

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**ALINORM 03/12**  
**April 2002**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX ALIMENTARIUS COMMISSION**

*Twenty-fifth Session*  
*Rome, Italy, 30 June – 5 July 2003*

**REPORT OF THE 34th SESSION OF THE CODEX COMMITTEE  
ON FOOD ADDITIVES AND CONTAMINANTS**

*Rotterdam, The Netherlands*  
*11-15 March 2002*

**Note:** This report includes Codex Circular Letter CL 2002/10-FAC



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**CX 4/30.2**

**CL 2002/10-FAC**  
**April 2002**

**TO:** - Codex Contact Points  
- Interested International Organizations

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

**SUBJECT: DISTRIBUTION OF THE REPORT OF THE THIRTY-FOURTH SESSION OF THE  
CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS  
(ALINORM 03/12)**

The report of the thirty-fourth Session of the Codex Committee on Food Additives and Contaminants will be considered by the 50<sup>th</sup> Session of the Executive Committee of the Codex Alimentarius Commission (Rome, 26-28 June 2002) and the 25<sup>th</sup> Session of the Codex Alimentarius Commission (Rome, 30 June – 5 July 2003).

**PART A: MATTERS FOR ADOPTION BY THE 25<sup>TH</sup> SESSION OF THE CODEX  
ALIMENTARIUS COMMISSION**

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

1. **Proposed Draft (Step 5/8) and Draft (Step 8) Revisions to the Codex General Standard for Food Additives (para. 61 and Appendix II).**
2. **Proposed Draft Revised Recommended International Code of Practice for Radiation Processing of Food at Step 5/8 (para. 88 and Appendix V).**
3. **Specifications for the Identity and Purity of Food Additives Arising from the 57<sup>th</sup> JECFA Meeting at Step 5/8 (para. 95 and Appendix VI).**
4. **Proposed Draft Amendments to the International Numbering System for Food Additives at Step 5/8 (para. 97 and Appendix VII).**
5. **Draft Maximum Level for Ochratoxin A in Raw Wheat, Barley, and Rye and Derived Products at Step 8 (para. 114 and Appendix IX).**
6. **Draft Maximum Level for Patulin in Apple Juice and Apple Juice Ingredients in Other Beverages at Step 8 (para. 118 and Appendix X).**

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 5/8 or 8) (*Codex Alimentarius Procedural Manual*, Twelfth Edition, pages 19-21) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; e-mail: [codex@fao.org](mailto:codex@fao.org)) **no later than 31 March 2003**.

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

- 1. Draft Amendment to the INS Number for Sodium Potassium Triphosphate at Step 5 (Accelerated)** (para. 97 and Appendix VII).

Governments wishing to propose amendments or to comment regarding the implications which the above text or any provisions thereof may have for their economic interests should do so in writing in conformity with the Uniform Accelerated Procedure for the Elaboration of Codex Standards and Related Texts (at Step 5) (*Codex Alimentarius Procedural Manual*, Twelfth Edition, pages 21-22) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; e-mail: [codex@fao.org](mailto:codex@fao.org)) **no later than 31 March 2003**.

#### **PART B: MATTERS FOR ADOPTION BY THE 50<sup>TH</sup> SESSION OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION**

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

- 1. Proposed Draft Amendments to the INS Numbers for Mineral Oil at Step 5** (para. 97 and Appendix VII).
- 2. Proposed Draft Code of Practice for the Prevention of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages at Step 5** (para. 122 and Appendix XI).
- 3. Proposed Draft Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes** (para. 125 and Appendix XII).

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 Procedural Manual*, Twelfth Edition, pages 19-21) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; e-mail: [codex@fao.org](mailto:codex@fao.org)) **no later than 31 May 2002**.

#### **PART C: 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 1 September 2002** 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, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: [Codex@fao.org](mailto:Codex@fao.org)).

- 1. Information on Food Additives Considered by the 57<sup>th</sup> JECFA Meeting in the Context of the Codex General Standard for Food Additives** (para. 20).

The Committee agreed with several recommendations and requests for information on additives considered by the 57<sup>th</sup> JECFA in the context of the Codex General Standard for Food Additives.

2. **Proposed Risk Assessment Policy Statement for the Application of Risk Analysis Principles to the Standard Setting Activities of the Codex Committee on Food Additives and Contaminants in Conjunction with Risk Assessments Performed by the Joint FAO/WHO Expert Committee on Food Additives** (para. 30 and Appendix XXI).

The Committee agreed to circulate the above proposed Policy Statement for comments at Step 3 and further consideration at its next meeting.

3. **Proposed Draft (Step 3) and Draft (Step 6) Revisions to the Codex General Standard for Food Additives** (para. 60 and Appendix III)

The Committee agreed to hold all GMP provisions for additives with numerical ADIs at Steps 3 and 6 so that specific numeric levels of use could be provided. The Committee also agreed to hold food additive provisions with specific numeric levels at Steps 3 and 6 and to request additional information, including technological need and justification, for their use.

4. **Draft Revised Annex to Table 3 of the Codex General Standard for Food Additives** (para. 64 and Appendix IV).

The Committee agreed to revisions to the Annex to Table 3 as proposed by the Working Group and decided to request additional comments at Step 6 for further consideration at its next meeting.

5. **Discussion Paper on Processing Aids and Carriers** (para. 68).

The Committee decided to request comments on the Discussion Paper on Processing Aids and Carriers (CX/FAC 02/9) for further consideration at the 35<sup>th</sup> CCFAC.

6. **Discussion Paper on the Use of Active Chlorine** (para. 73).

The Committee agreed that the Discussion Paper should be revised under the leadership of Denmark in light of the Committee's discussion and comments to be submitted in response to this Circular Letter for circulation, comment and further consideration at its next meeting.

7. **Proposed Draft Principles for Exposure Assessment of Contaminants and Toxins in Foods** (para. 109 and Appendix VIII).

The Committee agreed that the Principles would be circulated for comments at Step 3.

8. **Maximum Level for Patulin in Apple Juice and Apple Juice Ingredients in Other Beverages** (para. 119).

The Committee agreed to request more data on the level of patulin in apple juice and apple juice ingredients in other beverages and to reconsider the possible reduction of the maximum level of 50 µg/kg to 25 µg/kg once the Code of Practice had been implemented.

9. **Aflatoxin Contamination in Tree Nuts, including Methods of Analysis for the Determination of Aflatoxins in Tree Nuts** (para. 127).

The Committee agreed that information on aflatoxin contamination in tree nuts as well as methods of analysis for the determination of aflatoxins in tree nuts would be requested by circular letter to this report.

**10. Draft Maximum Level for Lead in Fish** (para. 133 and Appendices XIII and XX).

The Committee decided that the proposed level of 0.2 mg/kg, as well as certain species for which the level might not apply, should be returned to Step 6 for additional comments on specific issues.

**11. Maximum Levels for Lead in Milk and Milk Fat** (para. 137).

The Committee decided that comments should be requested on the maximum levels of lead in milk (0.02 mg/kg) and milk fat (0.1 mg/kg) for further consideration at its next meeting.

**12. Proposed Draft Maximum Levels for Cadmium** (para. 143 and Appendix XIV).

The Committee returned proposed draft maximum levels for fruit; wheat grain; milled rice; soybean and peanuts; meat of cattle, poultry, pig and sheep; meat of horse; vegetables; peeled potatoes, stem and root vegetables; leafy vegetables, fresh herbs, fungi and celeriac; and, molluscs to Step 3 for circulation, comment and further consideration at its next meeting.

**13. Proposed Draft Maximum Levels for Tin** (para. 146 and Appendix XV).

The Committee returned the maximum levels for tin (200 mg/kg in liquid canned foods and 250 mg/kg in solid canned foods) to Step 3 for circulation, comments and further consideration at its next meeting.

**14. Information on Actual Dioxin and Dioxin-Like PCB Levels and Methods of Analysis** (para. 153).

The Committee agreed to request information on actual dioxin and dioxin-like PCB levels and information on inexpensive, quick and validated analytical (screening, confirmation) methods.

**15. Proposed Draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin Like PCB Contamination of Foods** (para. 156).

The Committee agreed to request comments on the proposed draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin Like PCB Contamination of Foods (CX/FAC 02/27).

**16. Information and Data on the Occurrence of Deoxynivalenol in Cereals** (para. 163).

The Committee agreed to request additional information and data on the occurrence of deoxynivalenol in cereals, as well as the results of any studies on the effects of processing.

**17. Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA** (paras. 168 – 169 and Appendix XVI).

The Committee agreed to request additional comments for additions or amendments to its Priority List for consideration at its next Session.

## SUMMARY AND CONCLUSIONS

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

### **Matters for Adoption/Consideration by the 25<sup>th</sup> Session of the Codex Alimentarius Commission:**

- Agreed to forward food additive provisions to the Commission for final adoption at Step 5/8 or 8 as amendments to the Codex General Standard for Food Additives (para. 61);
- Forwarded the proposed draft Revised Recommended International Code of Practice for Radiation Processing of Food to the Commission for adoption at Step 5/8 (with the omission of Steps 6 and 7) (para. 88);
- The Committee forwarded Specifications in categories I and II to the Commission for adoption at Step 5/8 as Codex Advisory Specifications (para. 95);
- The Committee forwarded INS 452(iv) for Sodium potassium tripolyphosphate as an emulsifier, stabilizer, acidity regulator, raising agent, sequesterant and water retention agent to the Commission for final adoption at Step 5 of the accelerated procedure and for INS numbers 163(iv), 163(v), 165, 407, 445, 650, 949 and 961 for final adoption at Step 5/8 (para. 97);
- Forwarded the draft maximum level of 5 µg/kg for ochratoxin A in raw wheat, barley, and rye and derived products to the Commission for final adoption at Step 8 (para. 114);
- Forwarded the draft maximum level of 50 µg/kg for patulin in apple juice and apple juice ingredients in other beverages to the Commission for final adoption at Step 8 (para. 118), and;
- Recommended the deletion of the maximum level of 50 µg/kg for lead in butter (para. 135).

### **Matters for Adoption/Consideration by the 50<sup>th</sup> Session of the Executive Committee of the Codex Alimentarius Commission:**

- Forwarded various amendments to the INS numbers for Mineral Oil to the Executive Committee for preliminary adoption at Step 5 (para. 97);
- Agreed to forward the proposed draft Code of Practice for the Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages to the Executive Committee for preliminary adoption at Step 5 (para. 122);
- Agreed to forward the proposed draft Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes to the Executive Committee for preliminary adoption at Step 5 (para. 125);
- Agreed that a drafting group under the direction of China would elaborate a proposed draft Code of Practice for the Reduction of Aflatoxin Contamination in Tree Nuts for circulation, comment and consideration at its next meeting, and with the understanding that the proposal was subject to approval as new work by the Executive Committee (para. 128);
- Decided that a drafting group under the direction of the United States would elaborate a proposed draft Code of Practice for the Prevention and Reduction of Lead in Food, subject to confirmation by the Executive Committee (para. 138), and;
- Discontinued the elaboration of maximum levels for cadmium in liver and kidney (para. 142).

### **Matters of Interest to the Codex Alimentarius Commission and Other Codex Committees:**

- Decided to request information on several additives considered by the 57<sup>th</sup> JECFA in the context of the Codex General Standard for Food Additives (GSFA) (para. 20);
- Agreed that future versions of the document on Action Required as a Result of Changes in ADI Status and Other Toxicological Recommendations should be considered by the Ad Hoc Working Group on the Codex General Standard on Food Additives when considering amendments to the General Standard (para. 21);

- Agreed to circulate the Proposed Risk Assessment Policy Statement for the Application of Risk Analysis Principles to the Standard Setting Activities of the Codex Committee on Food Additives and Contaminants (CCFAC) in Conjunction with Risk Assessments Performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for comments at Step 3 and further consideration at its next meeting (para. 30);
- Attached the revised and endorsed food additive provisions for the draft Standard for Chocolate and Chocolate Products to its report (para. 35);
- Agreed that the additives listed in Appendix I of the Report of the Working Group on the Codex General Standard for Food Additives should be given priority for discussion at its 35<sup>th</sup> Session (para. 38);
- Agreed that a revised Table 1 of the GSFA with all food additive provisions (final provisions as well as provisions in the step process), including electronic versions of Tables 1, 2 and the source data for the priority additives, should be circulated for the Committee well in advance of the 35<sup>th</sup> CCFAC (paras. 39-40);
- Decided to reconvene the Ad Hoc Working Group on the General Standard for Food Additives prior to its next Session under the Chairmanship of the United States (para. 41);
- Reaffirmed and agreed on general principles and approaches concerning the Relationship Between Codex Commodity Standards and the Codex General Standard for Food Additives, including proposed revisions to the Procedural Manual of the Codex Alimentarius Commission (paras. 42 – 49);
- Decided to install a drafting group under the direction of France/USA to elaborate a proposed draft revision to the Preamble to the Codex General Standard for Food Additives (para. 51);
- Reaffirmed several points to promote the consistent interpretation of the Food Category System of the GSFA, and agreed that a drafting group under the direction of the USA would elaborate a revised version of the FCS for circulation, comment and additional consideration at its next meeting (paras. 52-54);
- Revised the Food Category System of the GSFA in relation to Pastas and Noodles (para. 55);
- The Committee agreed to hold all GMP provisions for additives with numerical ADIs at Steps 3 and 6 so that specific numeric levels of use could be provided. The Committee also agreed to hold food additive provisions with specific numeric levels at Steps 3 and 6 and to request additional information, including technological need and justification, for their use (para. 60);
- Agreed to revisions to the Annex to Table 3 of the GSFA and decided to request additional comments at Step 6 for further consideration at its next meeting (para. 64);
- Decided to request comments on the Discussion Paper on Processing Aids and Carriers (CX/FAC 02/9) for further consideration at the 35<sup>th</sup> CCFAC (para. 68);
- Agreed that the Discussion Paper on the Use of Active Chlorine should be revised by Denmark in light of the Committee's discussions and comments to be submitted in response to a Circular Letter to this report for circulation, comment and further consideration at its next meeting (para. 73);
- Decided to suspend further discussion of the Draft Revised Codex General Standard for Irradiated Foods and requested a drafting group led by the Philippines to revise the current Standard on the basis of written comments submitted and the Committee's discussions for circulation, additional comment and further consideration at its next meeting (para. 81);
- Decided to reconvene the Ad Hoc Working Group on Specifications prior to its next Session under the Chairmanship of the United States (para. 92);
- Agreed that the Codex Secretariat would prepare a Discussion Paper on the Harmonization of Terms Used by Codex and JECFA for Functional Sub-Classes and Technological Functions for consideration at the next CCFAC (para. 97);
- Decided to reconvene the Ad Hoc Working Group on Contaminants and Toxins prior to its next Session under the Chairmanship of Denmark (para. 102);
- Agreed that the Netherlands would provide an updated Schedule 1 of the Codex General Standard for Contaminants and Toxins in Foods every year and that the Codex Secretariat would investigate the feasibility of providing the Schedule in electronic form (paras. 104 – 105);



- Agreed that the proposed draft Principles for Exposure Assessment of Contaminants and Toxins in Food would be circulated for comments at Step 3, revised by a drafting group under the direction of Australia/France, circulated for additional comment and further consideration at its next meeting and with the understanding that the entire document (CX/FAC 02/17) would also be sent to JECFA for comments (paras. 109 – 110);
- Agreed to request more data on the level of patulin in apple juice and apple juice ingredients in other beverages by Circular Letter to this report (paras. 119);
- Agreed that a drafting group led by Iran would prepare a Discussion Paper on Aflatoxins in Tree Nuts for circulation, comment and further consideration at its next Session and that information on aflatoxins in tree nuts as well as information on methods of analysis would be requested by circular letter to this report (para. 127);
- Decided that the proposed level of 0.2 mg/kg, as well as certain species for which the level might not apply, should be returned to Step 6 for additional comments on specific issues. The Committee also agreed that a discussion paper would not be prepared (paras. 133-134);
- Decided that comments should be requested on the maximum levels of lead in milk (0.02 mg/kg) and milk fat (0.1 mg/kg) for further consideration at its next meeting (para. 137);
- Returned the proposed draft maximum levels for cadmium in various commodities to Step 3 for circulation, comment and further consideration at its next meeting (para. 143);
- Returned the proposed draft maximum levels for tin to Step 3 for circulation, comments and further consideration at its next meeting (para. 146);
- Agreed that the delegation of Australia would revise the Discussion Paper on Tin for circulation, comments and further consideration at its next meeting (para. 147);
- Agreed that a drafting group led by the Netherlands would revise the Position Paper on Dioxins and Dioxin Like PCBs, including Methods of Analysis for Dioxins and Dioxin Like PCBs, for circulation, comment and further consideration at its next meeting (para. 153);
- Agreed to request information on actual dioxin and dioxin-like PCB levels and on inexpensive, quick and validated analytical methods (para. 153);
- Agreed to request comments on the proposed draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin Like PCB Contamination of Foods (CX/FAC 02/27) and on the basis of the comments submitted, the proposed draft Code would be revised by the drafting group led by Germany for circulation, additional comments and further consideration at its next Session (para. 156);
- Agreed that a drafting group led by the United Kingdom would revise the Position Paper on Chloropropanols for circulation, comment and further consideration at its next Session (para. 160);
- Agreed that a drafting group led by Belgium would revise the Discussion Paper on Deoxynivalenol for circulation, comment and further consideration at its next meeting. The Committee also agreed to request additional information and data on the occurrence of deoxynivalenol in cereals, as well as the results of any studies on the effects of processing (para. 163);
- Agreed on the Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA and agreed to request additional comments for additions or amendments to the list for consideration at its next Session (paras. 168-169);
- Forwarded methods of analysis for the determination of food additives and contaminants in foods to the CCMAS for endorsement (para. 172);
- Agreed to request clarification from the Codex Committee on General Principles as to point (d) of the CCFAC terms of reference as to whether or not it allowed the consideration of analytical methods for both food additives and contaminants (paras. 174-175);
- Agreed that a drafting group led by South Africa would prepare a Discussion Paper on the Development of a Code of Practice for the Reduction of Aflatoxin Contamination in Peanuts for circulation, comment and further consideration at its next meeting (para. 176);

- Agreed that Sudan would send comments on the potential inclusion of sorghum in the proposed draft Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes for consideration at the next CCFAC (para. 177), and;
- Agreed that South Africa might raise the issue of toxic seed contamination in grains at the next CCFAC after reviewing the adequacy of existing Codex texts in this regard (para. 178).

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## **INTRODUCTION**

1. The 34th session of the Codex Committee on Food Additives and Contaminants was held in Rotterdam, The Netherlands, from 11-15 March 2002, at the kind invitation of the Government of The Netherlands. Mr. Edwin Hecker, Netherlands Ministry of Agriculture, Nature Management and Fisheries, chaired the meeting. The meeting was attended by 308 participants representing 48 Member Countries and 48 International Organizations. The List of Participants is attached at Appendix I.

## **OPENING OF THE SESSION**

2. The session was opened by Mr. Laurens Jan Brinkhorst, Netherlands Minister of Agriculture, Nature Management and Fisheries. Mr. Brinkhorst informed the Committee of recent developments in the area of food safety and their consequences on government structures in the Netherlands and Europe. He also noted the importance of developing food safety requirements on a global scale as well as the role of international organizations in capacity building efforts towards this end.

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

3. The Committee adopted the Provisional Agenda as proposed. The Committee agreed to discuss the maximum level for lead in butter and milk fat under Agenda Item 16(a). The Committee agreed to hold the informal ad hoc Working Groups on the International Numbering System (INS) (Agenda Item 12) and on JECFA Priorities (Agenda Item 17) under the chairmanship of Finland and the Netherlands, respectively.

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

4. The Committee agreed with the suggestion of the Chairman to appoint Dr. Bruce Lauer (Canada) as Rapporteur for the Session.

## **MATTERS REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 3)<sup>2</sup>**

5. The Committee noted matters arising from the 24<sup>th</sup> Session (July 2001) of the Codex Alimentarius Commission and the most recent 49<sup>th</sup> Session (September 2001) of the Executive Committee of the Codex Alimentarius Commission. These matters included a Report on the Financial Situation of the Joint FAO/WHO Food Standards Programme; the Consideration of the draft Strategic Framework, Proposed Draft Medium Term Plan 2003-2007 and the Chairperson's Action Plan; the Risk Analysis Policies of the Codex Alimentarius Commission; Consideration of Amendments to the Procedural Manual of the Codex Alimentarius Commission; the Consideration of Proposed Draft and Draft Standards; and, the Consideration of Proposals for New Work.

## **OFFICE INTERNATIONAL DU VIN ET DE LA VIGNE (OIV)**

6. In follow-up to Commission discussions on a Report by the Secretariat on Relations Between the Codex Alimentarius Commission and Other International Intergovernmental Organizations<sup>3</sup> the Representative of the OIV, referring to the Agreement between FAO and the OIV of 1948, explained that it had been impossible to obtain a copy of the aforesaid Agreement although it had been published in the official OIV Bulletin 221 of July 1949. He reminded the Committee that the Codex Alimentarius Commission, at its 10th Session, had already decided not to undertake the elaboration of Codex standards for wine<sup>4</sup>. Similarly, the 31<sup>st</sup> Session of the CCFAC had noted the necessity for the Codex General Standard for Food Additives (GSFA) to be consistent with the OIV standards for wine.<sup>5</sup> The Representative of the OIV stressed that Codex and the OIV should continue to strengthen the links that already existed between

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<sup>1</sup> CX/FAC 02/1

<sup>2</sup> CX/FAC 02/2

<sup>3</sup> ALINORM 01/41, paras. 29-30

<sup>4</sup> ALINORM 74/44 para. 363

<sup>5</sup> ALINORM 99/12A para. 51

both organizations in order to effectively coordinate work while awaiting the completion of the *Guidelines for Cooperation with other International Intergovernmental Organizations* that the 24<sup>th</sup> Session of the Commission had entrusted to the Codex Committee on General Principles (CCGP).<sup>6</sup>

7. The Codex Secretariat referred to Article I of the Statutes of the Codex Alimentarius Procedural Manual, which provided that one of the purposes of the Codex Alimentarius Commission was “promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations”<sup>7</sup>. The Codex Secretariat also noted that the Codex Alimentarius Commission Strategic Framework 2003-2007 included the Promotion of Linkages Between Codex and Other Multilateral Regulatory Instruments and Conventions (Objective 3) so that the Commission worked closely with other relevant international standard setting and regulatory bodies to promote close cooperation and dialogue on matters of common interest so as to minimize duplication of efforts.<sup>8</sup>

#### **PROPOSED DRAFT STANDARD FOR INFANT FORMULA**

8. The Committee noted the concern expressed at the 23rd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) on the large number of additives and levels of use proposed for infant formula and foods for infants and children in the draft sections of the General Standard for Food Additives (GSFA), and asked the CCFAC to defer finalization of those GSFA additive levels until the CCNFSDU had carried out a thorough review of the additives listed in both the proposed draft Standards for Infant Formula and for Processed Cereal-Based Foods for Infants and Young Children.<sup>9</sup> Switzerland and the representative of the European Community supported the request of the CCNFSDU. The delegation of Switzerland also clarified that there were inconsistencies between both the GSFA and the two aforesaid Standards, particularly in regard to the use of certain colours, sweeteners and thickeners and in this regard, the CCNFSDU had established a Working Group to examine the food additive provisions in these Standards.

9. The Committee noted that the Procedural Manual specified that in any case, “all provisions in respect of food additives contained in Codex commodity standards should be referred to the CCFAC, preferably after the standards had been advanced to Step 5”<sup>10</sup> and that the aforementioned Standards were at Step 3 of the Codex Step procedure. It was also noted that comments from Codex member countries and international organizations were requested during both the endorsement and/or elaboration of levels within the GSFA and furthermore, the Food Category System (FCS) was being thoroughly revised by the Working Group on the GSFA in order to avoid inconsistencies between the GSFA and individual Codex standards.

#### **SUMMARY REPORT OF THE FIFTY-SEVENTH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda item 4a)<sup>11</sup>**

10. The Expert Committee evaluated toxicologically approximately 20 food additives and 200 flavouring agents. Two chloropropanols and a large number of polychlorinated dibenzodioxins, polychlorinated dibenzofurans, and dioxin-like coplanar polychlorinated biphenyls were also evaluated.

11. The evaluations of some of the flavouring agents were not finalized because it was not clear whether they were in current use as flavouring agents or whether they had some other function in the formulation, such as use as a solvent, emulsifier, or preservative. The Committee stressed that the Procedure for the Safety Evaluation of Flavouring Agents should be used only for substances that impart flavour to food and not to non-flavour uses or to other chemicals that may be used in flavouring formulations.

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<sup>6</sup> ALINORM 01/41 para. 31

<sup>7</sup> Procedural Manual of the Codex Alimentarius Commission, page 4, 12<sup>th</sup> Edition.

<sup>8</sup> ALINORM 01/41, Appendix II

<sup>9</sup> ALINORM 03/26, paras. 63-69

<sup>10</sup> Procedural Manual of the Codex Alimentarius Commission, pages 84-85, 12<sup>th</sup> Edition.

<sup>11</sup> Summary and Conclusions of the 57th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (Unnumbered)

12. A total of 342 specifications were prepared, 317 of them for flavouring agents and 25 for food additives other than flavouring agents; two specifications were withdrawn. In addition fifty food additives (anticaking agents, flavouring agents, sweetening agents, thickening agents) were revised for heavy metal contents and new levels for those were proposed.

13. The Committee could not assess 13 food additives that had been referred to it from CCFAC because their use could not be verified.

14. The Committee discussed and modified considerably the General Specifications and Considerations for Enzyme Preparations, taking note of the necessity to issue in the future more comprehensive guidelines for the evaluation of enzymes used in food processing. The Committee once again recommended the revision of the *Guide to Specifications* (FAO FNP 5). In response to this recommendation, the Joint Secretariat had prepared a plan for the revision and is seeking sponsors, preferably Codex delegations, to provide funds to enable the revision of this document. The new edition of the *Guide to Specifications* will be revised in close co-ordination with the re-publication of FNP 52 (addendum 10 shall be the last of the current series).

15. The Committee established a provisional maximum tolerable daily intake (PMTDI) of 2 µg/kg bw for 3-chloro-1,2-propanediol. Based on the limited information available, the estimated mean intake of this contaminant by consumers of soya sauce would be at or above the PMTDI. The Committee noted that a regulatory limit on the concentration of 3-chloro-1,2-propanediol in soya sauce could markedly reduce intake by soya sauce consumers.

16. The limited information available on 1,3-dichloro-2-propanol indicated that it is genotoxic in vitro, hepatotoxic, and induces a variety of tumours in various organs in rats. The Committee concluded that the estimation of a tolerable intake was inappropriate because of the nature of the toxicity. However, it was noted that the dose that caused tumours in rats was about 20 000 times the highest estimated intake of 1,3-dichloro-2-propanol by consumers of soya sauce. The evidence suggests that this contaminant is associated with high concentrations of 3-chloro-1,2-propanediol in food. Regulatory control of the latter would obviate the need for specific controls on the dichloro contaminant.

17. The Committee performed a comprehensive review of PCDDs, PCDFs, and dioxin-like coplanar PCBs, relying upon the literature reviewed by the WHO Consultation that evaluated these substances in 1998 and information that had become available since that time. The Committee established a tolerable intake, which it expressed on a monthly basis to emphasize the long half-times of these contaminants in the body. The provisional tolerable monthly intake (PTMI) that the Committee established was 70 pg of toxic equivalents (TEQ), which is in the range of the tolerable daily intake of 1-4 pg/kg bw that was established by the 1998 WHO Consultation. Median and 90<sup>th</sup> percentile intakes may approach or exceed this value. The Committee identified a number of uncertainties in the assessment and some of the difficulties associated with regulatory limits.

18. A number of general items were considered. Among these is reference to a project to update principles for the risk assessment of chemicals in food, which FAO and WHO have initiated. A planning meeting was held in November of last year and a plan of work is being developed. This is a comprehensive project that will review the principles and procedures used by JECFA and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), facilitate the incorporation of new scientific tools, and harmonize risk assessment procedures for different classes of chemicals with other scientific assessment bodies. Comments will be solicited on various papers throughout the project; it is extremely important that feedback be received from the risk managers in Codex. The project plan and call for experts are on both the FAO and WHO web sites<sup>12</sup>.

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<sup>12</sup> <http://www.fao.org/es/ESN/Jecfa/Jecfa.htm> and [http://www.who.int/pcs/chem\\_fd\\_main.html](http://www.who.int/pcs/chem_fd_main.html)

## **ACTION REQUIRED AS A RESULT OF CHANGES IN ADI STATUS AND OTHER TOXICOLOGICAL RECOMMENDATIONS (Agenda Item 4b)<sup>13</sup>**

19. The Committee noted action required by the CCFAC as a result of changes to existing acceptable daily intakes (ADIs) and/or the establishment of new ADIs for food additives, or other toxicological recommendations for contaminants, as recommended by the 57th JECFA meeting.

20. The Committee agreed with the following recommendations and requests for information on those additives considered by the 57th JECFA in the context of the GSFA:

- In view of the numerical ADI assigned to hydrogenated poly-1-decene (907), information on the use of the additive should be requested for inclusion in Table 1.
- Calcium dihydrogen diphosphate (INS 450vii), monomagnesium phosphate (343i), Sodium calcium polyphosphate (452iii) and Trisodium diphosphate (450ii) should be included in the heading for phosphates in the GSFA upon receipt of information on use levels and food categories where these additives were used.
- The following additives have been assigned an ADI of “not specified” and therefore:
  - Acetylated oxidized starch (1451) should be included in Table 3 and information on the use of the additive in the food categories listed in the Annex to Table 3 should be requested;
  - alpha-cyclodextrin (458), curdlan (424), sodium sulfate (514), erythritol (968), polyglycitol syrup (964) and Sodium carboxy methyl cellulose, enzymatically hydrolyzed (469) are included in Table 3 and information on the use of these additives in the food categories listed in the Annex to Table 3 should be requested.
- For additives Invertase from *Saccharomyces cerevisiae*,  $\beta$ -carotene from *Blakeslea trispora* and D-tagatose information should be requested on their use for inclusion in Table 1.
- As the ADI for tartaric, acetic and fatty acid esters of glycerol, mixed (472f), was withdrawn due to its specifications being combined with diacetyltartaric and fatty acid esters of glycerol (472e), the listing for this additive (472f) in Table 3 should be deleted. Information should be requested on the use of diacetyltartaric and fatty acid esters of glycerol with respect to its listing in Tables 1 and 2.

21. On the recommendation of the Codex Secretariat, the Committee noted that future versions of the document on Action Required as a Result of Changes in ADI Status Other Toxicological Recommendations should be considered by the *ad hoc* Working Group on the Codex General Standard for Food Additives when considering amendments to the General Standard on Food Additives. It was noted that information in the document would include previous and current ADIs (or equivalent), Substance Name, INS Number and Secretariat Notes indicating the potential impact of the changes.

22. The table summarizing “Action Required as a Result of Changes in Acceptable Daily Intake (ADI) Status and Other Toxicological Recommendations Arising from the 57th JECFA Meeting” is attached to this report at Appendix XVIII.

## **DISCUSSION PAPER ON THE APPLICATION OF RISK ANALYSIS PRINCIPLES FOR FOOD ADDITIVES AND CONTAMINANTS (Agenda Item 5)<sup>14</sup>**

23. The 33rd CCFAC agreed<sup>15</sup> that the Discussion Paper on the Application of Risk Analysis Principles for Food Additives and Contaminants should be revised by a drafting group led by the United States on the basis of written comments submitted and the Committee’s discussions for circulation, comment and further consideration at its current meeting.

24. The Committee was reminded that the Commission recommended<sup>16</sup> that relevant Codex Committees should continue to develop and document the application of risk analysis in their work and that the risk

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<sup>13</sup> CX/FAC 02/3

<sup>14</sup> CX/FAC 02/4 and comments submitted by Denmark (CX/FAC 02/4-Add. 1) and the EC (CRD 4)

<sup>15</sup> ALINORM 01/12A, para. 29

<sup>16</sup> ALINORM 01/41, para. 85



analysis policies developed by the Committees would be presented in a single document to the next Session of the Commission.

