

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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ALINORM 06/29/12
May 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-ninth Session
Geneva, Switzerland, 3-7 July 2006

REPORT OF THE 38th SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

The Hague, The Netherlands
24-28 April 2006

Note: This report includes Codex Circular Letter CL 2006/11-FAC

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CL 2006/11-FAC
May 2006

TO: Codex Contact Points
Interested International Organizations

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

SUBJECT: **Distribution of the Report of the Thirty-eighth Session of the Codex Committee on Food Additives and Contaminants (ALINORM 06/29/12)**

The report of the Thirty-eighth Session of the Codex Committee on Food Additives and Contaminants will be considered by the 29th Session of the Codex Alimentarius Commission (Geneva, Switzerland, 3–7 July 2006).

MATTERS FOR ADOPTION BY THE 29TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

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

- 1. Draft revision of the Preamble of the Codex General Standard for Food Additives, at Step 8 (para. 55 and Appendix V);**
- 2. Draft and proposed draft food additive provisions of the General Standard for Food Additives (GSFA), at Step 8 and 5/8, respectively (paras 63 and 81 and Appendices VII and XI);**
- 3. Proposed draft amendments to the International Numbering System for Food Additives, at Step 5/8 (para. 104 and Appendix XVI);**
- 4. Specifications for the Identity and Purity of Food Additives arising from the 65th JECFA meeting, at Step 5/8 (para. 110 and Appendix XVII)**
- 5. Proposed draft Appendix to the Codex Code of Practice for the Prevention and Reduction of Aflatoxins Contamination in Tree Nuts – Additional Measures for the Prevention and Reduction of Aflatoxins Contamination in Brazil nuts (N08-2005), at Step 5/8 (para. 123 and Appendix XX);**
- 6. Draft Maximum Level for Lead in Fish, at Step 8 (para. 153 and Appendix XXIV);**
- 7. Draft Maximum Levels for Cadmium in marine bivalve molluscs (excluding oysters and scallops) and in cephalopods (without viscera) and in polished rice, at Step 8 (para. 159 and Appendix XXV);**
- 8. Proposed draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in foods and feed, at Step 5/8 (para. 169 and Appendix XXVI);**
- 9. Proposed draft revised Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency for Use in International Trade, at Step 5/8 (para. 198 and Appendix XXXI);**

10. **Codex General Standard for Contaminants and Toxins in Foods, including Schedule I, for adoption** (para. 119 and Appendix XVIII);
11. **Amended Annex to Table 3 of the GSFA, for adoption** (para. 63 and Appendix VIII);
12. **Revision of the Descriptor of Food Category 13.6 “Food supplements” of the GSFA, for adoption** (para. 214 and Appendix XXXIII).

Governments wishing to propose amendments or to comment on the above texts should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 8 or 5/8) (Codex Alimentarius Commission Procedural Manual, Fifteenth Edition) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; e-mail: codex@fao.org (*preferably*)) **no later than 31 May 2006.**

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

13. **Proposed draft revision of the Codex Class Names and International Numbering System for Food Additives – CAC/GL 36-2003” (N07-2005)** (para. 98 and Appendix XV);
14. **Proposed draft Maximum Level for Total Aflatoxins in Almonds, Hazelnuts and Pistachios “Ready-to-Eat”** (para. 132 and Appendix XXII);
15. **Proposed draft Maximum Levels for Tin in Canned foods (other than beverages) and in Canned Beverages** (para. 183 and Appendix XXVIII).

Governments wishing to propose amendments or to comment regarding the implications which the above texts or any provisions thereof may have for their economic interests should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 5) (Codex Alimentarius Commission Procedural Manual, Fifteenth Edition) to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; e-mail: codex@fao.org (*preferably*)) **no later than 31 May 2006.**

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION/CONSIDERATION BY THE 29TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

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

The Committee forwarded:

- Draft revision of the Preamble of the Codex General Standard for Food Additives, at Step 8 (para. 55 and Appendix V);
- Draft and proposed draft food additive provisions of the General Standard for Food Additives (GSFA), at Step 8 and 5/8, respectively (para. 81 and Appendix XI);
- Proposed draft Amendments to the International Numbering System for Food Additives, at Step 5/8 (para. 104 and Appendix XVI);
- Specifications for the Identity and Purity of Food Additives arising from the 65th JECFA meeting, at Step 5/8 (para. 110 and Appendix XVII)
- Proposed draft Appendix to the Codex Code of Practice for the Prevention and Reduction of Aflatoxins Contamination in Tree Nuts – Additional Measures for the Prevention and Reduction of Aflatoxins in Brazil nuts (N08-2005), at Step 5/8 (para. 123 and Appendix XX);
- Draft Maximum Level for Lead in Fish, at Step 8 (para. 153 and Appendix XXIV);
- Draft Maximum Levels for Cadmium in marine bivalve molluscs (excluding oysters and scallops) and in cephalopods (without viscera) and in polished rice, at Step 8 (para. 159 and Appendix XXV);
- Proposed draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in foods and feeds, at Step 5/8 (para. 169 and Appendix XXVI);
- Proposed draft revised Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency for Use in International Trade, at Step 5/8 (para. 198 and Appendix XXXI).

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

The Committee forwarded:

- Proposed draft revision of the Codex Class Names and the International Numbering System for Food Additives – CAC/GL 36-2003” (N07-2005) (para. 98 and Appendix XV);
- Proposed draft Maximum Level for Total Aflatoxins in Almonds, Hazelnuts and Pistachios “Ready-to-Eat” (para. 132 and Appendix XXII);
- Proposed draft Maximum Levels for Tin in Canned Foods (other than beverages) and in Canned Beverages (para. 183 and Appendix XXVIII)

Proposals for New Work and for Discontinuation of Work

The Committee agreed to submit, through the Executive Committee, the proposals for new work on:

- Guidelines for the Use of Flavourings (para. 87 and Appendix XIV);
- Revision of the Preamble of the Codex General Standard for Contaminants and Toxins in Foods and the Procedural Manual (para. 119 and Appendix XIX);
- Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine (para. 140 and Appendix XXIII);
- Code of Practice for the Reduction of Acrylamide in Food (para. 185 and Appendix XXIX);
- Code of Practice for the Reduction of Contamination of Food with PAH from Smoking and Direct Drying Processes (para. 188 and Appendix XXX).

The Committee agreed to:

- Discontinue work on a number of food additive draft and proposed draft provisions (para. 81 and Appendix XIII).

Other Matters for Consideration by the 29th Session of the Codex Alimentarius Commission

- The Committee agreed to:
- Forward to the Codex Alimentarius Commission, for inclusion in the GSFA, the food additive provisions of the Codex commodity standards with a one-to-one relationship to GSFA food categories and to recommend to the Commission to revoke the corresponding food additive provisions of the GSFA that are inconsistent with these provisions, including the consequential changes in parent food categories as illustrated in CX/FAC 06/38/7, Annex IV that would be prepared by the Codex Secretariat (para. 63 and see Appendix VII);
- Forward to the Codex Alimentarius Commission for inclusion in the GSFA, an amended Annex to Table 3 of the GSFA, so that the general provisions of Table 3 do not apply to these food categories or standardized foods (para. 63 and Appendix VIII);
- Request the Codex Alimentarius Commission to replace the list of food additives of those Codex commodity standards that have a one-to-one correspondence with GSFA food categories, with text that refers to the provisions of the relevant GSFA food categories (para. 63 and Appendix IX);
- Recommend to the Commission to request Codex commodity committees, when they consider new entries or revisions of food additive provisions in commodity standards, to provide to the Committee justification of technological need for the food additives based upon Section 3.2 of the Preamble to the GSFA (para. 63).
- Recommend the Codex Alimentarius Commission to revoke a number of food additive provisions (para. 81 and Appendix XII);
- Forward the Codex General Standard for Contaminants and Toxins in Foods, including Schedule I to the Commission for adoption (para. 119 and Appendix XVIII)
- Recommend to the Codex Alimentarius Commission that specific reference to the GSCTF be included in the sections on contaminants of Codex commodity standards, e.g. “The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the CAC” (para. 119);
- Forward a request for a FAO/WHO Expert Consultation on the health risks associated with methylmercury and dioxins and dioxin-like PCBs in fish and the health benefits of fish consumption; to postpone consideration on the need to revise the guideline levels for methylmercury in fish pending the outcomes of the requested FAO/WHO Expert Consultation and to retain the current Codex guideline levels for the time-being. In addition it was decided not to proceed with the development of a list of predatory fish and not to start compiling data on the ratio of methyl mercury to total mercury in different fish species and to possibly consider this at a later stage with a particular focus on the different ratios for shellfish. (paras 191-193),
- Request to revise the GSFA descriptor of food category 13.6 “Food supplements” (para para. 214 and Appendix XXXIII).

