft amendments to the International Numbering System for Food Additives to the Codex Alimentarius Commission for final adoption at Step 5/8 (with recommendation to omit Steps 6 and 7) (see Appendix XII).

### **DISCUSSION PAPER ON THE HARMONIZATION OF TERMS USED BY CODEX AND JECFA (Agenda Item 11c)<sup>32</sup>**

104. The 35<sup>th</sup> Session of the CCFAC requested the Codex Secretariat to prepare a discussion paper on the Harmonization of Terms used by Codex and the Joint FAO/WHO Expert Committee on Food Additives for sub-classes and technological functions for consideration at its next Session<sup>33</sup>. The work had been undertaken by a consultant to the Codex Secretariat (Dr Simon Brooke-Taylor, Australia).

105. The Committee was informed that the paper had also been considered by the Working Group on the International Numbering System. It noted that the use of the Table of Functional Classes, Definitions and Technological Functions for Food Additives in Section 2 of the Codex Guidelines on Class Names and the International Numbering System for Food Additives<sup>34</sup> and Class Names/Titles used in the Codex General Standard for the Labelling of Pre-packaged Foods<sup>35</sup> must be consistent and, therefore, any changes in the Table of Functional Classes made by CCFAC would also need to be taken up as new Class Names by the Codex Committee on Food Labelling (CCFL) in the form of an amendment to the Codex General Standard for the Labelling of Pre-packaged Foods.

106. The Committee agreed to the following recommendations in relation to new food additives to ensure that these were identified and designated by CCFAC and JECFA according to a common system of terminology:

- (a) In its requests for evaluation of an additive, CCFAC should ask JECFA to identify the functional classes and/or sub-classes that are relevant to the evaluation and specification using terms taken from the appropriate Codex texts; and,
- (b) in the case of a food additive, JECFA should be requested to describe the sub-category or technological function within the scope of the existing INS Table of Functional Classes. Where JECFA considers that the technological function of an additive is not properly described by Codex texts, it should be encouraged to advise CCFAC of its decision and recommend an amendment to the relevant Codex texts to add the new technological function.

107. The Committee noted that in the GSFA there were a number of adopted and non-adopted provisions for food additives which were associated with technological functions that did not occur in the INS Table of Functional Classes. The Committee agreed to harmonise the functional classes listed in the adopted and non-adopted provisions of the GSFA with the INS Table of Functional Classes and accepted the recommendations of the Working Group on the INS<sup>31</sup> to:

- (a) establish a working group under the direction of the United Kingdom, with the assistance of Brazil, EC, and the United States, to prepare a working document containing a clear proposal for the harmonisation of terms used by Codex and JECFA for circulation, comments, and consideration at its next Session; and,

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<sup>32</sup> CX/FAC 04/36/14; and, comments submitted by Canada, European Community, United States, and OFCA (CX/FAC 04/36/14-Add 1); and, Brazil (CRD 27).

<sup>33</sup> ALINORM 03/12A, para. 101.

<sup>34</sup> CAC/GL 36/2001.

<sup>35</sup> Codex STAN 1-1985, Rev. 1-1991.

- (b) establish a separate Working Group on the Harmonization of Terms used by Codex and JECFA to meet immediately prior to the next Session of CCFAC, to discuss the working document produced by the above-mentioned Working Group and provide advice to the Committee.

108. The Committee noted that the Working Group on the International Numbering System would also address the request of the 25<sup>th</sup> Session of the CCNFSU<sup>36</sup> with regard the establishment of functional classes that were not currently covered, especially enzymes and propellant gases.

#### **ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX STANDARDS (Agenda Item 12)<sup>37</sup>**

109. In accordance with the section concerning Relations between Commodity Committees and General Committees of the Codex Alimentarius Commission Procedural Manual, all provisions in respect to contaminants contained in Codex commodity standards should be referred to the Codex Committee on Additives and Contaminants for endorsement.

110. The Committee noted that no maximum levels for contaminants had been submitted for endorsement since its 35<sup>th</sup> Session and, therefore, no action was required.

#### **CONSIDERATION OF THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (Agenda Item 13)**

##### **REPORT OF THE *AD HOC* WORKING GROUP ON CONTAMINANTS AND TOXINS IN FOODS (Agenda Item 13a)<sup>38</sup>**

111. The 35<sup>th</sup> Session of the CCFAC decided to reconvene the *ad hoc* Working Group on Contaminants and Toxins in Foods prior to its current Session under the Chairmanship of Denmark<sup>39</sup>. The *ad hoc* Working Group temporarily appointed Mr Frans Verstraete (EC) as Chairperson of the *ad hoc* Working Group. Dr Paul Brent (Australia), Mr Rob Theelen (the Netherlands), and Mrs Maria Cecilia Toledo (Brazil) acted as rapporteurs.

112. The Committee noted that Dr Torsten Berg (Denmark), previous Chairperson of the *ad hoc* Working Group, would no longer be able to attend sessions of the Committee due to a new assignment and wished him all the best in his new position.

113. The Chairperson of the *ad hoc* Working Group briefly summarized its discussions and recommendations based on the Plenary Agenda of the Committee.

##### **Status of the *ad hoc* Working Group on Contaminants and Toxins in Foods**

114. The Committee agreed to reconvene the *ad hoc* Working Group on Contaminants and Toxins in Foods prior to its 37<sup>th</sup> Session under the Chairmanship of the European Community.

##### **SCHEDULE I OF THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (Agenda Item 13b)<sup>40</sup>**

115. The 35<sup>th</sup> Session of the CCFAC agreed that a revised version of Schedule I of the Codex General Standards for Contaminants and Toxins in Foods (GSCTF) should be presented for consideration at its next Session. The revision was performed by Dr David Kloet (the Netherlands) and Dr Yukiko Yamada (Japan).

116. The Committee based its discussion on the questions raised in paragraphs 1 to 5 of the working paper as follows:

<sup>36</sup> CX/FAC 04/27/26, paras 88-93.

<sup>37</sup> ALINORM 04/36/15 (not issued).

<sup>38</sup> CRD3.

<sup>39</sup> ALINORM 03/12A, para. 105.

<sup>40</sup> CX/FAC 04/36/16; and, comments submitted by Canada, Poland and IFU (CX/FAC 04/36/16-Add.1); European Community (CRD 6); and, Brazil (CRD 27).

### **Inclusion of Schedule I in the GSCTF**

117. The Committee agreed with the Recommendation of the *ad hoc* Working Group<sup>38</sup> to include Schedule I in the format presented in the working paper. It was noted that some editorial amendments needed to be made before its inclusion in the GSCTF and the Committee agreed to entrust this work to the Codex and JECFA Secretariats, the latter to correct the references to toxicological intake.

### **Removal of Annex IV (Annotated List of Contaminants and Toxins) of the GSCTF**

118. The Committee noted that Annex IV was an informative document encompassing contaminants and toxins for which maximum levels had been developed or were being developed in Codex. The document was considered useful in providing an overview of the situation regarding Codex decisions about contaminants and toxins, and to give guidance about further actions required by CCFAC.

119. The Committee agreed with the recommendation of the *ad hoc* Working Group<sup>38</sup> that such information should be part of a working document to be updated yearly and presented at each Session of the Committee for information and support for the discussions on the GSCTF. The Committee also agreed that the working document should not contain any reference to revoked maximum levels. In taking this decision, the Committee agreed to amend the GSCTF by removing Annex IV and all references to it in the General Standard. The Committee requested the Delegations of the Netherlands and Japan to revise the working document, using a suitable database, for presentation at the next Session of the Committee.

### **Exclusion of quality-related parameters from the GSCTF**

120. The Committee noted that the Preamble of the GSCTF clearly stated that the Standard did not apply to contaminants having food quality significance but not public health significance in foods<sup>41</sup>. It therefore agreed with the recommendation of the *ad hoc* Working Group<sup>38</sup> not to include maximum levels for quality-related parameters such as copper, zinc, iron, etc. in the General Standard but to keep this information in above-mentioned working document as a record of the complete range of contaminants in the Codex system.

121. In this connection, the Committee agreed to request Codex commodity committees that when developing such maximum levels to include them in the commodity standards under the appropriate Section related to quality factors i.e. "Essential Composition and Quality Factors". The Committee also agreed to request Codex commodity committees to refer to the GSCTF when mentioning maximum levels for safety-related contaminants in the commodity standards.