25. The delegation of the United States informed the Committee that the document was intended to strengthen the standard-setting activities of the CCFAC by clarifying the respective roles of the Committee and JECFA in risk analysis and to improve risk communication between both bodies. It was noted that these goals could be achieved through the further development of the proposed risk assessment policy statement.

26. The delegation of Spain, speaking on behalf of the European Community, reiterated remarks made at the 33rd Session of the CCFAC, including that the work of the commodity committees should be reflected in the Policy Statement and that it should be determined under what conditions input on the technological need for additives proposed by commodity committees was taken into account. It was also noted that the prioritization of additives by JECFA for evaluation might need further discussion.

27. It was also stated by the delegation of Morocco that CCFAC efforts to obtain scientific information necessary for JECFA to perform its risk assessment should be flexible while at the same time recognizing that the request for data and the information requested should be as precise as possible. It was also stressed that risk communication from JECFA to the CCFAC should be improved and in this regard, the Committee noted that the Commission was in the process of examining increased coordination in these areas.

28. The delegation of the United States noted that the intent of the Policy Statement was to improve communication between the CCFAC and JECFA and in this regard, the strict independence and scientific integrity of JECFA, including FAO and WHO procedures for the selection of experts, should be respected. In this regard, it was stated that the extent to which non-scientific factors were taken into account by JECFA needed to be clarified.

29. The WHO and FAO Secretaries to JECFA clarified that an earlier draft of the document was examined by JECFA, as reported in Section 2.2 of the report of the 53rd JECFA meeting. It was noted that the prioritisation of compounds for JECFA review was a responsibility of the CCFAC while at the same time recognising that JECFA was also accountable to other priority concerns raised outside the Codex system. In any case, it was stressed that the commitment to provide data was the responsibility of the CCFAC and in this regard, the importance of providing clear and concise priorities and questions to the JECFA was stressed.

### **Status of the Discussion Paper on the Application of Risk Analysis Principles for Food Additives and Contaminants**

30. The Committee agreed to circulate the *Proposed Risk Assessment Policy Statement for the Application of Risk Analysis Principles to the Standard Setting Activities of the Codex Committee on Food Additives and Contaminants (CCFAC) in Conjunction with Risk Assessments Performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)* for comments at Step 3 and further consideration at its next meeting (see Appendix XXI), with the understanding that the Executive Committee and the Codex Committee on General Principles would be informed.

31. It was noted that although the Policy Statement was developed at the request of the Commission for internal Codex guidance, the Committee would consider its inclusion in the Codex General Standards for Food Additives and for Contaminants and Toxins in Foods at its next meeting.

32. The Committee also agreed that document CX/FAC 02/4 would be revised by the United States on the basis of the above discussions and written comments submitted for forwarding to the 59th Meeting of JECFA for review and comment.

## **ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX STANDARDS (Agenda Item 6)<sup>17</sup>**

33. The Committee considered food additive provisions of the draft Standard for Chocolate and Chocolate Products<sup>18</sup>, which was forwarded by the 19<sup>th</sup> Session of Committee on Cocoa Products and Chocolate (CCCPC) to the 25<sup>th</sup> Session of the Commission for adoption at Step 8.

34. The Committee endorsed the food additive provisions as proposed. However, the Committee did not endorse the proposed level of 100 mg/kg for Neohesperidine dihydrochalcone (959) as the additive had not been evaluated by JECFA. The Committee also did not endorse the GMP level for Carnauba wax (903) in view of its numerical ADI. The Committee grouped the use level for Tertiary butylhydroquinone (319), Butylated hydroxyanisole (320), Butylated hydroxytoluene (INS 321) and Propylgallate (310) as “200 mg/kg, singly or in combination”. The delegation of the United States objected to the inclusion of cyclamates in the standard due to unresolved questions as to its safety.

35. The Committee attached the revised and endorsed food additive provisions for the draft Standard for Chocolate and Chocolate Products to its report as Appendix XIX.

## **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>19</sup>**

36. The 33rd Session of the CCFAC decided<sup>20</sup> to reconvene the *ad hoc* Working Group on the Codex General Standard for Food Additives prior to the 34th Session under the chairmanship of the United States. The *ad hoc* Working Group was chaired by Dr. D. Keefe (USA) and Mr. N. Kildemark (DK) acted as rapporteur.

37. The Chairman of the Working Group briefly summarised its discussions and proposed several general recommendations to the Committee as follows:

#### **PRIORITY ADDITIVES FOR THE 35TH CCFAC *AD HOC* WORKING GROUP ON THE GSFA**

38. The Committee agreed that the additives listed in Appendix 1 of the Working Group report should be given priority for discussion at its 35th session and that the source data and the recommendations of the Quality Control Working Group for these additives should be circulated well in advance of the 35th CCFAC.

#### **TABLES TO THE GSFA**

39. The Committee agreed that a revised Table 1 of the GSFA with all food additive provisions, including final provisions as well as those that are in the step process, should be circulated for the information of the Committee well in advance of the 35th CCFAC.

40. In addition, the Committee recommended that electronic versions of the revised Tables 1, 2 and the source data for priority additives for the 35th CCFAC should be made available. In this regard, the Codex Secretariat indicated that work was underway to make the final version of the GSFA accessible through the Internet and CD-ROM in its entirety.

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<sup>17</sup> CX/FAC 02/5

<sup>18</sup> ALINORM 03/14, Appendix II

<sup>19</sup> CRD 1

<sup>20</sup> ALINORM 01/12A, para. 55.

### **Future Status of the Ad Hoc Working Group on the Codex General Standard for Food Additives**

41. 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 and expressed its appreciation to the Working Group and its Chairman, Dr. D. Keefe, for their diligent work.

### **DISCUSSION PAPER ON THE RELATIONSHIP BETWEEN CODEX COMMODITY STANDARDS AND THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES, INCLUDING CONSIDERATION OF THE FOOD CATEGORY SYSTEM (Agenda Item 7b)<sup>21</sup>**

42. The 33rd CCFAC accepted the offer of the United States, assisted by a drafting group, to prepare a discussion paper on the relationship between Codex commodity standards and the Codex General Standard for Food Additives, including consideration of the Food Category System, for circulation, comment and consideration at its 34th Session. The Committee also agreed that the document should contain a full analysis of the differences between pastas and noodles<sup>22</sup>. The Chairman of the Working Group gave a brief introduction to the discussion paper.

### **COMMISSION'S MEDIUM TERM PLAN 1998 - 2002**

43. The Committee reaffirmed support for the General Approaches and Issues contained in the Commission's Medium Term Plan for 1998 to 2002, as follows:

- a. that continued priority should be given to the Commission's horizontal science based work in the areas of food additives, contaminants, etc.
- b. that the Commission should continue to reduce its work on commodity-specific (i.e., vertical) standards in favor of horizontal or general standards.
- c. that the modernization of current commodity standards, and the transfer of material from commodity standards to applicable general standards, should be completed in this period.

### **GENERAL PRINCIPLES OF THE CODEX GSFA**

44. The Committee reaffirmed the following general principles of the Codex GSFA:

- a. Only food additives that have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and found acceptable for use in foods are included in the GSFA.
- b. The food additives covered by the GSFA and their maximum levels of use are based in part on the food additive provisions of Codex commodity standards or upon the request of Codex Member States.
- c. Regardless of the maximum level specified for an additive in the GSFA, the use of the additive is limited by the principles of good manufacturing practices as specified in the Preamble to the Standard. Application of good manufacturing principles may well result in a level of use below the maximum level specified, the latter of which has been established on a health and safety basis and technologically justified.
- d. The format of the GSFA is based on the INS food additive functional class titles and also on a hierarchical food category system.
- e. The GSFA covers all foods, whether standardized or not.
- f. The food additive provisions of Codex commodity standards shall be included in the GSFA.
- g. The food additive section of Codex commodity standards should refer to the GSFA.
- h. When Codex commodity committees are of the opinion that the food additive provisions in a food category in the GSFA are not applicable to a commodity standard, the Codex commodity committee may request the CCFAC to endorse deviations from the GSFA. Such requests should be fully justified and supported by available scientific evidence and other relevant information. Such a

<sup>21</sup> CX/FAC 02/6 and comments submitted by Canada, Denmark, Israel, Japan, Poland, AAC, CPIV, ENCA, FOSFA, IBFAN, IFMA, IFU (CX/FAC 02/6-Add. 1), Korea, EC, IDF, IMACE/IFMA, CEFS (CRD 5) and India (CRD 6).

<sup>22</sup> ALINORM 01/12A, paras. 57 and 62

decision on the part of a Codex commodity committee should not affect permission to otherwise use the additive in non-standardized foods falling under the same food category in which the excluded standardized food lies.

- i. The primary objective for establishing maximum permitted levels of use of food additives in various food categories is to ensure that the intake of additives does not exceed their acceptable daily intake.
- j. The use of food additives is justified only when such use has an advantage, does not present a hazard to health of and does not mislead the consumer, and only where these objectives cannot be achieved by other means that are economically and technologically practicable.
- k. Priority for establishing maximum permitted levels of use for additives during elaboration of the GSFA should not be given to any group of additives based on functional class or to additives with “low” ADIs.

45. In addition, the Committee agreed to include the principle that “The CCFAC will consider relevant technological justification and need provided by commodity committees when endorsing food additive provisions given in Codex Standards. This information might also be taken into account when considering food additive provisions in similar non-standardized foods”.

46. There was some discussion about possible contradiction between points f) and g), and about i) with respect to potential need to invoke methodologies to ensure intakes for food additives do not exceed their ADIs. The Committee retained f) and g) without change because f) was a responsibility of the CCFAC whereas g) was a responsibility of commodity committees. It agreed that members should be made aware of processes to request placement of additives requiring exposure assessment on the JECFA priority list, apart from those additives for which exposure assessment have already been undertaken. Finally it was agreed that, if possible, ADIs would be entered next to entries in the GSFA Working Group worksheets to assist members in future deliberations.

#### **THE ROLE OF THE CODEX SECRETARIAT**

47. In regard to the role of the Codex Secretariat, the Committee agreed that:
- a. The Codex Secretariat should provide commodity committees with guidance on the GSFA food category in which their commodity standard falls.
  - b. The Codex Secretariat should encourage commodity committees to develop standards that fall within a single GSFA Food Category to avoid confusion in the interpretation of food additive provisions in the GSFA.
  - c. The Codex Secretariat should require commodity committees to identify the INS additive functional classes that meet the technological needs of the commodity and include them in the food additive section of their commodity standard. For example, the food additive section of a commodity standard for a commodity that falls under the food category 12.5 (soups and broth) could state: “Any acidity regulators listed in Table 3 of the General Standard for Food Additives” and “Any acidity regulators listed in Tables 1 and 2 of the General Standard for Food Additives in Food Category 12.5 (Soups and broths).
  - d. The Codex Secretariat should provide commodity committees with Annex C (Cross-reference of Codex commodity standards and the Food Category System) of the Preamble of the GSFA and a full description of the FCS to assist commodity committees in the development of their standards.

#### **THE ROLE OF CODEX COMMODITY COMMITTEES**

48. In regard to the role of Codex commodity committees, the Committee agreed that:
- a. When elaborating standards, commodity committees should only consider additives that have been assigned a full ADI by JECFA and have an assigned INS number. The technical effects assigned by the INS (i.e., those described in the list of added functional classes) and technological functions should be used for identifying the food additive use.
  - b. When elaborating standards, Codex commodity committees should provide the CCFAC with a list of all food additives, including the individual INS number (including any suffixes), within a particular functional class for which the technological need has been justified and may choose to recommend

their appropriate level of use. The CCFAC will incorporate this information in the Draft GSFA for further consideration by the Codex commodity committee.

- c. If equivalency between a Codex commodity standard and a single GSFA food category is unavoidable, then the Codex commodity committee should provide the CCFAC with a list of technical effects consistent with those listed in the INS for which technological need has been justified and whose use will not mislead the consumer. The commodity committee, if appropriate, may recommend to the CCFAC levels of use for specific additives that achieve the identified intended technical effects. The CCFAC will incorporate this information in the draft GSFA for further consideration by the Codex commodity committee

## **THE ROLE OF CCFAC**

49. In regard to the role of the CCFAC, the Committee agreed that:
- a. If food additive provisions are contained in a commodity standard, the CCFAC should consider revising the titles of the food category system to avoid having the same name as a commodity standard.
- b. The CCFAC should propose the following amendment to the guidance in the Procedural Manual for the standard format of commodity standards:
- i) The food additive section should contain the names of the functional classes of additives consistent with those listed in the INS for which a technological need has been justified for the promotion of fair trade practices. The food additive section should be prepared in accordance with guidance given on page 79 of the Codex Alimentarius Procedural Manual concerning the format for Codex Commodity Standards.
- ii) Then should follow the name of the INS “additive functional class” or “technological function” (e.g., acidity regulator, emulsifier), the appropriate Table of the GSFA (e.g., 1 & 2, or 3), and the appropriate GSFA food category.
- c. Once adopted at Step 8 by the Commission, all food additive provisions in commodity standards will be automatically included in the GSFA in the appropriate tables and food category. Recommendations to amend additive usage in standardized foods should be submitted to the respective Codex committee for technological justification and the commodity committee should refer these amendments to the CCFAC for endorsement. If endorsed, the additive provision would be included in the GSFA. Recommendations to amend additive usage in non-standardized foods should be submitted directly to the CCFAC.

## **PREAMBLE OF THE GSFA**

50. The Committee noted the opinion of several delegations, including Spain, on behalf of the European Community, that two of the principles for inclusion of an additive provision in the GSFA might need to be reexamined in the context of a revision to the Preamble of the GSFA. These two principles were:

- The reporting of the use of an additive by a member state in a food category is prima facia evidence for the technological need for the use of an additive.
- If at least two Codex member states permit the use of the additive up to the maximum level proposed in Table 1 and 2 in foods representative of the category, this is evidence of trade of these foods.

51. The Committee decided to install a drafting group under the direction of France/USA, with the assistance of Australia, Brazil, Canada, Italy, Japan, Netherlands, New Zealand, Norway and Switzerland, to elaborate a proposed draft revision to the Preamble of the GSFA as follows:

- Clarify the relationship between the GSFA and Codex commodity Standards
- Elaborate on appropriate criteria in the Preamble for establishing additive provisions in the GSFA
- Reconsider the criterion that reporting of the use of an additive by a member state in a food category is prima facia evidence for the technological need for the use of an additive.

- Reconsider the principle that if at least two Codex member states permit the use of the additive up to the maximum level proposed in Tables 1 and 2 in foods representative of the category, that is evidence of trade of these foods, taking into account the requirements for additives provisions in the Procedural Manual as regards Codex commodity standards.

## **FOOD CATEGORY SYSTEM AND THE GSFA**

52. The Committee reaffirmed the following points to promote the consistent interpretation of the GSFA food category system (FCS):

- a. The FCS is an integral component of the draft GSFA.
- b. The FCS was developed as a tool to simplify the reporting of food additive uses for constructing and elaborating the draft GSFA.
- c. The FCS should allow for the assignment of all foods to a food category, both standardized and non-standardized.
- d. The FCS is intended to be applicable to foods internationally.
- e. The FCS is intended as a basis for identifying food categories for additive intake assessment for the purpose of elaborating the draft GSFA.
- f. The FCS is hierarchical, meaning that when the use of an additive is permitted in a general category, it is automatically permitted in all its sub-categories, unless specific provisions are included.
- g. The FCS food category descriptors are not intended to be legal product designations, sales descriptions nor are they intended for labeling purposes.
- h. The FCS should be revised only to accommodate:
  - i. Foods that do not fit into existing categories.
  - ii. Foods that require the use of new or different food additive functional effects from those reported in existing categories.
  - iii. Foods that require different food additive use levels or restrictions from levels reported in existing categories.
  - iv. Foods for which there are different food consumption patterns; for example, due to differences in processing (e.g., dried vs. ready-to-eat) or in the consuming populations (e.g., infants and children vs. adults).

53. The Committee also reaffirmed that the Codex GSFA does not cover the use of additives in additives or flavors.

54. The Committee agreed to the amended Food Category System as presented in Appendix III of the Report of the Ad Hoc Working Group (CRD 1). However, in view of additional proposals for revisions to the Food Category System, the Committee agreed that a drafting group under the direction of the United States, with the assistance of Australia, India, Japan, Switzerland, Thailand, CEFS, IBFAN, IDF, IFMA, IOCCC, ISDI, OIV, would review the written comments submitted and the above discussions with a view towards elaborating an amended version of the FCS for circulation, comment and further consideration at its next meeting.

## **PASTAS AND NOODLES**

55. With the understanding that there would be few, if any, additives needed in the dried pasta and noodle category, the Committee agreed that Food Category 06.4 “Pasta and Noodles and like products” would be revised by creating three subcategories as follows:

### **06.4.1 FRESH PASTAS AND NOODLES AND LIKE PRODUCTS:**

Pasta and noodle products that are untreated (i.e., not heated, cooked, pre-gelatinated or frozen) and not dehydrated. These products are intended to be consumed soon after preparation. Examples include: unboiled noodles, and "skins" or crusts for spring rolls, wontons, and shuo mai.

**06.4.2 DRIED PASTAS AND NOODLES AND LIKE PRODUCTS:**

Pasta and noodle products that are untreated (i.e., not heated, cooked, pre-gelatinated or frozen) and are dehydrated. Examples include dried forms of: spaghetti, bean vermicelli, rice vermicelli, macaroni, and rice noodles.

**06.4.3 PRE-COOKED PASTAS AND NOODLES AND LIKE PRODUCTS:**

Pasta and noodle products that are treated (i.e., heated cooked, pre-gelatinated, or frozen). These products may be sold directly to the consumer (e.g., pre-cooked, chilled gnocchi to be heated prior to consumption), or may be the starch component of prepared meals (e.g., heat-and-serve frozen dinner entrees containing spaghetti, macaroni or noodles; canned spaghetti and meatballs entrée). Also includes Oriental instant noodles (ramen, sokuseki-men and rice noodles) that are pre-gelatinated and heated prior to sale to the consumer.

**COMMENTS ON TABLE 1 OF THE DRAFT CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 7c)<sup>23</sup>**

56. The 33rd CCFAC forwarded<sup>24</sup> all proposed draft food additive provisions at Step 3 to the 24th Session of the Commission for adoption at Step 5. The 49th Session of the Executive Committee adopted<sup>25</sup> the proposed draft food additive provisions at Step 5. The CCFAC also agreed<sup>26</sup> that several draft maximum levels for food additives in specific food categories be held at Step 6 for additional comment and consideration at the 34th CCFAC.

57. The Committee agreed that aluminium should be included on the JECFA priority list for intake assessment from all food additive uses under consideration and from other dietary sources, and for a full toxicological evaluation.

58. Beeswax (901) and Candelilla wax (902), are both assigned acceptable uses by JECFA as carriers for flavors. Their use in water-based flavored drinks, including “sport” or “electrolyte” drinks and particulated drinks (14.1.4) should be examined since the intake of these additives through carry-over has not been assessed by JECFA. The Committee decided to request JECFA to do this intake assessment.

59. Spain, speaking on behalf of the European Community and supported by several other countries, raised concerns about the limit of 1000 mg/kg benzoates in Category 14.1.4 (water-based flavoured drinks, including “sport” or “electrolyte” drinks and particulated drinks), suggesting a limit of 150 mg/kg taking into particular account childrens exposure in relation to the ADI. The delegation of the United States, citing a 14 day survey of intake recently undertaken, pointed out that the mean and 90th percentile consumers were well below the ADI. Several other countries supported this position. The Committee decided to return this entry to Step 6 for further consideration at the 35th Session of CCFAC as to the technological need in different regions. The data required includes information on climatic differences and specific types of soft drinks requiring higher levels.

**Status of Revisions to Table 1 of the Codex General Standard for Food Additives**

60. The Committee agreed that as a matter of principle, all food additives assigned a numerical ADI by JECFA should have a numerical limitation on their use in the GSFA. In this regard, the Committee agreed to hold all GMP provisions for these additives (i.e., with numerical ADIs) at Steps 3 or 6 so that specific numeric levels of use could be provided before its 35th Session. The Committee also agreed to hold food additive provisions with specific numeric levels at Steps 3 and 6 and to request additional information, including technological need and justification, for their use (see Appendix III). In both cases above, if this information was not provided by the 35<sup>th</sup> Session, the Committee agreed that these provisions would be

<sup>23</sup> Comments submitted in response to CL 2001/13-FAC and CL 2001/34-FAC from Australia, Brazil, Canada, Cuba, Japan, Poland, Spain, EC, ENCA, IADSA, IBFAN, IFAC (CX/FAC 02/7), Cuba, EC, CEFS, IFCGA, IFU (CRD 6).

<sup>24</sup> ALINORM 01/12A, para. 64 and Appendix III

<sup>25</sup> ALINORM 03/3, para. 18 and Appendix II

<sup>26</sup> ALINORM 01/12A, para. 65 and Appendix IV

deleted from the GSFA. In correlation to this decision, Switzerland asked when Table 1 adopted additives with numerical ADIs assigned with GMP proposals would be discussed. The Committee also agreed to apply these principles to already adopted additives at a future meeting.

61. The Committee also agreed to forward the provisions listed in Appendix II to the Commission for final adoption at Step 5/8 or 8 as amendments to the Standard.

### **COMMENTS ON THE DRAFT REVISED ANNEX TO TABLE 3 OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 7d)<sup>27</sup>**

62. The 33rd CCFAC forwarded<sup>28</sup> amendments to the Annex to Table 3 (Food Categories or Individual Food Items Excluded from the General Conditions of Table 3) of the Codex General Standard for Food Additives to the 24th Session of the Commission for adoption at Step 5/8. The Commission adopted<sup>29</sup> all proposed revisions to the Annex to Table 3 at Step 5 only.

63. The Committee noted concerns expressed by IBFAN and the OIV as to the excessive use of additives in categories 13.1/13.2 and 14.2.3, respectively and decided that these concerns would be discussed in the Working Group at the 35th CCFAC.

64. The Committee agreed to revisions to the Annex to Table 3 as proposed by the Working Group and decided to request additional comments at Step 6 for further consideration at its next meeting (see Appendix IV).

### **DISCUSSION PAPER ON PROCESSING AIDS AND CARRIERS (Agenda Item 8)<sup>30</sup>**

65. The 33rd Session of the CCFAC agreed<sup>31</sup> that a drafting group lead by New Zealand would prepare a discussion paper on the consideration of processing aids and carriers in the context of the Codex General Standard on Food Additives for circulation, comment and further consideration at its next meeting. The Committee also agreed that comments would be requested on document CX/FAC 01/10 by Circular Letter (CL 2001/13-FAC) to the 33rd CCFAC report for consideration by the drafting group.

66. The delegation of New Zealand gave a short introduction to the discussion paper by highlighting the main issues: definitions of processing aids, the definition and inclusion of carriers, consideration of a horizontal approach to processing aids and the role of the existing Inventory of Processing Aids.

67. Several delegations felt that the definition of a processing aid could be clarified and distinguished from a food additive by adding an indication that it has no technological effect in the final product. Many delegations felt that the Inventory of Processing Aids was a useful tool as an internal document provided the information in it was correct. There was general support for a horizontal approach to processing aids, however several delegations felt also that the Committee should focus on the GSFA and that processing aids and carriers should have a lower priority.

### **Status of the Discussion Paper on Processing Aids and Carriers**

68. As comments were not requested on document CX/FAC 02/9, the Committee decided to request comments on the current paper by means of the Circular Letter to this report. It was agreed that comments submitted would be further considered at the next meeting.

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<sup>27</sup> Comments submitted in response to CL 2001/34-FAC from Argentina, Japan, EC and ISPI (CX/FAC 02/8).

<sup>28</sup> ALINORM 01/12A, para. 50 and Appendix VI

<sup>29</sup> ALINORM 01/41, paras. 135-136 and Appendix IV

<sup>30</sup> CX/FAC 02/9 and CX/FAX 02/9-Add. 1 (not issued)

<sup>31</sup> ALINORM 01/12A, paras. 67 and 71.



## **DISCUSSION PAPER ON THE USE OF ACTIVE CHLORINE (Agenda Item 9)<sup>32</sup>**

69. The 33rd Session of the Codex Committee on Food Additives and Contaminants agreed<sup>33</sup> that Denmark, in cooperation with Finland, Israel, Norway and WHO, would prepare a Discussion Paper on the Use of Active Chlorine for consideration by the next CCFAC in view of the potential adverse effects of this chemical on health.

70. The Committee noted that active chlorine was commonly utilised as a food additive or decontaminating/disinfecting agent in water treatment or surface treatment of foodstuffs. In this regard, a number of delegations pointed out that safety problems that might be associated with the use of this compound were mainly related to inappropriate handling or misuse. It was noted that the work of CCFAC in this respect should not prevent countries from using this chemical in the prevention of microbial contamination that might occur in water or food. Other delegations indicated that the CCFAC should take account of the work being done in other Codex Committees and, in this regard, suggested that the Committee could work together with the Codex Committee on Food Hygiene in addressing this issue.

71. The Committee recognised the need for active chlorine to be assessed on a global basis by JECFA. In this regard, it was indicated that any risk assessment should take into account different uses of this compound including by-products of reactions between active chlorine and organic materials in food or water for food processing. The JECFA secretariat indicated that any question put to JECFA on the issue must be clear as to just exactly what aspect(s) are to be assessed. The delegation of the United States stated that both the microbiological and chemical risks must be considered and this could best be done by a FAO/WHO expert consultation.

72. The Representative of WHO indicated that the *WHO Guidelines for Drinking Water Quality* recommended a maximum level of 5 ppm of active chlorine and indicated that this level was both safe and protective of consumer's health. He drew the attention of the Committee to the fact that restrictions on the use of active chlorine in water treatment in food processing might compromise the benefits of reducing microbial contamination and public health. He strongly suggested that the CCFAC continue to study this issue so that all public health risk/benefits be considered in order that the health of consumers not be put at risk.

### **Status of the Discussion Paper on the Use of Active Chlorine**

73. In view of the above discussion, the Committee agreed that the Discussion Paper should be revised by Denmark, in cooperation with Finland, Israel, Norway and WHO, in light of the above discussion and comments to be submitted in response to a Circular Letter appended to this report, for circulation, comment and further consideration at its next meeting.

## **DRAFT REVISED CODEX GENERAL STANDARD FOR IRRADIATED FOODS (Agenda Item 10a)<sup>34</sup>**

74. The 33<sup>rd</sup> CCFAC forwarded<sup>35</sup> the proposed draft revised Codex General Standard for Irradiated Foods to the 24<sup>th</sup> Session of the Commission for adoption at Step 5. The 49<sup>th</sup> Session of the Executive Committee adopted<sup>36</sup> the proposed draft revised Standard at Step 5. The Committee considered Appendix VII of ALINORM 01/12A as the basis for its discussions.

75. The Committee agreed to revise the first sentence of Section 1 - Scope to read "This standard applies to food processed by ionizing radiation that is used in conjunction with applicable hygienic codes, food

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<sup>32</sup> CX/FAC 02/10

<sup>33</sup> ALINORM 01/12A, para. 204.

<sup>34</sup> Comments submitted in response to CL 2001/34-FAC from Argentina, Poland, USA, CI, EC, IAEA (CX/FAC 02/11), India (CRD 7) and Philippines (CRD 20).

<sup>35</sup> ALINORM 01/12A, para. 85 and Appendix VII

<sup>36</sup> ALINORM 03/3, para. 19 and Appendix II

standards and transportation codes". After some discussion, the Committee decided to retain the second sentence in its current form.

76. Despite the opposition of the delegation of Spain, speaking on behalf of the EC, several countries had indicated that they were using or were planning to use Cesium-137 as a radiation source. The Committee therefore agreed to amend Section 2.1 - Radiation Sources, Subsection (a) to include Cesium-137 (<sup>137</sup>Cs), so that Section (a) reads as "Gamma rays from the radionuclides <sup>60</sup>Co or <sup>137</sup>Cs".

77. The delegate of the Philippines proposed to delete the reference to an upper limit of 10 kGy, which appeared in square brackets in Section 2.2 - Absorbed Dose. She stated that such a limit was not necessary in the light of the report of the FAO/IAEA/WHO Study Group on high dose irradiation.<sup>37</sup> This recommendation was supported by Argentina, Australia, Brazil, China, India and ICGFI. The delegate of Spain, on behalf of the EC, proposed to retain the reference without square brackets because of toxicity concerns for 2-alkylcyclobutanones. An assessment being undertaken by the Scientific Committee for Food is not yet complete and while the representative of the EC was unable to give a date when the final report would be available, it will be published, made available to all concerned, and the data can be used by JECFA for further assessment.

78. Sweden questioned the need to delete the overall average dose of 10 as there were no applications known above 10 which would have an effect on international trade. However, the delegate of Australia noted that they had recently approved irradiation of herbs and spices up to a dose of 20 kGy. Consumers International suggested that it would be useful if countries could provide more information on their use of high dose food irradiation in order to facilitate the justification of technological need.

79. The WHO Representative noted that the FAO/IAEA/WHO Study Group conclusion that food irradiated to any dose appropriate to achieve the intended technical objective was both safe to consume and nutritionally adequate was still valid as no credible scientific evidence has been provided to the contrary. He noted that concerns about the safety of alkylcyclobutanones reported in a recent EC-supported study could not be substantiated because the three organizations could not obtain a copy of the report for review. However, he emphasized that WHO was willing to re-open any risk assessment if new evidence indicated a public health risk. He informed the Committee that JECFA would be able to consider the study at its meeting in June 2002 if it could be made available in the near future.

#### **Status of the Draft Revised Codex General Standard for Irradiated Foods**

80. To facilitate the revision of the Standard, the delegate of the Philippines requested that the question of the need for a limit of 10 kGy be linked to the results of the EC-supported study on the toxicity of 2-alkylcyclobutanones and that the EC provide the report of the study to JECFA for evaluation (see Agenda Item 17).

81. Because of the volume of comments received, the Committee agreed to suspend further discussion and to request a drafting group led by the Philippines and assisted by Australia, China, France, Germany, India, Japan, Korea, Poland, Sweden, Thailand, United Kingdom, United States, CI, EC, ICGFI, FAO and WHO to revise the current Standard on the basis of the written comments submitted and the committee's discussions for circulation, additional comment and further consideration at its next meeting.

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<sup>37</sup> *Report of the Joint FAO/IAEA/WHO Study Group on High Dose Irradiation, WHO Technical Report Series 890, WHO, Geneva (1999)*

**PROPOSED DRAFT REVISED RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR RADIATION PROCESSING OF FOOD (Agenda Item 10b)<sup>38</sup>**

82. The 33<sup>rd</sup> CCFAC decided<sup>39</sup> that the Recommended International Code of Practice for Radiation Processing of Food would be revised by the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture based on the Committee's discussions and written comments submitted for circulation, comment and further consideration at its next Session. The 49<sup>th</sup> Session of the Executive Committee approved<sup>40</sup> the elaboration of the proposed draft revised Code of Practice as new work. The Committee considered CX/FAC 01/12 as a basis for its discussions.

83. The representative of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture introduced the comments submitted by the EC and the USA. She noted that the comments improved the text and were mainly editorial in nature except for proposed changes in Sections 5.3.5 and 6.3 as discussed below. In addition, she noted that a proposal by the EC to amend Section 8 Labelling could only be made after agreement was reached on labelling requirements in the General Standard for Irradiated Food and in consultation with the Codex Committee on Food Labelling.

84. The Committee agreed to include the following new first paragraph to Section 5.3.5:

“An adequate system should be in place so that specific consignments of food products can be traced back both to the irradiation facility and the source from which they were received for processing.”

85. The Committee also agreed to revise the second sentence of the second paragraph in Section 6.3 to read:

“Relevant ISO/ASTM Standard Practices and Guides for dosimetry in food irradiation facilities have been developed and should be consulted”.