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVEL FOR FOOD ADDITIVES AND PROCESSING AIDS IN CODEX STANDARDS

The Committee:

- Agreed not to endorse provisions regarding the use of Annatto Extracts (INS 160b), included in several draft and proposed draft Standards, because JECFA had assigned a temporary ADI for this food additive (para. 40);

Codex Committee for Nutrition and Foods for Special Dietary Uses (CCNFSDU)

- Endorsed the food additive provisions in the draft revised Standard for Processed Cereal-Based Foods for Infants and Young Children. It endorsed the additional provisions presented related to Section 3.9 “Flavours” and recommended that the Codex Alimentarius Commission include them in Section 4 “Food Additives” (paras 42-43 and Appendix IV).

Codex Committee on Milk and Milk Products (CCMMP)

- Endorsed all the food additive provisions, except for Gluconic Acid (INS 574), in the draft and proposed draft Standards, with some modifications; it also endorsed the two lists of food additive provisions for use in plain fermented milks and in heat-treated fermented milks (plain) to be included in Codex Standard for Fermented Milks, and requested CCMMP to consider whether Microcrystalline Cellulose (INS 460i) and Powdered Cellulose (INS 460ii) should be used in these products (paras 44-45 and Appendix IV).

Codex Committee on Cereals, Pulses and Legumes (CCCPL)

- Endorsed the food additive provisions in the draft Standard for Instant Noodles, with some modifications and deleted all additives associated with the technological function “Sweetener”. It also noted that the Maximum Levels for Tartrazine (INS 102), Sunset Yellow FCF (INS 110), Amaranth (INS 123), Fast Green FCF (INS 143), Curcumin (INS 100i) and Carmines (INS 120) might be reconsidered in the future, depending on the outcome of the JECFA dietary exposure assessment (paras 46-47 and Appendix IV).

MATTERS REFERRED TO CODEX COMMITTEES AND TASK FORCES

The Committee agreed to :

Executive Committee (CCEXEC)

- Forward a table compiling all the information concerning the time frame for the completion of the ongoing work (see para. 9 and Appendix II).

Codex Committee on General Principles (CCGP)

- Forward the proposed Procedures to the Codex Alimentarius Commission, through the Codex Committee on General Principles, for adoption and inclusion in the Codex Procedural Manual (see paras 57-60 and Appendix VI);
- Establish an electronic Working Group to consider the relevant amendments to the Procedural Manual, including: i) Format for Codex commodity standards, section on food additives; ii) Relations between commodity committees and general committees, section on food additives and contaminants; and iii) Terms of reference of the Committee (para. 68);

Codex Committee on Food Labelling (CCFL)

- Request the Codex Committee on Food Labelling to clarify the labelling requirements of carrier and packaging gas and to forward the revised Section 2 (Table of functional classes, definitions and technological uses) of the Codex *Class Names and International Numbering System* for comment (paras 97 and 99 and Appendix XV).

Codex Committee on Methods of Analysis and Sampling (CCMAS)

- Reply that the work on methods of analysis for dioxin and dioxin-like PCB was necessary for the screening of the presence of dioxin and dioxin-like PCBs in feed and food, and eventually for the development of performance criteria for screening and confirmatory methods (para. 168).

Codex Committee on Nutrition and Food for Special Dietary Uses (CCNFSDU)

- Forward the revised Section 2 (Table of functional classes, definitions and technological uses) of the Codex *Class Names and International Numbering System* for information (para. 99 and Appendix XV).

Codex Committee on Pesticide Residues (CCPR)

- Treat the revision of the Codex Classification of Foods and Animal Feeds as a priority (para. 119).

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

The Committee agreed to:

- Discontinue work on other proposed draft and draft food additive provisions, as proposed in CX/FAC 06/38/7. It was agreed that these provisions would be included in the Appendix of the draft and proposed draft food additive provisions to be discontinued, arising from the discussion of Agenda Item 6b “Food Additive Provisions in the Codex General Standard for Food Additives” (para. 63 and Appendix XIII);
- Establish an electronic Working Group to prepare a discussion paper describing in full the impacts of the revisions on the food additive provisions in the relevant GSFA food categories with a one-to-many relationship to a commodity standard, for circulation, comments and further discussion at the next session of the Committee (para. 64);
- Request the Codex Secretariat to prepare every year an updated version of the “Working document for information and support to the discussion on the GSFA” (para. 72);
- Reconvene the physical *ad hoc* Working Group on the Codex General Standard for Food Additives prior to its next session (para. 74);
- Incorporate into the GSFA the proposed food additive provisions: for Lutein from *Tagetes erecta* L (INS 161b(i)) and Zeaxanthin (INS 161h) at Step 4 and for Aspartame-Acesulfame Salt (962) at Step 3 and to include peroxyacid antimicrobial solutions in the Inventory of Processing Aids as antimicrobial agent (para. 75);

- Re-establish the electronic Working Group on the GSFA to consider the outstanding recommendations contained in CX/FAC 06/38/10, comments contained in CX/FAC 06/38/9 Parts 1 and 2, relevant decisions of the 37th and 38th CCFAC and new comments submitted in response to the Circular Letter to be issued by the Codex Secretariat (para. 79);
- Request the Codex Secretariat to issue a separate Circular Letter requesting comments by 15 September 2006 on a number of food additive provisions (para. 80 and Appendix X);
- Consider the listing of additives used in glazes, coatings, marking inks and surface decorations in the GSFA at a later stage (para. 84);
- Establish an electronic Working Group to develop a discussion paper on guidelines and principles on the use of processing aids and accepted the offer of the Delegation of New Zealand to prepare a further updated version of the Inventory of Processing Aids (IPA) (paras 92-93) .
- Reconvene the *ad hoc* Working Group on Specifications prior to its next session, under the Chairmanship of Denmark (para. 107);
- Reconvene the *ad hoc* Working Group on Contaminants and Toxins in Foods prior to the next Session of the Committee under the Chairmanship of the European Community (para. 117);
- Retain the proposed draft Sampling Plan at Step 4 awaiting outcome of the discussion paper on Maximum Levels of aflatoxins in tree nuts (para. 126 and Appendix XXI);
- Establish an electronic Working Group to expand the discussion paper on the aflatoxin level in ready-to-eat tree nuts (para. 129);
- Re-establish the electronic Working Group to revise the discussion paper on aflatoxin contamination in Brazil nuts; it also agreed that discussion on a sampling plan for Brazil nuts should be performed as part of the ongoing discussion on a sampling plan for aflatoxin in tree nuts (para. 134);
- Re-establish the electronic Working Group to revise and update the Discussion Paper on Deoxynivalenol (DON) (para. 138);
- Establish two electronic Working Groups to prepare separate discussion papers on Ochratoxin A (OTA) in coffee and on Ochratoxin A (OTA) in cocoa (para. 145);
- Return the proposed draft Code of Practice for the Reduction of Chloropropanols during the Production of Acid Hydrolyzed Vegetable Protein (HVPs) and Products that Contain acid HVPs (N05-2005) to Step 2 for revision by the electronic Working Group (para. 174);
- Maintain the proposed draft Maximum Level for 3-MCPD in Liquid Condiments Containing HVPs at Step 4 and to re-establish the electronic Working Group on Acid-HVP Containing Products and other Products containing Chloropropanol (paras 176-177 and Appendix XXVII);
- Postpone discussion on the risk communication aspects of methylmercury in fish until a general discussion on this issue within Codex could give guidance on this matter (para. 194);
- Request proposals for addition or amendments to the revised Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants under a separate Circular letter which would also contain the questionnaire for submission, for consideration at its next session (para. 209 and Appendix XXXII);
- Establish an electronic Working Group to revise the Discussion paper on aflatoxin contamination in dried figs (para. 211);
- Establish an electronic Working Group to develop a discussion paper for the revision of the Food Category System of the GSFA (para. 215).