### **Inclusion of Schedule II in the GSCTF**

122. The Committee noted that Schedule II presented a list of maximum levels for contaminants and toxins arranged by food category. In this regard, the Committee noted that the current food categorization system used in the GSCTF was based on a system developed by the Codex Committee on Pesticide Residues (CCPR). The Committee further noted that CCPR developed this list mainly for primary food commodities although some processed foods such as fruit juices were already included. However, further work was required for processed, derived and multi-ingredient foods.

123. The Committee agreed with the recommendation of the *ad hoc* Working Group<sup>38</sup> that, in view of the lack of commodity codes for some existing commodities with contaminant maximum levels, it would not be advisable at this stage to include Schedule II in the GSCTF. Meanwhile, it was agreed that the Committee should enter into consultations with CCPR to determine the best approach to be followed for further development of the food categorization system, in order to allow inclusion of Schedule II in the GSCT at sometime in the future.

### **Revocation of Maximum Levels for Contaminants in Codex Commodity Standards**

124. In order to avoid current and future inconsistencies between the GSCTF and commodity standards, the Committee agreed with the recommendation of the *ad hoc* Working Group<sup>38</sup> to request the Codex Alimentarius Commission to endorse the following recommendations:

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<sup>41</sup> Codex General Standard for Contaminants and Toxins in Foods, Section 1.2.2 (1).

- (a) The Codex Alimentarius Commission should explicitly revoke existing safety-related maximum levels in commodity standards which are inconsistent with already adopted maximum levels by the Commission; and,
- (b) When CCFAC proposes maximum levels for final adoption at Step 8 it will simultaneously propose to explicit revocation of corresponding maximum levels in commodity standards which are inconsistent with the proposed maximum level.

#### **Status of the Codex General Standard for Contaminants and Toxins in Foods**

125. The Committee forwarded the amendment to the General Standard for Contaminants and Toxins in Foods (removal of Annex IV and its reference in the General Standard) for adoption by the Codex Alimentarius Commission (see para. 119 and Appendix XIII).

126. In addition, the Committee agreed to revise the General Standard for Contaminants and Toxins in Foods to include those relevant paragraphs in the CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups that should be considered as advice for governments and, therefore, agreed to request the Codex Alimentarius Commission to approve this revision as new work for the Committee. The Committee further agreed to entrust this work to a working group led by Japan with the assistance of France, India, and the Netherlands, for circulation, comments, and consideration at its next Session.

#### **DRAFT CCFAC POLICY FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS OR FOOD GROUPS (Agenda Item 13c)<sup>42</sup>**

127. The 26<sup>th</sup> Session of the Codex Alimentarius Commission adopted the proposed draft CCFAC for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups at Step 5 and advanced it to Step 6 as proposed by the 35<sup>th</sup> Session of the Committee. In making this decision, the Commission noted that the text should be included either in the Procedural Manual for the advice of the Commission or in the General Standard for Contaminants and Toxins in Foods for the advice of Members.

128. The Committee agreed with the following revisions to the draft text:

- (a) To delete the Annex containing the flowchart as it was rather complex and did not provide any information not already contained in the text. Consequently, paragraph 4 referring to the Annex was deleted;
- (b) To delete paragraph 5 as it was not necessary; and,
- (c) To add an additional paragraph at the end of Section 1 stating that JECFA should estimate the impact on dietary exposure of proposed alternative maximum levels, if requested by CCFAC. The Delegation of Belgium expressed its reservation on this decision.

#### **Status of the draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups**

129. The Committee forwarded the draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups to the Codex Alimentarius Commission, through the Codex Committee on General Principles, for final adoption at Step 8 and inclusion in the Procedural Manual (see Appendix XIV).

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<sup>42</sup> ALINORM 03/12A, Appendix VIII; CX/FAC 04/36/2-Part II; CL 2003/33-FAC; and, comments submitted by Brazil (CX/FAC 04/36/17); European Community (CRD 6); India (CRD 24); and, Japan (CRD 29).



**MYCOTOXIN IN FOOD AND FEED (Agenda Item 14)****MAXIMUM LEVEL FOR PATULIN IN APPLE JUICE AND APPLE JUICE INGREDIENTS IN OTHER BEVERAGES – New data submitted (Agenda Item 14a)<sup>43</sup>**

130. The 26<sup>th</sup> Session of the Codex Alimentarius Commission adopted the draft maximum level of 50 µg/kg for patulin in apple juice and apple juice ingredients in other beverages at Step 8. The Commission noted that the CCFAC had proposed the adoption of this maximum level on the understanding that the level might be lower to 25 µg/kg based on the application of the Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages (i.e. four years after its adoption). Meanwhile, the Commission supported the decision of the Committee to continue to collect data on the levels of patulin in apple juice and apple juice ingredients for other beverages to enable the Committee to reconsider the possible reduction of the maximum level once the Code of Practice had been implemented<sup>44</sup>.

131. The Committee agreed that the best way to deal with this decision was to remove patulin from the Agenda of the Committee and to include it on the Priority List for Evaluation by JECFA in 4 years time (i.e. 2007). In order to ease the comparison of data, the Committee also agreed that Members should submit data in the form of GEMS/Food directly to WHO which would yearly report back to the Committee on the status of the submission of data. The Committee further agreed that, based on the available data, it would make specific requests to JECFA as to the type of risk assessment that should be performed.

**DRAFT MAXIMUM LEVEL FOR OCHRATOXIN A IN RAW WHEAT, BARLEY, RYE, AND DERIVED PRODUCTS (Agenda Item 14b)<sup>45</sup>**

132. The 34<sup>th</sup> Session of the CCFAC forwarded a maximum level of 5 µg/kg in cereals such as wheat, barley, rye, and derived products to the Codex Alimentarius Commission for final adoption at Step 8<sup>46</sup>. The Commission concluded that there was a lack of consensus on the adoption of the maximum level regarding both the appropriate maximum level and the inclusion, or exclusion, of the reference to “derived products” and it therefore returned the draft maximum level to Step 6 for further work by the Committee<sup>47</sup>.

133. The Committee noted that given the wide range of derived products and that many of them were of little or no importance in international trade, the maximum level should be limited to raw wheat, barley, and rye.

134. The Delegation of the EC, informed the Committee that occurrence data and application of this maximum level in the European Union indicated that the level of 5 µg/kg in these products was technologically achievable. In addition, the Delegation of the EC stated that the 56<sup>th</sup> JECFA Meeting (February 2001) had recommended that all efforts should be made to lower overall contamination by ochratoxin A by appropriate agricultural, storage and processing practices. The Delegation noted that the recently adopted Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals and its Annex on ochratoxin A could assist Codex Members in achieving this maximum level. It was also noted that Ochratoxin A was a carcinogenic compound, the intake of which was also derived from other commodities. Thus, the ALARA (As Low As Reasonably Achievable) Principle should apply, as no data had been provided on the unfeasibility of reaching this level. This view was also shared by a number of delegations.

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<sup>43</sup> ALINORM 03/12, Appendix X; CL 2003/13-FAC; and, comments submitted by Brazil (CX/FAC 04/36/18); European Community (CRD 6); India (CRD 24); and, Brazil (CRD 27).

<sup>44</sup> ALINORM 03/41, paras. 43 – 44.

<sup>45</sup> ALINORM 03/12, Appendix IX; CX/FAC 04/36/2-Part II; CL 2003/33-FAC; and, comments submitted by Mexico (CX/FAC 04/36/19); European Community (CRD 6); and, India (CRD 24).

<sup>46</sup> ALINORM 03/12, para. 114.

<sup>47</sup> ALINORM 03/41, paras. 45 – 47.

135. Other delegations noted that when JECFA performed its risk assessment on the two proposed maximum levels of 5 and 20 µg/kg, it concluded that the difference in risk at these two levels, on the basis of available data, was not significant using mean intakes and, therefore, a maximum level of 20 µg/kg was adequate to ensure public health protection. In this regard, it was noted that the risk assessment performed by JECFA was mainly based on European data. In addition, these delegations indicated that the implementation of the Code would need some time and, meanwhile, it would be appropriate to commence with a higher level in order to bring it down gradually with the implementation of the Code. The Delegation of India, supported by some delegations, emphasized that risk/benefit rather than ALARA considerations should be the basis when putting forward lower levels for contaminants.

#### **Status of the draft Maximum Level for Ochratoxin A in Raw Wheat, Barley, Rice, and Derived Products**

136. The Committee could not come to an agreement on the maximum level for ochratoxin A in raw wheat, barley, and rice. Therefore, it agreed to hold the maximum level of 5 µg/kg for Ochratoxin A in raw wheat, barley, and rye at Step 7 (see Appendix XVII), while placing it on the Priority List for Evaluation by JECFA (see para. 208 and Appendix XXVII).