86. The Committee also agreed to revise footnote 5 to the above sentence to read:

“ISO/ASTM 51204 – Standard Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing; ISO/ASTM 51431 – Standard Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing; and, ISO/ASTM 51261 – Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing”.

87. The Committee reached the following conclusions concerning the Code:

- Paragraph 2 of Section 2.1 - Scope was amended so that “primary production and harvesting” read as “primary production and/or harvesting”. This change was also made to the title and text of Section 3.1 – Primary Production and/or harvesting.
- Sentence 1 of Section 2.3 – Definitions was amended to delete the words “and expressions”.
- In Section 2.3 – Definitions the phrase “electron beams” was revised to “accelerated electrons” in the definition for Food Irradiation.
- Paragraph 9 of Section 2.3 – Definitions, the term and definition for Authorization of Facility to Irradiate Food was moved to Section 5.
- Sentence 2 of paragraph 3 of Section 5.1 - Design and Layout was revised to insert the word “dose” before the word “uniformity”.
- Sentence 2 in Section 5.3.1 - Legislation was amended to insert the phrase “like any other food processing plant” after “A food irradiation facility”.
- The last sentence in paragraph 2 of Section 6.5 - Dosimetry and process control was deleted.

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<sup>38</sup> CX/FAC 01/12 and comments submitted by the United States (CX/FAC 01/12 - Add. 1) and the EC (CX/FAC 01/12 – Add. 2).

<sup>39</sup> ALINORM 01/12A, para. 89

<sup>40</sup> ALINORM 03/3, Appendix III

- Section 9 - Competency was deleted and footnote 10 was moved to Section 5.3.2 - Requirements for staff.
- Footnote 5 was revised.
- Footnote 6 was revised to read “ISO/ASTM 51261 – Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing”.
- Footnote 7 was revised.
- Footnote 8 was revised to read “ISO/ASTM 51204 – Standard Practice or Dosimetry in Gamma Irradiation Facilities for Food Processing and ISO/ASTM 51431 – Standard Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing”.

### **Status of the Proposed Draft Revised Recommended International Code of Practice for Radiation Processing of Food**

88. The Committee forwarded the proposed draft revised Recommended International Code of Practice for Radiation Processing of Food (see Appendix V) to the Commission for adoption at Step 5/8 (with the omission of Steps 6 and 7).

### **REPORT OF THE AD-HOC WORKING GROUP ON SPECIFICATIONS (Agenda Item 11a)<sup>41</sup>**

89. The 33rd Session of the CCFAC decided<sup>42</sup> to reconvene the ad hoc Working Group on Specifications prior to its current session under the Chairmanship of the USA. The ad hoc Working Group was chaired by Dr. P. Kuznesof (USA). Mrs. H. Wallin (Finland) acted as Rapporteur and Mrs. I. Meyland (Denmark) acted as Category Monitor. The recommendations of the report of the ad hoc Working Group (CRD 2) were considered by the Committee under Agenda Item 11(b).

90. The Committee was informed that 12 additives which had been removed from the draft GSFA and referred by the Committee to JECFA for evaluation, were removed from the agenda of the 57<sup>th</sup> meeting of JECFA in 2001 because there was no information that these additives were currently used and available data did not permit establishment of an ADI and specifications.

91. The Committee was informed that the Working Group discussed and provided feedback to the Joint Secretariat on general matters published in Section C of FNP 52 Add.9 as outlined in CRD 2. The Committee took notice of the information provided to the Working Group by the representative of the European Commission, which related to ongoing work within the European Union on the safety evaluation and establishment of purity criteria of approximately 2700 flavouring agents. The representative of the European Commission noted that the EC programme intended to avoid duplication of work with JECFA.

92. The Committee thanked the ad hoc Working Group for its efforts, and agreed to re-establish the ad hoc Working Group on Specifications to meet, under the Chairmanship of the USA, prior to the 35th Session of the CCFAC.

### **SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 57<sup>th</sup> MEETING OF THE JECFA (Agenda Item 11b)<sup>43</sup>**

93. The Committee forwarded 60 food additive specifications and 276 flavouring agent specifications in Category I to the Commission for adoption at Step 5/8 as Codex Advisory Specifications. Of the 60 food additive specifications, 42 specifications for anticaking agents (6), flavour enhancers (17), sweetening agents (11), and thickening agents (8) were forwarded for adoption of new limits for specific heavy metals like lead and arsenic. The limits for Heavy Metals (as lead) were deleted.

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<sup>41</sup> CRD 2

<sup>42</sup> ALINORM 01/12A, para 94

<sup>43</sup> Comments submitted in response to CX/FAC 02/13 from AAC, AMFEP (CX/FAC 02/13-Add. 1), Denmark, ESI and ISA (CRD 8).

94. The Committee agreed to forward one food additive specification in Category II to the Commission for adoption as a Codex Advisory Specification after editorial changes, and to refer back to JECFA for further revision. The General Specifications and Considerations for Enzyme Preparations used in Food Processing The Committee was informed that JECFA had withdrawn the tentative specifications for two food additives (oxystearin and tartaric, acetic, and fatty acid esters of glycerol, mixed).

#### **Status of the Specifications for the Identity and Purity of Food Additives Arising from the 57th JECFA Meeting**

95. Specifications in Categories I and II that were forwarded to the Commission for adoption as Codex Advisory Specifications at Step 5/8 are attached at Appendix VI.

#### **PROPOSED AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM (Agenda Item 12)<sup>44</sup>**

96. The 33rd CCFAC agreed to request comments for additional revisions to the INS System on a standing basis. The Committee also agreed<sup>45</sup> to circulate INS Number 452 (vi) for Sodium Potassium Tripolyphosphate as an emulsifier, stabilizer, acidity regulator, raising agent, sequesterant and water retention agent at Step 3 of the accelerated procedure for comments, subject to approval by the Executive Committee. The 49th Session of the Executive Committee approved<sup>46</sup> the use of the Accelerated Procedure in regard to Sodium Potassium Tripolyphosphate.

97. The Committee agreed to the recommendations of the *ad hoc* Informal Working Group on the International Numbering System, which was chaired by H. Wallin (Finland), as follows:

- Forwarded INS 452(vi) for Sodium potassium tripolyphosphate as an emulsifier, stabilizer, acidity regulator, raising agent, sequesterant and water retention agent to the Commission for final adoption at Step 5 of the Accelerated Procedure.
- Forwarded various new INS Numbers or revised text for compounds 163(iv), 163(v), 165, 407, 445, 650, 949 and 961 to the Commission for final adoption at Step 5/8.
- Forwarded various amendments to INS numbers for Mineral Oil to the Executive Committee for preliminary adoption at Step 5.
- The Codex Secretariat would prepare a Discussion Paper on the Harmonization of Terms Used by Codex and JECFA for Functional Sub-Classes and Technological Functions for consideration at the next CCFAC meeting.
- A substance consisting of chemical reaction products of INS numbered compounds (e.g. acesulfame-aspartame salt) should be assigned a new INS number.

98. The Committee also noted that the assignment of INS numbers to Invertase from *Saccharomyces cerevisiae*, Beta-carotene from *Blakeslea trispora* and D-tagatose would be considered at its next meeting.

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

99. The Committee forwarded draft and proposed draft amendments to the International Numbering System for Food Additives to the Executive Committee and the Codex Alimentarius Commission for preliminary or final adoption as indicated above (see Appendix VII).

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<sup>44</sup> Comments submitted in response to CL 2001/13-FAC from Brazil, Canada, Israel, Spain, USA, EC, ISDC (CX/FAC 02/14), Cuba, Japan, ISA (CRD 9).

<sup>45</sup> ALINORM 01/12A, para. 96-99 and Appendix IX

<sup>46</sup> ALINORM 03/3, Appendix III

## **ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX STANDARDS (Agenda Item 13)<sup>47</sup>**

100. The Committee noted that no maximum levels for contaminants had been submitted for endorsement since its 33<sup>rd</sup> Session and therefore, no action was required.

## **CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (GSCT) (Agenda item 14)**

### **REPORT OF THE AD HOC WORKING GROUP ON CONTAMINANTS AND TOXINS (Agenda item 14a)<sup>48</sup>**

101. The 33<sup>rd</sup> Session of the CCFAC decided<sup>49</sup> to reconvene the ad hoc Working Group on Contaminants and Toxins prior to its 34<sup>th</sup> Session. The Working Group was chaired by Dr. Torsten Berg (Denmark); Dr. Cecilia Toledo (Brazil) acted as Vice-Chair and Dr. Luba Tomaska (Australia), Ms. Frederique Heering (the Netherlands) and Ms. Nathalie Scheidegger (the Netherlands) acted as rapporteurs.

### **Future Status of the Ad Hoc Working Group on Contaminants and Toxins**

102. The Committee decided to reconvene the ad hoc Working Group on Contaminants and Toxins prior to its next Session under the Chairmanship of Denmark.

### **SCHEDULE 1 OF THE PROPOSED DRAFT CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (Agenda item 14b)<sup>50</sup>**

103. The 33<sup>rd</sup> CCFAC reiterated<sup>51</sup> its recommendation that the Netherlands should elaborate Schedule 1 to the Codex General Standard for Contaminants and Toxins in Foods for consideration at its current meeting.

104. The Committee agreed that the Netherlands would update and present Schedule 1 every year. Schedule 1 would contain two lists, i.e. List 1 with MLs for contaminants and toxins already adopted as final texts and List 2 with MLs for contaminant and toxins under discussion at different steps of the Codex procedure. It was understood that Schedule 1 would be used as a working document during the Working Group and the plenary sessions.

105. The Codex Secretariat was also requested to investigate the feasibility of providing an updated version of Schedule 1 in electronic form.

### **PROPOSED DRAFT PRINCIPLES FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS (Agenda Item 14c)<sup>52</sup>**

106. The 33<sup>rd</sup> CCFAC decided<sup>53</sup> that a drafting group led by Australia and France would elaborate proposed draft Principles for Exposure Assessment of Contaminants and Toxins in Foods for circulation, comment and further consideration at its 34<sup>th</sup> Session, with the understanding that the proposal would need to be approved as new work by the Commission. The 49<sup>th</sup> Session of the Executive Committee approved<sup>54</sup> the elaboration of the proposed draft Principles as new work.

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<sup>47</sup> CX/FAC 02/15

<sup>48</sup> CRD 3

<sup>49</sup> CX/FAC 01/12A, para. 113.

<sup>50</sup> CX/FAC 02/16

<sup>51</sup> ALINORM 01/12A, para. 118

<sup>52</sup> CX/FAC 02/17 and comments submitted by Canada (CX/FAC 02/17-Add.1), France and the European Community (CRD 10).

<sup>53</sup> ALINORM 01/12A, paras. 122 and 126

<sup>54</sup> ALINORM 03/3, Appendix III

107. The Committee was informed that the Principles proposed criteria to determine when food/food groups are considered to be a significant contributor to exposure to a contaminant or toxin through food. Annex 1 to the paper proposed components of exposure assessment performed by JECFA for a transparent, consistent and science-based risk assessment for contaminants and toxins in food. Annex 2 and 3 of the paper proposed the CCFAC policy for the different activities of the JECFA, CCFAC and member states in the risk analysis procedure.

108. The Committee agreed to change the title of Annex 1 to read as the “CCFAC Principles for Exposure Assessment of Contaminants and Toxins in Food or Food Groups”.

### **Status of the Proposed Draft Principles for Exposure Assessment of Contaminants and Toxins in Foods**

109. The Committee agreed that the CCFAC Principles for Exposure Assessment of Contaminants and Toxins in Foods (Annexes I, II and III of CX/FAC 02/17) would be circulated for comments at Step 3 (see Appendix VIII). The Committee further agreed that the Principles would be revised by the drafting group<sup>55</sup> for circulation, additional comment and further consideration at the next Session .

110. The Committee also agreed to forward the entire Proposed Draft Principles for Exposure Assessment of Contaminants and Toxins in Foods to JECFA (CX/FAC 02/17) for comments.

### **MYCOTOXINS IN FOOD AND FEED (Agenda item 15)**

#### **COMMENTS ON THE DRAFT MAXIMUM LEVEL FOR OCHRATOXIN A IN WHEAT, BARLEY AND RYE AND DERIVED PRODUCTS (Agenda item 15a)<sup>56</sup>**

111. The 33<sup>rd</sup> CCFAC forwarded<sup>57</sup> the proposed draft maximum level of 5 µg/kg Ochratoxin A in Wheat, Barley and Rye and Derived Products to the Commission for adoption at Step 5. The 49<sup>th</sup> Session of the Executive Committee adopted<sup>58</sup> the proposed draft maximum level at Step 5.

112. The delegations of India and Argentina, supported by several other delegations, indicated that, as the JECFA evaluation at its 56th meeting (February 2001) had showed that the difference in health risk between the two limits of 5 µg/kg and 20 µg/kg was negligible, a level of 20 µg/kg could be adequate in terms of food safety.

113. Other delegations indicated that, as the principle of setting MLs within the CCFAC should be based on the ALARA (As Low As Reasonable Achievable) principle, a level of 5 µg/kg was justified. Moreover, the French delegation, supported by the EC and other delegations, indicated that the JECFA in its 56th meeting (February 2001) stated that the mean contamination value of raw cereals found was 1 µg/kg, clearly indicating that a value of 5 µg/kg seemed to be reasonably achievable. These delegations also indicated that there seems to be no problem in international trade with the 5 µg/kg level.

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

114. After an extensive discussion, the Committee agreed to forward the draft maximum level of 5 µg/kg for Ochratoxin A in raw wheat, barley and rye and derived products to the Commission for final adoption at Step 8, with the understanding that the level will eventually be incorporated into the Codex General Standard for Contaminants and Toxins in Foods (see Appendix IX). The delegation of India expressed its reservation to this decision.

<sup>55</sup> Led by Australia and France, with the assistance of China, Denmark, Ireland, Italy, Japan, the Netherlands, Norway, the Philippines, Spain, Thailand, The United Kingdom, the United States and the IFT.

<sup>56</sup> Comments submitted in response to CL 2001/34-FAC by Argentina (CX/FAC 02/18), India and the EC (CRD 11).

<sup>57</sup> ALINORM 01/12A, para. 145 and Appendix XII

<sup>58</sup> ALINORM 03/3, Appendix II

**COMMENTS ON THE DRAFT MAXIMUM LEVEL FOR PATULIN IN APPLE JUICE AND APPLE JUICE INGREDIENTS IN OTHER BEVERAGES (Agenda Item 15b) <sup>59</sup>**

115. The 32<sup>nd</sup> CCFAC forwarded<sup>60</sup> the draft maximum level of 50 µg/kg for Patulin in Apple Juice and Apple Juice Ingredients in Other Beverages to the Commission for adoption at Step 8. As consensus could not be reached, the 24<sup>th</sup> Session of the Commission returned<sup>61</sup> the draft maximum level to Step 6 for further consideration by the CCFAC.

116. Several delegations and the representative of CI expressed their concern with the level of 50 µg/kg patulin due to the relatively high intake of apple juice by young children and the possibility that this vulnerable group of consumers might exceed the tolerable daily intake. These delegations and the representative of CI indicated that several surveys showed that the mean value of 6-8 µg/kg of patulin indicated that a level of 25 µg/kg seemed to be reasonably achievable.

117. Other delegations indicated that the level of 50 µg/kg patulin would give sufficient protection to the vulnerable consumers, including young children. The delegation of the United States pointed out that the preliminary results of the EC survey indicated that the TDI was not exceeded for any European population groups. Moreover, these delegations indicated that a level of 50 µg/kg seemed to be at this moment not yet reasonably achievable for all regions in the world, even with the use of Good Agricultural Practices.

**Status of the Draft Maximum Level for Patulin in Apple Juice and Apple Juice Ingredients in Other Beverages**

118. The Committee agreed to forward the draft Maximum Level of 50 µg/kg for Patulin in Apple Juice and Apple Juice Ingredients in Other Beverages to the Commission for adoption at Step 8 (see Appendix X). The delegations of Denmark, Germany, Norway, Spain, CI and IACFO expressed their reservation to this decision.

119. The Committee also agreed that the Code of Practice for the Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages should be finalized as soon as possible. Moreover, the Committee agreed to request more data on the level of patulin in apple juice and apple juice ingredients for other beverages in the Circular Letter to this report, and to reconsider the possible reduction of the maximum level of 50 µg/kg to 25 µg/kg once the Code of Practice had been implemented (i.e., after four years).

**PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION OF PATULIN CONTAMINATION IN APPLE JUICE AND APPLE JUICE INGREDIENTS IN OTHER BEVERAGES (Agenda item 15c) <sup>62</sup>**

120. The 33<sup>rd</sup> CCFAC agreed<sup>63</sup> that the delegation of the United Kingdom would revise the proposed draft Code of Practice for the Prevention of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages for circulation, comment and consideration at the 34<sup>th</sup> CCFAC.

121. The Committee agreed to change the term “prevention” to “reduction” in the Title.

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<sup>59</sup> Comments submitted in response to CL 2001/42-FAC by Argentina, Denmark, Poland, South Africa, USA, IFU, ISDU (CX/FAC 02/19), France, Thailand, United Kingdom (CRD 12) and Thailand (CRD 20).

<sup>60</sup> ALINORM 01/12, para. 104 and Appendix X

<sup>61</sup> ALINORM 01/41, para. 118

<sup>62</sup> CX/FAC 02/20 and CX/FAC 02/20-Add. 1 (not issued).

<sup>63</sup> ALINORM 01/12A, para 147



**Status of the Proposed Draft Code of Practice for the Reduction of Patulin Contamination in Apple Juice and Apple Juice ingredients in Other Beverages**

122. The Committee agreed to forward the proposed draft Code of Practice for the Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages to the Executive Committee for preliminary adoption at Step 5 (see Appendix XI).

**PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION OF MYCOTOXIN CONTAMINATION IN CEREALS, INCLUDING ANNEXES ON OCHRATOXIN A, ZEARALENONE, FUMONISINS AND TRICOTHECENES (Agenda item 15d)<sup>64</sup>**

123. The 33<sup>rd</sup> CCFAC agreed<sup>65</sup> to return the proposed draft Code of Practice for the Prevention of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes, for redrafting by a Drafting Group under the direction of the United States for circulation, comment and consideration at the 34<sup>th</sup> CCFAC.

124. The Committee agreed to amend the text on the basis of the comments submitted by Canada and Sweden.

**Status of the Proposed Draft Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes**

125. The Committee agreed to forward the revised proposed draft Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes, to the Executive Committee for preliminary adoption at Step 5 (see Appendix XII).

**DISCUSSION PAPER ON AFLATOXINS IN PISTACHIOS (Agenda Item 15e)<sup>66</sup>**

126. The 33<sup>rd</sup> CCFAC agreed<sup>67</sup> that the delegation of Iran, in collaboration with Sweden, would prepare a discussion paper on aflatoxins in pistachios for consideration at the 34<sup>th</sup> CCFAC.

**Status of the Discussion Paper on Aflatoxins in Pistachios**

127. The Committee agreed to broaden the scope of the Discussion Paper to Aflatoxins in Tree Nuts. The Committee decided that a drafting group led by Iran, with the assistance of Brazil, India, Netherlands, South Africa, Sweden, Thailand, the United Kingdom, the United States, the INC, the WHO and the EC, would revise the Discussion Paper on Aflatoxins in Tree Nuts for circulation, comment and further consideration at its next Session. It was also agreed that information on aflatoxin contamination in tree nuts as well as methods of analysis for the determination of aflatoxins in tree nuts would be requested by circular letter to this report.

128. The Committee also agreed that China, with the assistance of Brazil, Iran, Sweden, Thailand, the UK, the USA and the INC, would elaborate a proposed draft Code of Practice for the Reduction of Aflatoxin Contamination in Tree Nuts for circulation, comment and further consideration at its next meeting. It was understood that this proposal was subject as approval for new work by the Executive Committee.

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<sup>64</sup> CX/FAC 02/21 and comments submitted by Canada and Sweden (CX/FAC 02/21-Add. 1)

<sup>65</sup> ALINORM 01/12A, para. 151

<sup>66</sup> CX/FAC 02/22

<sup>67</sup> ALINORM 01/12A, para. 198

## **INDUSTRIAL AND ENVIRONMENTAL CONTAMINANTS IN FOODS (Agenda Item 16)**

### **COMMENTS ON THE DRAFT MAXIMUM LEVELS FOR LEAD IN FISH, CRUSTACEANS AND BIVALVE MOLLUSCS (Agenda Item 16a)<sup>68</sup>**

129. The 33<sup>rd</sup> CCFAC agreed<sup>69</sup> to return the draft maximum levels for lead in fish, crustaceans and bivalve molluscs to Step 6 for additional comment and further consideration at its 34<sup>th</sup> Session (ALINORM 01/12A, para. 162 and Appendix XIV). As decided under Agenda Item 1, the Committee also agreed to discuss the maximum level for lead in butter and milk fat under this agenda item.

#### **DRAFT MAXIMUM LEVELS FOR LEAD IN BIVALVE MOLLUSCS, CRUSTACEANS AND FISH**

130. The Committee decided that since lead exposure from bivalve molluscs and crustaceans did not significantly contribute to the total dietary lead exposure, the elaboration of maximum levels for bivalve molluscs (1.0 mg/kg) and crustaceans (0.5 mg/kg) should be discontinued, and the Executive Committee should be so informed.

131. Considerable discussion took place on the ML for lead in fish. Many delegations noted that the level of 0.2 mg/kg for fish was too low for several fish species. In view of the many fish species worldwide, it was suggested by the Netherlands to make a list of fish species for which the maximum level would apply. The delegation of the Philippines also noted that the establishment of maximum levels by species would create problems in trade as it was not possible to gather data for all species. The delegation of the Philippines also stated there were no problems in international trade due to lead in fish. Several member states felt that criteria should be developed to determine when lead was considered to be a significant contributor to exposure, as it was not evident that exposure to lead through fish consumption leads to health risks and that more information should be gathered on analytical methods and detection limits. Other delegations expressed the need for low levels since lead was a serious hazard to health, especially for children.

132. The Committee agreed that the discussion on MLs for lead in fish should be continued as there was a potential health risk for consumers (especially for children), consumption of fish took place worldwide and there was extensive trade in fish.

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

133. The Committee decided that the proposed level of 0.2 mg/kg, as well as certain species for which the level might not apply, should be returned to Step 6 with a request for comments by Circular Letter to this report on the following issues (see Appendices XIII and XX):

- Data on actual lead levels in fish (per specie and per treatment, e.g., canned, cooked and fresh fish) and species that should be included in the list of fish species not being able to meet the proposed maximum level for lead of 0.2 mg/kg;
- Information on analytical methods including detection limits
- Information on known or expected problems in trade and data on the relationship between lead exposure through fish consumption and health risks.

134. The delegate of Denmark offered to compile the above data into three annexes for next years session. The delegates from Australia, France, Italy, Korea, Norway, Philippines, Spain, Thailand, United Kingdom, and the EC offered to support Denmark in this work. The Committee also agreed that a discussion paper would not be prepared.

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<sup>68</sup> Comments submitted in response to CL 2001/13-FAC by Australia, Brazil, Canada, Malaysia, Philippines, Spain, USA, EC (CX/FAC 02/23), Cuba, Denmark, India, Korea, EC (CRD 13), Morocco and the Philippines (CRD 20).

<sup>69</sup> ALINORM 01/12A, para. 162 and Appendix XIV.

## **MAXIMUM LEVEL FOR LEAD IN BUTTER**

135. The Committee recalled that at its 33rd Session the Delegation of India had expressed<sup>70</sup> the view that there was no need for a maximum level of 0.05 mg/kg for lead in the Codex Standard for Butter and therefore, the Committee had agreed to request comments on the necessity of such a level. The Committee noted that since butter did not significantly contribute to total dietary intake, the maximum level of 0.05 mg/kg for lead in the Codex Standard for Butter (CODEX STAN A-1 1971, Rev. 1 – 1999) should be deleted, and the Codex Committee on Milk and Milk Products and the Codex Alimentarius Commission should be so informed.

## **MAXIMUM LEVELS FOR LEAD IN MILK AND MILK FAT**

136. The Committee recalled that maximum levels for lead in milk (0.02 mg/kg) and milk fat (0.1 mg/kg) were adopted<sup>71</sup> by the Commission as proposed, and requested the CCFAC to reevaluate the levels. The Delegation of India expressed the opinion that since the maximum level for lead in milk has a footnote that “a concentration factor applies”, there was no need for a separate maximum level for lead in milk fat, as it may very often lead to two different values in milk fat products.

137. The Committee decided that comments should be requested, by Circular Letter appended to this Report, on the maximum levels of lead in milk (0.02 mg/kg) and milk fat (0.1 mg/kg) for further consideration at the next meeting.

## **ELABORATION OF A PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF LEAD IN FOOD**

138. The Committee was informed that the Commission had agreed<sup>72</sup> that the CCFAC should develop a Code of Practice on the Prevention and Reduction of Lead Contamination in Food. In view of this request, the Committee decided that a drafting group under the direction of the United States, with the assistance of Australia, Brazil, Canada, Denmark, India, Italy, United Kingdom, Philippines, Thailand, and OIV would elaborate a proposed draft Code of Practice for the Prevention and Reduction of Lead in Food, subject to confirmation by the Executive Committee.

## **COMMENTS ON THE DRAFT MAXIMUM LEVELS FOR CADMIUM (Agenda Item 16b)<sup>73</sup>**

139. The 33<sup>rd</sup> CCFAC forwarded<sup>74</sup> proposed draft maximum levels for cadmium in various commodities to the Commission for adoption at Step 5. The 49<sup>th</sup> Session of the Executive Committee decided<sup>75</sup> to return all of the above (ALINORM 01/12A, Appendix XV) proposed draft maximum levels to Step 4 in view of the need to consider overall dietary intake data, in particular from staple foodstuffs. The 33<sup>rd</sup> CCFAC also returned<sup>76</sup> proposed draft maximum levels for various commodities (ALINORM 01/12A, para. 170) to Step 3 for circulation, comments and further consideration at its 34<sup>th</sup> Session.

140. The delegation of Japan indicated that epidemiological studies were being undertaken on cadmium and that the results of these studies would be available October 2002. The delegation of the United States, supported by several other delegations, was of the opinion that maximum limits should only be set for the major food groups that contribute to cadmium exposure. These delegations indicated that it would be useful for the CCFAC, before taking decisions on the maximum levels, to request JECFA to perform an exposure and risk assessment of different possible maximum levels of cadmium from the major contributors. In its 55th meeting, JECFA had indicated that the main contributors to cadmium exposure were cereals, fruits,

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<sup>70</sup> ALINORM 01/12A, para. 159.

<sup>71</sup> ALINORM 01/41, 121

<sup>72</sup> ALINORM 01/41, para. 124.

<sup>73</sup> Comments submitted in response to CL 2001/13-FAC by Australia, Brazil, Canada, USA (CX/FAC 02/24), Cuba, India, Japan, Thailand, EC (CRD 14), Morocco and Thailand (CRD 20).

<sup>74</sup> ALINORM 01/12A, paras. 168-169 and Appendix XV

<sup>75</sup> ALINORM 03/3, para. 20 and Appendix II

<sup>76</sup> ALINORM 01/12A, para. 170.

vegetables, meat and molluscs. The delegation of JECFA indicated that the exposure and risk assessment of different possible maximum levels and several food groups would be a very complex and time-consuming activity.

141. The Committee agreed with the opinion of the delegation of Japan that any consideration of setting a maximum level for cadmium in rice should apply to milled rice, as this commodity was the category of rice traded internationally in significant amounts. The Committee agreed that in order to prevent misunderstandings, the codes contained in the Codex Classification of Foods and Animal Feed/Food Categorization System of the Codex General Standard for Contaminants and Toxins in Foods should be added to the list of maximum levels.

### **Status of the Proposed Draft Maximum Levels for Cadmium**

142. The Committee decided to discontinue the setting of maximum levels for crustaceans, liver (cattle, poultry, pig and sheep) and kidney (cattle, poultry, pig and sheep) as these food groups were minor contributors to exposure from cadmium. The Executive Committee would be informed of this decision.

143. The Committee returned the proposed draft maximum levels for fruit; wheat grain; milled rice; soybean and peanuts; meat of cattle, poultry, pig and sheep; meat of horse; vegetables; peeled potatoes, stem and root vegetables; leafy vegetables, fresh herbs, fungi and celeriac and molluscs to Step 3, for circulation, comments and further consideration at its next Session (see Appendix XIV). The Committee agreed to request JECFA to 1) to give distribution curves for the cadmium contamination levels for the food groups mentioned above and, 2) to perform an exposure and risk assessment for cadmium resulting from consumption of foods in the above mentioned food groups taking into account three different levels, i.e., the draft maximum levels presently at step 3, one level lower and one level higher than the proposed draft maximum levels.

### **PROPOSED DRAFT MAXIMUM LEVELS FOR TIN (Agenda Item 16c)<sup>77</sup>**

144. The 31st CCFAC (March 1999) advanced<sup>78</sup> the proposed draft maximum levels for tin (200 mg/kg in liquid canned foods, 250 mg/kg in solid canned foods) to the Commission for adoption at Step 5. The 23rd Session (July 1999) of the Commission decided<sup>79</sup> to hold the proposed draft maximum levels at Step 5 pending the reevaluation of the acute toxicity of tin by the JECFA. The 55th JECFA meeting<sup>80</sup> (June 2000) maintained the provisional tolerable weekly intake (PTWI) of 14 mg/kg. JECFA reiterated the conclusion reached at its 33rd meeting (1989) that the limited human data available indicated that concentrations of 150 mg/kg in canned beverages and 250 mg/kg in other canned foods may produce acute manifestations of gastric irritation in certain individuals. The 33<sup>rd</sup> CCFAC (March 2001) agreed<sup>81</sup> to reexamine the proposed draft levels for tin at its current meeting.

145. The delegation of Thailand, supported by other delegations, indicated that the JECFA had based its conclusion on very limited data, so that more data should be available before taking any decisions on maximum levels. The delegation of Spain, speaking on behalf of the European Community, indicated that the European Scientific Committee on Foods had agreed with the JECFA opinion on the possible acute toxicity of 150 mg/kg in canned beverages and 250 mg/kg in other canned foods, but that in any case, the proposed draft maximum levels for tin were too high. This delegation indicated the need to establish maximum levels as soon as possible, and possibly to set separate levels for canned foods for young children. The delegation of the United Kingdom reported on several possible incidences of tin intoxication in the United Kingdom at levels in the range of 250 mg/kg. The delegation of the United States indicated that more data was needed on levels, the key features causing high tin levels, and also on the technological aspects of using uncoated tin cans.

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<sup>77</sup> CX/FAC 02/25

<sup>78</sup> ALINORM 99/12A, para. 131 and Appendix IX

<sup>79</sup> ALINORM 99/37, paras. 185-186.

<sup>80</sup> Report of the 55th Meeting of JECFA, WHO Technical Report Series 901.

<sup>81</sup> ALINORM 01/12A, para. 112

### **Status of the Proposed Draft Maximum Levels for Tin**

146. The Committee returned the maximum levels for tin (200 mg/kg in liquid canned foods and 250 mg/kg in solid canned foods) to Step 3 for circulation, comments and further consideration at its 35th Session (see Appendix XV). The Committee agreed to request information on acute toxicity, the levels in liquid canned foods and solid canned foods and the technological aspects in regard to the use of lacquered and non-lacquered cans in the Circular letter to this report.

147. The Committee also agreed that the delegation of Australia would revise the Discussion Paper on Tin for circulation, comments and further consideration at its 35th Session.

### **POSITION PAPER ON DIOXINS AND DIOXIN LIKE PCBs, INCLUDING METHODS OF ANALYSIS FOR DIOXINS AND DIOXIN LIKE PCBs (Agenda item 16d)**<sup>82</sup>

148. The 33<sup>rd</sup> CCFAC agreed that the Netherlands would revise the Position Paper on Dioxins and Dioxin Like PCBs for circulation, comment and consideration at the 34<sup>th</sup> CCFAC. The Committee also requested governments to submit all available information on methods of analysis for dioxins and dioxin like PCBs in foods and feedingstuffs to the delegation of the Netherlands.<sup>83</sup>

149. The Committee was informed that the revised Position Paper took account of the results of the 57th JECFA meeting (June 2001) and that the data on levels and regulations in several member states were included.