LIST OF ABBREVIATIONS USED IN THIS REPORT

3-MCPD	3-monochloropropane-1,2-diol
ARfD	Acute Reference Dose
ADI	Allowable Daily Intake
CAC/GL	Codex Alimentarius Commission / Guidelines
CCCPL	Codex Committee on Cereals, Pulses and Legumes
CCFFP	Codex Committee on Fish and Fishery Products
CCGP	Codex Committee on General Principles
CCMMP	Codex Committees on Milk and Milk Products
CCNFSDU	Codex Committees on Nutrition and Food for Special Dietary Uses
CL	Circular Letter
CRD	Conference Room Document
DON	Deoxynivalenol
EC	European Community
FAO	Food and Agriculture Organization of the United Nations
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practices
GSCTF	General Standard for Contaminants and Toxins in Foods
GSFA	General Standard for Food Additives
HVP	Hydrolyzed Vegetable Protein
IAEA	International Atomic Energy Agency
IPA	Inventory of Processing Aids
JECFA	Joint FAO/WHO Expert Committee on Food Additives
OIV	International Organisation of Vine and Wine
OTA	Ochratoxin A
PAH	Polycyclic Aromatic Hydrocarbons
PCBs	polychlorinated biphenyls
POP	Persistent Organic Pollutants
PTWI	Provisional Tolerable Weekly Intake
TDI	Tolerable Daily Intake
WHO	World Health Organization
WTO	World Trade Organization

INTRODUCTION

1. The 38th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) was held in The Hague, the Netherlands, from 24-28 April 2006, at the kind invitation of the Government of the Netherlands. Mrs Annie De Veer, Deputy Director of Food Quality and Animal Health of the Netherlands Ministry of Agriculture, Nature and Food Quality, chaired the Session. The Session was attended by delegates representing 64 Member Countries, one Member Organization, and 41 International Organizations. The List of Participants is attached to this report as Appendix I.

OPENING OF THE SESSION

2. Dr. Cees Veerman, the Minister of Agriculture, Nature and Food Quality of the Netherlands, opened the 38th Session of the Codex Committee on Food Additives and Contaminants. In his statement, Dr Veerman highlighted the large number of participants and he underlined the importance of the Codex Trust Fund to facilitate developing countries taking active participation in the discussions of the Committee. He emphasized the importance of the implementation of Codex standards and guidelines as tools to promote international trade and to protect human health. He congratulated the Committee with the recent launch of the Website on the GSFA Online. He underlined the importance of participation in the several side events, the training for the GSFA Online, the instruction of new delegates, and the risk communication workshop, held during the Committee meeting. He strongly encouraged Members to consider financial support for the provision of scientific advice to the Committee. Finally he declared that the Netherlands would like to continue hosting the contaminants discussions, once the Committee is split by the Commission.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

3. The Committee adopted the Provisional Agenda as proposed. It agreed that Agenda Item 14d “Proposed draft Code of Practice for the Reduction of Chloropropanols during the Production of Acid Hydrolyzed Vegetable Protein (HVPs) and Products that Contain acid HVPs” and Agenda Item 14e “Proposed draft Maximum Level for 3-MCPD in Liquid Condiments Containing HVPs” would be discussed together, as these two items were interrelated.

4. It further agreed to discuss the following under Agenda Item 16 “Other Business and Future Work”:

- Descriptor of Food Supplement in the Food Category System of GSFA (request from IADSA);
- Revision of the Food Category System of GSFA (request from Indonesia).

5. The Committee agreed to hold Working Groups on the International Numbering System (INS) (Agenda Item 9b) and on JECFA Priorities (Agenda Item 15) under the Chairmanships of Finland and the Netherlands, respectively.

6. The Delegation of the European Community presented CRD 8 (Annotated Agenda) on the division of competence between the European Community and its Member States, under the Austrian presidency, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission.

APPOINTMENT OF THE RAPPORTEUR (Agenda Item 2)

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

¹ CX/FAC 06/38/1.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES (Agenda Item 3a)²

8. The Secretariat informed the Committee on matters arising from the 28th Session of the Commission, from the 57th Session of the Executive Committee and other Codex Committees and Task Forces. The Committee noted that most of the matters were for information purposes, while the following two issues would be discussed as follows: the question from the Codex Committee on Methods of Analysis and Sampling (CCMAS) under Agenda Item 14c “Proposed draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feeds” and the question from the Codex Committee on Milk and Milk Products under Agenda Item 9b “Proposals for Addition and/or Amendments to the International Numbering System for Food Additives”.

9. With regard to the request from the 57th Session of the Executive Committee, it was agreed to discuss the timeframe for the completion of work under each relevant Agenda Item and a table compiling all the requisite information would be forwarded to the 58th Session of the Executive Committee (see Appendices II).

10. The Committee noted that the 23rd Session of the Codex Committee on General Principles (CCGP) had agreed that the Committees on Food Additives and on Contaminants, once established, would be invited to review their terms of reference and purposes.

MATTERS OF INTEREST FROM FAO and WHO (Agenda Item 4)³

11. The Joint FAO/WHO JECFA Secretariat presented, on behalf of FAO and WHO, working document CX/FAC 06/38/3. The Committee was informed that the Joint FAO/WHO Expert Committee on Food has provided scientific advice since its constitution in 1956 and that the 67th meeting to be held 20 – 29 June 2006 would mark the 50th anniversary of JECFA. The Committee expressed its gratitude and acknowledged the importance for its work of the scientific advice of JECFA and emphasized that the continued efforts of JECFA should be supported. The Committee members were reminded of the obligations of member countries with regard to extra contributions to support this work and/or the prioritization of the work of WHO.

Work on principles for exposure assessment for flavouring agents

12. The Committee noted that, on recommendation of the 65th JECFA, the FAO/WHO JECFA Secretariat had constituted an expert working group to address concerns raised in relation to the current procedure used by JECFA in the exposure assessment of flavouring agents. The conclusions and recommendations of the working group would be discussed at the 67th JECFA meeting.

13. The Joint FAO/WHO JECFA Secretariat informed the Committee that for future evaluations of flavouring agents submitted for review by JECFA, up-to-date and complete information on accurate poundage (yearly production) and use levels would be requested.

Publication of the combined compendium of Food Additive Specifications

14. The Committee was informed that the publication of an up-to-date combined compendium of food additive specifications would be available in the first half of 2006. The new combined compendium, published as the first in a new series of FAO JECFA Monographs, consists of 4 volumes, 3 volumes for the food additive specifications and a fourth volume for analytical methods, test procedures and laboratory solutions required and referenced in food additive specifications. This publication will replace FAO Food and Nutrition Paper 52 and its 13 addenda and the FAO Food and Nutrition Paper 5, rev. 2.

15. The specifications are available on-line at the FAO JECFA website⁴ in an updated database which provides query pages and background in five languages (English, Spanish, French, Arabic and Chinese). The specifications include information on the ADIs and INS numbers.

² CX/FAC 06/38/2; CX/FAC 06/38/2, Add.1.

³ CX/FAC 06/38/3.

⁴ <http://www.fao.org/ag/agn/jecfa-additives/search/html?lang=en>.

Provision of Scientific Advice

16. The Committee was informed that a new call for experts to serve on JECFA for the period of 2007 – 2011 has been issued and is available at the FAO JECFA website⁵. The call is specifically addressed to individuals having expertise on food additives and their manufacture, quality and use, and to individuals having expertise in contaminants and toxins and their occurrence, determination and prevention and to experts on exposure assessment. In addition, the WHO roster for experts in toxicology to undertake safety assessment of food additives, contaminants and toxins is open for applications at any time.

17. The Committee was also informed that a compilation of all procedures followed by FAO and WHO, in relation to the provision of scientific advice, will be completed and published by the end of 2006. In addition, a report from a recent meeting hosted by FAO and WHO to explore approaches to enhance the participation of experts and the use of data from developing countries in the provision of international scientific advice was distributed recently to all Codex contact points.

Stockholm convention on persistent organic pollutants (POPs)

18. The WHO representative informed the Committee about the ongoing global survey of POPs, including dioxins and dioxin-like PCBs, in human milk to provide baseline levels to evaluate the effectiveness of interventions to reduce these environmental pollutants.

Application of risk analysis of methylmercury in fish

19. The Committee was informed that WHO, in cooperation with FAO and UNEP, is preparing a guidance document for risk managers, employing the risk analysis paradigm, considering the health benefits and risks associated with the consumption of fish. The document was subject to an expert consultation in January 2006. The document is intended to provide advice to national governments for the purpose of risk communication activities in relation to fish consumption by vulnerable groups of the population. In response to a question from the delegation of the United States, the representative of WHO indicated that the draft document could be made available to the Committee. The Committee was informed that, at present, there is insufficient information and there are no scientific methods to perform a quantitative assessment of the health benefits and risks of fish consumption with respect to methylmercury.

GEMS/Food Consumption Cluster Diets and total diet studies

20. The WHO Representative reported that the work has been completed on the thirteen GEMS/Food Consumption Cluster Diets, which had been developed based on average FAO Food Balance Sheet data for the period 1997-2001. The Committee was informed that the cluster diets had been presented to the 38th Session of the Codex Committee on Pesticides (CCPR) and will be employed at the next JECFA and JMPR meetings.

21. The Committee was informed that WHO, in cooperation with FAO and the Chinese Centres for Disease Control, will organise a 5-day training course in October 2006 on total diet studies, as well as a workshop on the state-of-the-art methods in this scientific area.