137. The Committee also agreed, depending upon the available data, that JECFA should perform a comprehensive risk assessment by 2006, so that the Committee might reconsider this issue in the light of the outcome of the JECFA evaluation at its Session in 2007.

#### **DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN PEANUTS (Agenda item 14c)<sup>48</sup>**

138. The 26<sup>th</sup> Session of the Codex Alimentarius Commission adopted the proposed draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts at Step 5 and advanced it to Step 6 as proposed by the 35<sup>th</sup> Session of the Committee<sup>49</sup>.

139. The Committee agreed with the amendment to paragraph 56 as proposed by the *ad hoc* Working Group on Contaminants and Toxins in Foods<sup>38</sup> and considered some additional amendments, namely: the reference to “interested parties” instead of “all persons” and to “producing and handling” as handling was a critical point in the control of aflatoxin contamination in this product (paragraph 1); the inclusion of a number of soil pests to indicate that plants so infested should also be harvested separately as the infestation might cause damage to the pods which could facilitate fungal contamination (paragraph 22); and, a new sentence mentioning parameters linked to critical control points (paragraph 60). The Committee noted a number of other proposals for amendments from the Delegation of India in paragraphs 13, 17 and 40 but concluded that the current wording of the Code adequately covered the specific concerns raised by the Delegation.

#### **Status of the draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts**

140. The Committee forwarded the draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts to the Codex Alimentarius Commission for final adoption at Step 8 (see Appendix XV)

#### **PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN TREE NUTS (Agenda item 14d)<sup>50</sup>**

141. The 35<sup>th</sup> Session of the CCFAC agreed that a drafting group under the direction of China would revise the proposed draft Code for circulation, comments at Step 3 and consideration by the next Session of the Committee<sup>51</sup>.

142. The Committee agreed with the amendments as proposed by the *ad hoc* Working Group on Contaminants and Toxins in Foods<sup>38</sup> and decided to advance the amended text in the Step procedure.

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<sup>48</sup> ALINORM 03/12A, Appendix XI; CL 2003/33-FAC; and, comments submitted by Mexico, and Argentina (CX/FAC 04/36/20); European Community (CRD 6); and, India (CRD 24).

<sup>49</sup> ALINORM 03/12A, para. 136 and ALINORM 03/41, Appendix VI.

<sup>50</sup> CX/FAC 04/36/21; CX/FAC 04/36/21-Add.1 (not issued) and, comments submitted by India (CRD 24).

<sup>51</sup> ALINORM 03/12A, para. 131.

**Status of the proposed draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts**

143. The Committee forwarded the proposed draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts to the Codex Alimentarius Commission for preliminary adoption at Step 5 (see Appendix XX).

**DISCUSSION PAPER ON AFLATOXINS IN TREE NUTS (OTHER THAN ALMONDS, HAZELNUTS, AND PISTACHIOS) INCLUDING INFORMATION SUBMITTED ON AFLATOXIN CONTAMINATION AND METHODS OF ANALYSIS FOR THE DETERMINATION OF AFLATOXINS IN TREE NUTS (Agenda Item 14 e)<sup>52</sup>**

144. The 35<sup>th</sup> Session of the CCFAC agreed that the Delegation of Iran would revise the Discussion Paper on Aflatoxins in Tree Nuts (other than almonds, hazelnuts, and pistachios), including information submitted on Methods of Analysis for the Determination of Aflatoxins in Tree Nuts, for circulation, comments, and consideration at its next Session.

**Discussion Paper**

145. The Committee agreed to address only Brazil nuts as the other tree nuts mentioned in the Discussion Paper (e.g. cashew nut, macadamia, pecan, pine nut, walnut, etc.) had a lower incidence of aflatoxin contamination and their volume in international trade were not significant. However, some delegations noted that international trade in the other tree nuts was growing and in certain cases their consumption was higher than peanuts. They indicated that data on aflatoxin contamination in other tree nuts should be collected with a view to setting maximum levels at a later stage.

146. The Delegation of Ireland, speaking on behalf of the Member States of the EC, supported the recommendation to limit consideration to Brazil nuts, to call for further data on a in-shell/shelled basis but indicated that, given the fact that aflatoxins were amongst the most potent carcinogenic substances known and were mutagenic, possible maximum levels must be set following the ALARA Principle.

147. The Delegation of the United States, supported by a number of delegations, objected to the introduction of a reference to the ALARA Principle in the Discussion Paper, when JECFA had made the determination that there was no difference between a level of 20 µg/kg and 10 µg/kg for Aflatoxin B1, the most potent aflatoxin. The concern was that ALARA was going beyond that which was appropriate to ensure consumer health protection and fair trade practices in the commodities of concern.

148. The Committee agreed that the Delegation of Iran would prepare a revised Discussion Paper on Aflatoxin Contamination in Brazil Nuts which should consider, in-shell/shelled (peeled/unpeeled) Brazil nuts. The revision, for circulation, comments, and consideration at the next Session of the Committee, should be made on the basis of the written comments submitted to and made at the current Session and should take into account the ALARA Principle with due consideration of the JECFA assessment.

**Sampling Plans for Aflatoxins in Almonds, Brazil Nuts, Hazelnuts, and Pistachios**

149. The Committee agreed to commence work on the development of sampling plans for aflatoxins in almonds, Brazil nuts, hazelnuts, and pistachios, subject to approval as new work by the Codex Alimentarius Commission. The Committee also agreed that, once finalized, the sampling plans should be sent to the Codex Committee on Methods of Analysis and Sampling for endorsement. The Committee further agreed that a working group led by the United States with the assistance of Argentina, Brazil, Iran, EC, and the INC would prepare sampling plans for aflatoxins in almonds, Brazil nuts, hazelnuts, and pistachios for circulation, comments, and consideration by the next Session of the Committee.

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<sup>52</sup> CX/FAC 04/36/22; and, comments submitted by Cuba (CX/FAC 04/36/22-Add.1); European Community (CRD 6); and, Brazil (CRD 27).

150. In this regard, the Committee agreed to request the Codex Alimentarius Commission to amend paragraph 4 of the Critical Review<sup>53</sup> to include a reference to “methods of analysis and sampling plans” as part of the items that, together with the maintenance of the General Standard for Food Additives, the General Standard for Contaminants and Toxins, the Food Category System, and the International Numbering System, should be subject to procedures established by the Committees concerned, when deciding to undertake revision or new work such as the development of methods of analysis and sampling plans as they were in close relation with the setting of maximum levels of contaminants and the maintenance of the GSCTF.

#### **Methods of Analysis for Aflatoxins in Tree Nuts**

151. The Committee noted that there was no need for the Committee to work on the development of methods of analysis for the determination of aflatoxins in tree nuts as some methods were already developed in the Codex Committee on Methods of Analysis and Sampling while the development of additional methods could be taken up by this Committee upon request of CCFAC.

#### **MAXIMUM LEVELS FOR AFLATOXINS IN TREE NUTS (ALMONDS, HAZELNUTS, AND PISTACHIOS) – Proposals submitted (Agenda item 14 f)<sup>54</sup>**

152. The 35<sup>th</sup> Session of the CCFAC considered a Discussion Paper on Aflatoxins in Tree Nuts, including information submitted on Aflatoxin Contamination and Methods of Analysis for the Determination of Aflatoxins in Tree Nuts. On the basis of the data presented, the Committee agreed to the elaboration of maximum levels for aflatoxins in almonds, hazelnuts, and pistachios<sup>55</sup>. The 26<sup>th</sup> Session of the Codex Alimentarius Commission approved the elaboration of maximum levels for these three tree nuts as new work for the Committee<sup>56</sup>.

153. The Delegation of the EC, indicated that maximum levels for aflatoxins should be set by following the ALARA Principle and proposed to have two separate levels for total aflatoxins and aflatoxin B1 of 10 µg/kg (total aflatoxins) and 5 µg/kg (aflatoxin B1), respectively, in almonds, hazelnuts, and pistachios for further processing and 4 µg/kg (total aflatoxins) and 2 µg/kg (aflatoxin B1) in these tree nuts for direct human consumption.