150. The delegation of the WHO informed the meeting that the Stockholm Convention on Persistent Organic Pollutants (POPs), which included dioxins and dioxin-like PCBs, contained useful information for the CCFAC. This delegation also informed the meeting about a third survey of dioxin-levels in breast milk as an indicator of general dioxin-contamination in the environment, and invited member states to participate in this ongoing survey. The delegation of IBFAN indicated concern about the risk of prenatal and postnatal exposure of infants who are at the end of the food chain and suggested that it was therefore important to reduce dioxin-levels in breast milk.

151. Many delegations indicated that the Position Paper should be kept on the agenda of the CCFAC, as it was important to reduce global dioxin levels in the environment and in food. They recognized the lack of data on dioxins in foods and feedingstuffs from most regions of the world. These delegations indicated that it was important to reduce dioxin levels by a combination of source directed measures and the setting of maximum levels in the future for dioxins and dioxin-like PCBs in foods and feedingstuffs, as it might be possible that in some countries or regions, the lifelong median intake will exceed the PTMI as set by the JECFA. Other delegations argued that the CCFAC should focus only on source directed measures as the most effective tool to reduce dioxin levels on a global level.

152. Several delegations indicated that there was a need for inexpensive, practical and validated analytical (screening) methods to determine dioxins and dioxin-like PCBs, especially for use by developing countries. The Committee was informed that the CCMAS was considering analytical methods for dioxins and dioxin-like PCBs and that the next Session of the CCMAS would take place in November 2002 (see Agenda Item 18a).

### **Status of the Position Paper on Dioxins and Dioxin-Like PCBs, Including Methods of Analysis for Dioxins and Dioxin Like PCBs**

153. The Committee agreed that it should focus its discussions on dioxins and dioxin-like PCBs only and that non-dioxin like PCBs should not be considered at present. The Committee agreed that it should not draft maximum levels at this time. The Committee agreed that the Netherlands, assisted by Argentina, Belgium, Brazil, Canada, Iceland, Japan, Korea, Norway, the United Kingdom, the United States, the EC and the FEFAC, would revise the Position Paper on Dioxins and Dioxin Like PCBs, including Methods of Analysis for Dioxins and Dioxin Like PCBs, to take account of the above discussions and the comments received for circulation,

<sup>82</sup> CX/FAC 02/26 and comments submitted by Australia, Brazil, Germany, EC (CX/FAC 02/26-Add.1), Argentina, Cuba, India, USA, CIAA, EC (CRD 15), Canada, Japan, Philippines (CRD 20)

<sup>83</sup> ALINORM 01/12A, paras. 176-177.

additional comments and further consideration at its next Session. The Committee stressed the need of collecting data on dioxin levels in foods and feedingstuffs as well as exposure data from regions outside Europe. The Committee also agreed to request information on actual dioxin and dioxin-like PCB levels and information on inexpensive, quick and validated analytical (screening, confirmation) methods in the Circular Letter to this report.

**PROPOSED DRAFT CODE OF PRACTICE FOR SOURCE DIRECTED MEASURES TO REDUCE DIOXIN CONTAMINATION OF FOODS (Agenda item 16e)<sup>84</sup>**

154. The 33<sup>rd</sup> CCFAC agreed<sup>85</sup> to return the proposed draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin Like PCB Contamination of Foods to Step 2 for revision under a drafting group led by Germany for circulation, comment and consideration at the 34<sup>th</sup> CCFAC.

155. The delegations of the United States and Canada indicated that the text on the reduction of chlorine dioxide as a bleaching agent in paper pulp production by chlorine-free bleaching in paragraph 10 should be deleted as the use of chlorine dioxide in pulp and paper manufacturing, as a substitute for chlorine, had led to a marked reduction of emissions of dioxins in the environment.

**Status of the Proposed Draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin-like PCB Contamination of Foods**

156. The Committee agreed to request comments on the proposed draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin Like PCB Contamination of Foods (CX/FAC 02/27) in the Circular Letter to this report. On the basis of the comments submitted, the proposed draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin Like PCB Contamination of Foods would be revised by the drafting group led by Germany, with the assistance of Canada, Finland, Japan, the Netherlands, the United States and the CEFC, for circulation, additional comments and further consideration at its next Session.

**POSITION PAPER ON CHLOROPROPANOLS (Agenda item 16 f)<sup>86</sup>**

157. The 33<sup>rd</sup> CCFAC requested<sup>87</sup> the drafting group led by the United Kingdom to revise the Position Paper on Chloropropanols for circulation, comment and consideration at the 34<sup>th</sup> CCFAC.

158. The delegation of Thailand pointed out that industries and government of Thailand have worked on the process of production of soy sauce made from acid-HVP and have been able to reduce 3-MCPD down to the level of 1 mg/kg. At this level, it is sufficient to protect consumers health and technologically achievable, therefore, setting the maximum level for 3-MCPD in soy sauce made from acid-VP at 1 mg/kg was proposed. Most delegations and the representative of the IHPC were in favour of setting maximum levels for chloropropanols in non-naturally fermented soy-sauce and hydrolyzed vegetable protein (HVP) as soon as possible as international trade problems existed at the moment. Some delegations indicated that limits should only be set for non-naturally fermented soy sauces. The delegation of the United Kingdom indicated that also other food groups like bread and meat might contribute to the chloropropanol exposure in food, but that more data was needed.

159. The 57<sup>th</sup> JECFA meeting (June 2001) had indicated that 1,3-DCP could be considered controllable by controlling the levels of its precursor, 3-MCPD, based on the fixed ratio found on the basis of the data available to JECFA at that moment. The delegation of the United Kingdom indicated that recent surveys showed that the ratio between 3-MCPD and 1,3 DCP was not as fixed as was reported by the JECFA meeting.

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<sup>84</sup> CX/FAC 02/27 and CX/FAC 02/27-Add. 1 (not issued)

<sup>85</sup> ALINORM 01/12A, para. 180

<sup>86</sup> CX/FAC 02/28 and comments submitted by Australia (CX/FAC 02/28-Add. 1), Australia, Japan, Thailand, CIAA, EC, IHPC (CRD 16) and the Philippines (CRD 20)

<sup>87</sup> ALINORM 01/12A, para. 182

### **Status of the Position Paper on Chloropropanols**

160. The Committee agreed that the United Kingdom, with the assistance of Canada and the United States, would revise the Position Paper on Chloropropanols, taking into account the comments received, including a proposal for maximum levels for chloropropanols in relevant foodstuffs, for circulation, additional comments and further consideration at its next Session.

### **DISCUSSION PAPER ON DEOXYNIVALENOL (Agenda Item 16g)<sup>88</sup>**

161. The 33<sup>rd</sup> CCFAC agreed<sup>89</sup> that a drafting group under the direction of Belgium would elaborate a Discussion Paper on Deoxynivalenol for consideration at its current meeting.

162. The delegation of Belgium, supported by several other delegations, indicated that the analytical methods for Deoxynivalenol and mean intakes from 4 out of 5 regions were available. It was stressed that the presence of Deoxynivalenol in cereals was affected by Good Agricultural Practices and levels may vary dramatically from year to year, but also that levels are highly dependent on climatic conditions. Moreover, it was stated that exposure of young children sometimes exceeded the TDI. The delegation of the United States indicated that more information was needed on DON levels worldwide and on the influence of processing on the removal of Deoxynivalenol. The Committee deleted paragraph 50 from the discussion paper.

### **Status of the Discussion Paper on Deoxynivalenol**

163. The Committee agreed that the drafting group led by Belgium, with the assistance of Canada, Denmark, Germany, the Netherlands, Switzerland, the United States and the EC, would revise the Discussion Paper on Deoxynivalenol while introducing, if possible, a proposal for a maximum limit for Deoxynivalenol in cereals for circulation, comment and further consideration at its next meeting. The Committee also agreed to request additional information and data on the occurrence of deoxynivalenol in cereals, as well as the results of any studies on the effects of processing, in the Circular Letter to this report.

### **COMMENTS ON THE PRIORITY LIST OF FOOD ADDITIVES, CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda item 17)<sup>90</sup>**

164. The 33<sup>rd</sup> Session of the CCFAC agreed to request<sup>91</sup> additional comments for additions or amendments to its Priority List for consideration at the current meeting. Mr J. Dornseiffen (Netherlands) introduced the report of the Informal *ad hoc* Working Group on Priorities.

165. The Committee agreed to add several food additives and contaminants to the priority list. Information was required on the availability of relevant data on beeswax, candelilla wax, and aluminium, which were added to the priority list on the basis of their consideration for inclusion in the General Standard for Food Additives, especially as no country or international organization had offered to provide data. This information, as well as information on the distribution of contamination of relevant commodities by cadmium, would be solicited by means of the circular letter to this report.

166. The Delegation of the Netherlands informed the Committee that a two-year toxicity study on benzo[a]pyrene had been completed and could be made available to JECFA at any time. The Committee confirmed that other polycyclic aromatic hydrocarbons should be included in the review of benz[a]pyrene.

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<sup>88</sup> CX/FAC 02/29

<sup>89</sup> ALINORM 01/12A, para. 197

<sup>90</sup> Comments submitted in response to CL 2001/13-FAC and CL 2001/41-FAC from Australia, Brazil, Canada, Czech Republic (CX/FAC 02/30), Cuba, Denmark, Japan (CRD 17), Iceland, USA (CRD 19), and Report of the Informal *ad hoc* Working Group on Priorities (CRD 21).

<sup>91</sup> ALINORM 01/12A, para. 187 and Appendix XVI

167. Recognizing the need for long-term planning in view of the large number of substances that have been placed on the priority list, the Committee agreed that it would begin developing tentative schedules for more than one year in the future. To assist in this process, information would be solicited on when data could be made available on the substances on the priority list. Delegations and international organizations that propose more than one substance to be placed on the priority list in the future would be asked to prioritize them, which would also assist the Committee in establishing its priorities.

168. The Committee agreed on the Priority List of Food Additives, Contaminants, and Naturally Occurring Toxicants Proposed for Evaluation by JECFA as presented in Appendix XVI. The substances of highest priority were indicated with a footnote. The JECFA Secretariat stated that it might not be possible to include all of the substances given high priority on the agenda of the sixty-first meeting of JECFA in 2003.

169. The Committee agreed to request additional comments for additions or amendments to its Priority List for consideration at its next Session.

## **OTHER BUSINESS AND FUTURE WORK (Agenda Item 18)**

### **COMMENTS ON METHODS OF ANALYSIS FOR THE DETERMINATION OF FOOD ADDITIVES AND CONTAMINANTS IN FOODS (Agenda Item 18a)<sup>92</sup>**

170. The 33rd Session of the CCFAC agreed<sup>93</sup> to request information on all available analytical methods for dioxins and dioxin like PCBs in food and feedingstuffs as well as sampling plans when recommending methods of analysis for the determination of food additives and contaminants in foods.

#### **Endorsement of Methods of Analysis by the Codex Committee on Methods of Analysis and Sampling**

171. The Committee noted that the 23rd Session of the CCMAS endorsed methods of analysis for the determination of cadmium, copper, iron, lead and zinc in all foods as well as methods of analysis for the detection of irradiated foods.<sup>94</sup> It was also noted that the CCMAS felt that it would not be procedurally correct to endorse a method before relevant Codex provisions had been established.

#### **Methods of Analysis Forwarded for Endorsement to the Codex Committee on Methods of Analysis and Sampling**

172. The Committee agreed to forward methods of analysis for the determination of food additives and contaminants in foods, as contained in working document CX/FAC 01/31-Add.1, with the exception of analytical methods for the determination of vitamins as they did not fall under the Terms of Reference of the CCFAC (see Appendix XVII), to the 24<sup>th</sup> Session of the CCMAS for endorsement.

173. With regard to methods of analysis for the determination of dioxins and dioxin like PCBs, the CCFAC noted that the next CCMAS would consider a paper in which information on methodologies for the determination of these compounds was being compiled.<sup>95</sup> In view of this, the Committee agreed that comments should be submitted directly to the CCMAS and in this regard, the Secretariat would provide a report to the next Session of the CCFAC as to the outcome of the CCMAS discussions.

#### **Methods of Analysis for the Determination of Contaminants**

174. At the suggestion of the delegation of France, the Committee agreed to request clarification from the CCGP as to point (d) of the CCFAC terms of reference<sup>96</sup> which state that the Committee *considers methods of analysis for their determination in food*. The Committee requested clarification as to whether or not the

<sup>92</sup> Comments submitted in response to CL 2001/13-FAC by Brazil, EC (CX/FAC 02/31), Germany (CX/FAC 02/31-Add.1) and Cuba (CRD18).

<sup>93</sup> ALINORM 01/12A, paras. 176 and 194

<sup>94</sup> ALINORM 01/23 paras. 86-87, 100-106 and Appendix IV-Part III.

<sup>95</sup> ALINORM 01/23 paras. 13-15

<sup>96</sup> Codex Alimentarius Procedural Manual, 12th Edition, pages 97-98.



term of reference allowed the consideration of analytical methods for both food additives and contaminants by the CCFAC. This was felt to be especially important because of apparent inconsistencies with point (d) of the CCMAS terms of reference<sup>97</sup> in that exemptions from the consideration of methods of analysis by the CCMAS appeared to only apply to the assessment of food additive specifications.

175. In addition, the section concerning Relations Between Commodity Committees and General Committees in regard to methods of analysis and sampling<sup>98</sup> apparently only exempts methods of analysis for food additive specifications in that “*Methods of Analysis included in Codex Advisory Food Additives Specifications, for the purpose of verifying the criteria of purity and identity of the food additive, need not be referred to the Codex Committee on Methods of Analysis and Sampling for endorsement. The Codex Committee on Food Additives and Contaminants is responsible for carrying out the steps of the Procedure.*”

## **FUTURE WORK**

### **Discussion Paper on the Development of a Code of Practice for the Reduction of Aflatoxin Contamination in Peanuts**

176. The Committee agreed that South Africa, with the assistance of Australia, Brazil, India, Thailand, United Kingdom and the USA, would prepare a Discussion Paper on the Development of a Code of Practice for the Reduction of Aflatoxin Contamination in Peanuts for circulation, comment and further consideration at its next meeting.

### **Inclusion of Sorghum in the Proposed Draft Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes**

177. The delegation of Sudan, supported by Ghana, referred to the need for establishing MRLs for Ochratoxin A and Aflatoxins in sorghum as this was an important commodity in the African Region affected by mycotoxin contamination. The Committee recalled that the proposed ML for Ochratoxin A in raw wheat, barley and rye and derived products was already put forward for adoption at Step 8 by the Commission. The Committee therefore agreed that Sudan would send comments on the potential inclusion of sorghum in the *Proposed Draft Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes* for consideration at the next CCFAC.

### **Toxic Seed Contamination in Grains**

178. The Committee also considered a proposal from South Africa to examine toxic seed contamination in grain as an item for discussion at its next meeting. In this regard, the Committee was reminded that the Codex Committee on Cereals, Pulses, Legumes (CCCPL) had already considered this matter under the contaminants section in several of its commodity standards and therefore, no action was required at present by the CCFAC in this respect. The Committee agreed however that South Africa might raise this issue again at the next CCFAC session after reviewing the adequacy of the CCCPL texts.

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

179. The Committee was informed that the 35th Session of the Codex Committee on Food Additives and Contaminants was tentatively scheduled to be held in the Netherlands from 17-21 March 2003, subject to discussions between the Dutch and Codex Secretariats.

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<sup>97</sup> Codex Alimentarius Procedural Manual, 12th Edition, pages 101-102

<sup>98</sup> Codex Alimentarius Procedural Manual, 12th Edition, pages 86-88

**AVE ATQUE VALE**

180. The Committee noted the pending retirement of Dr. John Herrman, WHO Secretary to JECFA, after over more than ten years of contribution to the work of CCFAC. The Committee expressed its sincere appreciation for the work and devotion of Dr. Herrman to the goals of the CCFAC and wished him good health and long life in his retirement.

**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 03/12)</b>
Proposed Draft and Draft Revisions to Table 1 of the Codex General Standard for Food Additives	5/8 and 8	25 <sup>th</sup> CAC	Para. 61 and Appendix II
Draft Revision to the INS for Food Additives (Sodium potassium tripolyphosphate – INS 452(vi))	5 (Accel)	25 <sup>th</sup> CAC	Para. 97 and Appendix VII
Draft Maximum Level for Ochratoxin A in Raw Wheat, Barley and Rye and Derived Products	8	25 <sup>th</sup> CAC	Para. 114 and Appendix IX
Draft Maximum Level for Patulin in Apple Juice and Apple Juice Ingredients in Other Beverages	8	25 <sup>th</sup> CAC	Para. 118 and Appendix X
Proposed Draft Revised Recommended International Code of Practice for Radiation Processing of Food	5/8	25 <sup>th</sup> CAC	Para. 88 and Appendix V
Specifications for the Identity and Purity of Food Additives	5/8	25 <sup>th</sup> CAC	Para. 95 and Appendix VI
Proposed Draft Revisions to the INS for Food Additives (163(iv), 163(v), 165, 407, 445, 650, 949, 961)	5/8	25 <sup>th</sup> CAC	Para. 97 and Appendix VII
Proposed Draft and Draft Revisions to Table 1 of the Codex General Standard for Food Additives	3 and 6	Comments 35 <sup>th</sup> CCFAC	Para. 60 and Appendix III
Draft Revisions to the Annex to Table 3 of the Codex General Standard for Food Additives	6	Comments 35 <sup>th</sup> CCFAC	Para. 64 and Appendix IV
Draft Revised Codex General Standard for Irradiated Foods	6	Philippines Comments 35 <sup>th</sup> CCFAC	Para. 81
Draft Maximum Level for Lead in Fish	6	Comments Denmark 35 <sup>th</sup> CCFAC	Paras. 133-134 and Appendices XIII and XX
Proposed Draft Revisions to the INS for Food Additives (Mineral Oil – INS 905)	5	50 <sup>th</sup> CCEXEC Comments 35 <sup>th</sup> CCFAC	Para. 97 and Appendix VII
Proposed Draft Code of Practice for the Prevention of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages	5	50 <sup>th</sup> CCEXEC Comments 35 <sup>th</sup> CCFAC	Para. 122 and Appendix XI
Proposed Draft Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, Including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes	5	50 <sup>th</sup> CCEXEC Comments 35 <sup>th</sup> CCFAC	Para. 125 and Appendix XII
Proposed Risk Assessment Policy Statement for the Application of Risk Analysis Principles to the Standard Setting Activities of the CCFAC in Conjunction with Risk Assessments Performed by JECFA	3	Comments 35 <sup>th</sup> CCFAC	Para. 30 and Appendix XXI
Proposed Draft Principles for Exposure Assessment of Contaminants and Toxins in Foods	3	Comments Australia/FRA 35 <sup>th</sup> CCFAC	Para. 109 and Appendix VIII
Proposed Draft Maximum Levels for Cadmium	3	Comments 35 <sup>th</sup> CCFAC	Para. 143 and Appendix XIV
Proposed Draft Maximum Levels for Tin	3	Comments 35 <sup>th</sup> CCFAC	Para. 146 and Appendix XV
Proposed Draft Code of Practice for Source Directed Measures to Reduce Dioxin and Dioxin Like PCB Contamination of Foods	2/3	Germany Comments 35 <sup>th</sup> CCFAC	Para. 156

Proposed Draft Revised Preamble to the Codex General Standard for Food Additives	1/2/3	France/USA Comments 35 <sup>th</sup> CCFAC	Para. 51
Proposed Draft Revised Food Category System of the Codex General Standard for Food Additives	1/2/3	USA Comments 35 <sup>th</sup> CCFAC	Para. 54
Proposed Draft Code of Practice for the Reduction of Aflatoxin Contamination in Tree Nuts	1/2/3	50 <sup>th</sup> CCEXEC China Comments 35 <sup>th</sup> CCFAC	Para. 128
Proposed Draft Code of Practice for the Prevention and Reduction of Lead in Food	1/2/3	50 <sup>th</sup> CCEXEC USA Comments 35 <sup>th</sup> CCFAC	Para. 138
Discussion Paper on Processing Aids and Carriers	-----	Comments 35 <sup>th</sup> CCFAC	Para. 68
Discussion Paper on the Use of Active Chlorine	-----	Denmark Comments 35 <sup>th</sup> CCFAC	Para. 73
Discussion Paper on the Harmonization of Terms Used by Codex and JECFA for Sub-Classes and Technological Functions	-----	Codex Comments 35 <sup>th</sup> CCFAC	Para. 97
Schedule 1 of the Codex General Standard for Contaminants and Toxins in Foods	-----	NL/Codex 35 <sup>th</sup> CCFAC	Para. 104 - 105
Maximum Level for Patulin in Apple Juice and Apple Juice Ingredients in Other Beverages	-----	Comments 35 <sup>th</sup> CCFAC	Para. 119
Discussion Paper on Aflatoxins in Tree Nuts	-----	Iran Comments 35 <sup>th</sup> CCFAC	Para. 127
Information on Aflatoxin Contamination in Tree Nuts, including Methods of Analysis for the Determination of Aflatoxins in Tree Nuts	-----	Comments 35 <sup>th</sup> CCFAC	Para. 127
Maximum Levels for Lead in Milk and Milk Fat	-----	Comments 35 <sup>th</sup> CCFAC	Para. 137
Discussion Paper on Tin	-----	Australia Comments 35 <sup>th</sup> CCFAC	Para. 147
Position Paper on Dioxins and Dioxin Like PCBs, Including Methods of Analysis for Dioxins and Dioxin-Like PCBs	-----	Netherlands Comments 35 <sup>th</sup> CCFAC	Para. 153
Position Paper on Chloropropanols	-----	United Kingdom Comments 35 <sup>th</sup> CCFAC	Para. 160
Discussion Paper on Deoxynivalenol	-----	Belgium Comments 35 <sup>th</sup> CCFAC	Para. 163
Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA	-----	Comments 35 <sup>th</sup> CCFAC	Para. 168 – 169 and Appendix XVI
Methods of Analysis for the Determination of Food Additives and Contaminants in Foods	-----	24 <sup>th</sup> CCMAS	Para. 172 and Appendix XVII
Discussion Paper on the Development of a Code of Practice for the Reduction of Aflatoxin Contamination in Peanuts	-----	South Africa Comments 35 <sup>th</sup> CCFAC	Para. 176

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**PROPOSED DRAFT (AT STEP 5/8) AND DRAFT (AT STEP 8) AMENDMENTS TO TABLE 1 OF  
THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES**

**ALUMINIUM AMMONIUM SULPHATE**

Aluminium Ammonium Sulphate                      INS: 523

Function: Firming Agent, Raising Agent, Stabilizer

Food Cat. No.	Food Category	Max Level	Comments	Step
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds and seaweeds in vinegar, oil, brine, or soy sauce	35 mg/kg	Note 6	8
10.4	Egg-based desserts (e.g., custard)	380 mg/kg	Note 6	8

**ASCORBYL ESTERS**

Ascorbyl Palmitate                                      INS: 304                      Ascorbyl Stearate                                      INS: 305

Function: Antioxidant

Food Cat. No.	Food Category	Max Level	Comments	Step
02.1	Fats and oils essentially free from water	500 mg/kg	Note 10	8
06.4.3	Pre-cooked pastas and noodles and like products	20 mg/kg	Note 10	8
07.0	Bakery wares	1000 mg/kg	Notes 10 & 15	8
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	200 mg/kg	Note 10	8
12.4	Mustards	500 mg/kg	Note 10	8
13.6	Food supplements	500 mg/kg	Note 10	8

**BEESWAX, WHITE AND YELLOW**

Beeswax, White and Yellow                              INS: 901

Function: Bulking Agent, Glazing Agent, Release Agent, Stabilizer

Food Cat. No.	Food Category	Max Level	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP		8
04.2.1.2	Surface-treated fresh vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds and nuts and seeds	GMP	Note 79	8
05.3	Chewing gum	GMP		8
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	GMP		8

**CANDELILLA WAX**

Candelilla Wax                                              INS: 902

Function: Bulking Agent, Carrier Solvent, Glazing Agent, Release Agent

Food Cat. No.	Food Category	Max Level	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP		8
04.2.1.2	Surface-treated fresh vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds and nuts and seeds	GMP	Note 79	8
05.3	Chewing gum	GMP		8
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	GMP		8

**CARNAUBA WAX**

Carnauba Wax

INS: 903

Function: Anticaking Agent, Adjuvant, Bulking Agent, Carrier Solvent, Glazing Agent, Release Agent

Food Cat. No.	Food Category	Max Level	Comments	Step
05.3	Chewing gum	1200 mg/kg	Note 3	8
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte" drinks and particulated drinks	200 mg/kg	Note 119	8

**SHELLAC**

Shellac

INS: 904

Function: Bulking Agent, Glazing Agent, Release Agent

Food Cat. No.	Food Category	Max Level	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP		8
04.2.1.2	Surface-treated fresh vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds and nuts and seeds	GMP	Note 79	8
05.3	Chewing gum	GMP	Note 3	8
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	GMP		8

**BENZOATES**

Benzoic Acid

INS: 210

Sodium Benzoate

INS: 211

Potassium Benzoate

INS: 212

Calcium Benzoate

INS: 213

Function: Preservative

Food Cat. No.	Food Category	Max Level	Comments	Step
04.1.2.2	Dried fruit	800 mg/kg	Note 13	8
04.2.2.2	Dried vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds seaweeds, and nuts and seeds	1000 mg/kg	Note 13	8
05.1.3	Cocoa-based spreads, including fillings	1500 mg/kg	Note 13	8
05.1.5	Imitation chocolate, chocolate substitute products	1500 mg/kg	Note 13	8
05.2	Confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	1500 mg/kg	Note 13	8
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	1500 mg/kg	Note 13	8
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	1000 mg/kg	Note 13	8
09.2.4.2	Cooked mollusks, crustaceans, and echinoderms	2000 mg/kg	Notes 13 & 82	8
09.3.	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	2000 mg/kg	Note 13 & 120	8
10.2.1	Liquid egg products	5000 mg/kg	Note 13	8
10.4	Egg-based desserts (e.g., custard)	1000 mg/kg	Note 13	8
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1000 mg/kg	Note 13	8
11.6	Table-top sweeteners, including those containing high intensity sweeteners	2000 mg/kg	Note 13	5/8
12.2	Herbs, spices, seasonings (including salt substitutes), and condiments (e.g., seasoning for instant noodles)	1000 mg/kg	Note 13	8
12.3	Vinegars	1000 mg/kg	Note 13	8
12.4	Mustards	1000 mg/kg	Note 13	8
12.6	Sauces and like products	1000 mg/kg	Note 13	8
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	1500 mg/kg	Note 13	8
13.3.1	Dietetic foods for special medical purposes intended for adults	1500 mg/kg	Note 13	8

13.4	Dietetic formulae for slimming purposes and weight reduction	1500 mg/kg Note 13	8
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4	2000 mg/kg Note 13	8
13.6	Food supplements	2000 mg/kg Note 13	5/8
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	600 mg/kg Note 13	8
14.2.4	Wines (other than grape)	1000 mg/kg Note 13	8
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spiritous cooler-type beverages, low alcoholic refreshers)	1000 mg/kg Note 13	8

#### Notes to the Comments for the Revised Draft General Standard for Food Additives (34<sup>th</sup> CCFAC)

**Note 1:** As adipic acid

**Note 2:** On dry ingredient, dry weight, dry mix or concentrate basis.

**Note 3:** Surface treatment.

**Note 4:** For decoration, stamping, marking or branding the product.

**Note 5:** Used in raw materials for manufacture of the finished food.

**Note 6:** As aluminium.

**Note 7:** Use level not in finished food.

**Note 8:** As bixin.

**Note 9:** As total bixin or norbixin.

**Note 10:** As ascorbyl stearate.

**Note 11:** Flour basis.

**Note 12:** Carryover from flavouring substances.

**Note 13:** As benzoic acid.

**Note 14:** Served at greater than 5-fold dilution.

**Note 15:** Fat or oil basis.

**Note 16:** For use in glaze, coatings or decorations for fruit, vegetables, meat or fish.

**Note 17:** As cyclamic acid.

**Note 18:** Added level; residue not detected in ready-to-eat food.

**Note 19:** Used in cocoa fat; use level on ready-to-eat basis.

**Note 20:** On total amount of stabilizers, thickeners and/or gums.

**Note 21:** As anhydrous calcium disodium EDTA.

**Note 22:** For use in smoked fish products only.

**Note 23:** As iron.

**Note 24:** As anhydrous sodium ferrocyanide.

**Note 25:** As formic acid.

**Note 26:** For use in baking powder only.

**Note 27:** As p-hydroxybenzoic acid.

**Note 28:** ADI conversion: if a typical preparation contains 0.025 µg/U, then the ADI of 33,000 U/kg bw becomes:  

$$[(33000 \text{ U/kg bw}) \times (0.025 \text{ µg/U}) \times (1 \text{ mg}/1000 \text{ µg})] = 0.825 \text{ mg/kg bw}$$

**Note 29:** Reporting basis not specified.

**Note 30:** As residual NO<sub>3</sub> ion.

**Note 31:** Of the mash used.

**Note 32:** As residual NO<sub>2</sub> ion.

**Note 33:** As phosphorus.

**Note 34:** Anhydrous basis.

**Note 35:** Except for use in special formula at 20,000 mg/kg.

**Note 36:** Residual level.

**Note 37:** As weight of nonfat milk solids.

**Note 38:** Level in creaming mixture.

**Note 39:** Only when product contains butter or other fats and oils.

**Note 40:** Except for use in special formula at 200 mg/kg.

**Note 41:** Use in breading or batter coatings only.

**Note 42:** As sorbic acid

**Note 43:** As tin.

**Note 44:** As residual SO<sub>2</sub>.

**Note 45:** As tartaric acid.

**Note 46:** As thiodipropionic acid.

**Note 47:** On egg yolk weight, dry basis.

**Note 48:** For olives only.

**Note 49:** For use on citrus fruits only.

**Note 50:** For use in fish roe only.

**Note 51:** For use in herbs and salt substitutes only.

**Note 52:** For use in butter only.

**Note 53:** For use in coatings only.

**Note 54:** For use in dried products only.

**Note 55:** Added level.

**Note 56:** Provided starch is not present.

**Note 57:** GMP is 1 part benzoyl peroxide and not more than 6 parts of the subject additive by weight.

**Note 58:** As calcium.

**Note 59:** Use as packing gas.

**Note 60:** If used as a carbonating agent, the CO<sub>2</sub> in the finished wine shall not exceed 39.2 mg/kg.

**Note 61:** For use in minced fish only.

**Note 62:** As copper.

**Note 63:** On amount of dairy ingredients.

- Note 64:** Level added to dry beans; 200 mg/kg in ready-to-eat food, anhydrous basis.
- Note 65:** Carryover from nutrient preparations.
- Note 66:** As formaldehyde. For use in provolone cheese only.
- Note 67:** Carryover from use in casings.
- Note 68:** For use in natural mineral waters only.
- Note 69:** Use as carbonating agent.
- Note 70:** As the acid.
- Note 71:** Calcium, potassium and sodium salts only.
- Note 72:** Ready-to-eat basis.
- Note 73:** Except whole fish.
- Note 74:** Use level for deep orange coloured cheeses; 25 mg/kg for orange coloured cheeses; 10 mg/kg for normal coloured cheeses.
- Note 75:** Use in milk powder for vending machines only.
- Note 76:** Use in potatoes only.
- Note 77:** As mono-isopropyl citrate.
- Note 78:** For use in tocino (fresh, cured sausage) only.
- Note 79:** For use on nuts only.
- Note 80:** Equivalent to 2 mg/dm<sup>2</sup> surface application to a maximum depth of 5 mm.
- Note 81:** Equivalent to 1 mg/dm<sup>2</sup> surface application to a maximum depth of 5 mm.
- Note 82:** For use in shrimp; 6000 mg/kg for Crangon crangon and Crangon vulgaris.
- Note 83:** For use in sauce only.
- Note 84:** For use in special formula at 10,000 mg/kg.
- Note 85:** Excluding use in surimi and fish roe products at 500 mg/kg.
- Note 86:** Use in whipped dessert toppings other than cream only.
- Note 87:** Treatment level.
- Note 88:** Carryover from the ingredient.
- Note 89:** Except for use in dried tangle (KONBU) at 150 mg/kg.
- Note 90:** For use in milk-sucrose mixtures used in the finished product.
- Note 91:** For use in special formula only.
- Note 92:** On the weight of the protein before re-hydration.
- Note 93:** Except natural wine produced from Vitis Vinifera grapes.
- Note 94:** For use in loganiza (fresh, uncured sausage) only.
- Note 95:** For use in surimi and fish roe products only.
- Note 96:** Carryover from use in fats.
- Note 97:** In cocoa and chocolate products.
- Note 98:** For dust control.
- Note 99:** For use in fish fillets and minced fish only.
- Note 100:** For use as a dispersing agent in dill oil used in the final food.
- Note 101:** Level based on the maximum recommended daily dose of 475 mg/dose, assuming one 600 mg tablet is consumed per day.
- Note 102:** For use as a surfactant or wetting agent for colours in the food.
- Note 103:** Except for use in special white wines at 400 mg/kg.
- Note 104:** Maximum 5000 mg/kg residue in bread and yeast-leavened bakery products.
- Note 105:** Except for use in dried gourd strips (KAMPYO) at 5000 mg/kg.
- Note 106:** Except for use in Dijon mustard at 500 mg/kg.
- Note 107:** Except for use in concentrated grape juice for home wine making at 2000 mg/kg.
- Note 108:** For use on coffee beans only.
- Note 109:** Use level reported as 25 lbs/1000 gal x (0.45 kg/lb) x (1 gal/3.75 L) x (1 L/kg) x (60 mg/kg) = 3000 mg/kg
- Note 110:** For use in frozen French fried potatoes only.
- Note 111:** For use in dipping solution only.
- Note 112:** For use in grated cheese only.
- Note 113:** Excluding butter.
- Note 114:** Excluding cocoa powder.
- Note 115:** Except for use in special formula at 12,000 mg/kg.
- Note 116:** For use in doughs only.
- Note 117:** Except for use in loganiza (fresh, uncured sausage) at 1000 mg/kg.
- Note 118:** Except for use in tocino (fresh, cured sausage) at 1000 mg/kg.
- Note 119:** As carrier for flavours
- Note 120:** Except for use in caviar at 2500 mg/kg