INFOSAN and INFOSAN Emergency

22. The Committee was informed about latest developments by WHO to create a network to promote exchange of food safety information and to improve collaboration among food safety authorities (INFOSAN), including a food safety emergency network (INFOSAN Emergency) as an integral part.

65TH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 4a)⁶

23. The WHO Joint Secretary of JECFA drew the attention of the Committee to the difficult financial situation still faced by the WHO part of the JECFA. It was noted that the JECFA programme cannot be continued at the present level if additional funds are not made available. In particular, the present WHO JECFA budget for 2007 only provides funds for one JECFA meeting. Additional extra budgetary resources specifically allocated to JECFA are required to enable the continuation of the work.

⁵ http://www.fao.org/ag/agn/jecfa/experts_en.stm.

⁶ Draft report available online at the Joint Secretariat's web pages at WHO <http://www.who.int/ipcs/food/jecfa/en/>.

24. The Representative of FAO informed the Committee about FAO's serious concern about this situation. The Committee was also informed that FAO, following the recommendations made by the recent Codex evaluation and in consideration of the priority given by FAO governing bodies to Codex and Codex-related activities, has prioritized budgetary allocations for Codex and all expert bodies, including JECFA, to provide the necessary scientific advice in food safety. However, due to the joint FAO/WHO nature of the activities for the provision of scientific advice, the increased allocation of FAO resources might be jeopardized due to the lack of WHO resources.

25. The Joint Secretariat to JECFA presented the results of 65th Meeting (June 2005), as they were reported in the Summary and Conclusions of the Meetings.

26. JECFA at its 65th meeting evaluated 13 food additives, 7 of them for specifications only, and one nutrient supplement.

27. A group ADI was established for Quillaia extracts Type 1 and Type 2 based on the saponin content. An ADI 'not specified' was allocated to Pullulan. For Beeswax and Candelilla wax, JECFA concluded that there was no safety concern at the predicted dietary exposure.

28. JECFA concluded that there was no safety concern for the use of the calcium salt of L-methyltetrahydrofolic acid as a replacement for folic acid as a dietary supplement. The safety of folate fortification as such was not assessed.

29. JECFA also evaluated 138 substances in seven groups as flavouring agents using the current JECFA procedure, 4 of them for specifications only. All flavouring agents except one were considered to be of no safety concern at their intended use and estimated intake levels.

30. JECFA noted that the available data for acetamide indicated that the substance is carcinogenic in rodents and a genotoxic mechanism can not be excluded. Therefore, JECFA considered that the use of this substance as a flavouring agent or for other food additive purpose was inappropriate.

31. JECFA also prepared specifications for 152 food additives, including flavouring agents.

32. JECFA reaffirmed use of the concept of 'threshold of toxicological concern' as an approach for the safety evaluation of flavouring agents and considered that this approach could also be applied to the evaluation of other substances present in small amounts in foods. JECFA recommended that further work be undertaken to develop guidance in this area. This work has yet to be initiated.

33. JECFA also considered the risk assessment principles for the evaluation of enzymes produced by Genetically Modified Microorganisms and recommended that guidelines need to be developed to specify the necessary information required for the enzyme preparations, as well as that for characterization of the microbial strains involved, taking into account the work of the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology. This work has yet to be completed.

ACTION REQUIRED AS A RESULT OF CHANGES IN THE ADI STATUS AND OTHER TOXICOLOGICAL RECOMMENDATIONS (Agenda Item 4b)⁷

34. The Committee noted actions required by CCFAC as a result of changes to existing ADIs and/or the establishment of new ADIs for food additives, or other toxicological recommendations for contaminants, as recommended by the 65th JECFA Meeting.

35. The Committee agreed with the recommendation of the *ad hoc* Working Group on the GSFA that no action was required for Phospholipase A1 from *Fusarium venenatum* expressed in *Aspergillus oryzae* in view of the JECFA's toxicological recommendation. It was also decided that the recommendations by JECFA on Beeswax (INS 901) and Candelilla Wax (INS 902) would be discussed under Agenda Item 6b "Food Additive Provisions of the Codex General Standard for Food Additives".

36. The Committee, noting that JECFA had evaluated Pullulan (INS 1204) as "Not Specified", agreed to include it in Table 3 of the GSFA at Step 4 and to request proposed maximum use levels in the food categories listed in the Annex to Table 3.

⁷ CX/FAC 06/38/4. CRD 2 (Report of the *ad hoc* Working Group on GSFA); CRD 6 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods).

37. The Committee agreed with the recommendation of the *ad hoc* Working Group that the issue about whether it was necessary to assign separate INS numbers for Quillaia extract Type 1 and Quillaia extract Type 2, should be considered under the Agenda Item 9b “Proposals for Addition and/or Amendments to the International Numbering System for Food Additives”.

38. The final recommendations of the Committee are summarised in Appendix III.

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES AND PROCESSING AIDS IN CODEX STANDARDS (Agenda Item 5)⁸

39. In accordance with the section of the Codex Alimentarius Commission Procedural Manual concerning the relations between Commodity Committees and General Committees, the Committee considered the endorsement of food additive and processing aid provisions arising from the Codex Committees on Nutrition and Food for Special Dietary Uses (CCNFSDU), on Milk and Milk Products (CCMMP), and on Cereals, Pulses and Legumes (CCCPL).

40. The Committee agreed not to endorse provisions regarding the use of Annatto Extracts (INS 160b), included in several draft and proposed draft Standards, because JECFA had assigned a temporary ADI for this food additive.

41. The Committee noted that the discussion of Agenda Item 9b “Proposals for Addition and/or Amendments to the International Numbering System for Food Additives” would clarify the issues related to the INS number of the following additives included in the draft and proposed draft standards: Beta-Carotene Natural Extracts (INS 160aii); Salts of Fatty Acids (with the cations Al, Ca, Na, Mg, K, and NH₄) (INS 470), and Mixed Tocopherol Concentrates (INS 306), Alpha-Tocopherol (INS 307); both Starch Acetate Esterified with Acetic Anhydride (INS 1420) and Starch Acetate Esterified with Vinyl Acetate (INS 1421).

Codex Committee for Nutrition and Foods for Special Dietary Uses

42. The Committee endorsed the food additive provisions in the draft revised Standard for Processed Cereal-Based Foods for Infants and Young Children submitted by the 27th Session of CCNFSDU with some modifications.

43. The Committee also endorsed the additional provisions presented in CRD 24 related to Section 3.9 “Flavours” of the draft Standard and recommended that the Codex Alimentarius Commission include them in Section 4 “Food Additives”. It clarified that the acronym “RTU” corresponded to “ready to use”. The Committee noted that the request from AIDGUM to include Acacia Gum to the list of food additives would be submitted to the next Session of the CCNFSDU.

Codex Committee on Milk and Milk Products

44. The Committee endorsed all the food additive provisions, except for Gluconic Acid (INS 574), in the draft and proposed draft Standards submitted by the 7th Session of CCMMP, with some modifications.

45. The Committee endorsed the two lists of food additive provisions for use in plain fermented milks and in heat-treated fermented milks (plain) to be included in Codex *Standard for Fermented Milks*, and requested CCMMP to consider whether Microcrystalline Cellulose (INS 460i) and Powdered Cellulose (INS 460ii) should be used in these products.

Codex Committee on Cereals, Pulses and Legumes

46. The Committee endorsed the food additive provisions in the draft Standard for Instant Noodles submitted by the Codex Committee on Cereals, Pulses and Legumes with some modifications. It agreed to delete all additives associated with the technological function “Sweetener” from the list in view of the information provided by Members that sweeteners were not used for manufacturing instant noodles in themselves.

47. The Committee also noted that the Maximum Levels for Tartrazine (INS 102), Sunset Yellow FCF (INS 110), Amaranth (INS 123), Fast Green FCF (INS 143), Curcumin (INS 100i) and Carmines (INS 120) might be reconsidered in the future, depending on the outcome of the JECFA dietary exposure assessment.

⁸ CX/FAC 06/38/5; CRD 9 (Comments of Malaysia and AIDGUM); CRD 24 (Endorsement and/or Revision of Maximum Levels for Food Additives in Codex Standards – CCNFSDU Additional submission).

Status of Endorsement and/or Revision of Maximum Level for Food Additives and Processing Aids in Codex Standards

48. The status of endorsement and/or revision of Maximum Levels for food additives in Codex Standards, taking into account the outcome of the considerations under other relevant Agenda Items, is shown in Appendix IV of this report.