154. The Delegation of the United States, supported by a number of delegations, stated that the ALARA Principle should be based on JECFA risk assessment and that the health risk at a maximum level of 20 µg/kg for total aflatoxins in nuts was negligible and would not cause undue disruption in international trade. In this regard, the Observer of the INC noted that 44% of tree nuts rejections in the European Union from 1998 to 2002 would have been avoided at a maximum level of 15 µg/kg for total aflatoxins.

155. Based on the proposal of the Delegation of Iran, supported by a number of delegations including Argentina, Brazil, Cuba, India, Kenya, South Africa, and Turkey, the Committee agreed to set up a proposed draft maximum level of 15 µg/kg (total aflatoxins) for unprocessed and processed almonds, hazelnuts, and pistachios, and to circulate it for comments at Step 3 and consideration at its next Session (see Appendix XXV). The Delegations of the EC, Czech Republic, Hungary, Norway, Poland, and Romania expressed their reservation on this decision.

#### **MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) – Proposals submitted (Agenda Item 14g)<sup>57</sup>**

156. The 35<sup>th</sup> Session of the CCFAC agreed to discontinue the consideration of the Discussion Paper on Deoxynivalenol, including information and data submitted on the occurrence of deoxynivalenol in cereals and to commence work on the elaboration of maximum levels for deoxynivalenol<sup>58</sup>. The 26<sup>th</sup> Session approved the development of maximum levels for deoxynivalenol as new work for the Committee<sup>59</sup>.

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<sup>53</sup> ALINORM 04/27/33, Appendix III-Part 2: Critical Review, paragraph 4.

<sup>54</sup> CL 2003/13-FAC; and, comments submitted by Argentina, Brazil (CX/FAC 04/36/23); European Community (CRD 6); Iran (CRD 9); India (CRD 24); and, Brazil (CRD 27).

<sup>55</sup> ALINORM 03/12A, paras 129 – 130.

<sup>56</sup> ALINORM 03/41, Appendix VIII.

<sup>57</sup> CL 2003/13-FAC; and, comments submitted by Japan (CX/FAC 04/36/24); European Community (CRD 6); and, India (CRD 24).

<sup>58</sup> ALINORM 03/12A, para. 182.

<sup>59</sup> ALINORM 03/41, Appendix VIII.

157. The Committee had an exchange of views on the appropriateness of setting maximum levels for deoxynivalenol at this time. The Committee felt that more work needed to be done before moving towards the establishment of maximum levels as there were currently insufficient data from most regions of the world to have a scientific basis to establish maximum levels for DON. The Committee recognized that, based on the data collected, a refined exposure assessment of DON in selected commodities i.e. raw cereal grains or processed cereal-based commodities should be performed by JECFA to ensure food safety and the availability of cereal-based foods on a global basis.

158. The Committee agreed to discontinue the consideration of maximum levels for deoxynivalenol for the time being. Instead, it agreed to request information on: the occurrence of deoxynivalenol in cereals; the influence of processing, decontamination, sorting, etc. to lower the level of DON in a lot; national levels or guideline levels for DON; sampling procedures and methods of analysis; etc. for consideration by the next Session of the Committee.

#### **MYCOTOXIN CONTAMINATION IN SORGHUM – Information and data submitted (Agenda Item 14h)<sup>60</sup>**

159. The 35<sup>th</sup> Session of the CCFAC agreed to solicit data on mycotoxin contamination in sorghum for consideration at its 36<sup>th</sup> Session<sup>61</sup>.

160. The Committee noted that working paper CX/FAC 04/36/25 could not be prepared because no data were received in response to CL 2003/13-FAC. In recognizing that sorghum was an important crop for many countries, in particular developing countries, and because of the need to move towards the establishment of maximum levels, the Committee agreed to request information on: source of contamination; type of mycotoxin involved; analytical methods and sampling procedures; consumer protection from the point of view of health; actual and potential problems in international trade; work already undertaken by other international organizations; etc. for discussion at its next Session.

#### **INDUSTRIAL AND ENVIRONMENTAL CONTAMINANTS IN FOODS (AGENDA ITEM 15)**

##### **DRAFT MAXIMUM LEVEL FOR LEAD IN FISH - including Statistical Analysis of data on lead content for significantly traded fish species that might cause problems in international trade (Agenda Item 15a)<sup>62</sup>**

161. The 35<sup>th</sup> Session of the CCFAC could not reach consensus on the draft maximum level for lead in fish and returned the draft maximum levels to Step 6 for comments and further consideration at its next Session. The Committee agreed that, in the interim, a statistical analysis should be performed based on the comments submitted and additional data available using different levels of concern (e.g., 0.2, 0.4 and 0.5 mg/kg) as a basis for making a decision on whether or not to adopt a tiered approach. It was noted that the analysis should provide information on the percentage of rejected samples using different maximum levels for species traded internationally in significant quantities<sup>63</sup>.

162. In introducing the paper, the Delegation of Denmark explained that due to the lack of data, it could not provide a further in-depth analysis on the impact of different maximum levels and that Table 4 presented in working document CX/FAC 04/36/26 was a compilation of the species that had been internationally traded based on the data from the EC, FAO and WHO.

163. The Committee noted that the list was not an exhaustive one and it was proposed only to facilitate the consideration of maximum levels. The Committee stressed the need to take into account the results of the JECFA evaluation (53<sup>rd</sup> Meeting, June 1999) in future consideration of maximum levels of lead in fish. The difficulties for many countries to achieve levels lower than 0.2 mg/kg and to effectively analyze levels lower than 0.4 mg/kg were also noted.

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<sup>60</sup> CL 2003/13-FAC ; CX/FAC 04/36/25 (not issued); and, comments submitted by India (CRD 24).

<sup>61</sup> ALINORM 03/12A, para. 196.

<sup>62</sup> ALINORM 03/12, Appendix XIII; CX/FAC 04/36/26; CL 2003/13-FAC; and, comments submitted by Japan, Philippines, South Africa, Spain, and IFAC (CX/FAC 04/36/26-Add.1); European Community (CRD 10); Philippines (CRD 14); India (CRD 24); and, Brazil (CRD 27).

<sup>63</sup> ALINORM 03/12A, paras 141-142.

164. The Committee agreed to maintain the draft maximum level for lead in fish at Step 7. It agreed to further elaborate the list in Table 4 of working document CX/FAC 04/36/26 following the structure of the Table presented by the EC in CRD 10. Therefore, the Committee agreed to request comments on the list of the main internationally traded fish species (see Appendix XIX), information on additional fish species internationally traded to be included in the list, and information on levels of lead contamination for further consideration at the next Session. The Committee noted the kind offer of the Delegation of Denmark to update the list prior to the next CCFAC Session.

#### **Status of the draft Maximum Level for Lead in Fish**

165. The Committee agreed to retain the draft maximum level of 0.2 mg/kg for lead in fish at Step 7 (see Appendix XVIII) and to review the level at its next Session in the light of the result of the assessment of the 53<sup>rd</sup> JECFA Meeting, the list of the main internationally traded fish to be elaborated by Denmark, and comments received.

#### **DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF LEAD CONTAMINATION IN FOODS (Agenda Item 15 b)<sup>64</sup>**

166. The Committee noted that the 26<sup>th</sup> Session of the Codex Alimentarius Commission adopted at Step 5 and advanced to Step 6 the proposed draft Code of Practice for the Prevention and Reduction of Lead Contamination in Foods as proposed by the 35<sup>th</sup> Session of the Committee<sup>65</sup>.

167. The Committee agreed with the amendment as proposed by the *ad hoc* Working Group on Contaminants and Toxins in Foods<sup>38</sup> and considered some additional amendments, namely : the deletion of the sentence referring to the JECFA evaluation in 1987 in paragraph 1; and, the addition of a new phrase in paragraph 44 for consistency with language in paragraph 42.

#### **Status of the draft Code of Practice for the Prevention and Reduction of Lead Contamination in Foods**

168. The Committee forwarded the draft Code of Practice for the Prevention and Reduction of Lead Contamination in Foods to the Codex Alimentarius Commission for final adoption at Step 8 (see Appendix XVI).

#### **PROPOSED DRAFT MAXIMUM LEVELS FOR TIN (Agenda Item 15 c)<sup>66</sup>**

169. The 35<sup>th</sup> Session of the CCFAC could not reach consensus on the draft maximum levels for tin and decided to return (with the revised product descriptors) the levels to Step 3 for comments and further consideration at its 36<sup>th</sup> Session. In addition, the Committee decided to ask JECFA to evaluate current tin levels in “canned foods other than beverages” and “canned beverages”, and to determine an acute reference dose<sup>67</sup>.