**PROPOSED DRAFT (AT STEP 3) AND DRAFT (AT STEP 6) AMENDMENTS TO TABLE 1 OF THE  
CODEX GENERAL STANDARD FOR FOOD ADDITIVES****ALUMINIUM AMMONIUM SULPHATE**

Aluminium Ammonium Sulphate                      INS: 523

Function: Firming Agent, Raising Agent, Stabilizer

Food Cat. No.	Food Category	Max Level	Comments	Step
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds products	GMP	Note 6	3
06.2	Flours and starches	GMP	Notes 6 & 26	6
07.2.1	Cakes, cookies and pies (e.g., fruit-filled or custard types)	GMP	Note 6	3
12.2	Herbs, spices, seasonings (including salt substitutes), and condiments (e.g., seasoning for instant noodles)	GMP	Note 6	3
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	GMP	Note 6	3

**ASCORBYL ESTERS**

Ascorbyl Palmitate                      INS: 304                      Ascorbyl Stearate                      INS: 305

Function: Antioxidant

Food Cat. No.	Food Category	Max Level	Comments	Step
12.6.2	Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	500 mg/kg	Note 10	6
13.4	Dietetic formulae for slimming purposes and weight reduction	GMP	Note 10	3
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4	GMP	Note 10	3

**BEESWAX, WHITE AND YELLOW**

Beeswax, White and Yellow                      INS: 901

Function: Bulking Agent, Glazing Agent, Release Agent, Stabilizer

Food Cat. No.	Food Category	Max Level	Comments	Step
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte" drinks and particulated drinks	200 mg/kg		6

**CANDELILLA WAX**

Candelilla Wax                      INS: 902

Function: Bulking Agent, Carrier Solvent, Glazing Agent, Release Agent

Food Cat. No.	Food Category	Max Level	Comments	Step
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte" drinks and particulated drinks	200 mg/kg		6

**CARNAUBA WAX**

Carnauba Wax                      INS: 903

Function: Anticaking Agent, Adjuvant, Bulking Agent, Carrier Solvent, Glazing Agent, Release Agent

Food Cat. No.	Food Category	Max Level	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP		6
04.1.2	Processed fruit	GMP		6
04.2.1.2	Surface-treated fresh vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds and nuts and seeds	GMP	Note 79	6
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	10000 mg/kg		6
12.6	Sauces and like products	GMP		6
14.1.2.1	Canned or bottled (pasteurized) fruit juice	GMP		6

## BENZOATES

Benzoic Acid	INS: 210	Sodium Benzoate	INS: 211
Potassium Benzoate	INS: 212	Calcium Benzoate	INS: 213

Function: Preservative

Food Cat. No.	Food Category	Max Level	Comments	Step
04.1.2.4	Canned or bottled (pasteurized) fruit	800 mg/kg	Note 13	6
04.1.2.5	Jams, jellies and marmelades	1500 mg/kg	Note 13	3
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds	1000 mg/kg	Note 13	6
05.1.1	Cocoa mixes (powders) and cocoa mass/cake other than food categories 05.1, 05.3 and 05.4	700 mg/kg	Note 13	6
05.3	Chewing gum	1500 mg/kg	Note 13	6
06.4.3	Pre-cooked pastas and noodles and like products	1000 mg/kg	Note 13	6
07.0	Bakery wares	1000 mg/kg	Note 13	6
08.2.1.2	Cured (including salted) and dried non-heat treated processed meat, poultry, and game products in whole pieces or cuts	GMP	Notes 3 & 13	6
08.3.1.2	Cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products	1000 mg/kg	Note 13	6
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	1000 mg/kg	Note 13	3
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200 mg/kg	Note 13	6
12.5	Soups and broths	1000 mg/kg	Note 13	6
14.1.1.2	Table waters and soda waters	200 mg/kg	Note 13	6
14.1.2.1	Canned or bottled (pasteurized) fruit juice	2000 mg/kg	Note 13	6
14.1.2.2	Canned or bottled (pasteurized) vegetable juice	2000 mg/kg	Note 13	6
14.1.2.3	Concentrate (liquid or solid) for fruit juice	2000 mg/kg	Note 13	6
14.1.2.4	Concentrate (liquid or solid) for vegetable juice	1400 mg/kg	Note 13	6
14.1.3.1	Canned or bottled (pasteurized) fruit nectar	2000 mg/kg	Note 13	6
14.1.3.2	Canned or bottled (pasteurized) vegetable nectar	2000 mg/kg	Note 13	6
14.1.3.3	Concentrate (liquid or solid) for fruit nectar	1000 mg/kg	Note 13	6
14.1.3.4	Concentrate (liquid or solid) for vegetable nectar	500 mg/kg	Note 13	6
14.1.4	<b>Water-based flavoured drinks, including "sport" or "electrolyte" drinks and particulated drinks</b>	<b>1000 mg/kg</b>	<b>Note 13</b>	<b>6</b>
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	1000 mg/kg	Note 13	3
14.2.2	Cider and perry	1000 mg/kg	Note 13	6
14.2.5	Mead	1000 mg/kg	Note 13	6
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	1000 mg/kg	Note 13	6
16.0	Composite foods - foods that could not be placed in categories 01 - 15	1000 mg/kg	Note 13	6

**Notes to the Comments for the Revised Draft General Standard for Food Additives (34<sup>th</sup> CCFAC)**

- Note 1:** As adipic acid
- Note 2:** On dry ingredient, dry weight, dry mix or concentrate basis.
- Note 3:** Surface treatment.
- Note 4:** For decoration, stamping, marking or branding the product.
- Note 5:** Used in raw materials for manufacture of the finished food.
- Note 6:** As aluminium.
- Note 7:** Use level not in finished food.
- Note 8:** As bixin.
- Note 9:** As total bixin or norbixin.
- Note 10:** As ascorbyl stearate.
- Note 11:** Flour basis.
- Note 12:** Carryover from flavouring substances.
- Note 13:** As benzoic acid.
- Note 14:** Served at greater than 5-fold dilution.
- Note 15:** Fat or oil basis.
- Note 16:** For use in glaze, coatings or decorations for fruit, vegetables, meat or fish.
- Note 17:** As cyclamic acid.
- Note 18:** Added level; residue not detected in ready-to-eat food.
- Note 19:** Used in cocoa fat; use level on ready-to-eat basis.
- Note 20:** On total amount of stabilizers, thickeners and/or gums.
- Note 21:** As anhydrous calcium disodium EDTA.
- Note 22:** For use in smoked fish products only.
- Note 23:** As iron.
- Note 24:** As anhydrous sodium ferrocyanide.
- Note 25:** As formic acid.
- Note 26:** For use in baking powder only.
- Note 27:** As p-hydroxybenzoic acid.
- Note 28:** ADI conversion: if a typical preparation contains 0.025 µg/U, then the ADI of 33,000 U/kg bw becomes:  $[(33000 \text{ U/kg bw}) \times (0.025 \text{ µg/U}) \times (1 \text{ mg}/1000 \text{ µg})] = 0.825 \text{ mg/kg bw}$
- Note 29:** Reporting basis not specified.
- Note 30:** As residual NO<sub>3</sub> ion.
- Note 31:** Of the mash used.
- Note 32:** As residual NO<sub>2</sub> ion.
- Note 33:** As phosphorus.
- Note 34:** Anhydrous basis.
- Note 35:** Except for use in special formula at 20,000 mg/kg.
- Note 36:** Residual level.
- Note 37:** As weight of nonfat milk solids.
- Note 38:** Level in creaming mixture.
- Note 39:** Only when product contains butter or other fats and oils.
- Note 40:** Except for use in special formula at 200 mg/kg.
- Note 41:** Use in breading or batter coatings only.
- Note 42:** As sorbic acid
- Note 43:** As tin.
- Note 44:** As residual SO<sub>2</sub>.
- Note 45:** As tartaric acid.
- Note 46:** As thiodipropionic acid.
- Note 47:** On egg yolk weight, dry basis.
- Note 48:** For olives only.
- Note 49:** For use on citrus fruits only.
- Note 50:** For use in fish roe only.
- Note 51:** For use in herbs and salt substitutes only.
- Note 52:** For use in butter only.
- Note 53:** For use in coatings only.
- Note 54:** For use in dried products only.
- Note 55:** Added level.
- Note 56:** Provided starch is not present.
- Note 57:** GMP is 1 part benzoyl peroxide and not more than 6 parts of the subject additive by weight.
- Note 58:** As calcium.
- Note 59:** Use as packing gas.
- Note 60:** If used as a carbonating agent, the CO<sub>2</sub> in the finished wine shall not exceed 39.2 mg/kg.
- Note 61:** For use in minced fish only.
- Note 62:** As copper.
- Note 63:** On amount of dairy ingredients.
- Note 64:** Level added to dry beans; 200 mg/kg in ready-to-eat food, anhydrous basis.
- Note 65:** Carryover from nutrient preparations.
- Note 66:** As formaldehyde. For use in provolone cheese only.
- Note 67:** Carryover from use in casings.
- Note 68:** For use in natural mineral waters only.
- Note 69:** Use as carbonating agent.
- Note 70:** As the acid.

- Note 71:** Calcium, potassium and sodium salts only.
- Note 72:** Ready-to-eat basis.
- Note 73:** Except whole fish.
- Note 74:** Use level for deep orange coloured cheeses; 25 mg/kg for orange coloured cheeses; 10 mg/kg for normal coloured cheeses.
- Note 75:** Use in milk powder for vending machines only.
- Note 76:** Use in potatoes only.
- Note 77:** As mono-isopropyl citrate.
- Note 78:** For use in tocino (fresh, cured sausage) only.
- Note 79:** For use on nuts only.
- Note 80:** Equivalent to 2 mg/dm<sup>2</sup> surface application to a maximum depth of 5 mm.
- Note 81:** Equivalent to 1 mg/dm<sup>2</sup> surface application to a maximum depth of 5 mm.
- Note 82:** For use in shrimp; 6000 mg/kg for Crangon crangon and Crangon vulgaris.
- Note 83:** For use in sauce only.
- Note 84:** For use in special formula at 10,000 mg/kg.
- Note 85:** Excluding use in surimi and fish roe products at 500 mg/kg.
- Note 86:** Use in whipped dessert toppings other than cream only.
- Note 87:** Treatment level.
- Note 88:** Carryover from the ingredient.
- Note 89:** Except for use in dried tangle (KONBU) at 150 mg/kg.
- Note 90:** For use in milk-sucrose mixtures used in the finished product.
- Note 91:** For use in special formula only.
- Note 92:** On the weight of the protein before re-hydration.
- Note 93:** Except natural wine produced from Vitis Vinifera grapes.
- Note 94:** For use in loganiza (fresh, uncured sausage) only.
- Note 95:** For use in surimi and fish roe products only.
- Note 96:** Carryover from use in fats.
- Note 97:** In cocoa and chocolate products.
- Note 98:** For dust control.
- Note 99:** For use in fish fillets and minced fish only.
- Note 100:** For use as a dispersing agent in dill oil used in the final food.
- Note 101:** Level based on the maximum recommended daily dose of 475 mg/dose, assuming one 600 mg tablet is consumed per day.
- Note 102:** For use as a surfactant or wetting agent for colours in the food.
- Note 103:** Except for use in special white wines at 400 mg/kg.
- Note 104:** Maximum 5000 mg/kg residue in bread and yeast-leavened bakery products.
- Note 105:** Except for use in dried gourd strips (KAMPYO) at 5000 mg/kg.
- Note 106:** Except for use in Dijon mustard at 500 mg/kg.
- Note 107:** Except for use in concentrated grape juice for home wine making at 2000 mg/kg.
- Note 108:** For use on coffee beans only.
- Note 109:** Use level reported as 25 lbs/1000 gal x (0.45 kg/lb) x (1 gal/3.75 L) x (1 L/kg) x (10 mg/kg) = 3000 mg/kg
- Note 110:** For use in frozen French fried potatoes only.
- Note 111:** For use in dipping solution only.
- Note 112:** For use in grated cheese only.
- Note 113:** Excluding butter.
- Note 114:** Excluding cocoa powder.
- Note 115:** Except for use in special formula at 12,000 mg/kg.
- Note 116:** For use in doughs only.
- Note 117:** Except for use in loganiza (fresh, uncured sausage) at 1000 mg/kg.
- Note 118:** Except for use in tocino (fresh, cured sausage) at 1000 mg/kg.
- Note 119:** As carrier for flavours
- Note 120:** Except for use in caviar at 2500 mg/kg

**DRAFT AMENDMENTS TO FOOD CATEGORIES OR INDIVIDUAL FOOD ITEMS  
EXCLUDED FROM THE GENERAL CONDITIONS OF TABLE THREE  
(ANNEX TO TABLE 3 OF THE GENERAL STANDARD FOR FOOD ADDITIVES)  
(AT STEP 6 OF THE PROCEDURE)**

The use of additives listed in Table Three in the following foods is governed by the provisions in Tables One and Two.

<b>Category Number</b>	<b>Food Category</b>
01.1.1	Milk and buttermilk (excluding heat-treated buttermilk)
01.2	Fermented and renneted milk products (plain) excluding food category 01.1.2 (dairy based drinks)
01.4.1	Pasteurized cream
01.4.2	Sterilized, UHT, whipping or whipped, and reduced fat creams
02.1	Fats and oils essentially free from water
02.2.1.1	Butter and concentrated butter (Only butter)
04.1.1	Fresh fruit
04.2.1	Fresh vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes[(including soybeans)], and aloe vera), seaweeds, and nuts and seeds
04.2.2.1	Frozen vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes [(including soybeans)], and aloe vera), seaweeds, and nuts and seeds
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes[(including soybeans)], and aloe vera), seaweeds, products
06.1	Whole, broken or flaked grain, including rice
06.2	Flours and starches
06.4.1	Fresh pastas and noodles and like products
06.4.2	Dried pastas and noodles and like products
08.1	Fresh meat, poultry, and game
09.1	Fresh fish and fish products, including mollusks, crustaceans and echinoderms
09.2	Processed fish and fish products, including mollusks, crustaceans and echinoderms
10.1	Fresh eggs
10.2.1	Liquid egg products
10.2.2	Frozen egg products
11.1	Refined and raw sugars
11.2	Brown sugar, excluding products of food category 11.1.3 (soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar)
11.3	Sugar solutions and syrups, also (partially inverted, including treacle and molasses, excluding products of food category 11.1.3 (soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar)
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)
11.5	Honey
12.1	Salt
12.2	Herbs, spices, seasoning (including salt substitutes) and condiments (Only herbs and salt substitutes)
13.1	Infant formulae and follow-on formulae
13.2	Weaning foods for infants and young children
14.1.1.1	Natural mineral waters and source waters (Only natural mineral waters)
14.1.2.1	Canned or bottled (pasteurized) fruit juice
14.1.2.3	Concentrates (liquid and solid) for fruit juice
14.1.3.1	Canned or bottled (pasteurized) fruit nectar
14.1.3.3	Concentrates (liquid and solid) for fruit nectar
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal beverages, excluding cocoa
14.2.3	Grape wines

**PROPOSED DRAFT RECOMMENDED INTERNATIONAL CODE  
OF PRACTICE FOR RADIATION PROCESSING OF FOOD  
(At Step 5/8 of the Procedure)**

## **INTRODUCTION**

Food irradiation is the processing of food products by ionizing radiation in order to, among other things, control foodborne pathogens, reduce microbial load and insect infestation, inhibit the germination of root crops, and extend the durable life of perishable produce. Many countries are using industrial irradiators for processing of food products for commercial purposes.

The regulatory control of food irradiation should take into consideration the Codex General Standard for Irradiated Foods (CX-STAN 106-1983, under revision) and this Code.

The purpose of regulatory control of irradiated food products should be:

- a) to ensure that radiation processing of food products is implemented safely and correctly, in accordance with all relevant Codex standards and codes of hygienic practice;
- b) to establish a system of documentation to accompany irradiated food products, so that the fact of irradiation can be taken into account during subsequent handling, storage and marketing; and
- c) to ensure that irradiated food products that enter into international trade conform to acceptable standards of radiation processing and are correctly labelled.

The purpose of this Code is to provide principles for the processing of food products with ionizing radiation that are consistent with relevant Codex Standards and codes of hygienic practice. Food irradiation may be incorporated as part of a HACCP-plan where applicable; but a HACCP-plan is not required for the use of radiation processing of food processed for purposes other than for food safety. The provisions of this Code will provide guidance to the radiation processor to apply the Hazard Analysis and Critical Control Point (HACCP) system, as recommended in the Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 3-1997, Amd. 1-1999), where applicable for food safety purposes, to foods processed by ionizing radiation.

## **1. OBJECTIVES**

This Codex Code of Practice for Radiation Processing of Food identifies the essential practices to be implemented to achieve effective radiation processing of food products in a manner that maintains quality and yields food products that are safe and suitable for consumption.

## **2. SCOPE, USE and DEFINITIONS**

### **2.1 Scope**

This Code is concerned with food products processed by gamma rays, X-rays or accelerated electrons for the purpose of, among other things, control of foodborne pathogens, reduction of microbial load and insect infestation, inhibition of the germination of root crops, and extension of durable life for perishable foods.

This Code covers the requirements of the irradiation process in a facility; it also considers other aspects of the process as primary production and/or harvesting, post-harvest treatment, storage and shipment, packaging, irradiation, labelling, post-irradiation storage and handling, and training.<sup>1</sup>

## 2.2 Use

The Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 3-1997, Amd. 1-1999) and its annex on application of the HACCP system, as well as other relevant Codex Standards and codes of hygienic practice should be used with this document. Of particular relevance are the Codex General Standard for Irradiated Foods (CX-STAN 106-1983 - under revision) and the General Standard for the Labelling of Pre-Packaged Foods (CX-STAN 1-1985, Rev 1 - 1991).

## 2.3 Definitions

For purposes of this Code, the terms below are defined as follows:

**Food Irradiation:** Processing of food products by ionizing radiation, specifically gamma rays, X-rays or accelerated electrons as specified in the Codex General Standard for Irradiated Foods.

**Irradiated Food:** Food products processed by ionizing radiation in accordance with the Codex General Standard for Irradiated Foods. Such food is subject to all relevant standards, codes and regulations applicable to the non-irradiated counterpart.

**Dosimetry:** The measurement of the absorbed dose of radiation at a particular point in a given absorbing medium.

**Dose (absorbed):** The absorbed dose, sometimes referred to simply as 'dose', is the amount of energy absorbed per unit mass of irradiated food product.

**Dose Uniformity Ratio:** The ratio of maximum to minimum absorbed dose in the production lot.

**Dose Distribution:** The spatial variation in absorbed dose throughout the production lot with extreme values being the maximum absorbed dose and the minimum absorbed dose.

**Dose Limit:** The minimum or maximum radiation dose absorbed by a food product prescribed in regulations as required for technological reasons. Such dose limits are expressed as ranges or as single lower or upper values (i.e., no part of the food product shall absorb less than or more than a specified amount).

## 3. PRE-IRRADIATION TREATMENT

### 3.1 Primary production and/or harvesting

Primary food products intended for radiation processing should comply with the Codex General Principles of Food Hygiene with reference to the hygienic requirements as well as other relevant Codex standards and codes of practice for primary production and/or harvesting, which ensure that food is safe and suitable for human consumption.

### 3.2 Handling, storage and transport

The intent to process food products by irradiation poses no unique requirements regarding handling, storage and transport of the food products prior to and subsequent to irradiation. All stages of the processing,

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<sup>1</sup> Codes of good irradiation practice, compilations of technical data for the authorization and control of the irradiation of several food classes and also training manuals for facility operators and control officials have been produced by the International Consultative Group on Food Irradiation (ICGFI), available through the International Atomic Energy Agency, PO Box 100, A-1400 Vienna, Austria.

i.e., pre-irradiation, irradiation and post-irradiation, should be in accordance with good manufacturing practices to maximize quality, to minimize contamination, and, if packaged, to maintain package integrity.

Radiation is applied to food products in forms in which they are normally prepared for processing, commercially traded or otherwise used. Food intended for radiation processing should conform to handling, storage and transport requirements of the Codex General Principles of Food Hygiene as well as relevant Codex standards and codes of practice for specific food products.

#### **4. PACKAGING**

In general, in order to avoid contamination or infestation after irradiation, food products should be packaged in materials that provide an effective barrier to re-contamination and re-infestation. Packaging must also meet the requirements of the importing country.

The size and shape of containers that may be used for irradiation are determined, in part, by the operating characteristics of the irradiation facility. These characteristics include the product transport systems and the irradiation source, as they affect the dose distribution within the container.

#### **5. ESTABLISHMENT: DESIGN, FACILITIES and CONTROL**

Authorization of a facility to irradiate food is granting approval to a facility licensed for radiation processing in general to irradiate food products. Authorization may be general in nature or issued for specific classes or groups of food products.

Facilities which carry out irradiation of food products should meet appropriate standards of occupational safety and good hygiene conditions, including:

- Regulations regarding design, construction and operation of radiation facilities
- General Principles of Food Hygiene
- General Standard for Irradiated Foods and this Code.

##### **5.1 Design and layout**

This section is concerned with the areas in which food products are stored and irradiated. Prevention of contamination requires that all measures be taken to avoid direct or indirect contact of the food product with sources of potential contamination and to minimize growth of microorganisms.

Irradiation establishments are laid out to provide storage for irradiated and non-irradiated food products (under ambient, refrigerated and/or freezing temperature conditions), an irradiator, and the normal accommodation and infrastructure for staff and plant services including record maintenance. In order to achieve inventory control there should be provision in both the design and operation of the establishment to keep irradiated and non-irradiated food products separate. This separation can be accomplished by controlled single-direction movement of the food products through the plant and by separated storage areas for irradiated and non-irradiated food products.

Radiation facilities must be designed to provide an absorbed dose in the food product within minimum and maximum limits in accordance with process specifications and government regulatory requirements. For economic and technical reasons (e.g. maintaining product quality), various techniques are used to minimize the ratio, which is termed the dose uniformity ratio.

The following factors largely govern the selection of irradiator design:

- a) Means of transporting food products: The mechanical design of the irradiation and transport systems, including the source-to-product geometry in a given process, as required by the form of the product, e.g. bulk or packaged, and its properties.



- b) Range of doses: The range of doses needed to process a wide variety of products for various applications.
- c) Throughput: The amount of product to be processed within a defined period of time.
- d) Reliability: The property of providing correct performance as needed.
- e) Safety-systems: The systems intended to protect operating personnel from hazards posed by radiation.
- f) Compliance: The adherence to good manufacturing practices and relevant government regulations.
- g) Capital and operational costs: The basic economic considerations necessary for sustainable operation.

## 5.2 Radiation sources

As described in the Codex General Standard for Irradiated Foods, the following sources of ionizing radiation may be used in food irradiation:

- a) Gamma rays from radionuclides  $^{60}\text{Co}$  or  $^{137}\text{Cs}$ ;
- b) X-rays generated from machine sources operated at or below an energy level of 5 MeV; and
- c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

## 5.3 Control of operation

### 5.3.1 Legislation

Food processing establishments are constructed and operated in accordance with regulatory requirements in order to ensure safety of the processed foods for consumption and occupational safety of the plant personnel and the environment. A food irradiation facility, like any other food processing plant, is also subject to such regulation and should be designed, constructed and operated in compliance with relevant regulations.

### 5.3.2 Requirements for staff

The staff at an irradiation facility is subject to relevant sections of the Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 3-1997, Amd. 1-1999) for personal hygiene recommendations and to the General Standard for Irradiated Foods for recommendations regarding the need for an adequate, trained and competent personnel.<sup>2</sup>

### 5.3.3 Requirements for process control

Requirements for process control are included in the General Standard for Irradiated Foods. Measuring the dose and monitoring of the physical parameters of the process are essential for process control. The need for adequate record keeping, including records of quantitative dosimetry, is emphasized in the General Standard. As for other physical methods of food processing, records are essential means for the regulatory control of processing by ionizing radiation. Evidence for correct processing, including adherence to any legal or technological dose limits, depends on the maintenance of full and accurate records by the irradiation facility. The facility's records link all the information from several sources to the irradiated food products. Such records enable verification of the irradiation process and should be kept.

### 5.3.4 Control of applied dose

The effectiveness of the irradiation process depends on proper application of the dose and its measurement. Dose distribution measurements should be carried out to characterize the process for each food product; and

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<sup>2</sup> Training manuals for facility operators and control officials have been produced by ICGFI, available through the International Atomic Energy Agency, PO Box 100, A-1400 Vienna, Austria. ICGFI also, through its FIPCOS, provides such training.

thereafter dosimeters should be used routinely to monitor correct execution of the process in accordance with internationally accepted procedures.<sup>3</sup>

For certain public health or quarantine applications, there may be specific requirements to regulate the minimum absorbed dose in order to ensure that the desired technological effect is achieved.

### **5.3.5 Product and inventory control**

An adequate system should be in place so that specific consignments of food products can be traced back both to the irradiation facility and the source from which they were received for processing.

Plant design and administrative procedures should ensure that it is impossible to mix irradiated and non-irradiated food products. Incoming products should be logged and given a code number to identify the packages at each step in its path through the irradiation plant. All relevant parameters such as date, time, source strength, minimum and maximum dose, temperature, etc. should be logged against the code number of the product.

It is not possible to distinguish irradiated from non-irradiated product by visual inspection. Therefore, it is essential that appropriate means, such as physical barriers, be employed for keeping the irradiated and non-irradiated product separate. Affixing colour change indicator label on each package, where applicable, provides another means of distinguishing irradiated and non-irradiated product.

## **6. IRRADIATION**

### **6.1 General**

Refer to the Codex General Standard for Irradiated Foods (CX-STAN 106-1983, under revision).

### **6.2 Process determination**

It is important that all steps in the determination of process procedures are documented to:

- a) ensure that the application of the process complies with relevant regulatory requirements;
- b) establish a clear statement for the technological objectives of the process;
- c) estimate the dose range to be applied to achieve the technological objective based on appropriate knowledge of the food product;
- d) demonstrate that irradiation of test samples has been carried out to confirm the estimated dose range under practical production conditions;
- e) ensure that it is possible to meet the technological requirements, e.g. dose range and effectiveness of treatment, under practical production conditions; and
- f) establish the process parameters under practical production conditions.

### **6.3 Dosimetry**

Successful radiation processing practice depends on the ability of the processor to measure the absorbed dose delivered to each point in the food product and in the production lot.

Various techniques for dosimetry pertinent to radionuclide and machine sources are available for measuring absorbed dose in a quantitative manner. Relevant ISO/ASTM Standard Practices and Guides for dosimetry in food irradiation facilities have been developed and should be consulted.<sup>4</sup>

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<sup>3</sup> Such procedures are specified, for example, by the American Society for Testing and Materials (ASTM) in their annual handbooks.

<sup>4</sup> ISO/ASTM 51204 – Standard Practice or Dosimetry in Gamma Irradiation Facilities for Food Processing;

In order to implement these irradiation practices, facilities should be adequately staffed by competent personnel trained in dosimetry and its application in radiation processing.

The calibration of the dosimetry system used in radiation processing should be traceable (i.e., calibrated) to national and international standards.

#### 6.4 Dosimetry systems

Dosimeters are devices that are capable of providing a quantitative and reproducible measurement of dose through a change in one or more of the physical properties of the dosimeters in response to the exposure to ionizing radiation energy. A dosimetry system consists of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use. Selection of appropriate dosimetry system for radiation processing of food will depend on a variety of factors, including the dose range needed to achieve a particular technological objective, cost, availability, and ease of use. A variety of dosimetry systems are available.<sup>5</sup>

#### 6.5 Dosimetry and process control

In food irradiation, the key quantity that governs the process is the absorbed dose. It is influenced by various parameters, such as: radiation source type, strength and geometry; conveyor speed or dwell time; food product density and loading configuration; and carrier size and shape.<sup>6</sup> Their overall influence on dose distribution must be taken into account to ensure that the intended technological objective is achieved throughout the production lot.

The application of radiation processing is mainly governed by the minimum absorbed dose achieved in the dose distribution within a given product. If the required minimum is not applied, the intended technical effect may not be achieved (e.g. sprout inhibition, pathogen reduction). There are also situations where the application of too high a dose would impair the quality of the treated food (e.g. off flavours or odours).<sup>7</sup>

#### 6.6 Records of irradiation

Radiation processors should maintain adequate records showing the food processed, identifying marks if packaged or, if not, the shipping details, the bulk density of the food, the dosimetry results, including the type of dosimeters used and details of their calibration, the date of irradiation and the type of radiation source. All documentation should be available to authorized personnel and accessible for a period of time established by food control authorities.

#### 6.7 Control of hazards

Controls of microbiological hazards are described in the International Code of Practice - General Principles of Food Hygiene (RCP 01-1969, Rev 3-1997, Amd 1-1999).

The radiation processor should apply HACCP principles, as described in the Codex Hazard Analysis Critical Control Point System and Guidelines for Its Application (1999), as appropriate. In the overall HACCP context,

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ISO/ASTM 51431 – Standard Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing; ISO/ASTM 51261 – Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing.

<sup>5</sup> ISO/ASTM 51261 – Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

<sup>6</sup> ISO/ASTM 51204 – Standard Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing and ISO/ASTM 51431 – Standard Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing

<sup>7</sup> Codes of good irradiation practice and compilations of technical data for the authorization and control of the irradiation of several food classes have been produced by ICGFI, available through the International Atomic Energy Agency, PO Box 100, A-1400 Vienna, Austria.

irradiation is a means of reducing hazards associated with infectious parasites and microbial contamination of foods and may be used as a method of control.