CONSIDERATION OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 6)

PREAMBLE OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 6a)⁹

49. Dr Junshi Chen (China), Chair of the physical Working Group on the Working Principles of the General Standard for Food Additives (GSFA)¹⁰, which met on 20 April 2006, introduced the report of the meeting. The Committee was informed that the physical Working Group had discussed: i) the draft revision of the Preamble of the General Standard for Food Additives; and ii) the report of the electronic Working Group on the Working Principles of the GSFA, established at its 37th Session, as contained in CX/FAC 06/38/7.

i) Draft Revision of the Preamble of the General Standard for Food Additives

50. The Committee considered the changes to the draft revision of the Preamble proposed by the physical Working Group, as contained in the Appendix 2 of CRD 1, and, in addition to some editorial changes (e.g. consistent use of the term “maximum use level” throughout the text), agreed to the following:

Section 1.2 - Food in Which Additives May Be Used

51. The Committee agreed to retain the text of the section as previously drafted and changed the third sentence, related to the food additive provisions of the Codex commodity standards with the following text “The General Standard for Food Additives (GSFA) should be the single authoritative reference point for food additives” which reflected the decision of the 28th Session of the Codex Alimentarius Commission. It further agreed not to retain the two sub-sections, proposed by the physical Working Group, on the roles of Commodity Committees and of the Codex Committee on Food Additives and Contaminants and to refer these sub-sections to the electronic Working Group that will consider amendments to the Codex Procedural Manual (see paras 68-69).

Section 4.1 - Conditions Applying to Carry-Over of Food Additives

52. The Committee improved the clarity of the section by moving the second sentence of the first paragraph after the numbered points.

Section 5 – Food Category System

53. The Committee agreed to take out the last sentence of the first enumerated principle, proposed by the physical Working Group, and refer it to the electronic Working Group that will consider amendments to the Procedural Manual.

Section 7 - Review and Revision of the Standard

54. The Committee agreed to delete the entire section as its content was already included in the “Procedures for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives”.

⁹ ALINORM 05/28/12, Appendix VII; CX/FAC 06/38/6 (Comments at Step 6 in response to CL 2005/36-FAC of Canada, Mexico, Morocco, United States, ELC and IFU); CX/FAC 06/38/6, Add.1 (Comments of Norway); CX/FAC 06/38/7 (Report of the Working Group on the Working Principles of the GSFA); CX/FAC 06/38/7, Add.1 (Comments of Canada, Costa Rica, European Community, United States, Venezuela, CEFS, ICGMA, IDF and IFU); CX/FAC 06/38/7, Add.2 (Comments of Norway); CRD 1 (Report of the Meeting of the Working Group on the Working Principles of the GSFA); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia).

¹⁰ Ms Marike Herbts (South Africa) and Mr John van den Beuken (New Zealand) served as rapporteurs of the physical Working Group.

Status of the draft revision of the Preamble of the Codex General Standard for Food Additives

55. The Committee agreed to forward the revised draft Preamble to the Codex Alimentarius Commission for adoption at Step 8 (see Appendix V).

ii) Report of the electronic Working Group on the Working Principles of the GSFA

56. The Committee noted that the physical Working Group had made recommendations on the three parts of the report of the electronic Working Group: Part I “Proposed Procedure for Consideration of the Entry and Review of Food Additives in the GSFA”; Part II “Analysis of the Relationship between the Food Additive Provisions of the GSFA and those of the Commodity Standards, including Options for Moving Commodity Standard Food Additive Provisions into the GSFA”; and Part III “Proposed Revisions to the Codex Procedural Manual”.

Part I “Proposed Procedure for Consideration of the Entry and Review of Food Additive Provisions in the GSFA”

57. The Committee was informed that the physical Working Group had an extensive discussion on the proposed Procedures and had amended the diagram to more accurately reflect the proposed procedure described in the text. It was noted that the proposed procedures also included provisions for seeking inputs from commodity committees on food additive provisions of standardised foods.

58. The Committee considered the revised Procedure proposed by the physical Working Group, as contained in Appendix 3 of CRD 1. The Committee recalled that the physical Working Group, during its discussion on Section 7 of the Preamble had revised sub-section “Revision”. In noting that these amendments were not reflected in the proposed Procedures, it agreed to the following changes in bullet point “Maximum use level for the food additive in the specified food categories” of the section “Revision”:

- To add at the end of the first open bullet “although for certain cases, a level of GMP may be appropriate”;
- To add a new open bullet “For additives with an “acceptable” ADI, either a numerical maximum use level for the acceptable level of treatment of a food or a level of GMP, consistent with the JECFA evaluation”;
- To change the phrase “of this Standard” in the fourth and sixth bullets to “of the GSFA”.

59. The Committee agreed to some minor editorial changes to the diagram, e.g. insertion of two missing arrows.

Status of the proposed Procedures for Consideration of Entry and Review of Food Additive Provisions in the GSFA

60. With these changes, the Committee agreed with the recommendation of the physical Working Group to forward the proposed Procedures to the Codex Alimentarius Commission, through the Codex Committee on General Principles, for adoption and inclusion in the Codex Procedural Manual (see Appendix VI).

Part II “Analysis of the Relationship between the Food Additive Provisions of the GSFA and those of the Commodity Standards, including Options for Moving Commodity Standard Food Additive Provisions into the GSFA”

61. The Committee endorsed the recommendation of the physical Working Group related to the inclusion in the GSFA of the food additive provisions of Codex commodity standards that have a full correspondence with a GSFA food category (one-to-one relationship), i.e. the food category corresponds exactly in scope to a single food standard and contains no non-standardised foods. In particular, it agreed that the inclusion of food additive provisions of the Codex commodity standards that have one-to-one correspondence with a GSFA food category should be based on the following principles:

- a) Only food additives evaluated by JECFA and assigned a full ADI will be considered for inclusion in the GSFA;
- b) Only food additives assigned an INS number will be considered;
- c) The Maximum Use Level for the food additive listed in the respective commodity standard will be listed in the GSFA;

- d) Food additives that share a JECFA group ADI will be entered in the GSFA under the group name (e.g., phosphates) without further restrictions, unless an additive or group of additives can be shown, for example, to present a hazard to health or promote deception of the consumer. Such exceptions should be fully justified and should be restricted as much as possible;
- e) Food additives should not be included in GSFA when their technological need can not be justified, based upon the criteria in subparagraphs a) through d) in section 3.2 of the Preamble of the GSFA;
- f) Food additives that have multiple functional effect classes will be entered in the GSFA without further restrictions to their functional effect class.

62. The Committee noted that due to the hierarchical nature of the GSFA Food Category System, the inclusion of the food additive provisions of Codex commodity standards with a one-to-one relationship to GSFA food categories would result in changes not only in corresponding food categories but also in parent food categories. It would consequently be necessary to revoke and/or discontinue work on and/or reassign a number of food additive provisions in the GSFA.

63. The Committee agreed with the recommendations of the physical Working Group to:

- Forward to the Codex Alimentarius Commission, for inclusion in the GSFA, the food additive provisions of the Codex commodity standards with a one-to-one relationship to GSFA food categories and to recommend to the Commission to revoke the corresponding food additive provisions of the GSFA that are inconsistent with these provisions (see Appendix VII), including the consequential changes in parent food categories as illustrated in CX/FAC 06/38/7, Annex IV that would be prepared by the Codex Secretariat.
- Forward to the Codex Alimentarius Commission for inclusion in the GSFA, an amended Annex to Table 3 of the GSFA, so that the general provisions of Table 3 do not apply to these food categories or standardized foods, as contained in Appendix VIII;
- Discontinue work on other proposed draft and draft food additive provisions, as proposed in CX/FAC 06/38/7. It was agreed that these provisions would be included in the Appendix of the draft and proposed draft food additive provisions to be discontinued, arising from the discussion of Agenda Item 6b “Food Additive Provisions of the Codex General Standard for Food Additives” (see Appendix XIII);
- Request the Codex Alimentarius Commission to replace the list of food additives of those Codex commodity standards that have a one-to-one correspondence with GSFA food categories, with text that refers to the provisions of the relevant GSFA categories, as contained in Appendix IX;
- Recommend to the Commission to request Codex commodity committees, when they consider new entries or revisions of food additive provisions in commodity standards, to provide to the Committee justification of technological need for the food additives based upon Section 3.2 of the Preamble to the GSFA.

64. The Committee considered the physical Working Group’s recommendation related to those GSFA food categories which span several Codex commodity standards (one-to-many relationships) and which may or may not contain non-standardised foods. It agreed to establish an electronic Working Group, led by the United States¹¹, to prepare a discussion paper describing in full the impacts of the revisions on the food additive provisions in the relevant GSFA food categories with a one-to-many relationship to a commodity standard, for circulation, comments and further discussion at the next session of the Committee. It was agreed that the electronic Working Group would work in English only.