170. The Committee noted that the re-evaluation of inorganic tin, scheduled for consideration by the 64<sup>th</sup> JECFA Meeting, would facilitate risk management decisions. The Joint Secretariat to JECFA commented that new data were available. The Delegation of the EC recalled that possible gastric irritation had been reported at the proposed draft maximum levels. The Delegation suggested that the JECFA assessment should, when possible, among other issues, take into consideration the population sensitivity to tin intake when considering these new data. The Delegation of the United States requested JECFA to assess the likelihood of these effects at the proposed draft maximum levels.

#### **Status of the proposed draft Maximum Levels for Tin**

171. In view of the next JECFA re-evaluation, the Committee decided to hold the current levels of 250 mg/kg (canned foods other than beverages) and 200 mg/kg (canned beverages) at Step 4 (see Appendix XXIV), and reconsider these levels in the light of the 64<sup>th</sup> JECFA re-evaluation.

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<sup>64</sup> ALINORM 03/12A, Appendix XII; CL 2003/33-FAC; CX/FAC 04/36/27 (not issued).

<sup>65</sup> ALINORM 03/12, para. 152 and ALINORM 03/41, Appendix VI.

<sup>66</sup> ALINORM 03/12A, Appendix XIII; CL 2003/13-FAC; and, comments submitted by Australia, Poland, and Sudan (CX/FAC 04/36/28); European Community (CRD 10); and, India (CRD 24).

<sup>67</sup> ALINORM 03/12A, paras 160-161.

**PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF TIN CONTAMINATION IN FOODS (Agenda Item 15d)<sup>68</sup>**

172. The Committee noted that the 26<sup>th</sup> Session of the Codex Alimentarius Commission approved the elaboration of a proposed draft Code of Practice for the Prevention and Reduction of Tin Contamination in Foods as new work for the Committee<sup>69</sup>.

173. The Committee agreed with the amendments by the *ad hoc* Working Group on Contaminants and Toxins in Foods<sup>38</sup> and considered some minor amendments, namely: in paragraph 21 the term “normal” was change to “high”; and, in Section “Processing” the second sentence of the last bullet was amended to read “*Cans that are not adequately cooled can ...*”.

**Status of the proposed draft Code of Practice for the Prevention and Reduction of Tin Contamination in Foods**

174. The Committee forwarded the renamed proposed draft Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods to the Codex Alimentarius Commission for preliminary adoption at Step 5 (see Appendix XXI).

**PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM (Agenda Item 15 e)<sup>70</sup>**

175. The 35<sup>th</sup> Session of the CCFAC decided to return the proposed draft maximum levels for cadmium in rice, polished; soybean (dry); molluscs (including cephalopods); and, peanuts to Step 3 and to forward the remaining proposed draft maximum levels to the 26<sup>th</sup> Session of the Codex Alimentarius Commission for adoption at Step 5<sup>71</sup>. The 26<sup>th</sup> Session of the Codex Alimentarius Commission decided to return the proposed draft maximum levels to Step 3<sup>72</sup>.

176. The Committee decided to discontinue the work on developing maximum levels for cadmium in fruits; meat of cattle, pigs, sheep, and poultry; horse meat; herbs, fungi (edible); celeriac; soybeans (dry); and, peanuts as no levels were necessary because these foods were no major contributors to cadmium intake.

177. The Delegation of Japan proposed a maximum level of 0.4 mg/kg for cadmium in polished rice. The Delegation explained that the level of 0.2 mg/kg was not achievable in Japan as a result of the higher background levels of cadmium due to geological characteristics of the soil. The Delegation also explained that the probabilistic exposure assessment conducted by Japan using national data revealed that the level of 0.4 mg/kg would not cause any public health concern. This position was supported by several other delegations. The Delegation of the EC mentioned that the PTWI could be easily exceeded by consuming rice containing cadmium at this maximum level especially for young children.

178. In view of the above discussion, the Committee decided to replace the current proposed draft maximum level of 0.2 mg/kg for polished rice by a proposed draft ML of 0.4 mg/kg. The Committee further decided to forward the proposed draft maximum levels for cadmium in rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; and, other vegetables, to the Codex Alimentarius Commission for preliminary adoption at Step 5.

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<sup>68</sup> CX/FAC 04/36/29; and, comments submitted by Canada (CX/FAC 04/36/29-Add. 1); and, the European Community (CRD 10).

<sup>69</sup> ALINORM 03/12A, para. 162 and ALINORM 03/41, Appendix VIII

<sup>70</sup> ALINORM 03/12A, Appendix XIV; CX/FAC 04/36/2-Part II; CL 2003/13-FAC; CL 2003/33-FAC; and, comments submitted by Argentina, Australia, Canada, Japan, Mexico, New Zealand, Poland, USA, and CIA (CX/FAC 04/36/30); European Community (CRD 10); Philippines (CRD 14); Indonesia (CRD 21); and, India (CRD 24).

<sup>71</sup> ALINORM 03/12A, para. 165.

<sup>72</sup> ALINORM 03/41, paras. 125 – 126.

179. The Committee had an extensive discussion on the maximum levels for and the classification of molluscs. Several delegations expressed concern that the proposed level of 1.0 mg/kg was not reasonably achievable for oysters, scallops, and cephalopods when included the viscera due to the natural occurrence of the cadmium contamination at higher levels than 1.0 mg/kg. The Committee considered a proposal to divide the category IM 0150 Molluscs (including cephalopods) in three sub-categories IM 0151 Marine bivalve molluscs, IM 1005 Scallops without digestive caecum, and IM 0152 Cephalopods with maximum levels of 1.0, 1.0, and 2.0 mg/kg respectively. The Committee also noted a proposal to break out oysters at a proposed ML of 3.0 mg/kg or to remove oysters from the proposed maximum levels.

180. The Committee could not agree on the maximum levels and classification of the category IM 0150 Molluscs (including cephalopods) and decided to leave it unchanged while JECFA undertook its exposure assessment in 2005.

181. The Committee agreed to request JECFA to conduct risk assessments for rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; other vegetables; and molluscs, taking into account three different levels, i.e., the proposed draft maximum levels, one level lower and one level higher than the proposed draft maximum levels, with distribution curves for the cadmium contamination in these foods. JECFA agreed to evaluate exposure for additional levels in the sub-categories of molluscs and to inform the Committee on the basis of the data submitted. The Committee noted that JECFA would carry out the exposure assessment in February 2005 and encouraged Codex Members to submit their raw national occurrence and consumption data to WHO GEMS/Food.

#### **Status of the proposed draft Maximum Levels for Cadmium**

182. The Committee forwarded the proposed draft maximum levels for cadmium in rice polished; wheat grain; potato; stem and root vegetables; leafy vegetables; and, other vegetables to the Codex Alimentarius for preliminary adoption at Step 5 while returning the proposed draft maximum level for molluscs (including cephalopods) to Step 3 for circulation, comments, and consideration at its next Session (see Appendix XXIII).

#### **PROPOSED DRAFT CODE OF PRACTICE FOR SOURCE DIRECTED MEASURES TO REDUCE DIOXIN AND DIOXIN-LIKE PCB CONTAMINATION IN FOODS (Agenda Item 15 f)<sup>73</sup>**

183. The 35<sup>th</sup> Session of the CCFAC agreed that the proposed draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin-Like PCB Contamination of Foods would be revised by a drafting group for circulation, comments at Step 3, and further consideration at the current Session.

184. The Committee agreed with the recommendations of the *ad hoc* Working Group on Contaminants and Toxins in Foods<sup>38</sup> that the proposed draft Code should be revised to: (a) include the relevant parts of the Introduction and Global source directed measures into the Code of Practice; (b) rephrase the references to the Persistent Organic Pollutants (POP) Convention and to clarify paragraph 24 with regard to the reference to the Codex Alimentarius Commission; (c) soften the language into a more descriptive wording; and, (d) remove the explicit reference to (supra)national legislation.

#### **Status of the proposed draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin-like PCB Contamination in Foods**

185. The Committee returned the proposed draft Code of Practice for Source Directed Measures to reduce Dioxin and Dioxin-like PCB Contamination in Foods to Step 2 for revision by a working group led by Germany, with the assistance of Australia, Belgium, Canada, China, EC, Finland, Iceland, Japan, United States, IBFAN, and IDF, for circulation, comments at Step 3, and further consideration at the next Session of the Committee.