## **7. POST-IRRADIATION STORAGE AND HANDLING**

Refer to the International Code of Practice - General Principles of Food Hygiene (RCP 01-1969, Rev 3-1997, Amd 1-1999) for general storage and handling guidance.

## **8. LABELLING**

The Codex General Standard for Irradiated Foods (CX-STAN 106-1983, under revision) and the Codex General Standard for the Labelling of Pre-Packaged Foods (CX-STAN-002, Rev 2, 1999) contain provisions for labelling of irradiated foods, including the internationally recognized symbol (logo) and the inclusion of information in shipping documents, and for the labelling of prepackaged irradiated foods, respectively. All food labelling must meet any additional requirements established by competent authorities.

**SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM  
THE FIFTY-SEVENTH MEETING OF THE JOINT FAO/WHO  
EXPERT COMMITTEE ON FOOD ADDITIVES  
(At step 5/8 of the Procedure)**

Note. Food additive specifications under Categories III, IV and V are included in the Report of the Working Group on Specifications (Conference Room Document 2)

**CATEGORY I (RECOMMENDED TO THE COMMISSION FOR ADOPTION)**

**Food additives (18 substances)**

• Acesulfame potassium	• DL-Malic acid
• Blackcurrant extract	• Modified starches
• Calcium dihydrogen diphosphate	• Pectins
• Carrageenan	• Processed Euchema seaweed
• Curcumin	• Smoke flavourings
• Curdlan	• Sodium calcium polyphosphate
• alpha-Cyclodextrin	• Sodium sulfate
• Hydrogenated poly-1-decene	• D-Tagatose
• Invertase from <i>Saccharomyces cerevisiae</i>	• Tagetes extract

**Certain anticaking agents, flavouring agents, sweetening agents and thickening agents:  
deletion of Heavy Metals (as Lead) and new limits for arsenic and lead**

Substance	As mg/kg	Pb mg/kg	Substance	As mg/kg	Pb mg/kg
<b>ANTICAKING AGENTS</b>			<b>SWEETENING AGENTS</b>		
Calcium aluminium silicate	-	5	Alitame	-	1
Ferrocyanides of Ca, K, and Na	3	5	Aspartame	-	1
Magnesium silicates (synthetic)	-	5	Cyclohexylsulfamic acid	-	1
Silicon dioxide (amorphous)	-	5	Isomalt	-	1
Tricalcium phosphate	-	4	Lactitol	-	1
Trimagnesium phosphate	-	4	Mannitol	-	1
<b>FLAVOUR ENHANCERS</b>			Saccharin and its Na, K and Ca salts	-	1
Calcium-5'-guanylate	-	1	Sorbitol	-	1
Calcium-5'-inosinate	-	1	Sorbitol syrup	-	1
Calcium-5'-ribonucleotides	-	1	Sucralose	-	1
Calcium di-L-glutamate	-	1	Xylitol	-	1
Dipotassium-5'-guanylate	-	1	<b>THICKENING AGENTS</b>		
Dipotassium-5'-inosinate	-	1	Ammonium alginate	-	2
Disodium-5'-guanylate	-	1	Ethyl cellulose	-	2
Disodium-5'-inosinate	-	1	Karaya gum	-	2
Disodium-5'-ribonucleotides	-	1	Konjac flour	-	2
Ethyl maltol	-	1	Methyl cellulose	-	2
L-Glutamic acid	-	1	Powdered cellulose	-	2
5'-Guanylic acid	-	1	Tara gum	-	2
5'-Inosinic acid	-	1	Tragacanth gum	-	2
Magnesium di L-glutamate	-	1			
Monoammonium L-glutamate	-	1			
Monopotassium L-glutamate	-	1			

Monosodium L-glutamate	-	1		
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**Flavouring agents (276 substances)**

JECFA No.	Flavouring agent	JECFA No.	Flavouring agent
10	Allyl tiglate	789	2-Ethyl(or methyl)-(3,5 or 6)-methoxypyrazine
12	Allyl cyclohexane acetate	790	2-Methoxy-(3,5 or 6)-isopropylpyrazine
14	Allyl cyclohexane butyrate	791	2-Methoxy-3-(1-methylpropyl)-pyrazine
15	Allyl cyclohexane valerate	792	2-Isobutyl-3-methoxypyrazine
16	Allyl cyclohexane hexanoate	793	2-Methyl-3,5 or 6-ethoxypyrazine
22	Benzaldehyde	794	2-(Mercaptomethyl)pyrazine
23	Benzyl acetate	795	2-Pyrazinylethanethiol
24	Benzyl benzoate	796	Pyrazinylmethyl methyl sulfide
25	Benzyl alcohol	797	(3,5 or 6)-(Methylthio)-2-methylpyrazine
42	Isoamyl formate	798	5-Methylquinoxaline
51	Isoamyl 2-methyl butyrate	799	$\alpha$ -Methylbenzyl alcohol
58	Geranyl acetate	800	$\alpha$ -Methylbenzyl formate
64	Rhodinyl propionate	801	$\alpha$ -Methylbenzyl acetate
70	Geranyl hexanoate	802	$\alpha$ -Methylbenzyl propionate
72	Geranyl isobutyrate	803	$\alpha$ -Methylbenzyl butyrate
74	Rhodinyl isobutyrate	804	$\alpha$ -Methylbenzyl isobutyrate
77	Rhodinyl isovalerate	805	p, $\alpha$ - Dimethylbenzyl alcohol
78	3,7-Dimethyl-2,6-octadien-1-yl-2-ethyl butanoate	806	Acetophenone
95	Heptanal	807	4-Methylacetophenone
101	Nonanal	808	p-Isopropylacetophenone
107	Undecanal	809	2,4-Dimethylacetophenone
117	Propyl formate	810	Acetanisole
119	n-Amyl formate	811	Methyl $\beta$ -naphthyl ketone
124	Isobutyl formate	812	4-Acetal-6-t-butyl-1,1-dimethylindan
170	n-Amyl heptanoate	813	1-(p-Methoxyphenyl)-2-propanone
172	Isobutyl heptanoate	815	4-Phenyl-2-butanol
178	Nonyl octanoate	816	4-Phenyl-2-butyl acetate
180	Methyl laurate	818	4-(p-Methoxyphenyl)-2-butanone
184	Butyl stearate	819	4-Phenyl-3-buten-2-ol
191	<i>trans</i> -3-Heptenyl-2-methyl propanoate	820	4-Phenyl-3-buten-2-one
205	Methyl 2-methylbutyrate	821	3-Methyl-4-phenyl-3-buten-2-one
212	2-Methylbutyl 2-methylbutyrate	822	1-Phenyl-1-propanol
240	$\omega$ -6-Hexadecene lactone	823	$\alpha$ -Ethylbenzyl butyrate
249	<i>cis</i> -4-Hydroxy-6-dodecenoic acid lactone	824	Propiophenone
260	2-Methylpentanal	825	$\alpha$ -Propylphenethyl alcohol
265	2-Methylhexanoic acid	826	1-(p-Methoxyphenyl)-1-penten-3-one
266	5-Methylhexanoic acid	827	$\alpha$ -Isobutylphenethyl alcohol
270	2-Methyloctanal	828	4-Methyl-1-phenyl-2-pentanone
273	2,6-Dimethyloctanal	829	1-(4-Methoxyphenyl)-4-methyl-1-penten-3-one
275	2-Methylundecanal	830	3-Benzyl-4-heptanone
304	Isopropyl formate	831	Benzophenone
306	Isopropyl propionate	832	1,3-Diphenyl-2-propanone
308	Isopropyl hexanoate	833	1-Phenyl-1,2-propanedione
322	<i>cis</i> -5-Octen-1-ol	834	Ethyl benzoylacetate
323	<i>cis</i> -5-Octenal	835	Ethyl 2-acetyl-3-phenyl-propionate

JECFA No.	Flavouring agent	JECFA No.	Flavouring agent
325	<i>cis</i> -6-Nonenal	836	Benzoin
326	4-Decenal	837	Benzaldehyde dimethyl acetal
328	9-Decenoic acid	838	Benzaldehyde glyceryl acetal
330	10-Undecenal	839	Benzaldehyde propylene glycol acetal
334	Methyl 3-hexenoate	840	Benzyl 2-methoxyethyl acetal
344	Butyl 10-undecenoate	841	Benzyl formate
347	2-Methyl-3-pentenoic acid	842	Benzyl propionate
348	2,6-Dimethyl-6-hepten-1-ol	843	Benzyl butyrate
350	Ethyl 2-methyl-3-pentenoate	844	Benzyl isobutyrate
352	Hexyl 2-methyl-3&4-pentenoate (mixture)	845	Benzyl isovalerate
367	Terpinyl formate	846	Benzyl trans-2-methyl-2-butenolate
370	Terpinyl butyrate	848	Benzyl acetoacetate
372	Terpinyl isovalerate	849	Benzyl phenylacetate
374	<i>p</i> -Menth-8-en-1-ol	850	Benzoic acid
388	beta-Ionone	851	Methyl benzoate
401	Allyl-beta-ionone	852	Ethyl benzoate
404	alpha-iso-Methylionone	853	Propyl benzoate
416	5-Hydroxy-4-octanone	854	Hexyl benzoate
424	2-Hydroxy-2-cyclohexen-1-one	855	Isopropyl benzoate
428	<i>d</i> -neo-Menthol	856	Isobutyl benzoate
434	<i>p</i> -Menth-1-en-3-ol	857	Isoamyl benzoate
440	2-Ethyl-1,3,3-trimethyl-2-norbornanol	858	<i>cis</i> -3-Hexenyl benzoate
442	Methyl 1-acetoxycyclohexyl ketone	859	Linalyl benzoate
448	1-Ethylhexyl tiglate	860	Geranyl benzoate
457	(1-Buten-1-yl) methyl sulfide	863	Methylbenzyl acetate (mixed <i>o,m,p</i> )
461	3-(Methylthio)propanol	864	<i>p</i> -Isopropylbenzyl alcohol
478	3-(Methylthio)propyl acetate	865	4-Ethylbenzaldehyde
510	2-Propanethiol	867	Tolualdehyde glyceryl acetal
531	2-Naphthalenethiol	868	Cuminaldehyde
543	Trithioacetone	869	2,4-Dimethylbenzaldehyde
562	2,5-Dimethyl-2,5-dihydroxy-1,4-dithiane	871	Anisyl alcohol
580	2-Methyl-2-(methylthio)propanal	873	Anisyl acetate
581	Ethyl 2-(methylthio)propionate	874	Anisyl propionate
591	Methyl 2-oxo-3-methyl-pentanoate	875	Anisyl butyrate
599	Geranyl acetoacetate	876	Anisyl phenylacetate
645	3-Phenylpropionaldehyde	877	Veratraldehyde
648	Cinnamaldehyde ethylene glycol acetal	878	<i>p</i> -Methoxybenzaldehyde
652	Cinnamyl butyrate	879	<i>p</i> -Ethoxybenzaldehyde
656	Cinnamaldehyde	880	Methyl <i>o</i> -methoxybenzoate
660	Propyl cinnamate	881	2-Methoxybenzoic acid
663	Butyl cinnamate	882	3-Methoxybenzoic acid
666	Heptyl cinnamate	883	4-Methoxybenzoic acid
671	Phenethyl cinnamate	884	Methyl anisate
672	3-Phenylpropyl cinnamate	885	Ethyl <i>p</i> -anisate
673	Cinnamyl cinnamate	886	Vanillyl alcohol
676	$\alpha$ -Amylcinnamyl formate	887	Vanillyl ethyl ether
677	$\alpha$ -Amylcinnamyl acetate	888	Vanillyl butyl ether
681	$\alpha$ -Amylcinnamaldehyde dimethyl acetal	889	Vanillin

JECFA No.	Flavouring agent	JECFA No.	Flavouring agent
698	o-Tolyl acetate	890	Vanillin acetate
711	p-Vinylphenol	891	Vanillin isobutyrate
719	Guaiacyl phenylacetate	892	Ethyl vanillin $\beta$ -d-glucopyranoside
720	Hydroquinone monoethyl ether	893	Ethyl vanillin
723	4-Ethyl-2,6-dimethoxyphenol	894	Piperonyl acetate
724	4-Propyl-2,6-dimethoxyphenol	895	Piperonyl isobutyrate
726	4-Allyl-2,6-dimethoxyphenol	896	Piperonal
732	Vanillylidene acetone	897	Salicylaldehyde
740	Furfuryl propionate	898	2-Hydroxy-4-methylbenzaldehyde
741	Furfuryl pentanoate	899	Methyl salicylate
742	Furfuryl octanoate	900	Ethyl salicylate
743	Furfuryl 3-methylbutanoate	901	Butyl salicylate
748	Amyl 2-furoate	902	Isobutyl salicylate
749	Hexyl 2-furoate	903	Isoamyl salicylate
750	Octyl 2-furoate	904	Benzyl salicylate
759	Furfuryl butyrate	905	Phenethyl salicylate
760	Cinnamyl benzoate	907	o-Tolyl salicylate
761	2-Methylpyrazine	908	2,4-Dihydroxybenzoic acid
762	2-Ethylpyrazine	912	Heptanal glyceryl acetal (mixed 1,2 and 1,3 acetals)
763	Propylpyrazine	913	1,2,3-Tris[(1'-ethoxy)ethoxy]propane
764	Isopropylpyrazine	927	1,2-Di[(1-ethoxy)ethoxy]propane
765	2,3-Dimethylpyrazine	928	4-Methyl-2-pentyl-1,3-dioxolan
766	2,5-Dimethylpyrazine	929	2,2,4-Trimethyl-1,3-oxacyclopentane
767	2,6-Dimethylpyrazine	930	Lactic acid
768	2-Ethyl-3-methylpyrazine	931	Ethyl lactate
769	2-Ethyl-6-methylpyrazine	932	Butyl lactate
770	2-Ethyl-5-methylpyrazine	933	Potassium 2-(1'-ethoxy)ethoxypropanoate
771	2,3-Diethylpyrazine	934	cis-3-Hexenyl lactate
772	2-Methyl-5-isopropylpyrazine	935	Butyl butyryllactate
773	2-Isobutyl-3-methylpyrazine	936	Pyruvic acid
774	2,3,5-Trimethylpyrazine	938	Ethyl pyruvate
775	2-Ethyl-3, (5 or 6)-dimethylpyrazine	939	Isoamyl pyruvate
776	3-Ethyl-2,6-dimethylpyrazine	940	1,1-Dimethoxyethane
777	2,3-Diethyl-5-methylpyrazine	941	Acetal
778	2,5-Diethyl-3-methylpyrazine	942	Octanal dimethyl acetal
779	3,5-Diethyl-2-methylpyrazine	944	Citral dimethyl acetal
780	2,3,5,6-Tetramethylpyrazine	945	Decanal dimethyl acetal
781	5-Methyl-6,7-dihydro-5H-cyclopentapyrazine	946	2,6-Nonadienal diethyl acetal
782	6,7-Dihydro-2,3-dimethyl-5H-cyclopentapyrazine	947	Heptanal, dimethyl acetal
783	(Cyclohexylmethyl)pyrazine	948	Citral diethyl acetal
784	Acetylpyrazine	949	4-Heptenal diethyl acetal
785	2-Acetyl-3-ethylpyrazine	950	2-Acetyl-3-methylpyrazine
786	2-Acetyl-3,(5 or 6)-dimethylpyrazine	951	Pyrazine
787	Methoxypyrazine	952	5,6,7,8 -Tetrahydroquinoxaline
788	(2,5 or 6)-Methoxy-3-methylpyrazine	953	Ethyl vanillin isobutyrate



**CATEGORY II (RECOMMENDED FOR ADOPTION AFTER EDITORIAL CHANGES, INCLUDING TECHNICAL REVISIONS)****Food Additives**

Diacetyltartaric and fatty acid esters of glycerol Remark: Insert the percentage for Free Fatty Acids

**Flavouring agents**

None

**DRAFT AMENDMENTS TO THE INTERNATIONAL  
NUMBERING SYSTEM FOR FOOD ADDITIVES  
(At Step 5 of the Accelerated Procedure)**

<b>INS NUMBER</b>	<b>COMPOUND</b>	<b>TECHNOLOGICAL FUNCTION</b>
452(vi)	Sodium potassium tripolyphosphate	Emulsifier, Stabilizer, Acidity regulator, Raising agent Sequesterant, Water retention agent

**DRAFT AMENDMENTS TO THE INTERNATIONAL  
NUMBERING SYSTEM FOR FOOD ADDITIVES  
(At Step 5/8 of the Procedure)**

<b>INS NUMBER</b>	<b>COMPOUND</b>	<b>TECHNOLOGICAL FUNCTION</b>
163 (iv)	Purple corn colour	Colour
163 (v)	Red cabbage colour	Colour
165	Gardenia blue	Colour
407	Carrageenan and its Na, K, NH <sub>4</sub> , Ca and Mg salts (includes furcellaran)	Thickener, Gelling agent, Stabilizer
445	Glycerol esters of wood rosin	Emulsifier, Stabilizer, Glazing agent
650	Zinc acetate	Flavour enhancer
949	Hydrogen	Packing gas
961	Neotame	Sweetener, Flavour enhancer

**PROPOSED DRAFT AMENDMENTS TO THE INTERNATIONAL  
NUMBERING SYSTEM FOR FOOD ADDITIVES  
(At Step 5 of the Procedure)**

<b>INS NUMBER</b>	<b>COMPOUND</b>	<b>TECHNOLOGICAL FUNCTION</b>
905d	Mineral oil, high viscosity	Glazing agent, Release agent, Sealing agent
905e	Mineral oil, medium and low viscosity (Class I)	Glazing agent, Release agent, Sealing agent
905f	Mineral oil, medium and low viscosity (Class II)	Glazing agent, Release agent, Sealing agent
905g	Mineral oil, medium and low viscosity (Class III)	Glazing agent, Release agent, Sealing agent

**DRAFT AMENDMENTS TO THE INTERNATIONAL  
NUMBERING SYSTEM FOR FOOD ADDITIVES  
(At Step 5 of the Accelerated Procedure)**

<b>INS NUMBER</b>	<b>COMPOUND</b>	<b>TECHNOLOGICAL FUNCTION</b>
452(vi)	Sodium potassium tripolyphosphate	Emulsifier, Stabilizer, Acidity regulator, Raising agent Sequesterant, Water retention agent

**DRAFT AMENDMENTS TO THE INTERNATIONAL  
NUMBERING SYSTEM FOR FOOD ADDITIVES  
(At Step 5/8 of the Procedure)**

<b>INS NUMBER</b>	<b>COMPOUND</b>	<b>TECHNOLOGICAL FUNCTION</b>
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**PROPOSED DRAFT AMENDMENTS TO THE INTERNATIONAL  
NUMBERING SYSTEM FOR FOOD ADDITIVES  
(At Step 5 of the Procedure)**

<b>INS NUMBER</b>	<b>COMPOUND</b>	<b>TECHNOLOGICAL FUNCTION</b>
905d	Mineral oil, high viscosity	Glazing agent, Release agent, Sealing agent
905e	Mineral oil, medium and low viscosity (Class I)	Glazing agent, Release agent, Sealing agent
905f	Mineral oil, medium and low viscosity (Class II)	Glazing agent, Release agent, Sealing agent
905g	Mineral oil, medium and low viscosity (Class III)	Glazing agent, Release agent, Sealing agent

**PROPOSED DRAFT PRINCIPLES FOR EXPOSURE ASSESSMENT OF  
CONTAMINANTS AND TOXINS IN FOODS  
(At Step 3 of the Procedure)**

Annex I

**CCFAC PRINCIPLES FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND  
TOXINS IN FOODS OR FOOD GROUPS**

**Introduction**

1. Exposure assessment is a basic component of risk assessment of contaminants and toxins. Risk assessments and exposure assessments requested by CCFAC and performed by JECFA, must be guided by clearly articulated policies elaborated by CCFAC with the aim of increasing the transparency of risk management decisions. This annex includes:

- A framework that outlines the basic components of exposure assessment
- Definition of criteria for selecting foods that contribute significantly to exposure for a contaminant or toxin

2. The following components of exposure assessment performed by JECFA make up the conduct of a transparent, consistent, science-based risk assessment for contaminants and toxins in foods. CCFAC will take into account this information to establish risk management options and recommendations for contaminants and toxins in foods. *These components do not need to be done consecutively.*

**Component 1**

*JECFA uses available data to estimate dietary exposure to a contaminant or toxin, expressed as a percentage of the tolerable intake (e.g., PTDI, PTWI or other appropriate toxicological reference point). For a carcinogen with no clear threshold, JECFA uses available data on intake, combined with data on carcinogenic potency to estimate potential population risks.*

**Component 2**

*From dietary exposure estimates obtained in Component 1, JECFA identifies food/food groups that contribute significantly to exposure to that contaminant or toxin (significant as defined by CCFAC policy).*

**Component 3**

(concurrent with Component 2; or subsequent step)

*If requested by CCFAC, for foods or food groups identified in Component 2, JECFA uses available data on contaminant levels to generate distribution curves for concentrations of the contaminant or toxin in specific foods or food groups.*

**Component 4**

(concurrent with Component 2; or subsequent step)

*If requested by CCFAC, JECFA will assess the impact of agricultural and production practices on contaminant levels in food.*

**Criteria for selecting food or food groups that constitute a significant contribution to dietary exposure for a contaminant or toxin**

3. The proposed criteria include the following:

Food or food groups that represent 10% or more of the total dietary exposure in one of the GEMS/Food Regional diets

*and/or*

Food or food groups that represent 5% or more of the total dietary exposure in two or more of the GEMS/Food Regional diets

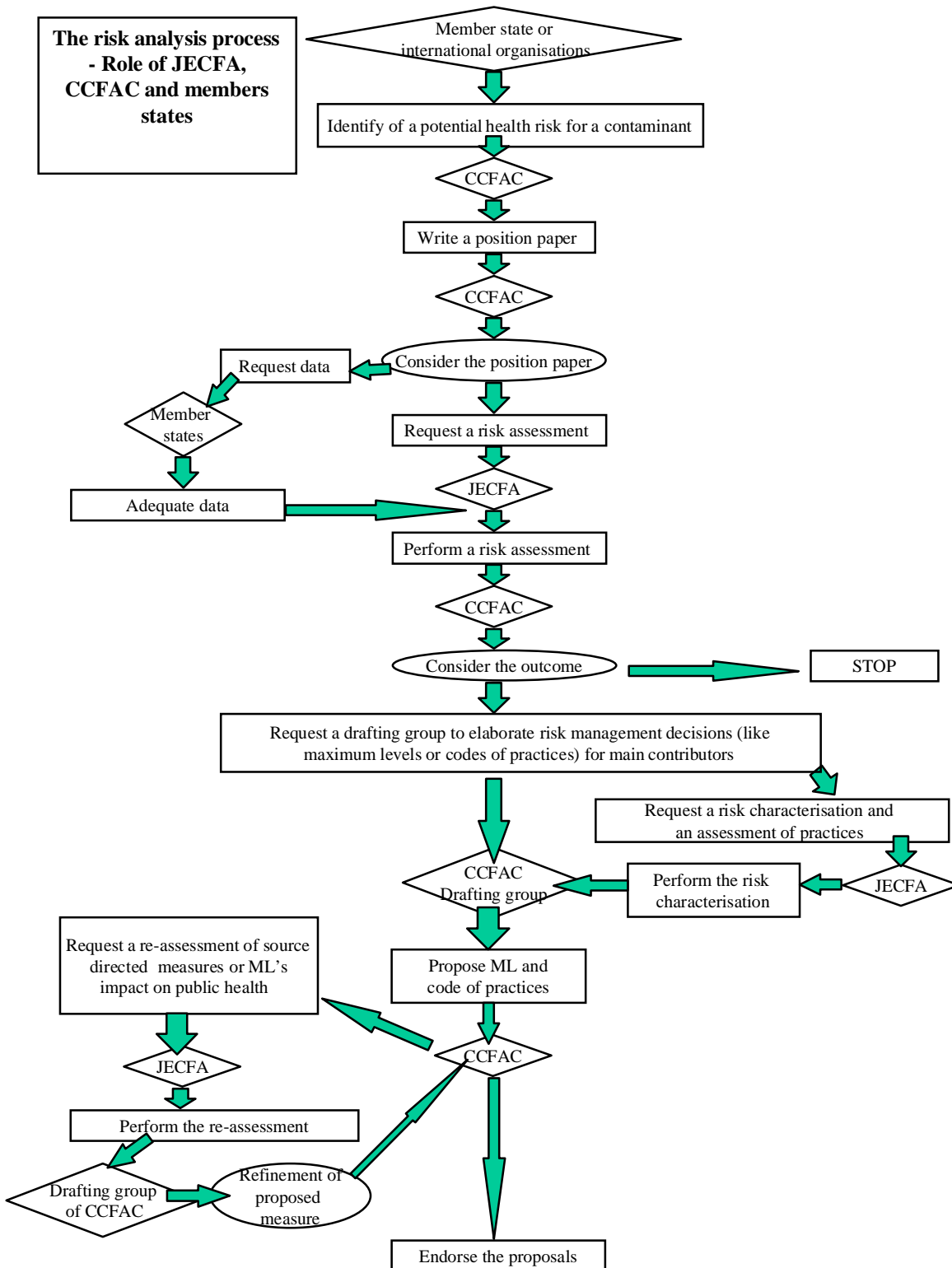
*and/or*

Food or food groups that may have a significant impact on exposure for specific group of consumers, although it may not exceed 5% of the total dietary exposure in any of the GEMS/Food Regional diets. These would be considered on a case-by-case basis.

**THE RISK ANALYSIS PROCESS**  
**Role of JECFA, CCFAC and members states (MS)**

ACTIVITIES	JECFA	CCFAC	MS
1. Identification of a potential health risk for a contaminant			X
2. Write a position paper		X	X
3. Check for availability of data and commitment to submit those to JECFA		X	
4. Request risk assessment with specific question (PTWI, exposure as a percentage of TDI, PTWI or PTMI, distribution curves etc.)		X	
5. Call for data for risk assessment and information on processing factors	X		
6. Submit data and information on processing factors			X
7. Perform risk assessment as a concise report	X		
8. Define risk management options (ML's or/and source directed measures) on basis of the risk assessment		X	
9. Drafting group appointed to propose ML's on main contributors		X	
10. Drafting group discusses risk assessment and proposes ML's to plenary		X	
11. Endorse proposed draft ML's in CCFAC plenary and propose new work to CAC		X	
12. CAC agrees to new work			
13. If required by members, request risk characterisation and assessment of source directed measures or practices		X	
14. Perform risk characterisation	X		
15. If Required by members, request specially the re-assessment of source directed measures or ML's impact on public health for general population or specific subgroups		X	
16. Re-assessment of risk characterisation with an emphasis on exposure assessment after risk management options are decided	X		
17. Refinement of proposed measures		X	

**The risk analysis process  
- Role of JECFA,  
CCFAC and members  
states**



**DRAFT MAXIMUM LEVEL FOR OCHRATOXIN A IN RAW  
WHEAT, BARLEY AND RYE AND DERIVED PRODUCTS**

**(At Step 8 of the Procedure)**

**Ochratoxin A**            **5 µg/kg** in Raw Wheat, Barley and Rye and Derived Products



**DRAFT MAXIMUM LEVEL FOR PATULIN**

**(At Step 8 of the Procedure)**

**Patulin**                    **50 µg/kg** in apple juice and apple juice ingredients in other beverages

**PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF PATULIN  
CONTAMINATION IN APPLE JUICE AND APPLE JUICE INGREDIENTS  
IN OTHER BEVERAGES  
(At Step 5 of the Procedure)**

## INTRODUCTION

1. Patulin is a secondary metabolite produced by a number of fungal species in the genera *Penicillium*, *Aspergillus* and *Byssochlamys* of which *Penicillium expansum* is probably the most commonly encountered species. Patulin has been found as a contaminant in many mouldy fruits, vegetables, cereals and other foods, however, the major sources of contamination are apples and apple products.

2. Alcoholic fermentation of fruit juices destroys patulin (1,2) and, therefore, fermented products such as cider and perry will not contain patulin. Ascorbic acid has been reported to cause the disappearance of patulin from apple juice, although the optimal conditions for inactivation have not been fully established (3,4). Patulin is relatively temperature stable, particularly at acid pH. High temperature (150° C) short-term treatments have been reported to result in approximately 20% reduction in patulin concentrations. However, thermal processing alone is not sufficient to ensure a product free of patulin (5).

3. There is no clear evidence that patulin is carcinogenic, however, it has been shown to cause immunotoxic effects (6) and is neurotoxic in animals (7). The IARC (8) concluded that no evaluation could be made of the carcinogenicity of patulin to humans and that there was inadequate evidence in experimental animals. Patulin was evaluated by the JECFA in 1990 and re-evaluated in 1995. The latter evaluation took into account the fact that most of the patulin ingested by rats is eliminated within 48 hours and 98% within 7 days. A study on the combined effects of patulin on reproduction, long-term toxicity and carcinogenicity pointed to a harmless intake of 43 µg/kg body weight per day. On the basis of this work and using a safety factor of 100, the JECFA set a provisional maximum tolerable daily intake of 0.4 µg/kg body weight.

4. Patulin occurs mainly in mould-damaged fruits although the presence of mould does not necessarily mean that patulin will be present in a fruit but indicates that it may be present. In some instances, internal growth of moulds may result from insect or other invasions of otherwise healthy tissue, resulting in occurrence of patulin in fruit which externally appears undamaged. However, it can also occur in bruised fruit after controlled atmosphere storage and exposure to ambient conditions both with and without core rot being present. Washing of fruit, or removal of mouldy tissue, immediately prior to pressing will not necessarily remove all the patulin present in the fruit since some may have diffused into apparently healthy tissue. Washing apples with ozone solution is reported to contribute substantially to the control of patulin during processing (9).

5. Although the spores of many of the moulds capable of producing patulin will be present on fruit whilst it is still on the tree, they will generally not grow on fruit until after harvest. However, mould growth and patulin production can occur in fruit pre-harvest if the fruit becomes affected by disease or damaged by insects or where fallen fruit is gathered for processing. The condition of the fruit at harvest, the way in which the fruit is handled subsequently (especially during storage) and the extent to which storage conditions are inhibitory to the growth of moulds, will all affect the likelihood of patulin contamination of juice and other products prepared from fresh and stored fruit.

6. The recommendations for reducing patulin contamination in apple juice in this document are divided into two parts:

- I) Recommended practices based on Good Agricultural Practice (GAP).
- II) Recommended practices based on Good Manufacturing Practices (GMP).

## I. RECOMMENDED PRACTICES BASED ON GAP

### ***PREHARVEST***

7. During the dormant season cut off, remove and destroy all diseased wood and mummified fruits.
8. Prune trees in line with good commercial practice producing a tree shape which will allow good air movement through the tree and light penetration into the tree. This will also enable good spray cover to be achieved.
9. Measures should be taken to control pests and diseases which directly cause fruit rots or allow entry sites for patulin-producing moulds. These include canker, eye rot (*Botrytis* spp and *Nectria* spp), codling moth, fruitlet mining tortrix moth, winter moth, fruit tree tortrix, blastobasis, sawfly and dock sawfly.
10. Wet weather around the time of petal fall and of harvesting is likely to increase the risk of rot and appropriate measures, such as application of fungicide to prevent spore germination and fungal growth should be considered.
11. Apples of poor mineral composition are more likely to suffer physiological disorders in store and hence are more susceptible to particular types of rot especially by *Gloeosporium* spp and secondary rots such as *Penicillium*. Consignments of apples for the fresh fruit market which do not meet the recommended mineral compositional standards (10), as determined by fruit analysis, should therefore be excluded from long-term storage i.e. storage for longer than 3 - 4 months.
12. Where levels of minerals in the fruit for the fresh fruit market are outside optimum ranges (10), improving calcium and phosphorus levels in the fruit, particularly increasing the calcium/potassium ratio by controlled fertiliser usage, will improve cell structure, which will then reduce susceptibility to rotting (11,12).
13. Records of rot levels should be kept each year for individual orchards since historical data is the best guide, at present, to potential rot levels, which will indicate the need for fungicide application and the storage potential of the fruit from that orchard.