65. The Committee agreed that the discussion would also contain proposals to revise the GSFA to integrate the food additive provisions of the Codex commodity standards and encouraged the Working Group to consider solutions that could be applied consistently throughout commodities.

¹¹ With the assistance of Australia, Canada, China, Cuba, France, European Community, India, Indonesia, Japan, Malaysia, New Zealand, Republic of Korea, Switzerland, Thailand, IDF and IFT.

66. It was agreed that in developing these proposals, any additional restrictions on the use of food additives that are exceptions to the general principles used in the development of the GSFA will be considered based on the following criteria:

- a) The use of a specific food additive in a food conforming to all other provisions (e.g., name, labelling, and hygiene) of an individual Codex commodity standard is not safe.
- b) The specific food additive can not perform its intended functional effect in the Codex standardized food because of physico-chemical considerations respecting either the food additive or the standardized food.
- c) The use of a specific food additive in a food conforming to an individual Codex commodity standard would mislead the consumer.
- d) Any exceptions to the general principles of the GSFA must be fully documented and supported by information provided to CCFAC.

67. The Committee also agreed that, to the extent possible, exceptions to the general principles of the GSFA would be implemented in the simplest, most transparent and pragmatic manner possible, for example, by the use of notes in GSFA Food Additive Tables 1 and 2, revisions to the Annex to Table 3, or by revisions to the GSFA Food Category System.

Part III “Proposed Revisions to the Codex Procedural Manual”

68. The Committee endorsed the recommendation of the physical Working Group to establish an electronic Working Group led by Switzerland¹² to consider the relevant amendments to the Procedural Manual, including: i) Format for Codex commodity standards, section on food additives; ii) Relations between commodity committees and general committees, section on food additives and contaminants; and iii) Terms of reference of the Committee and to prepare a report with a first proposal of amendments to the Procedural Manual for circulation, comments and further consideration at the next session of the Committee. It was agreed that the electronic Working Group would work in English only.

69. It was further agreed to inform the Codex Alimentarius Commission and the Codex Committee on General Principles of this work and that the proposed changes to the Procedural Manual should be consistent with the Preamble of the GSFA.

FOOD ADDITIVE PROVISIONS OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 6b)¹³

Ad hoc Working Group on the Codex General Standard for Food Additives

70. The Committee recalled that at its 37th Session it had decided to reconvene the *ad hoc* Working Group on the Codex General Standard for Food Additives (GSFA) prior to its 38th Session and to re-establish the Electronic Working Group on the GSFA to provide a report with recommendations on the draft Maximum Levels for the food additives listed in Appendix VIII of its report¹⁴ to the 38th Session of the Committee.

¹² With the assistance of Brazil, China, Cuba, France, European Community, India, Japan, New Zealand, Serbia and Montenegro, Sri Lanka, Thailand, United States and ELC.

¹³ CX/FAC 06/38/8 (Working Document for Information and Support to the Discussion on the General Standard for Food Additives); CRD 2 (Report of the *ad hoc* Working Group on the GSFA); CL 2005/34-FAC (Request for Comments and Information on Food Additives Provisions for Priority Food Additives in the GSFA); CL 2005/45-FAC (Request for Information on Neotame - INS 961, Polyvinyl alcohol - INS 1203 and Aspartame acesulfame – INS 962); CL 2005/50-FAC (Request for Information on Lutein from *Tagetes erecta* L – INS 161b, Zeaxanthin – INS 161h and on Peroxid antimicrobial solutions); CX/FAC 06/38/9, Parts 1 and 2 (Comments in response to CL 2005/34-FAC, CL 2005/45-FAC and CL 2005/50-FAC of Brazil, Canada, European Community, Iran, Malaysia, Mexico, Sri Lanka, Venezuela, CEFS, CEFIC, CIAA, ELC, FEDIOL, IADSA, ICBA, ICGA, IFAC, IFU, ISA, ISDI, NATCOL, OIV and WSRO); CX/FAC 06/38/10 (Report of the Electronic Working Group on the GSFA); CX/FAC 06/38/11 (Discussion Paper on Food Additives Provisions in Glazes for Foods); CRD 10 (Comments of Cuba); CRD 12 (Comments of Canada, Japan, Malaysia, Thailand and CEFIC); CRD 13 (Comments of IADSA).

¹⁴ ALINORM 05/28/12, paras 68 and 70.

71. Dr Dennis Keefe (United States), Chair of the *ad hoc* Working Group on GSFA¹⁵, which met on 21 April 2006, introduced the report of the meeting and proposed several general recommendations for endorsement by the Committee.

General Recommendations

72. The Committee agreed to the recommendation of the *ad hoc* Working Group to request the Codex Secretariat to prepare every year an updated version of the “Working document for information and support to the discussion on the GSFA” similar to CX/FAC 06/38/8.

73. The Committee noted that those recommendations of the *ad hoc* Working Group that involved issues relating to INS numbers and the JECFA priority list would be considered during the discussion of Agenda Items 9b “Proposals for Addition and/or Amendments to the International Numbering System for Food Additives” and 15 “Priority List of Food Additive, Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA”, respectively.

74. The Committee decided to reconvene the physical *ad hoc* Working Group on the Codex General Standard for Food Additives prior to its next session, under the Chairmanship of the United States. It was agreed that the physical Working Group would work in English only.

Food Additive Provisions of the Codex General Standard for Food Additives

Recommendations for Lutein, Zeaxanthin, Aspartame-Acesulfame salt and Peroxyacid antimicrobial solutions

75. The Committee endorsed the recommendation of the *ad hoc* Working Group to incorporate into the GSFA the proposed food additive provisions: for Lutein from *Tagetes erecta* L (INS 161b(i)) and Zeaxanthin (INS 161h) submitted in response to CL 2005/50-FAC at Step 4 and for Aspartame-Acesulfame Salt (962) submitted in response to CL 2005/45-FAC at Step 3. It also agreed to include peroxyacid antimicrobial solutions in the Inventory of Processing Aids as antimicrobial agents. It was noted that under some conditions of use, Codex Members consider peroxyacid antimicrobial solutions as processing aids. Some, but not all Codex Members noted that under other conditions of use peroxyacids are considered food additives.

Recommendations for adoption of draft (at Step 8) and proposed draft (at Step 5/8) food additive provisions

76. The Committee endorsed the recommendation of the *ad hoc* Working Group to forward to the Commission for adoption at Step 8 or Step 5/8 the draft and proposed draft food additive provisions listed in Appendix II of CRD 2, with the exception of Quillaia extracts in food category 14.1.4 (Water-based flavoured drinks, including “sport”, “energy” or “electrolyte” drinks and particulated drinks) because it was unclear which type of Quillaia extract was referenced and whether or not the use level was based on saponin content. An observer informed that the use level was based on Quillaia Extract (Type 1) and suggested using the maximum saponin content in the specification (26%) to express the Maximum Level based on saponin content. It was further noted that the food additive provision for the use of BHA in food category 2.4 (Fat-based desserts excluding dairy-based dessert products of food category 01.7) had been inadvertently omitted from the list.

Recommendations for revocation of adopted food additive provisions

77. The Committee endorsed the recommendation of the *ad hoc* Working Group to revoke a number of food additive provisions as listed in Appendix III of CRD 2 with the exception of the provisions for the use of Caramel Colour, Class III and Caramel Colour, Class IV. It was noted that provisions for the use of BHT and for the use of BHA in food category 02.3 (fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions) and 02.4 (Fat-based desserts excluding dairy-based dessert products of food category 01.7) had been inadvertently included in the list.

¹⁵ Ms Ingvild Tommerberg (Norway) served as Rapporteur of the physical Working Group.

Recommendations for discontinuation of draft and proposed draft food additive provisions

78. The Committee endorsed the recommendation of the *ad hoc* Working Group to discontinue work on a number of draft and proposed draft food additive provisions as listed in Appendix IV of CRD 2, with the exception of the following provisions for which additional information would be requested (see para. 80): Benzoates in food category 04.1.2.5 (jams, jellies and marmalades); Polydimethylsiloxane in food category 12.9.1.3 (other soybean products, including non-fermented soy sauce); Diacetyltartaric and fatty acid esters of glycerol in food categories 01.4 (cream-plain and the like), 09.2.2 (frozen battered fish, fish fillets, and fish products, including molluscs, crustaceans, and echinoderms) and 09.2.3 (frozen minced and creamed fish products, including molluscs, crustaceans, and echinoderms), and 09.4 (fully preserved, including canned or fermented fish and fish products, including molluscs, crustaceans, and echinoderms); Sulphites in food category 11.3 (Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3); and Canthaxanthin in food categories 14.1.4.3 (concentrates (liquid or solid) for water based flavoured drinks) and 15.1 (snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)).