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<sup>73</sup> CX/FAC 04/36/31; and, comments submitted by Canada, United States, and IBFAN (CX/FAC 04/36/31-Add. 1); Malaysia (CRD 15); European Community (CRD 18); India (CRD 24); and, Brazil (CRD 27).



**POSITION PAPER ON DIOXINS AND DIOXIN-LIKE PCBs (Agenda item 15 g)<sup>74</sup>**

186. The 35<sup>th</sup> Session of the CCFAC requested the Delegation of the Netherlands to revise the Position Paper on the basis of written comments submitted. It also agreed that the document should include a new section to cover ranges of data on background levels of dioxins and dioxin-like PCBs in food and feed, with a view to identifying sources of contamination by these compounds<sup>75</sup>.

187. The Committee noted that the paper provided an overview of available information on source and occurrence in food and feed, the dietary intake of dioxins and dioxin-like PCBs, and also presented information on existing legislation and methods of analysis.

188. The Committee agreed with the recommendations of the *ad hoc* Working Group on Contaminants and Toxins in Foods<sup>38</sup>. The Committee noted that the Delegation of the Netherlands would update the paper in the light of the comments received for a possible future consideration. The Committee encouraged Codex Members to submit data on dioxins and dioxin-like PCBs in foods to the WHO GEMS/Food database. In addition, it agreed to request WHO to report in a detailed way to the Committee on the data submitted within three years time.

189. In view of the above, the Committee agreed to discontinue the consideration of the Position Paper.

**POSITION PAPER ON CHLOROPROPANOLS (Agenda item 15 h)<sup>76</sup>**

190. The 35<sup>th</sup> Session of the CCFAC agreed that the Delegation of the United Kingdom would revise the Position Paper on Chloropropanols on the basis of its discussions, written comments submitted and data to be made available for circulation, comments, and further consideration at its next Session. The Committee also agreed that the document should include proposals for the elaboration of maximum levels for chloropropanols in the relevant foods<sup>77</sup>.

191. The Delegation of the United Kingdom informed the Committee that the paper could not be made available to the Committee due to the lack of data on relevant commodities and because the study carried out in the European Community was not yet published. In addition, the Delegation indicated that there was a proposed draft Codex Standard for Soy Sauce scheduled for discussion at the 22<sup>nd</sup> Session of the Codex Committee on Processed Fruits and Vegetables (September 2004) that would include definitions for various types of soy sauce and that it might be advisable to wait for the completion of this Standard before setting a maximum level for chloropropanol in this product.

192. Some delegations were of the view that there was enough scientific basis to establish a maximum level for 3-monochloropropane-1,2-diol (3-MCPD) in acid-hydrolysed vegetable proteins (acid-HVPs) at a level of 1 mg/kg on a dry basis, equivalent to 0.4 mg/kg on a liquid basis. The Delegation of the EC was of the opinion that a maximum level of 0.02 mg/kg in 40% liquid basis was appropriate. In addition, the Delegation of Thailand suggested that if the Committee decided to set maximum levels for 3-MCPD in products using acid-HVP a risk assessment at different levels should be requested to JECFA. Other delegations were of the opinion that more data should be available for JECFA to update the risk assessment before setting any maximum level for chloropropanols. These delegations favoured the development of a discussion paper containing proposals for the elaboration of maximum levels for chloropropanols in the relevant foods.

193. The Committee agreed to commence work on the establishment of a maximum level for 3-MCPD in acid-HVPs and acid-HVP containing products subject to approval as new work by the Codex Alimentarius Commission while requesting comments on proposals for maximum levels for chloropropanol in these commodities.

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<sup>74</sup> CX/FAC 04/36/32; and, comments submitted by Germany, and Japan (CX/FAC 04/36/32-Add. 1); Malaysia (CRD 15); European Community (CRD 18); and, Brazil (CRD 27).

<sup>75</sup> ALINORM 03/12A, para. 169.

<sup>76</sup> CX/FAC 04/36/33 (not issued); CX/FAC 04/36/33-Add. 1 (not issued); and, comments submitted by IHPC (CRD 12); and, Philippines (CRD 14).

<sup>77</sup> ALINORM 03/12A, para. 179.

194. In addition, the Committee agreed that a working group under the direction of the United Kingdom with the assistance of Australia, Canada, China, EC, Japan, Korea, Philippines, Russia, Thailand, United States, and IHPC would prepare an updated Discussion Paper on Chloropropanols with proposals for maximum levels for 3-MCPD in acid-HVPs and foods containing acid-HVP for circulation, comments, and consideration at the next Session of the Committee.

#### **DISCUSSION PAPER ON ACRYLAMIDE (Agenda item 15i)<sup>78</sup>**

195. The 35<sup>th</sup> Session of the CCFAC agreed that a working group led by the United Kingdom and the United States would prepare a Discussion Paper on Acrylamide for circulation, comments, and consideration at its current Session. The Delegation of the United Kingdom briefly introduced the Discussion Paper and asked the Committee to comment on the recommendations to JECFA as proposed in the document.

196. The Committee noted the importance of reducing the level of acrylamide in foods and that progress had already been made to reduce these levels in certain commodities based on current information. The Delegation of Sudan stressed the importance of making available to developing countries analytical methods for the determination of acrylamide in foods.

197. The Committee agreed with the recommendations of the *ad hoc* Working Group on Contaminants and Toxins in Foods<sup>38</sup> to forward to FAO and WHO the following terms of reference for the JECFA evaluation on acrylamide, scheduled in February 2005:

- (a) To comment on the extent to which acrylamide is bioavailable in food and on the safety implications;
- (b) To consider the threshold based endpoints of concern, such as neurotoxicity and reproductive toxicity, and eventually derive a tolerable dietary intake;
- (c) To evaluate the degree of uncertainty related to the assessments made;
- (d) To provide estimates of dietary exposure for various population groups, including susceptible groups such as young children and regional population, and identify and quantify as far as possible the major sources (e.g., food groups/commodities) of dietary exposure;
- (e) To provide estimates of margins of exposure safety and/or exposure for various endpoints of concern (non-cancer and cancer). These estimates should include comparisons between the levels of acrylamide exposure shown to produce effects in animal studies and the demonstrated no-effect levels versus estimates of dietary exposure for humans;
- (f) To provide quantitative estimates of risk for various endpoints, including cancer, for varying degrees of dietary exposure to acrylamide; and,
- (g) To provide comments on the toxicological significance of the main metabolite glycidamide, and whether this may be more genotoxic than the parent compound.

198. The Committee also agreed that the Discussion Paper on Acrylamide would be revised, taking into account comments submitted and discussions in the Session, by a working group led by the United Kingdom and the United States, with the assistance of the EC, Japan, Korea, Sweden, CIAA, ICGMA, and INC for circulation, comments, and further consideration at its next Session.

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<sup>78</sup> CX/FAC 04/36/34; and, comments submitted by Canada, Denmark, and Sweden (CX/FAC04/36/34-Add.1); Germany (CRD 8); European Community (CRD 10); Belgium (CRD 13); and, the Netherlands (CRD 22).

**PROPOSED DRAFT REVISED CODEX GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS FOLLOWING ACCIDENTAL NUCLEAR CONTAMINATION FOR USE IN INTERNATIONAL TRADE (CAC/GL 5-1989), INCLUDING GUIDELINE LEVELS FOR LONG-TERM USE (Agenda Item 16)<sup>79</sup>**

199. The 35<sup>th</sup> Session of the CCFAC requested the International Atomic Energy Agency (IAEA), in collaboration with the Delegation of Finland, to prepare a revised version of the Codex Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade for circulation, comments at Step 3, and further consideration at its 36<sup>th</sup> Session<sup>80</sup>. The 26<sup>th</sup> Session of the Codex Alimentarius Commission approved as new work the revision of the Codex Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989), including Guideline Levels for Long-Term Use<sup>81</sup>.

200. In presenting the newly named “Revised Codex Guideline Levels for Radionuclides in Foods for Use in International Trade”, the Representatives of the IAEA informed the Committee that the revision was based on an intervention exemption level of 1 mSv from annual consumption of food containing artificial radionuclides at the Guideline Levels. Naturally-occurring radionuclides were excluded from consideration in the document because the resources required to calculate exposures would be out of proportion to the health benefits achieved. Twenty radionuclides were selected for consideration because of their importance in relation to uptake into the food chain and because of the large quantities of these contained in nuclear facilities or industrial radiation sources, which could potentially contaminate foods because of an accident or malevolent act.