### ***HARVESTING AND TRANSPORTATION OF FRUIT***

14. Apples for processing are from two different origins:
  - a) **Mechanically harvested fruit**
    15. Mechanically harvested fruit is obtained by shaking the tree and collecting the fruit from the ground with appropriate mechanical machinery.
    16. All fruit should be handled as gently as possible and every effort made to minimize physical damage at all stages of the harvesting and transportation procedures.
    17. Before shaking the trees, deteriorated fallen fruit (rotten, fleshed etc.) should be removed from the ground in order to make sure that only fresh and/or sound fruit is collected.
    18. Mechanically harvested fruit has to be transported to processing plants within 3 days after harvest.
    19. All containers used to transport harvested fruit should be clean, dry and free of any debris.
  - b) **Fruit for the fresh fruit market**
    20. Fruit from orchards with a history of high levels of rot should be harvested separately and not considered for storage.

21. Ideally all fruit should be picked in dry weather conditions, when the fruit is mature, and placed in clean bins or other containers (e.g. boxes) suitable for transportation directly to store. Bins or boxes should be cleaned, ideally by hosing with clean water or preferably by scrubbing with soap and water, and fruit and leaf debris should be removed. Cleaned bins and boxes should be dried prior to use. Avoid exposure of fruit to rain.
22. Adequate training and supervision should be provided to ensure good damage-free picking practice.
23. All fruit in which the skin is damaged, or with the flesh exposed, as well as all diseased fruit, should be rejected in the orchard at the time of picking and fruit bruising should be minimised as far as possible.
24. All soil-contaminated fruit, i.e. rain splashed fruit or fruit on the ground, should be rejected for storage purposes.
25. Care must be taken to avoid the inclusion of leaves, twigs etc. in the picked fruit.
26. Fruit should be placed in cold storage within 18 hours of harvest and cooled to the recommended temperatures (see Table 1) within 3 - 4 days of picking.
27. During transport and storage, measures should be taken to avoid soil contamination.
28. Care must be taken during handling and transport of the bins or boxes in the orchard, and between the orchard and store, to avoid soil contamination of the container and the fruit and to minimize physical damage e.g. bruising of the fruit.
29. Harvested fruit should not be left in the orchard overnight but moved to a hard standing area, preferably under cover.

### ***POST-HARVEST HANDLING AND STORAGE PRACTICES OF FRUIT FOR THE FRESH FRUIT MARKET***

30. All fruit, whether for the fresh market or for later processing, should be handled as gently as possible and every effort made to minimise physical damage e.g. bruising at all stages of post-harvest handling prior to pressing.
31. Apple growers, and other producers of juice who do not have controlled storage facilities, need to ensure that fruits for juicing are pressed as soon as possible after picking.
32. For controlled atmosphere storage ensure that stores are checked for gas tightness, where appropriate, and that all monitoring equipment is tested before harvesting commences. Pre-cool stores thoroughly before use.
33. Where appropriate post harvest fungicide treatments may be applied in accordance with manufacturers' recommendations.
34. Stored apples should be examined regularly, at least once a month, for rot levels; a record of the levels should be maintained from year to year. The sampling procedure used should minimize the risk of atmospheric changes occurring in the store (see para. 37).
35. Random samples of fruit should be placed in suitable containers (e.g. net bags) situated close to the inspection hatches to permit monitoring of fruit condition during the storage period (see para. 36). Samples should be examined for rots, general fruit condition and shelf life at least every month. Shorter intervals may be recommended in stores where the fruit storage conditions are less than optimum and/or the fruit has a predicted storage life of less than 3 months, because of adverse growth and/or harvesting conditions.

36. Where samples indicate problems with fruit condition appropriate action should be taken to remove the fruit for use before extensive damage occurs.

37. Mould growth normally occurs in a warm environment. Rapid cooling and maintenance of store atmosphere conditions will improve fruit condition. Ideally fruit should be loaded and cooled to less than 5 ° C in 3 - 4 days and to optimum temperatures within a further 2 days. Controlled atmosphere conditions should be achieved within 7 - 10 days from the start of loading, and ultra-low oxygen regimes (i.e. less than 1.8% oxygen) should be established within a further 7 days (13).

### ***POST-STORAGE GRADING OF FRUIT FOR THE FRESH MARKET OR JUICE MANUFACTURE***

38. All rotten fruits, even those with only small areas of rot, should be eliminated as far as possible and wholesome fruit should be kept in a clean bulk container.

39. When containers are removed from storage to select fruit for retail distribution, the containers of fruit remaining for juicing should be specifically marked and returned to cold store within 12 hours of sorting. The time the fruit is at ambient temperatures should be kept to a minimum. Ideally fruit for juicing should be kept at < 5° C between withdrawal from store and juicing and should be utilized as soon as possible.

40. Fruit which is to be sent for juicing should be utilized as soon as possible and within the normal shelf life which would be recommended for fruit from the same store. Any bruising will encourage patulin formation hence bruising should be kept to a minimum, especially if fruit is to be stored for longer than 24 hours at ambient temperature before juicing (14).

## **II. RECOMMENDED PRACTICES BASED ON GMP**

### ***TRANSPORTATION, CHECKING, AND PRESSING OF FRUIT***

#### **Mechanically harvested fruit and fruit for the fresh market**

##### **(a) fruit for the fresh market**

41. Stored fruit should be transported from the cold store to the processor in the shortest time possible (ideally <24 hours to pressing unless cold stored).

42. Varieties with an open calyx are particularly susceptible to core rots. These varieties should be examined for internal rots by regular checks immediately prior to pressing. An appropriate random sample of apples should be preferably taken from each separate batch of fruit. Each apple is then cut across its equator and examined for signs of mycelial growth. If the frequency of core rots exceeds an agreed level the consignment should not be used for juicing. The processor should specify the maximum proportion of supplied fruit which can have any sign of rotting, taking into account the capacity of the processor to remove the rotting fruit during pre-process inspection. If this proportion is exceeded the whole consignment of fruit should be rejected.

43. On arrival at the factory the fruit should be checked for quality, particularly for evidence of both external and internal mould damage (see para. 44).

##### **(b) mechanically harvested fruit and fruit for the fresh market**

44. During processing and prior to pressing, the fruit should be sorted carefully to remove any visually mouldy fruit (check randomly and routinely for internal mould by cutting some fruit as in para. 44) and washed thoroughly, using potable or suitably treated water.

45. Juice presses and other manufacturing equipment should be cleaned and sanitised in accordance with industry "best practices". Juice presses and other equipment will generally be washed down with pressured water hoses and sanitised by application of a suitable sanitiser, followed by a further rinse with potable cold

water. In some plants, which operate almost continuously, this should preferably be a once per shift or once per day cleaning operation.

46. After pressing samples of juice should be taken for analysis. A representative bulk production sample should be analysed for patulin by an appropriate method in a laboratory which is accredited to carry out such analyses.

47. The juice should preferably be chilled to  $<5^{\circ}\text{C}$  and maintained chilled until it is concentrated, packaged or pasteurised.

48. Juice should only be sent for packing on a positive release basis after patulin analysis has been confirmed as being below the maximum agreed limit. Specifications for the purchase of apple juice should include an appropriate limit for patulin subject to confirmation by the recipient.

### ***PACKAGING AND FINAL PROCESSING OF JUICE***

49. Moulds which are capable of producing patulin may occur, together with other moulds and yeasts, particularly in NFC juice. It is essential to prevent the development of such organisms during transport and storage to prevent spoilage of the product and by the same means prevent the production of patulin.

50. If juice is to be held for a period prior to use the temperature should preferably be reduced to  $5^{\circ}\text{C}$  or less, in order to reduce microbial development.

51. Most juice will be heat processed to ensure destruction of enzymes and spoilage organisms. It must be recognized that whilst such processes will generally destroy fungal spores and vegetative mycelium the process conditions will not destroy any patulin which is already present.

### ***QUALITY ASSESSMENT OF JUICE***

52. Specifications for the purchase of apple juice or apple juice concentrates should include a maximum limit for patulin based on an appropriate method of analysis.

53. A sampling plan should be developed for random sampling of product to assure that the finished product is within the maximum limit for patulin.

54. The packer must satisfy himself that the juice supplier is able to control properly his own operations to ensure that the recommendations given above are carried out.

55. Assessment of the quality of apple juice by the packer will include  $^{\circ}\text{Brix}$ , acidity, flavour, colour, turbidity, etc. The microbiological quality should be carefully monitored since this indicates not only the risk level of potential organisms for the production of patulin but also the hygienic aspects of the previous stages in the production cycle.

56. Further checks should be carried out on the packaged product to ensure that no deterioration has taken place during the packaging stage.

### **CONCLUSION**

57. In conclusion, this Code of Practice elaborated in Codex Alimentarius can only contain general principles for the prevention of patulin in apple juice. It is important that these general principles are given sanction by national authorities, taking into account the local varieties of apples, climate, storage facilities and production conditions, in order to make them useful for the growers and processors.

58. At the Third International Conference on Mycotoxins, which took place in Tunisia in March 1999, one of the general recommendations was that integrated mycotoxin control programmes should incorporate Hazard

Analysis and Critical Control Points (HACCP) principles in the control of risks associated with mycotoxin contamination of foods and feeds (15).

59. HACCP is a food safety management system that is used to identify and control hazards within the production and processing system. The general principles of HACCP have been described in several documents (16-18) and FAO/IAEA have recently published a HACCP manual for mycotoxin prevention and control (19).

60. A post-harvest management system based on HACCP for reduction of patulin in apple juice is a possible approach for future consideration.

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**Table 1: Recommended temperatures for storage of apples in air (13)**

Variety	Temperature		Variety	Temperature	
	°C	°F		°C	°F
BRAMLEY	3.0 - 4.0	37 - 39	IDARED	3.5 - 4.0	38 - 39
COX'S ORANGE PIPPIN	3.0 - 3.5	37 - 38	JONAGOLD	0.0 - 0.5	32 - 33
DISCOVERY	1.5 - 2.0	35 - 36	RED DELICIOUS	0.0 - 1.0	32 - 34
EGREMONT	3.0 - 3.5	37 - 38	SPARTAN	0.0 - 0.5	32 - 33
GOLDEN DELICIOUS	1.5 - 2.0	35 - 36	WORCESTER	0.0 - 1.0	32 - 34
CRISPIN	1.5 - 2.0	35 - 36			

**PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION (REDUCTION) OF  
MYCOTOXIN CONTAMINATION IN CEREALS, INCLUDING ANNEXES ON  
OCHRATOXIN A, ZEARALENONE, FUMONISINS AND TRICOTHECENES  
(At Step 5 of the Procedure)**

1. The complete elimination of mycotoxin contaminated commodities is not achievable at this time. The elaboration and acceptance of a General Code of Practice by Codex will provide uniform guidance for all countries to consider in attempting to control and manage contamination by various mycotoxins. In order for this Code of Practice to be effective, it will be necessary for the producers in each country to consider the general principles given in the Code, taking into account their local crops, climate, and agronomic practices, before attempting to implement provisions in the Code. It is important for producers to realize that good agricultural practices (GAP) represent the primary line of defense against contamination of cereals with mycotoxins, followed by the implementation of good manufacturing practices (GMP) during the handling, storage, processing, and distribution of cereals for human food and animal feed.
2. The recommendations for the reduction of mycotoxins in cereals are divided into two parts: recommended practices based on Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP); a complementary management system to consider in the future is Hazard Analysis Critical Control Point (HACCP) principles.
3. This General Code of Practice contains general principles for the reduction of various mycotoxins in cereals that should be sanctioned by national authorities. National authorities should educate producers regarding the environmental factors that promote infection, growth and toxin production in cereal crops at the farm level. Emphasis should be placed on the fact that the planting, preharvest and postharvest strategies for a particular crop will depend on the climatic conditions of that particular year, taking into account the local crops, and traditional production conditions for that particular country or region. There is need to develop quick, affordable and accurate test kits and associated sampling plans that will allow testing of grain shipments without undue disruption of operations. Procedures should be in place to properly handle, through segregation, reconditioning, recall or diversion, cereal crops that may pose a threat to human and/or animal health. National authorities should support research on methods and techniques to prevent fungal contamination in the field and during harvest and storage.

**I. RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP)  
AND GOOD MANUFACTURING PRACTICES (GMP)**

**PLANTING**

4. Consider developing and maintaining a crop rotation schedule to avoid planting the same commodity in a field in two consecutive years. Wheat and maize have been found to be particularly susceptible to *Fusarium* species and they should not be used in rotation with each other. Crops such as potato, other vegetables, clover and alfalfa that are not hosts to *Fusarium* species should be used in rotation to reduce the inoculum in the field.
5. When possible and practical, prepare the seed bed for each new crop by plowing under or by destroying or removing old seed heads, stalks, and other debris that may have served, or may potentially serve as substrates for the growth of mycotoxin-producing fungi. In areas that are vulnerable to erosion, no-till practices may be required in the interests of soil conservation.
6. Utilize the results of soil tests to determine if there is need to apply fertilizer and/or soil conditioners to assure adequate soil pH and plant nutrition to avoid plant stress, especially during seed development.

7. When available, grow seed varieties developed for resistance to seed-infecting fungi and insect pests. Only seed varieties recommended for use in a particular area of a country should be planted in that particular area.
8. As far as practical, crop planting should be timed to avoid high temperature and drought stress during the period of seed development and maturation.
9. Avoid overcrowding of plants by maintaining the recommended row and intra-plant spacing for the species/varieties grown. Information concerning plant-spacing may be provided by seed companies.

## **PREHARVEST**

10. Minimize insect damage and fungal infection in the vicinity of the crop by proper use of registered insecticides, fungicides and other appropriate practices within an integrated pest management program.
11. Control weeds in the crop by use of mechanical methods or by use of registered herbicides or other safe and suitable weed eradication practices.
12. Minimize mechanical damage to plants during cultivation.
13. If irrigation is used, ensure that it is applied evenly and that all plants in the field have an adequate supply of water. Irrigation is a valuable method of reducing plant stress in some growing situations. Excess precipitation during anthesis (flowering) makes conditions favorable for dissemination and infection by *Fusarium* spp.; thus irrigation during anthesis and during the ripening of the crops, specifically wheat, barley, and rye, should be avoided.
14. Plan to harvest grain at low moisture content and full maturity, unless allowing the crop to continue to full maturity would subject it to extreme heat, rainfall or drought conditions. Delayed harvest of grain already infected by *Fusarium* species may cause a significant increase in the mycotoxin content of the crop.
15. Before harvest time, make sure that all equipment, which is to be used for harvesting and storage of crops, is functional. A breakdown during this critical period may cause grain quality losses and enhance mycotoxin formation. Keep important spare parts available on the farm to minimize time loss from repairs. Make sure that the equipment needed for moisture content measurements is available and calibrated.

## **HARVEST**

16. Containers (e.g., wagons, trucks) to be used for collecting and transporting the harvested grain from the field to drying facilities, and to storage facilities after drying, should be clean, dry and free of insects and visible fungal growth before use and re-use.
17. As far as possible, avoid mechanical damage to the grain and avoid contact with soil during the harvesting operation. Steps should be taken to minimize the spread of infected seed heads, chaff, stalks, and debris onto the ground where spores may inoculate future crops.
18. During the harvesting operation, the moisture content should be determined in several spots of each load of the harvested grain since the moisture content may vary considerably within the same field.
19. Immediately after harvest, determine moisture levels of the crop; where applicable, dry the crop to the moisture content recommended for storage of that crop. Samples taken for moisture measurements should be as representative of the lot as possible. To reduce the variation of moisture content within a lot, the grain may be moved to another facility (or silo) after the drying process.

20. Cereals should be dried in such a manner that damage to the grain is minimized and moisture levels are lower than those required to support mold growth during storage (generally less than 15%). This is necessary to prevent further growth of a number of fungal species that may be present on fresh grains, especially *Fusarium* species.

21. Freshly harvested cereals should be cleaned to remove damaged kernels and other foreign matter. Kernels containing symptomless infections cannot be removed by standard cleaning methods. Seed cleaning procedures, such as gravity tables, may remove some infected kernels. More research is needed to develop practical procedures for separating symptomless infected kernels from those that are not infected.

## **STORAGE**

22. Avoid piling or heaping wet, freshly harvested commodities for more than a few hours prior to drying or threshing to lessen the risk of fungal growth. Sun drying of some commodities in high humidity may result in fungal infection. Aerate the commodities by forced air circulation.

23. Make sure that the storage facilities include dry, well-vented structures that provide protection from rain, drainage of ground water, protection from entry of rodents and birds, and minimum temperature fluctuations.

24. Crops to be stored should be dried to safe moisture levels and cooled as quickly as possible after harvest. Minimize the amount of foreign materials and damaged kernels in stored grains. Refer to paragraph 29 to evaluate the use of approved pesticides.

25. The mycotoxin level in in-bound and out-bound grain should be monitored when warranted, using appropriate sampling and testing programs.

26. For bagged commodities, ensure that bags are clean, dry and stacked on pallets or incorporate a water impermeable layer between the bags and the floor.

27. Where possible, aerate the grain by circulation of air through the storage area to maintain proper and uniform temperature levels throughout the storage area. Check moisture content and temperature in the stored grain at regular intervals during the storage period.

28. Measure the temperature of the stored grain at several fixed time intervals during storage. A temperature rise of 2-3°C may indicate microbial growth and/or insect infestation. Separate the apparently infected portions of the grain and send samples for analysis. When separated, lower the temperature in the remaining grain and aerate. Avoid using infected grain for food or feed production.

29. Use good housekeeping procedures to minimize the levels of insects and fungi in storage facilities. This may include the use of suitable, registered insecticides and fungicides or appropriate alternative methods. Care should be taken to select only those chemicals that will not interfere or cause harm based on the intended end use of the grains and should be strictly limited.

30. The use of a suitable, approved preservative (e.g., organic acids such as propionic acid ) may be beneficial. These acids are effective in killing various fungi and thus prevent the production of mycotoxins in grains intended only for animal feed. The salts of the acids are usually more effective for long-term storage. Care must be taken because these compounds can negatively affect the taste and odor of the grain.

31. Document the harvesting and storage procedures implemented each season by making notes of measurements (e.g., temperature, moisture, and humidity) and any deviation or changes from traditional practices. This information may be very useful for explaining the cause(s) of fungal growth and mycotoxin formation during a particular crop year and help to avoid similar mistakes in the future.

## TRANSPORT FROM STORAGE

32. Transport containers should be dry and free of visible fungal growth, insects and any contaminated material. As necessary, transport containers should be cleaned and disinfected before use and re-use and be suitable for the intended cargo. The use of registered fumigants or insecticides may be useful. At unloading, the transport container should be emptied of all cargo and cleaned as appropriate.

33. Shipments of grain should be protected from additional moisture by using covered or airtight containers or tarpaulins. Avoid temperature fluctuations and measures that may cause condensation to form on the grain, which could lead to local moisture build-up and consequent fungal growth and mycotoxin formation.

34. Avoid insect, bird and rodent infestation during transport by the use of insect-and rodent proof containers or insect and rodent repellent chemical treatments if they are approved for the intended end use of the grain.

## II. A COMPLEMENTARY MANAGEMENT SYSTEM TO CONSIDER IN THE FUTURE

35. The Hazard Analysis Critical Control Point (HACCP) system is a food safety management system that is used to identify and control hazards within the production and processing system. The general principles of HACCP have been described in several documents.<sup>1,2</sup>

36. The HACCP concept is an all-encompassing integrated management system. When properly implemented, this system should result in a reduction of the levels of mycotoxins in many cereal grains. The use of HACCP as a food safety management system has many benefits over other types of management control systems in some segments of the food industry. At farm level, especially in the field, many factors that influence the mycotoxin contamination of cereals are environmentally related, such as weather and insects, and are difficult or impossible to control. In other words, critical control points often do not exist in the field. However, after harvesting, critical control points may be identified for mycotoxins produced by fungi during storage. For example, a critical control point could be at the end of the drying process and one critical limit would be the water content/water activity.

37. It is recommended that resources be directed to emphasizing Good Agricultural Practices (GAPs) at the preharvest level and Good Manufacturing Practices (GMPs) during the processing and distribution of various products. A HACCP system should be built on sound GAPs and GMPs.

38. It is also recommended that before further consideration is given to the HACCP system, reference should be made to the Codex Annex to CAC/RCP 1-1969, Rev.3 (1997) "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Management".

39. Consideration should also be given to a HACCP manual for mycotoxin control recently published by FAO/IAEA.<sup>3</sup>

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<sup>1</sup> FAO. 1995. The use of hazard analysis critical control points (HACCP) principles in food control. FAO Food and Nutrition Paper No. 58 Rome

<sup>2</sup> ILSI. 1997. A simple guide to understanding and applying the hazard analysis critical control point concept, ILSI Europe Concise Monograph series. 2<sup>nd</sup> edition, ILSI Europe, Brussels

<sup>3</sup> FAO/IAEA training and reference center for food and pesticide control, 2001. Manual on the Application of the HACCP System in Mycotoxin Prevention and Control. FAO Food and Nutrition Paper No. 73. Rome.

40. At the Third International Conference on Mycotoxins, which took place in Tunisia in March 1999, one of the general recommendations was that integrated mycotoxin control programs should incorporate HACCP principles in the control of risks associated with mycotoxin contamination of foods and feeds.<sup>4</sup> The implementation of HACCP principles will minimize mycotoxin contamination through applications of preventive controls to the extent feasible in the production, handling, storage and processing of each cereal crop.

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<sup>4</sup> FAO. Preventing mycotoxin contamination. Food, Nutrition and Agriculture No. 23, 1999. Food and Nutrition Division, FAO, Rome

**REDUCTION OF CONTAMINATION BY ZEARALENONE IN CEREAL GRAINS****RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICE (GAP) AND GOOD MANUFACTURING PRACTICE (GMP)**

1. Good Agricultural Practice includes methods to reduce *Fusarium* infection and zearalenone contamination of cereals in the field and during planting, harvest, storage, transport and processing.

**PLANTING**

2. Refer to paragraphs 4-9 in the General Code of Practice.

**PREHARVEST**

3. Refer to paragraphs 10-15 in the General Code of Practice
4. The establishment of *Fusarium* infection in cereal heads during flowering should be monitored before harvest by sampling and determination of infection by standard microbiological methods. Also, mycotoxin content in representative preharvest samples should be determined. Utilization of the crop should be based on prevalence of infection and mycotoxin content of the grain.

**HARVEST**

5. Refer to paragraphs 16-21 in the General Code of Practice.

**STORAGE**

6. Refer to paragraphs 22-31 in the General Code of Practice.

**TRANSPORT FROM STORAGE**

7. Refer to paragraphs 32-34 in the General Code of Practice

**PROCESSING**

8. Small, shriveled grain may contain more zearalenone than healthy normal grain. Winnowing grains at harvest or later will remove shriveled grain.

**ZEARALENONE MANAGEMENT SYSTEM BASED ON HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM (HACCP)**

9. Refer to paragraphs 35-40 in the General Code of Practice.

**REDUCTION OF CONTAMINATION BY FUMONISINS IN CEREAL GRAINS****RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP) AND GOOD MANUFACTURING PRACTICE (GMP)**

1. Good Agricultural Practice includes methods to reduce *Fusarium* infection and fumonisin contamination of cereals during planting, harvest, storage, transport and processing.

**PLANTING**

2. Refer to paragraphs 4-9 in the General Code of Practice.

**PREHARVEST**

3. Refer to paragraphs 10-15 in the General Code of Practice.

**HARVEST**

4. Refer to paragraphs 16-21 in the General Code of Practice.
5. The time of harvest for maize should be carefully planned. It has been shown that maize grown and harvested during warm months may have fumonisin levels significantly higher than maize grown and harvested during cooler months of the year.

**STORAGE**

6. Refer to paragraphs 22-31 in the General Code of Practice.

**TRANSPORT FROM STORAGE**

7. Refer to paragraphs 32-34 of the General Code of Practice.

**FUMONISINS MANAGEMENT SYSTEM BASED ON HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM (HACCP)**

8. Refer to paragraphs 35-40 in the General Code concerning HACCP.



**REDUCTION OF CONTAMINATION BY OCHRATOXIN A IN CEREALS****RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP) AND GOOD MANUFACTURING PRACTICE (GMP)**

1. Good Agricultural Practice includes methods to reduce fungal infection and ochratoxin A contamination of cereals during harvest, storage, transport and processing.

**PLANTING**

2. Refer to paragraphs 4-9 in the General Code of Practice.

**PREHARVEST**

3. Refer to paragraphs 10-15 in the General Code of Practice.

4. Factors during preharvest that may affect levels of ochratoxin A in harvested grains include frost damage, presence of competitive fungi, excessive rainfall and drought stress.

**HARVEST**

5. Refer to paragraphs 16-21 in the General Code of Practice.

**PRESERVATION**

6. Grain should be allowed to dry as much as possible before harvest consistent with local environment and crop conditions. If unable to harvest the grain when it has a water activity below 0.70, then dry the grain to a moisture content corresponding to a water activity of less than 0.70 (less than 14% moisture content in small grain) as quickly as possible. To avoid ochratoxin A formation, start the drying process immediately after harvest and preferably use heated-air drying. In the temperate climate region, when intermediate or buffer storage is necessary because of low drying capacity, make sure that the moisture content is less than 16%, that the buffer storage time is less than 10 days, and the temperature is less than 20 °C.

**STORAGE**

7. Refer to paragraphs 22-31 in the General Code of Practice.

**TRANSPORT**

8. Refer to paragraphs 32-34 in the General Code of Practice.

**OCHRATOXIN A MANAGEMENT SYSTEM BASED ON HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP)**

9. Refer to paragraphs 35-40 in the General Code of Practice.

## **REDUCTION OF CONTAMINATION BY TRICOTHECENES IN CEREAL GRAINS**

### **RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP) AND GOOD MANUFACTURING PRACTICE (GMP)**

1. Good Agricultural Practices includes methods to reduce *Fusarium* infection and tricothecene contamination of cereals during planting, harvest, storage, transport and processing.

#### **PLANTING**

2. Refer to paragraphs 4-9 in the General Code of Practice.

#### **PREHARVEST**

3. Refer to paragraphs 10-15 in the General Code of Practice.

4. Do not permit mature grains to remain in the field for extended periods of time, particularly in cold, wet weather. T-2 and HT-2 toxins are not usually found in grains at harvest, but can result from grains that are water-damaged in the field or grains that become wet at harvest or during storage.

5. Refer to paragraph 4 in Annex 1.

6. Cereal growers should maintain close relations with local cereal trade groups. Such groups should be important sources of information and advice regarding choice of appropriate plant protection products, cultivars and strains that will take into account those resistant to *Fusarium* and are available for their location.

#### **HARVEST**

7. Refer to paragraphs 16-21 in the General Code of Practice.

#### **STORAGE**

8. Refer to paragraphs 22-31 in the General Code of Practice.

9. Be aware that cereal grains may be contaminated by more than one tricothecene mycotoxin along with their derivatives; therefore simple, rapid screening methods should be available for the analysis of several tricothecenes. Zearalenone, which is not a tricothecene, has been noted to regularly co-occur in cereals contaminated with DON and other tricothecenes.

#### **TRANSPORT FROM STORAGE**

10. Refer to paragraphs 32-34 in the General Code of Practice.

### **TRICOTHECENE MANAGEMENT SYSTEM BASED ON HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM (HACCP)**

11. Refer to paragraphs 35-40 in the General Code of Practice.

**DRAFT MAXIMUM LEVELS FOR LEAD**  
(At Step 6 of the Procedure)

Code No.	Food	ML (mg/kg)	Step	Remarks
WF115, VD120, WS125	Fish	0.2	6	Excluding Appendix 1

**Non-Exhaustive List of Fish Species Indicated by Member States on the Basis of Not Being  
Able to Meet the Draft Maximum Level for Lead of 0.2 mg/kg**

Family	Species	English name
Clupeidae	Clupea harengus	Herring
Nototheniidae Gadidae	Lotella rhacina, Paranotothenia microlepidota, Gadus macrocepholus, G. morhua	Cod
Ictalurus spp.	Ictalurus punctatus	Catfish, Channel
Carangidae	Trachurus symmetricus	Mackerel (canned)
Chanidae	Chanos chanos	Milkfish
Salmonidae	Oncorhynchus tshawytscha, O. keta, O.kisutch, O. gorbuscha, O. nerka, Salmo salar	Salmon
Salmonidae Sciaenidae	Cynoscion spp. Oncorhynchus mykiss, Salvelinus namaycush, S. fontinalis	Trout
Clupeidae	Sardinella spp	Sardines
Xiphiidae	Xiphias gladius	Swordfish
		Shark
		Sea Mullet

**PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM  
(At Step 3 of the Procedure)**

<b>Code No.</b>	<b>Food</b>	<b>ML (mg/kg)</b>	<b>Step</b>	<b>Remarks</b>
	Fruit	0.05	3	
	Wheat Grain	0.2	3	Including Bran and Germ
	Milled Rice	0.2	3	
	Soybean and Peanuts	0.2	3	
	Meat of Cattle, Poultry, Pig and Sheep	0.05	3	
	Molluscs	1.0	3	
	Meat of Horse	0.2	3	
	Vegetables	0.05	3	Excluding Leafy Vegetables, Fresh Herbs, Stem and Root Vegetables, Fungi, Tomatoes and Peeled Potatoes
	Peeled Potatoes, Stem and Root Vegetables	0.1	3	Excluding Celeriac
	Leafy Vegetables, Fresh Herbs, Fungi and Celeriac	0.2	3	

**PROPOSED DRAFT MAXIMUM LEVELS FOR TIN**  
**(At Step 3 of the Procedure)**

**Tin**                    **250 mg/kg** for solid canned foods  
                         **200 mg/kg** for liquid canned foods

**PRIORITY LIST OF FOOD ADDITIVES, CONTAMINANTS AND NATURALLY OCCURRING  
TOXICANTS PROPOSED FOR EVALUATION BY JECFA**

<i>Food additives for toxicological and intake evaluation and development of specifications</i>	<i>Data availability</i>	<i>Originally proposed by</i>
Aluminium from all sources (toxicity and intake of aluminium from its use in food additives and from other sources)	Unknown	CCFAC (GSFA)
Arpink red (new evaluation)	2002	Czech Republic
Beeswax } consider the acceptability of use as carriers for	Unknown	CCFAC (GSFA)
Candelilla wax } flavours in category 14.4.4	Unknown	CCFAC (GSFA)
Benzoyl peroxide (data identified as necessary at fifty-fifth meeting of JECFA)	2002	Canada
Enzyme preparations (new evaluations): <sup>1</sup>	2002	Denmark
• laccase enzyme preparation, produced by a strain of <i>Aspergillus oryzae</i> , containing the gene coding for laccase in <i>Myceliophthora thermophila</i> , inserted by recombinant DNA techniques		
• an $\alpha$ -amylase enzyme preparation, produced by a strain of <i>Bacillus licheniformis</i> , containing a protein engineered gene of <i>Bacillus licheniformis</i> coding for $\alpha$ -amylase, inserted by recombinant DNA techniques		
• xylanase enzyme preparation, produced by a strain of <i>Fusarium venenatum</i> , containing the gene coding for xylanase from <i>Thermomyces lanuginosus</i> , inserted by recombinant DNA techniques		
• mixed xylanase, $\beta$ -glucanase enzyme preparations, produced by a strain of <i>Humicola insolens</i> .		
Ferrous bisglycinate (new evaluation -nutritional source of iron) <sup>1</sup>	2002	USA
Approx. 200 flavouring agents (new evaluations) <sup>1,2</sup>	2002	USA
Magnesium silicate (use as a filtration aid) <sup>1</sup>	2002	USA
Magnesium sulfate (new evaluation)	2002	USA
Neotame (new evaluation) <sup>1</sup>	2002	Australia
Polyvinyl alcohol (new evaluation) <sup>1</sup>	2002	Philippines
<b><i>Food additives for specifications only</i></b>		
Revision of <i>General specifications and considerations for enzyme preparations used in food processing</i>	-----	CCFAC (WG on Specifications)
Sucrose esters of fatty acids <sup>1</sup>	2002	Japan
<b><i>Contaminants and naturally occurring toxicants</i></b>		
2-Alkyl cyclobutanones (data to be provided by the EC)	unknown	CCFAC (standard for irradiated foods)
Arsenic <sup>1</sup>	2002	JECFA Secretariat
Cadmium <sup>1</sup>		
• toxicity (review of studies requested at fifty-fifth meeting of JECFA)	2002	Japan
• impact of alternative maximum levels	unknown	CCFAC (GSCTF)
Ergot alkaloids (full evaluation)	unknown	Canada
Ethyl carbamate (full evaluation) <sup>1</sup>	2002	CCFAC
Glycyrrhizic acid (full evaluation)	anytime	Denmark
Phenylhydrazines, including agaritine (full evaluation)	anytime	Denmark
Polycyclic aromatic hydrocarbons, including benz[a]pyrene (full evaluation) <sup>1</sup>	2002	Netherlands, Canada, Denmark, Finland
Polybrominated diphenyl ether	unknown	Canada

<sup>1</sup> High priority for evaluation by JECFA in 2003.