Recommendations for the work of the Electronic Working Group (priority food additives identified for further discussion and request for additional information)

79. The Committee endorsed the recommendation of the *ad hoc* Working Group to re-establish the electronic Working Group on the GSFA, led by the United States¹⁶ to consider the outstanding recommendations contained in CX/FAC 06/38/10, comments contained in CX/FAC 06/38/9 Parts 1 and 2, relevant decisions of the 37th and 38th CCFAC and new comments submitted in response to the Circular Letter to be issued by the Codex Secretariat (see para. 80). It was agreed that the electronic Working Group would take a horizontal approach to its discussion of the provisions for colours and sweeteners in its priority list and that the report will contain recommendations to the Committee with a view towards advancing these provisions in the Codex Step process and making progress on the GSFA. It was agreed that the electronic Working Group would work in English only.

80. The Committee endorsed the recommendation of the *ad hoc* Working Group to request the Codex Secretariat to issue a separate Circular Letter requesting comments by 15 September 2006 on the food additive provisions contained in Appendix X of this report, with the understanding that if this information was not provided, the next session of the Committee will discontinue work on these food additive provisions. Comments will also be requested on the food additive provisions for Aspartame-Acesulfame Salt at Step 3 (see para. 75). It was understood that the comments submitted in response to this Circular Letter will be referred to the electronic Working Group and not be published.

Status of the Food Additive Provisions of the Codex General Standard for Food Additives

81. The Committee agreed:

- To forward the draft and proposed draft food additive provisions of the GSFA to the 29th Session of the Commission for adoption at Step 8 and Step 5/8 (with recommendation to omit Steps 6 and 7) (see Appendix XI);
- To request the 29th Session of the Codex Alimentarius Commission to revoke a number of food additive provisions (see Appendix XII);
- To discontinue work on a number of food additive draft and proposed draft provisions (see Appendix XIII).
- To circulate for comments at Steps 3 and 6 and information a number of food additive provisions (see Appendix X and para. 80).

¹⁶ With the assistance of Australia, Brazil, Canada, European Community, Indonesia, Japan, Malaysia, Mexico, New Zealand, Norway, Republic of Korea, Thailand, South Africa, Switzerland, ELC, IADSA, ICBA, ICGA, ICGMA, IDF, IFAC, IFDI, IFU, ISA and ISDI.

Discussion paper on Food Additive Provisions in Glazes for Foods¹⁷

82. The Committee recalled that at its 37th Session it had been agreed that the Delegation of Canada draft a discussion paper to propose options for addressing, in a uniform and consistent manner, the food additive provisions in glazes for foods in the GSFA.¹⁸

83. The Delegation of Canada briefly introduced the paper and explained that the scope of the document had been enlarged beyond “glazes” and included any surface-applied food preparation including coatings, marking inks and decorating preparations. It was explained that currently the GSFA contained numerous provisions for maximum use levels of food additives bearing accompanying notes referring to use of the latter in coatings, glazes, meat or egg marking preparations or external decorations. It was also indicated, however, that the Food Category System (FCS) accommodated some glazes and coatings, marketed as such.

84. The Committee recognised the importance to add clarity to the GSFA by addressing in a more transparent manner the listing of additives used in glazes, coatings, marking inks and surface decorations. However, in view of the need to complete the entry of the provisions of the food additives evaluated by JECFA into the GSFA and to integrate the food additives listed in the Codex commodity standards, it was agreed to consider this issue at a later stage.

DISCUSSION PAPER ON THE DEVELOPMENT OF GUIDELINES FOR FLAVOURING AGENTS (Agenda Item 7)¹⁹

85. The Committee recalled that at its 37th Session it had agreed to initiate new work on the elaboration of guidelines that refer to evaluations completed by JECFA and that establish safe conditions for the use of flavouring substances and natural flavouring complexes in foods, similar to the principles for the safe use of food additives contained in the Preamble of the Codex *General Standard for Food Additives*. The Committee had established an electronic Working Group to prepare a discussion paper on the development of Guidelines, which would take into account the various terms and definitions used in Codex related to ‘flavourings’ and which would include a project document for starting new work for possible submission to the Codex Alimentarius Commission.²⁰

86. The Delegation of the United States, lead of the electronic Working Group, briefly introduced the Discussion Paper.

87. As there was no objection, the Committee agreed to start new work on the elaboration of a Guideline for the Use of Flavourings. It revised the project document by identifying a need for industries to provide JECFA with updated poundage and use level data and agreed to submit the document to the 29th Session of the Codex Alimentarius Commission for approval as new work (Appendix XIV). It was further agreed that, subject to the approval of the Commission, an electronic Working Group led by the United States²¹ would prepare a proposed draft Guideline for circulation, comments at Step 3 and further consideration at its next session. It was suggested that data on intake estimation of flavouring agents by JECFA and other relevant data should be taken into consideration when elaborating the draft Guidelines.

88. Further, the Committee agreed to establish a physical Working Group prior to its next Session, under the Chairmanship of the European Community, to consider the proposed draft Guideline along with comments submitted at Step 3. It was agreed that both the electronic and physical Working Groups would work in English only.

¹⁷ CX/FAC 06/38/11.

¹⁸ ALINORM 05/28/12, para 67.

¹⁹ CX/FAC 06/38/12; CX/FAC 06/38/12, Add.1 (Comments of Canada, European Community, New Zealand, United States, ICBA, ICGA and IOFI); CX/FAC 06/38/12, Add.2 (Comments of Kenya and Norway); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia).

²⁰ ALINORM 06/29/12, para. 102.

²¹ With assistance of Australia, Canada, European Community, France, Indonesia, Japan, Mexico, Norway, Switzerland, FAO, WHO, CIAA, ICBA, ICGA, IFT, IOFI and ISDI.

INVENTORY OF PROCESSING AIDS (IPA), UPDATED LIST (Agenda Item 8)²²

89. The Committee recalled that at its 37th Session it had accepted the offer of the Delegation of New Zealand to prepare a further updated version of IPA, which would also include the proposals made at that meeting, for consideration at the current session and that an introductory text with an explanation of changes, suggestions on the use of IPA and possible future work would be included in the document.²³

90. The Delegation of New Zealand presented the document CX/FAC 06/38/13, which included the updated IPA that incorporating the previous decisions of the Committee on processing aids, proposals and information from Members, JECFA and industry. The Committee expressed its appreciation to the delegation of New Zealand.

91. One delegation proposed to reformat the IPA into two parts, one for the processing aids evaluated by JECFA and the other for the processing aids which had not been evaluated by JECFA and to delete those processing aids which were also used as food additives. In this regard, the Committee recalled its decision to use IPA as a document for information to the Committee.

92. The Committee agreed that there was a need for guidance about the use of processing aids. For this purpose, it was agreed to establish an electronic Working Group, led by Indonesia²⁴, to develop a discussion paper on guidelines and principles on the use of processing aids, which would address: technological justification; safe use and suitable controls on processing aids; the relationship between processing aids and food additives; and other issues related to processing aids. It was agreed that the Electronic Working Group would work in English only.

93. The Committee accepted the offer of the Delegation of New Zealand to prepare a further updated version of the IPA for consideration at its next session, with the improvements indicated in CX/FAC 06/38/13, para. 16.

INTERNATIONAL NUMBERING SYSTEM (INS) FOR FOOD ADDITIVES (Agenda Item 9)**PROPOSED DRAFT REVISION OF THE CODEX CLASS NAMES AND INTERNATIONAL NUMBERING SYSTEM - CAC/GL 36-1989 (Agenda Item 9a)²⁵**

94. The Committee noted that the 28th Session of the Codex Alimentarius Commission had approved the revision of the *Codex Class Names and International Numbering System* as new work for the Committee.²⁶ It recalled that at its 37th Session, it had agreed to reconvene prior to its 38th Session the *ad hoc* Working Group on the Harmonisation of Terms used by Codex and JECFA to consider the revised Section 2 “Table of functional classes, definitions and technological uses” along with the comments submitted at Step 3.²⁷

95. Dr Brian Whitehouse (United Kingdom) served as Chair and Ms Harriet Wallin served as Rapporteur of the *ad hoc* Working Group, which met on 23 April 2006. Dr Whitehouse, briefly introduced the report of the meeting and explained that the Committee had agreed to a revised version of Section 2, as presented in CRD 3. The report recorded that discussion was still needed to get to an agreement on whether carrier and packaging gas should be considered additives or processing aids and whether they should be included in the table. It further explained that the left column of the table included functional classes for labelling purposes that were defined by the definitions in the central column and that the right column included the technological uses of additives, for subsequent use by GSFA and JECFA.