201. It was further noted that appropriate human exposure and health risk assessments had been conducted both for infants and adults during the first year after a major radionuclide release into the environment and for the long term. Statistical data of the FAO on production and import of major foodstuffs had been used in order to make a realistic assessment. As a result, the proposed draft revised Guideline Levels covered both the immediate aftermath of emergencies or malevolent acts and prolonged exposure situations. The list of radionuclides for which the Guideline Levels were proposed had been substantially extended, and they covered most of the realistic food contamination conditions.

202. In noting the comments made by the Delegation of the EC, the Representative of the IAEA proposed to amend Table 1 of the document, i.e., to introduce an additional safety factor for the actinides (Plutonium (Pu) and Americium (Am)) while taking into account assessment uncertainty. It was also noted that, in consideration that Technetium-99 (<sup>99</sup>Tc) was basically present in the marine environment (seafood) and could not contribute substantially to ingestion by infants, the Guideline Level for <sup>99</sup>Tc could be based on the assessment for adults and increased correspondingly.

203. The Delegation of the EC welcomed certain elements of the text suggested at the current Session by the IAEA, in particular the reduction of the guideline levels for actinides. However, in view of the reservations of the Delegation of the EC, in particular concerning the deletion of a category for “infant foods”, it was suggested that this should be further considered at the next Session of the CCFAC. The Delegation of the United States noted that the latest IAEA revisions were compatible to recently published draft United States policy.

**Status of the Proposed Draft Revised Codex Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989), including Guideline Levels for Long-Term Use**

204. The Committee agreed on the above revisions to the text as suggested by the IAEA and forwarded the newly named proposed draft Codex Guideline Levels for Radionuclides in Foods for Use in International Trade to the Codex Alimentarius Commission for preliminary adoption at Step 5 (see Appendix XXII).

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<sup>79</sup> CX/FAC 04/36/35; CX/FAC 04/36/35-Add. 1 (not issued); and, comments submitted by the European Community (CRD 18).

<sup>80</sup> ALINORM 03/12A, paras. 79 and 84.

<sup>81</sup> ALINORM 03/41, Appendix VIII.

**PRIORITY LIST OF FOOD ADDITIVES, CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 17)**

**COMMENTS SUBMITTED (AGENDA ITEM 17A)<sup>82</sup>**

205. The 35<sup>th</sup> Session of the CCFAC agreed to request comments for additions or amendments to its Priority List for consideration at the current Session. Mr J. Dornseiffen (the Netherlands) introduced the report of the Working Group on JECFA Priorities. He noted that most of the food additives and contaminants that had been added to the Priority List at the 35<sup>th</sup> Session of the Committee were due for evaluation by the 63<sup>rd</sup> and 64<sup>th</sup> Meetings of JECFA.

**REPORT OF THE WORKING GROUP ON THE JECFA PRIORITY LIST (AGENDA ITEM 17B)<sup>83</sup>**

206. The Working Group proposed the addition of the following food additives to the CCFAC list of priorities: approximately 400 flavouring agents, 6 annatto extracts, aspartame-acesulfame salt, laccase from *Myceliophora thermophila* expressed in *Aspergillus oryzae*, phospholipase from *Fusarium venenatum* expressed in *Aspergillus oryzae*, pullulan, stearyl tartrate, quillaia extracts, sucralose, and sucrose esters of fatty acids.

207. The Committee noted that the Delegation of the United States would make available to the Joint Secretariat to JECFA by the end of this year some missing information about the list of flavouring agents proposed for evaluation. It was noted that these additional flavours were all substances of chemical classes that had been evaluated at previous meetings of JECFA.

208. The Working Group proposed the addition of the following contaminants to the CCFAC list of priorities: chloropropanols, ochratoxin A, and cadmium. In addition, the Committee added patulin to the list for the evaluation in 2007 with the understanding that more detailed questions for JECFA would be agreed upon at a future Session of the Committee.

209. The Committee noted that the Working Group on JECFA Priorities agreed that the proposed evaluation of the peroxide value (PV) for instant noodles was not a question of safety and should therefore not be proposed for evaluation by JECFA. In this regard, it was also mentioned that there were no data proving a positive correlation between peroxide values of foods and food toxicological parameters. The Committee was informed of a WHO project that would study the safety of used cooking oils.

210. The Committee agreed to the recommended additions and amendments to CCFAC's Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants Proposed for the Evaluation by JECFA as presented in Appendix XXVII. The substances of highest priority were indicated by a footnote.

211. The Committee agreed to ask the Codex Secretariat, in coordination with the Joint Secretariat to JECFA, to request comments for additions or amendments to the Priority List for consideration at its next Session.

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 18)<sup>84</sup>**

**OTHER BUSINESS**

212. The Committee noted the request of the OIV on the establishment of a maximum level of 2µg/kg for ochratoxin A in wine. The Delegation of the Netherlands indicated their intention to propose starting work on the elaboration of a Code of Practice for Prevention and Reduction of Ochratoxin A Contamination in Coffee and Cacao at the next CCFAC.

213. The Delegation of India expressed real concern about selected application of the ALARA Principle and, therefore, suggested the explanation of this Principle.

<sup>82</sup> CL 2003/13-FAC; CL 2003/46-FAC; CX/FAC 04/36/2-Part II; and, comments submitted by Japan, Switzerland, United States and, IDSI (CX/FAC 04/36/36); and, Denmark (CRD 11)..

<sup>83</sup> CRD5.

<sup>84</sup> [Comments submitted by OIV](#) (CRD 7) Comments submitted by OIV (CRD 7) and Denmark (CRD 20).

**FUTURE WORK****Flavouring agents**

214. The Delegation of the United States proposed that the Committee considered possible options to integrate flavouring agents into Codex system in view of the completion of several hundred recent reviews of flavours by JECFA.

215. The Committee agreed that a working group led by the United States with the assistance of the EC, Finland, Italy, India, Japan, Norway, United Kingdom, and IOFI would prepare a discussion paper, to consider possible options to integrate flavouring agents into the Codex system for circulation, comments, and consideration at its next Session.

216. In view of the magnitude of this new task and the current workload of CCFAC, the Delegation of France suggested that the Working Group addressed, in detail, the practical constraints that such a long-term project would face, particularly as to the updating of flavouring agents in a regular and timely manner.

**Polycyclic aromatic hydrocarbons (PAH) contamination**

217. The Delegation of Denmark proposed the development of a Code of Practice for reduction of PAH (Polycyclic Aromatic Hydrocarbons) contamination during food processing. In noting that these substances would be evaluated by JECFA in 2005, the Committee considered it premature to start elaboration of a Code of Practice and agreed that a working group led by Denmark, with the assistance of Australia, Brazil, Cuba, EC, Finland, Poland, Spain, and the United States, would prepare a discussion paper to set out the issues concerning PAHs in foods, for circulation, comments, and consideration at its next Session.

**Guideline levels for methylmercury in fish**

218. The Committee noted the request of the 53<sup>rd</sup> Session of the Executive Committee<sup>85</sup> to consider whether the current Guideline Level for Methylmercury in Fish needed to be revised in the light of the recent risk assessment performed by JECFA and/or if any other risk management options, including formulation of specific dietary advice, would be appropriate. The Committee established a working group led by the EC, with the assistance of Australia, Canada, France, India, Italy, Japan, Kenya, South Africa, and the United States to prepare a discussion paper on the possible need to revise the Guideline Level for Methylmercury in Fish including the examination of other possible management options for circulation, comments, and consideration at its next Session.

**DATE AND PLACE OF THE NEXT SESSION (Agenda Item 19)**

219. The Committee was informed that the 37<sup>th</sup> Session of the Codex Committee on Food Additives and Contaminants was tentatively scheduled to be held in the Netherlands from 21-25 March 2005, subject to discussion between the Dutch and Codex Secretariats.

220. The Committee noted the kind offer of the Delegation of Cuba to host a Session of the Committee in the future.

**AVE ATQUE VALE**

221. The Delegation of the United States informed the Committee that this would be the last Session at which Dr Andy Ebert of IFAC would be in attendance. The Delegates recognized Dr Ebert's contribution to CCFAC and his thoughtful interventions over the past 30 years.

**CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**  
**SUMMARY STATUS OF WORK**

<b>SUBJECT</b>	<b>STEP</b>	<b>FOR ACTION BY:</b>	<b>DOCUMENT REFERENCE (ALINORM 04/27/12)</b>
Draft Risk Analysis Principles applied by the Codex Committee on Food Additives and Contaminants	8	27 <sup>th</sup> CAC	Para. 39 and Appendix II
Draft Food Category System of the Codex General Standard for Food Additives	8	27 <sup>th</sup> CAC	Para. 68 and Appendix V
Draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups	8	27 <sup>th</sup> CAC	Para. 129 and Appendix XIV
Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts	8	27 <sup>th</sup> CAC	Para. 140 and Appendix XV
Draft Code of Practice for the Prevention and Reduction of Lead Contamination in Foods	8	27 <sup>th</sup> CAC	Para. 168 and Appendix XVI
Draft and proposed draft revisions to Table 1 of the Codex General Standard for Food Additives	8 and 5/8	27 <sup>th</sup> CAC	Para. 81 and Appendix VI
Specifications for the Identity and Purity of Food Additives (Category I) arising from the 61 <sup>st</sup> JECFA Meeting	5/8	27 <sup>th</sup> CAC	Para. 99 and Appendix XI
Proposed draft Amendments to the International Numbering System for Food Additives	5/8	27 <sup>th</sup> CAC	Para. 103 and Appendix XII
Draft Maximum Level for Ochratoxin A in Raw Wheat, Barley, and Rye	7	39 <sup>th</sup> CCFAC	Para. 136 and Appendix XVII
Draft Maximum Level for Lead in Fish	7	37 <sup>th</sup> CCFAC	Para. 165 and Appendix XVIII
Draft and proposed draft Food Additive Provisions of the Codex General Standard for Food Additives	6 and 3	Comments 37 <sup>th</sup> CCFAC	Para. 76 and Appendix IX
Proposed draft Maximum Levels for Cadmium (rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; and, other vegetables)	5	27 <sup>th</sup> CAC Comments 37 <sup>th</sup> CCFAC	Para. 182 and Appendix XXIII
Proposed draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts	5	27 <sup>th</sup> CAC Comments 37 <sup>th</sup> CCFAC	Para. 143 and Appendix XX

SUBJECT	STEP	FOR ACTION BY:	DOCUMENT REFERENCE (ALINORM 04/27/12)
Proposed draft Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods	5	27 <sup>th</sup> CAC Comments 37 <sup>th</sup> CCFAC	Para. 174 and Appendix XXI
Proposed draft revised Guideline Levels for Radionuclides in Foods for Use in International Trade	5	27 <sup>th</sup> CAC Comments 37 <sup>th</sup> CCFAC	Para. 204 and Appendix XXII
Proposed draft Maximum Levels for Tin in Canned Beverages and Canned Foods other than Beverages	4	38 <sup>th</sup> CCFAC	Para. 171 and Appendix XXIV
Proposed draft Maximum Level for Total Aflatoxins in Processed and Unprocessed Almonds, Hazelnuts, and Pistachios	3	Comments 37 <sup>th</sup> CCFAC	Para. 155 and Appendix XXV
Proposed draft Maximum Level for Cadmium in Molluscs (including Cephalopods)	3	Comments 37 <sup>th</sup> CCFAC	Para. 182 and Appendix XXIII
Revision to the Codex General Standard for Contaminants and Toxins in Foods	1/2/3	27 <sup>th</sup> CAC Working Group Comments 37 <sup>th</sup> CCFAC	Para. 126
Sampling Plans for Aflatoxins in Almonds, Brazil Nuts, Hazelnuts, and Pistachios	1/2/3	27 <sup>th</sup> CAC Working Group Comments 37 <sup>th</sup> CCFAC	Para. 149
Maximum Levels for 3-MCPD (Chloropropanol) in Acid-hydrolyzed Vegetable Proteins (acid-HVPs) and acid-HVP containing products	1/2/3	27 <sup>th</sup> CAC Comments 37 <sup>th</sup> CCFAC	Para. 193
Proposed draft Code of Practice for Source Directed Measures to reduce Dioxin and Dioxin-like PCB Contamination in Foods	1/2/3	Working Group Comments 37 <sup>th</sup> CCFAC	Para. 185
Revision to the Preamble of the Codex General Standard for Food Additives	1	37 <sup>th</sup> CCFAC	Paras. 53 - 60
Amendment to the Codex General Standard for Food Additives	---	27 <sup>th</sup> CAC	Para.80 and Appendix IV
Amendment to the Codex General Standard for Contaminants and Toxins in Foods	---	27 <sup>th</sup> CAC	Para. 125 and Appendix XIII
Revocation of Food Additives Provisions of the Codex General Standard for Food Additives	---	27 <sup>th</sup> CAC	Para. 83 and Appendix VII
Discontinuation of draft and proposed draft Food Additive Provisions of the Codex General Standard for Food Additives	---	27 <sup>th</sup> CAC	Para. 84 and Appendix VIII

<b>SUBJECT</b>	<b>STEP</b>	<b>FOR ACTION BY:</b>	<b>DOCUMENT REFERENCE (ALINORM 04/27/12)</b>
Proposed draft Code of Practice for the Safe Use of Active Chlorine	discontinued	27 <sup>th</sup> CAC	Paras. 91 - 93
Maximum Levels for Patulin	discontinued	39 <sup>th</sup> CCFAC	Paras. 130 - 131
Maximum Levels for Deoxynivalenol	discontinued	27 <sup>th</sup> CAC	Para. 158
Proposed draft Maximum Levels for Cadmium in fruits; meat of cattle, pigs, sheep, and poultry; horse meat; herbs, fungi (edible); celeriac; soybeans (dry); and, peanuts	discontinued	27 <sup>th</sup> CAC	Para. 176
Discussion Paper on Processing Aids	discontinued	---	Para. 87
Methods of Analysis for Aflatoxins in Tree Nuts	discontinued	---	Para. 151
Position Paper on Dioxins and Dioxin-like PCBs	discontinued	---	Para. 189
Discussion Paper on Carriers	---	Working Group Comments 37 <sup>th</sup> CCFAC	Para. 89
Terms of Reference for a FAO/WHO Expert Consultation on Active Chlorine	---	Working Group 37 <sup>th</sup> CCFAC	Para. 92
Discussion Paper on Aflatoxin Contamination in Brazil Nuts	---	Working Group Comments 37 <sup>th</sup> CCFAC	Para. 148
Discussion Paper on Chloropropanols	---	Working Group Comments 37 <sup>th</sup> CCFAC	Para. 194
Discussion Paper on Acrylamide	---	Working Group Comments 37 <sup>th</sup> CCFAC	Para. 198
Discussion Paper on the Integration of Flavouring Agents in the Codex System	---	Working Group Comments 37 <sup>th</sup> CCFAC	Para. 215
Discussion Paper on Polycyclic Aromatic Hydrocarbon Contamination in Foods	---	Working Group Comments 37 <sup>th</sup> CCFAC	Para. 217
Discussion Paper on Guideline Level for Methylmercury in Fish	---	Working Group Comments 37 <sup>th</sup> CCFAC	Para. 218
Report of the CCFAC Electronic Working Group	---	Working Group 37 <sup>th</sup> CCFAC	Para. 70



SUBJECT	STEP	FOR ACTION BY:	DOCUMENT REFERENCE (ALINORM 04/27/12)
Report on the Working Principles of the GSFA and Relationship between CCFAC/GSFA and Commodity Committees/Codex commodity standards in relation to Food Additives	---	Working Group 37 <sup>th</sup> CCFAC	Paras. 43, 59-60
Inventory of Processing Aids, updated List	---	New Zealand 37 <sup>th</sup> CCFAC	Para. 88
Harmonization of Terms used by Codex and JECFA	---	Working Group Comments 37 <sup>th</sup> CCFAC	Para. 107
Deoxynivalenol Contamination in Cereals	---	Comments 37 <sup>th</sup> CCFAC	Para. 158
Mycotoxin Contamination in Sorghum	---	Comments 37 <sup>th</sup> CCFAC	Para. 160
Provisional List of Main Internationally Traded Fish Species (including proposals for maximum levels for lead in fish in different fish species)	---	Comments Denmark 37 <sup>th</sup> CCFAC	Para. 164 and Appendix XIX
Action required as a Result of Changes in the Acceptable Daily Intake Status and other Toxicological Recommendations arising from the 61 <sup>st</sup> JECFA Meeting	---	Comments 37 <sup>th</sup> CCFAC	Para. 21 and Appendix XXVI
Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants proposed for Evaluation by JECFA	---	Comments 37 <sup>th</sup> CCFAC	Paras. 78, 211 and Appendix XXVII