<sup>2</sup> Groups of flavouring agents should be prioritized in the event that the JECFA Secretariat is unable to include all of them on the agenda of the sixty-first meeting of JECFA in 2003.

**METHODS OF ANALYSIS FOR THE DETERMINATION OF  
FOOD ADDITIVES AND CONTAMINANTS IN FOODS  
(For Endorsement by the Codex Committee of Method Analysis and Sampling)**

**Additives****Determination of sulfites**

EN 1988-1 : 1998-02	Foodstuffs - Determination of sulfite - Part 1: Optimized Monier-Williams method	Type III
EN 1988-2 : 1998-02	Foodstuffs - Determination of sulfite - Part 2: Enzymatic method	Type III

**Determination of intense sweeteners**

EN 1376 : 1996-09 (confirmed 2001)	Foodstuffs - Determination of saccharin in table top sweetener preparations – Spectrometric method	Type III
EN 1377 : 1996-09 (confirmed 2001)	Foodstuffs - Determination of acesulfame K in table top sweetener preparations – Spectrometric method	Type II
EN 1378 : 1996-09 (confirmed 2001)	Foodstuffs - Determination of aspartame in table top sweetener preparations - Method by high performance liquid chromatography	Type II
EN 1379 : 1996-09 (confirmed 2001)	Foodstuffs - Determination of cyclamate and saccharin in liquid table top sweetener preparations - Method by high performance liquid chromatography	Type II
EN 12856 : 1999-04	Foodstuffs - Determination of acesulfame-K, aspartame and saccharin - High performance liquid chromatographic method	Type II
EN 12857 : 1999-04	Foodstuffs - Determination of cyclamate - High performance liquid chromatographic method	Type II

**Contaminants****Determination of PCBs**

EN 1528-1: 1996-10 (confirmed 2001)	Fatty food - Determination of pesticides and polychlorinated biphenyls (PCBs) - Part 1: General considerations	Type III
EN 1528-2: 1996-10 (confirmed 2001)	Fatty food - Determination of pesticides and polychlorinated biphenyls (PCBs) - Part 2: Extraction of fat, pesticides and PCBs and determination of fat content	Type III
EN 1528-3: 1996-10 (confirmed 2001)	Fatty food – Determination of pesticides and polychlorinated biphenyls (PCBs) - Part 3: Clean-up methods	Type III
EN 1528-4: 1996-10 (confirmed 2001)	Fatty food – Determination of pesticides and polychlorinated biphenyls (PCBs) - Part 4: Determination, confirmatory tests, Miscellaneous	Type III

**Determination of nitrates/nitrites (partly also to be assessed as additives)**

EN 12014-1:1997-04	Foodstuffs - Determination of nitrate and/or nitrite content - Part 1: General considerations	Type III
EN 12014-2:1997-04	Foodstuffs - Determination of nitrate and/or nitrite content - Part 2: HPLC/IC method for the determination of nitrate content of vegetables and vegetable products	Type II
ENV 12014-3:1998-06	Foodstuffs - Determination of nitrate and/or nitrite content - Part 3: Spectrometric determination of nitrate and nitrite content of meat products after enzymatic reduction of nitrate to nitrite	Type III
ENV 12014-4:1998-06	Foodstuffs - Determination of nitrate and/or nitrite content - Part 4: Ion-exchange chromatographic (IC) method for the determination of nitrate and nitrite content of meat products	Type III
EN 12014-5:1997-04	Foodstuffs - Determination of nitrate and/or nitrite content - Part 5: Enzymatic determination of nitrate content of vegetable-containing food for babies and infants	Type II
EN 12014-7:1998-06	Foodstuffs - Determination of nitrate and/or nitrite content - Part 7: Continuous flow method for the determination of nitrate content of vegetables and vegetable products after cadmium reduction	Type III

**Determination of mycotoxins**

EN 12955 : 1999-07	Foodstuffs - Determination of aflatoxin B <sub>1</sub> , and the sum of aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub> in cereals, shell-fruits and derived products - High performance liquid chromatographic method with post column derivatization and immunoaffinity column clean up	Type III
EN 13595 : 2001 - 11	Foodstuffs – Determination of fumonisins B <sub>1</sub> and B <sub>2</sub> in maize – HPLC method with solid phase extraction clean-up	Type I
EN ISO 15141-1:1998-10	Foodstuffs - Determination of ochratoxin A in cereals and cereal products - Part 1: High performance liquid chromatographic method with silica gel clean up (ISO 15141-1:1998)	Type II
EN ISO 15141-2:1998-10	Foodstuffs - Determination of ochratoxin A in cereals and cereal products - Part 2: High performance liquid chromatographic method with bicarbonate clean up (ISO 15141-2:1998)	Type III



ACTION REQUIRED AS A RESULT OF CHANGES IN ACCEPTABLE DAILY INTAKE (ADI)  
STATUS AND OTHER TOXICOLOGICAL RECOMMENDATIONS

SUBSTANCE	PREVIOUS ADI AND OTHER TOXICOLOGICAL RECOMMENDATIONS	PRESENT ADI AND OTHER TOXICOLOGICAL RECOMMENDATIONS
<b>Emulsifiers</b> Diacetyltartaric and fatty acid esters of glycerol Tartaric, acetic and fatty acid esters of glycerol, mixed Quillaia extracts	0-50 mg/kg bw  Not Limited 0-5 mg/kg bw	0-50 mg/kg bw (temporary) <sup>a</sup>  ADI withdrawn <sup>b</sup> 0-5 mg/kg bw (temporary) <sup>c</sup>
<b>Enzyme preparations</b> Invertase from <i>Saccharomyces cerevisiae</i>	None	Acceptable <sup>d</sup>
<b>Food colours</b> $\beta$ -Carotene from <i>Blakeslea trispora</i> Curcumin	None 0-1 mg/kg bw (temporary)	0-5 mg/kg bw (group ADI with synthetic $\beta$ -carotene) <sup>e</sup> 0-1 mg/kg bw (temporary) <sup>f</sup>
<b>Food salts</b> Calcium dihydrogen diphosphate Monomagnesium phosphate Sodium calcium polyphosphate Trisodium diphosphate	None None <sup>g</sup> None None <sup>g</sup>	Included in the maximum tolerable daily intake of 70 mg/kg bw for phosphates, diphosphates, and polyphosphates
<b>Glazing agent</b> Hydrogenated poly-1-decene	No ADI Allocated	0-6 mg/kg bw
<b>Preservative</b> Natamycin (pimaricin)	0-0.3 mg/kg bw <sup>h</sup>	0-0.3 mg/kg bw
<b>Sweetening agent</b> D-Tagatose	No ADI Allocated	0-80 mg/kg bw
<b>Thickening agents</b> Carrageenan Processed <i>Eucheuma</i> seaweed Curdlan	Not Specified (Temporary). Not Specified (Temporary). Not Specified (ADI Temporary)	ADI "not specified" <sup>i</sup> (group ADI for carrageenan and processed <i>Eucheuma</i> seaweed) ADI "not specified" <sup>i</sup>
<b>Miscellaneous substances</b> Acetylated oxidized starch $\alpha$ -Cyclodextrin Sodium sulfate	None None Not Specified (Temporary).	ADI "not specified" <sup>i,j</sup> ADI "not specified" <sup>i</sup> ADI "not specified" <sup>i</sup>
<b>Contaminants</b> 3-Chloro-1,2-propanediol	Levels in hydrolysed vegetable protein should be reduced as far as technically possible	PMTDI (provisional maximum tolerable daily intake): 2 $\mu$ g/kg bw
1,3-Dichloro-2-propanol	Levels in hydrolysed vegetable protein should be reduced as far as technically possible	Establishment of a tolerable intake was considered to be inappropriate because of the nature of toxicity (tumorigenic in various organs in rats and the contaminant can interact with chromosomes and/or DNA); The Committee noted that the dose that caused tumours in rats (19 mg/kg bw per day) was about 20 000 times the highest

		estimated intake of 1,3-dichloro-2-propanol by consumers of soya sauce (1 µg/kg bw per day).
Polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and dioxin-like polychlorinated biphenyls (PCBs)	None	PTMI (provisional tolerable monthly intake): 70 pg/kg bw <sup>k</sup>

<sup>a</sup> The Codex Alimentarius Commission has adopted International Numbering System as numbers 472e for diacetyltartaric and fatty acid esters of glycerol and as 472f for tartaric, acetic, and fatty acid esters of glycerol mixed respectively. At the 51<sup>st</sup> meeting of JECFA(1998) established one specification under name of diacetyltartaric and fatty acid esters of glycerol to cover these two substances, and 57<sup>th</sup> JECFA established this ADI as temporary.

<sup>b</sup> The ADI was withdrawn because the specifications for tartaric, acetic and fatty acid esters of glycerol, mixed, were combined with those of diacetyltartaric and fatty acid esters of glycerol under the latter name at the fifty-first meeting (WHO Technical Report Series, No. 891, 2000).

<sup>c</sup> The existing specifications for quillaia extracts were revised in order to clarify the differences between unpurified and semi-purified extracts. Additional information on composition (minimum and maximum percentages of saponins unpurified and semi-purified extracts) is necessary, so the specifications were designated as tentative. Once the requested information has been received, the Committee will consider whether separate specifications for unpurified and semi-purified extracts are required. This information is required for evaluation in 2003. The ADI was made temporary pending clarification of the specifications. The temporary ADI is applicable only to the unpurified extract.

<sup>d</sup> Invertase from *Saccharomyces cerevisiae* that meets the specifications developed at the present meeting was considered to be acceptable because *S. cerevisiae* is commonly used in the preparation of food. Its use should be limited by Good Manufacturing Practice.

<sup>e</sup> Information is required on the method of analysis for residual solvents (ethyl acetate and isobutyl acetate). This information is required for evaluation in 2003.

<sup>f</sup> The results of a reproductive toxicity study on a substance complying with the specifications for curcumin, known to be in progress, is required for evaluation in 2003.

<sup>g</sup> Information is required on the loss on drying, loss on ignition, test method for loss on ignition and assay method for the hydrates. This information is required for evaluation in 2003.

<sup>h</sup> Information is required on the level and determination of water content, lead limit, specific rotation, assay value and method of assay for the commercial product. Comments on other aspects of the monograph are invited. This information is required for evaluation in 2003.

<sup>i</sup> ADI “not specified” is used to refer to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological and other) and the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effects and from its acceptable background levels in food, does not, in the opinion of the Committee, represent a hazard to health. For that reason, and for the reasons stated in the individual evaluations, the establishment of an ADI expressed in numerical form is not deemed necessary. An additive meeting this criterion must be used within the bounds of good manufacturing practice, i.e. it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal food of inferior quality or adulterated food, and it should not create a nutritional imbalance.

<sup>j</sup> The new specifications for Acetylated Oxidized Starch were integrated into the revised specifications for Modified Starches

<sup>k</sup> the long half-times of PCDDs, PCDFs, and coplanar PCBs result in each daily ingestion having a small or even negligible effect on overall intake. Only after consideration of the total or average intake of PCDDs, PCDFs, and coplanar PCBs over months can their long- or short-term risk to health be assessed. The tolerable intake should therefore be assessed over 1 month or longer. To encourage this view, the Committee decided to express the tolerable intake as a monthly value in the form of a *provisional tolerable monthly intake* (PTMI).

**ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN THE  
DRAFT STANDARD FOR CHOCOLATE AND CHOCOLATE PRODUCTS**

<i>INS No.</i>	<i>Food additive</i>	<i>Maximum level</i>	<i>ADI (mg/kg body weight)</i>	<i>Notes</i>
<b>ALKALIZING AND NEUTRALIZING AGENTS</b>				/ <sup>1</sup>
<b>Acidity regulators</b>				
503(i)	Ammonium carbonate		NOT SPECIFIED	
527	Ammonium hydroxide		NOT LIMITED	
503(ii)	Ammonium hydrogen carbonate		NOT SPECIFIED	
170(i)	Calcium carbonate		NOT LIMITED	
330	Citric acid		NOT LIMITED( Group ADI for citric acid and its calcium, potassium, sodium, and ammonium salts)	
504(i)	Magnesium carbonate		NOT LIMITED	
528	Magnesium hydroxide	Limited by GMP	NOT LIMITED	
530	Magnesium Oxide		NOT LIMITED	
501(i)	Potassium carbonate		NOT LIMITED	
525	Potassium hydroxide		NOT LIMITED	
501(ii)	Potassium hydrogen carbonate		NOT LIMITED ( Included in the group ADI for hydrogen carbonates)	
500(i)	Sodium carbonate		NOT LIMITED	
524	Sodium hydroxide		NOT LIMITED	
500(ii)	Sodium hydrogen carbonate		NOT LIMITED	
526	Calcium hydroxide		NOT LIMITED	
338	Orthophosphoric acid	2.5 g/kg expressed as P <sub>2</sub> O <sub>5</sub> in finished cocoa and chocolate products	MTDI 70 (Expressed as phosphorus from all sources)	

<sup>1</sup> Alkalizing and neutralizing agents carried over as a result of processing cocoa material in proportion to the maximum quantity as provided for.

334	L-Tartaric acid	5 g/kg in finished cocoa and chocolate products		0-30 (Group ADI for L-(+)-tartaric acid and its sodium, potassium, potassium sodium salts)	
<b>Emulsifiers</b>					
471	Mono- and di-glycerides of edible fatty acids	Limited by GMP		NOT LIMITED	Product described <sup>2</sup>
322	Lecithin			NOT LIMITED	”
422	Glycerol			NOT SPECIFIED	”
442	Ammonium salts of phosphatidic acids	10 g/kg		0-30 (The phosphorus content is to be included in the ADI for phosphates)	”
476	Polyglycerol esters of interesterified ricinoleic acid	5 g/kg	15g/Kg	0-7.5	”
491	Sorbitan monostearate	10 g/kg	In combination	0-25	”
492	Sorbitan tristearate	10 g/kg		0-25	”
435	Polyoxyethylene (20) sorbitan monostearate	10 g/kg		0-25 (as total polyoxyethylene(20) sorbitan esters)	”

### Flavouring Agents

Natural and artificial flavours, except those which reproduce the flavour of chocolate or milk	Limited by GMP			Temporarily endorsed
Vanillin	1 g/kg in combination		0-10	Products described <sup>3</sup> No safety concern at current levels of intake when used as a flavouring agent. Products described <sup>3</sup>
Ethyl vanillin	1 g/kg in combination		0-3	No safety concern at current levels of intake when used as a flavouring agent Products described <sup>3</sup>

<sup>2</sup>

Products described under provision 2.1 and 2.2 in Draft Standard for Chocolate and Chocolate Products.

<b>Sweeteners</b>				
950	Acesulfame Potassium	500 mg/kg	0-15	Products described <sup>3</sup>
951	Aspartame	2000 mg/kg	0-40	”
952	Cyclamic acid and its Na and Ca salts	500 mg/kg	0-11	”
954	Saccharin and its Na and Ca salts	500 mg/kg	0-5	”
957	Thaumatococcus		NOT SPECIFIED	”
420	Sorbitol and sorbitol syrup		NOT SPECIFIED	”
421	Mannitol	Limited by GMP	NOT SPECIFIED	”
953	Isomalt (Isomaltitol)		NOT SPECIFIED	”
965	Maltitol and maltitol syrup		NOT SPECIFIED	”
966	Lactitol		NOT SPECIFIED	”
967	Xylitol		NOT SPECIFIED	”
<b>Glazing agents</b>				
414	Gum Arabic (Acacia gum)		NOT SPECIFIED	Products described <sup>3</sup>
440	Pectin		NOT SPECIFIED (Group ADI for pectins and amidated pectins, singly or in combination)	”
901	Beeswax, white and yellow	GMP	ACCEPTABLE (Present uses (as a release and glazing agent in bakery products, a glazing agent on fresh and frozen fruit, a glazing agent on candy, a carrier for flavours, and a component of chewing-gum base) not of toxicological concern)	”
902	Candelilla wax		ACCEPTABLE (Present uses (as a glazing agent, a component of chewing-gum base, a surface-treating agent, and a carrier for flavouring substances) not of toxicological concern)	”
904	Shellac		ACCEPTABLE (Present uses (as a coating, glazing, and surface-finishing agent externally applied to food) not of toxicological concern)	”
<b>Antioxidants</b>				
304	Ascorbyl palmitate	200 mg/kg	0-1.25 (As ascorbyl palmitate or ascorbyl stearate, or the sum of both)	Product described in White chocolate calculated on a fat content basis

319	Tertiary butylhydroquine	200 mg/kg singly or in combination	0-0.7	”
320	Butylated hydroxyanisole	200 mg/kg singly or in combination	0-0.5	”
321	Butylated hydroxytoluene	200 mg/kg singly or in combination	0-0.3	”
310	Propylgallate	200 mg/kg singly or in combination	0-1.4	”
307	$\alpha$ -Tocopherol	750 mg/kg	0.15-2 (Group ADI for dl-alpha-tocopherol and d-alpha-tocopherol concentrate, singly or in combination)	”
<b>Colours (for decoration purpose only)</b>				
175	Gold	GMP	NO ADI ALLOCATED (Very limited use. Not considered to present a hazard)	Products described <sup>3</sup>
174	Silver	GMP	DECISION POSTPONED	”
<b>Bulking agents</b>				
1200	Polydextrose A and N	GMP	Not Specified	”
<b>Processing Aid</b>				
	Hexane (62°C - 82°C)	1 mg/kg	Limited by GMP	Calculated on a fat content basis

**REQUEST FOR DATA SUBMISSION FOR THE ESTABLISHMENT OF A  
MAXIMUM LEVEL FOR LEAD IN FISH**

It is preferable to receive individual data (see Annex 1) to support the maximum level for lead in fish. However, if this is not possible, please submit aggregate data (annex 2). Data should preferably be submitted in Excel format.

**Annex 1****Instruction for submission of INDIVIDUAL DATA on lead in fish**

Please fill in the fields for which you have information.

**Fields from the GEMS/FOOD**

Instructions for electronic submission of data on chemical contaminants in food to be found on the web site:  
<http://www.who.int/fsf>

- Field No. 1: Serial Number of the Record
- Field No. 2: Date of Record Creation
- Field No. 3: Country Providing the Record
- Field No. 4: Food Identifier
- Field No. 5: Food Origin
- Field No. 6: Time Period of Food Sampling
- Field No. 7: Representativeness of the Samples
- Field No. 8: Number of Laboratories Participating in Sample Analyses
- Field No. 9: Indicator of analytical Quality assurance
- Field No. 10: Contaminant identifier
- Field No. 11: Unit of Reporting for Contaminant Levels (mg/kg)
- Field No. 12: Range of Analytical Limits in the Data Set
  - 12a: Limit of detection
  - 12c: Limit of quantification
- Field No. 13: Basis for the Analytical values (fresh weight)
- Field No. 21: Confidentiality of data
- Field No. 22: Remarks/References

**Additional fields**

- Field No. 23: Fish Family name in Latin
- Field No. 24: Fish Species name in Latin
- Field No. 25: Fish Species name in English
- Field No. 26: Reference of method of analysis
- Field No. 27: Concentration value

**Instruction for submission of AGGREGATE DATA on lead in fish**

Please fill in the fields for which you have information.

**Fields from the GEMS/FOOD**

Instructions for electronic submission of data on chemical contaminants is located at: <http://www.who.int/fsf>

- Field No. 1: Serial Number of the Record
- Field No. 2: Date of Record Creation
- Field No. 3: Country Providing the Record
- Field No. 4: Food Identifier
- Field No. 5: Food Origin
- Field No. 6: Time Period of Food Sampling
- Field No. 7: Representativeness of the Samples
- Field No. 8: Number of Laboratories Participating in Sample Analyses
- Field No. 9: Indicator of analytical Quality assurance
- Field No. 10: Contaminant identifier
- Field No. 11: Unit of Reporting for Contaminant Levels (mg/kg)
- Field No. 12: Range of Analytical Limits in the Data Set
  - 12a: Limit of Detection – minimum
  - 12b: Limit of detection – maximum
  - 12c: Limit of quantification – minimum
  - 12d: Limit of quantification - maximum
- Field No. 13: Basis for the Analytical values (fresh weight)
- Field No. 14: Number of Samples analysed
- Field No. 15: Number of Samples with concentrations below Limit of Quantification
- Field No. 16: Range of Quantified analytical concentrations
  - 16a: Minimum concentration
  - 16b: Maximum concentration
- Field No. 17: Mean concentrations
  - 17a: Mean concentration
  - 17b: Mean lower bound
  - 17c: Mean upper bound
- Field No. 18: Median concentration
- Field No. 19: 90th Percentile Concentration
- Field No. 20: Standard Deviation (Optional)
- Field No. 21: Confidentiality of data
- Field No. 22: Remarks/References

**Additional fields**

- Field No. 23: Fish Family name in Latin
- Field No. 24: Fish Species name in Latin
- Field No. 25: Fish Species name in English
- Field No. 26: reference of method of analysis



**PROPOSED RISK ASSESSMENT POLICY STATEMENT FOR THE APPLICATION OF RISK ANALYSIS PRINCIPLES TO THE STANDARD-SETTING ACTIVITIES OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS (CCFAC) IN CONJUNCTION WITH RISK ASSESSMENTS PERFORMED BY THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)  
(At Step 3 of the Procedure)**

**CCFAC and JECFA**

- a) CCFAC and JECFA recognize that communication between risk assessors and risk managers is critical to the success of their risk analysis activities.
- b) CCFAC and JECFA will continue to develop procedures to enhance communication between the two committees.
- c) CCFAC and JECFA will ensure that their contributions to the risk analysis process are fully transparent, thoroughly documented and available in a timely manner to Member States.
- d) JECFA, in consultation with CCFAC, will continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria will be used by CCFAC in preparing its Priority List for JECFA. The JECFA Secretariat will consider whether these minimum quality criteria for data have been met when preparing the provisional agenda for meetings of JECFA.

**CCFAC**

- e) CCFAC is primarily responsible for recommending risk management proposals for adoption by the CAC.
- f) CCFAC will base its risk management recommendations to the CAC on JECFA's risk assessments or safety assessments of food additives, naturally occurring toxicants, and contaminants in food.
- g) In cases where JECFA has performed a safety assessment and CCFAC or the CAC determines that additional scientific guidance is necessary, CCFAC or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.
- h) CCFAC's risk management recommendations to the CAC with respect to food additives shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Food Additives.
- i) CCFAC's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food.
- j) CCFAC's risk management recommendations to the CAC that involve health and safety aspects of food standards will be based on JECFA's quantitative risk assessments or, if sufficient, safety assessments, and other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade.
- k) CCFAC's risk management recommendations to the CAC will take into account the relevant uncertainties and safety factors described by JECFA.
- l) CCFAC will endorse maximum use levels only for those additives for which 1) JECFA has established

specifications of identity and purity, 2) JECFA has established an ADI or has completed a quantitative risk assessment, and 3) the level of the additive in food can be determined through appropriate methods.

- m) CCFAC will take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum limits for contaminants and naturally occurring toxicants in food,
- n) Before finalising proposals for MLs for contaminants and naturally occurring toxicants, CCFAC shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCFAC.
- o) When establishing its standards, codes of practice, and guidelines, CCFAC will clearly state when it applies any non-science-based considerations in addition to JECFA's risk assessment and specify its reasons for doing so.
- p) CCFAC's risk communication with JECFA will include prioritizing substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives and elaborating safe maximum limits or codes of practice for contaminants and naturally occurring toxicants in food.
- q) CCFAC will consider the following when preparing its priority list of substances for JECFA review:
  - Consumer protection from the point of view of health and prevention of unfair trade practices;
  - CCFAC's Terms of Reference;
  - JECFA's Terms of Reference;
  - The Codex Alimentarius Commission's Medium-Term Plan of Work;
  - The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment;
  - The prospect of completing the work in a reasonable period of time;
  - The diversity of national legislation and any apparent impediments to international trade;
  - The impact on international trade (i.e., magnitude of the problem in international trade).
  - Work already undertaken by other international organizations;
- r) When referring substances to JECFA, CCFAC may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.
- s) CCFAC will request JECFA to review any methods and guidelines being considered by CCFAC for assessing maximum use levels for additives or Maximum Limits for contaminants and naturally occurring toxicants. CCFAC will make any such request with a view toward obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a method or guideline for CCFAC's work.

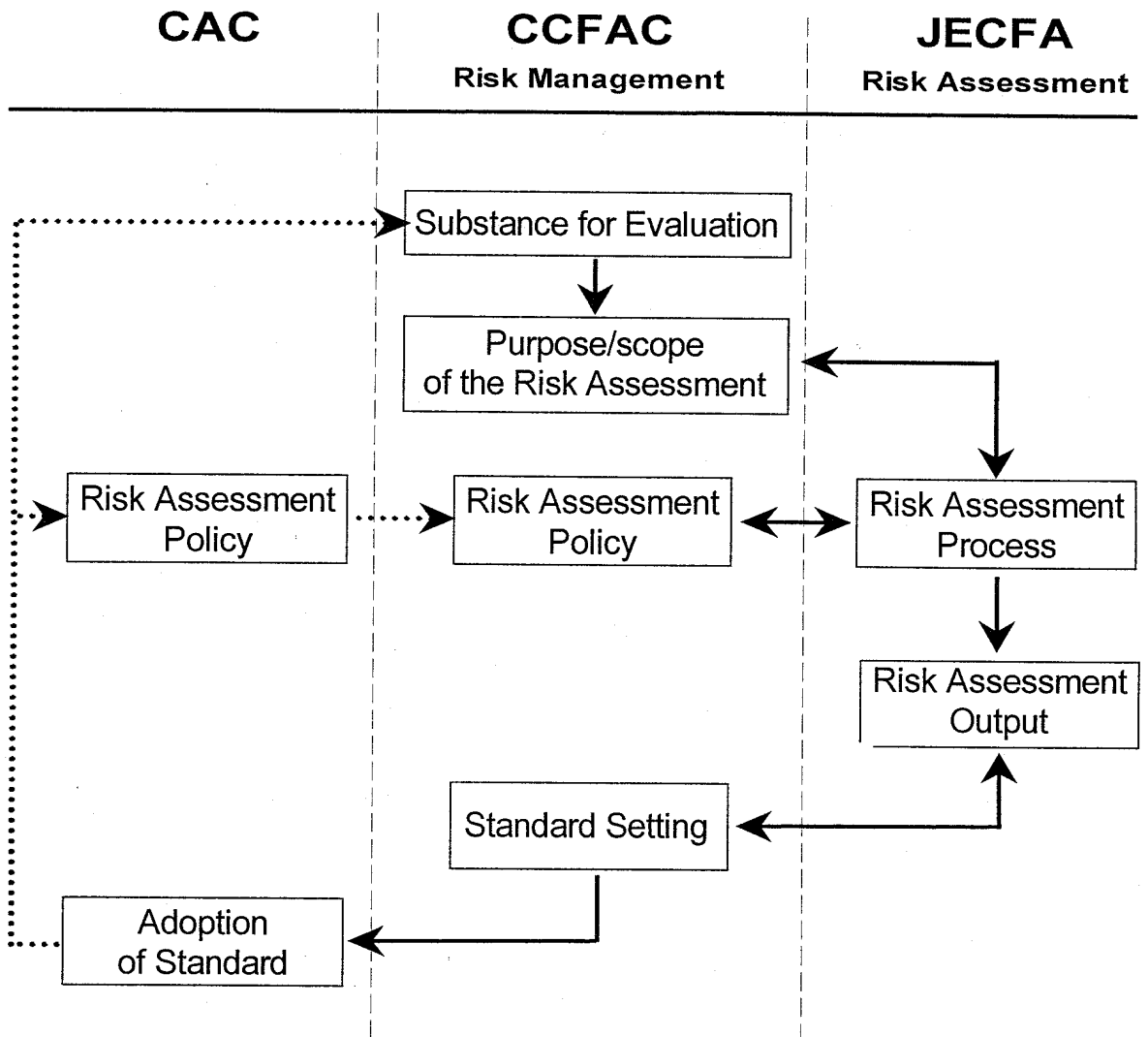
### **JECFA**

- t) JECFA is primarily responsible for performing the risk assessments upon which CCFAC and ultimately the CAC base their risk management decisions.
- u) JECFA will select scientific experts on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.
- v) JECFA will strive to provide CCFAC with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCFAC's risk-management discussions. For contaminants and naturally occurring toxicants, JECFA will

determine to the extent possible the risks associated with various levels of intake. Because of the lack of appropriate information, including data in humans, however, this will be possible in only a few cases in the foreseeable future. For additives, JECFA will continue to use its safety assessment process for establishing ADIs.

- w) JECFA will strive to provide CCFAC with science-based quantitative risk assessments and safety assessments for food additives, contaminants, and naturally occurring toxicants in a transparent manner.
- x) JECFA will provide CCFAC information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to vulnerable populations (e.g., children, women of child-bearing age, the elderly).
- y) JECFA will also strive to provide CCFAC with specifications of identity and purity essential to assessing risk associated with the use of additives.
- z) Recognizing that primary production in developing countries is largely through small and medium size enterprises, JECFA will strive to base its risk assessments on global data, including that from developing countries. These data should include epidemiological surveillance data and exposure studies.
- aa) JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants as part of the risk assessments provided to CCFAC.
- bb) When evaluating intake of additives or contaminants and naturally occurring toxicants during its risk assessment, JECFA will take into account regional differences in food consumption patterns.
- cc) JECFA will provide to CCFAC its scientific views on the validity and the distribution aspects of the available data regarding contaminants and naturally occurring toxicants in foods which have been used for exposure assessments, and will give details on the magnitude of the contribution to the exposure from specific foods as may be relevant for risk management actions or options of CCFAC.
- dd) JECFA will communicate to CCFAC the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA will provide CCFAC a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.
- ee) JECFA will communicate to CCFAC the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.
- ff) When establishing an ADI, PTWI, PTMDI, or PTMI, JECFA will identify and provide a description of the scientific basis for the toxicological endpoint used to determine a NOEL or a Lowest Observed Effect Level (LOEL).
- gg) When establishing an ADI, PTWI, PMTDI, or PTMI, JECFA is responsible for choosing the appropriate safety factor to be applied to the NOEL or LOEL and for providing an explanation of the scientific basis for the choice to account for any attendant uncertainties in the safety assessment.
- hh) JECFA's risk assessment output to CCFAC is limited to presenting its deliberations and the conclusions of its risk assessments and safety assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the general risk analysis guidelines of Codex and CCFAC.

- ii) When establishing the agenda for a JECFA meeting, the JECFA Secretariat will work closely with CCFAC to ensure that CCFAC's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat will normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority will be normally given to food additives or groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority will be normally given to food additives that have not been previously evaluated. With respect to contaminants and naturally occurring toxicants, the JECFA Secretariat will give priority to substances that present both a significant risk to public health and are a known or expected problem in international trade.
  
- jj) When establishing the agenda for a JECFA meeting, the JECFA Secretariat will give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

FIGURE 1<sup>1</sup>

The interactions of CAC, CCFAC and JECFA in the risk analysis process (the dotted arrows represent the iterative exchange of information).