²² CX/FAC 06/38/13.

²³ ALINORM 05/28/12, para. 99.

²⁴ With the assistance of New Zealand, Russia, AMFDP, ETA, IDF, IFAC and IFT.

²⁵ CL 2005/32-FAC (Request for comments at Step 3 on the proposed draft Revision of the *Codex Class Names and International Numbering System* – CAC/GL 36-1989); CX/FAC 06/38/14 (Comments at Step 3 of Brazil, Canada, European Community, United States, Venezuela, EFEMA, ELC, IDF, IFAC, ISA and ITF); CX/FAC 06/38/14, Add.1 (Comments of European Community); CRD 3 (Report of the Working Group on the Harmonisation of Terms used by Codex and JECFA); CRD 10 (Comment of Cuba); CRD 11 (Comment of Indonesia).

²⁶ ALINORM 05/28/41, para. 93 and Appendix VIII.

²⁷ ALINORM 05/28/12, para. 95.

96. The Committee agreed with the revised table prepared by the *ad hoc* Working Group and revised the definition of “Emulsifying salt” to make it broader to encompass food and not only cheese. It deleted “flavour modifier” as it was found inconsistent with the definition of “flavour enhancer”. An observer noted that flavour modifiers were an active area of innovation and suggested that the Committee reconsider the matter in future.

97. With regard to carrier and packaging gas, the Committee noted that the GSFA included additives which have these functions and, therefore, agreed to retain these two functional classes in the Table and to request the Codex Committee on Food Labelling to clarify the labelling requirements of carrier and packaging gas. In waiting for this clarification, the Committee agreed to put the two terms in square brackets.

Status of the proposed draft Revision of the Codex Class Names and International Numbering System (CAC/GL 36-1989) (N07-2005)

98. The Committee agreed to forward the revised Section 2 (Table of functional classes, definitions and technological uses) of the Codex *Class Names and International Numbering System* to the 29th Session of the Codex Alimentarius Commission for adoption at Step 5 (see Appendix XV).

99. It was also agreed to forward the revised Table to both the Codex Committee on Food Labelling (CCFL) for comment and to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) for information.

PROPOSALS FOR ADDITION AND/OR AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES (Agenda Item 9b)²⁸

100. The Committee noted that the Working Group on the International Numbering System (INS) that was chaired by Ms H.C. Wallin (Finland), had considered the comments received in response to CL 2005/38-FAC, the referral of the 7th Session of the Codex Committee on Milk and Milk Products²⁹ and the recommendation of the *ad hoc* Working Group on the GSFA (see para.73).

101. The Chair of the Working Group introduced the document and reminded the Committee that the INS was intended as an identification system for food additives approved for use in one or more countries and that assignment of an INS number does not imply technological approval by the Codex but is only a means of identifying food additives on a world-wide basis. The list extends well beyond those additives currently evaluated by JECFA.

102. The Committee agreed to the following recommendations of the Working Group:

- To add “Acidity regulator” to the technological functions of Calcium carbonate (INS 170 (i)), Sodium lactate (INS 325), Monosodium tartrate (INS 335 (i)), Disodium tartrate (INS 335 (ii)), Monopotassium tartrate (INS 336 (i)), Dipotassium tartrate (INS 336 (ii)), and Potassium sodium tartrate (INS 337);
- To add “Stabilizer” to the technological functions of Calcium citrates (INS 333), Propylene glycol alginate (INS 405), Potassium chloride (INS 508), and Calcium chloride (INS 509);
- To add “Clouding agent” to the technological functions of Beeswax (INS 901) and Candelilla wax (INS 902);
- To add “Carrier ” to the technological functions of Cyclodextrin, beta- (INS 459);
- To change the INS numbers and names as follows: Luteins (INS 161b), Lutein from *Tagetes erecta* (INS 161b (i)), *Tagetes* extract (INS 161b (ii)); Zeaxanthins (INS 161h), Zeaxanthin- (synthetic) (INS 161h (i)), Zeaxanthin-rich extract from *Tagetes erecta* (INS 161h (ii)); Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium (470 (i)), Salts of oleic acids with calcium, potassium and sodium (INS 470 (ii)), Quillaia extract (Type 1) (INS 999 (i)), and Quillaia extract (Type 2) (INS 999 (ii));

²⁸ CL 2005/38-FAC (Request for comments on the Codex International Numbering System (INS) for Food Additives); CX/FAC 06/38/14; CX/FAC 06/38/15; CRD 6 (Report of the Working Group on the International Numbering System); CRD 10 (Comments of Cuba); CRD 14 (Comments of AAC).

²⁹ CX/FAC 06/38/2, Add.1.

- To combine “Starch acetate esterified with acetic anhydride” (INS 1420) and “Starch acetate esterified with vinyl acetate (INS 1421)” under a single INS 1420 “Starch acetate” with the deletion of the current INS 1421 (Starch acetate esterified with vinyl acetate), also with addition of Binder, Emulsifier as additional technological functions to this new INS 1420;
- To designate new INS numbers and technological functions as follows; INS 1451 to “Acetylated oxidised starch” with the assignment of Stabilizer, Thickener, Binder, Emulsifier as its technological function, and INS 1452 to “Starch aluminium octenyl succinate” with the assignment of Anticaking agent, Carrier, Stabilizer as its technological function.

103. The Committee noted that the Working Group had to postpone the considerations of the following requests to the next session due to the late arrival of the requests or insufficient time to discuss them. These included:

- To reconsider the INS numbers for all compounds currently listed under INS 160a;
- To consider amending the INS with regard to modified starches in order to increase consistency between JECFA specifications for modified starches and the INS list. The request included amendments to technological functions, renaming of some substances and possible deletion of substances no longer believed to be manufactured and used (INS 1423 and 1443);
- To clarify INS numbers of tocopherol derivatives because of noted inconsistencies between INS numbers in the INS list and JECFA specifications.

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

104. The Committee agreed to forward the proposed draft amendments to the International Numbering System for Food Additives to the 29th Session of the Codex Alimentarius Commission for adoption at Step 5/8 (with recommendation to omit Steps 6 and 7) (see Appendix XVI).

SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES (Agenda Item 10)³⁰

105. The Committee recalled that at its 37th Session, it agreed to reconvene the *ad hoc* Working Group on Specifications prior to the present Session³¹.

106. The *ad hoc* Working Group met on 23 April 2006. It was chaired by Dr Paul Kuznesof (United States); Ms H.C. Wallin (Finland) acted as Rapporteur and Ms I. Meyland (Denmark) acted as Category Monitor. The *ad hoc* Working Group considered the specifications monographs for the identity and purity of food additives and flavouring agents established at the 65th Meeting of JECFA, which were published in FAO Food and Nutrition Paper 52 Addendum 13 (FNP 52-Add.13) and posted on the JECFA website in September in 2005. Comments received on FNP 52-Add.13 were also considered.

Status of the *ad hoc* Working Group on Specifications

107. The Committee decided to reconvene the *ad hoc* Working Group on Specifications prior to its next session, under the Chairmanship of Denmark. It was agreed that the Working Group would work in English only. The Committee expressed its appreciation to Dr. Kuznesof for his contributions to the Working Group and the Committee over many years.

SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 65TH JECFA MEETING

108. The Committee agreed with the following recommendations of the *ad hoc* Working Group;

- To endorse and forward the Category I specifications of the 6 food additives and 130 flavouring agents to the 29th Codex Alimentarius Commission for adoption as Codex Specifications;

³⁰ CX/FAC 06/38/16; CX/FAC 05/37/16, Add.1 (Comments of Canada); CRD 4 (Report of the *ad hoc* Working Group on Specifications); CRD 10 (comments of Cuba).

³¹ ALINORM 05/28/12, para. 112.

- To endorse and forward the Category II specifications of one food additive and one flavouring agent with editorial changes to the 29th Codex Alimentarius Commission for adoption as Codex Specifications.

109. The Committee was informed that the “tentative” specifications monographs for Monomagnesium phosphate and Trisodium diphosphate were withdrawn by the 65th JECFA due to a lack of response to its call for information to resolve their tentative status. Moreover, it was noted in CRD 4 that the specification monographs for substances designated tentative (Category V) at the 65th JECFA would be withdrawn unless the information requested in FNP 52-Add.13 was received by JECFA before the end of 2006.

Status of the Specifications for the Identity and Purity of Food Additives arising from the 65th JECFA Meeting

110. The Committee agreed to forward Specifications for the Identity and Purity of Food Additives arising from the 65th JECFA meeting in Categories I and II to the 29th Session of the Commission for adoption at Step 5/8 (with a recommendation to omit Steps 6 and 7) as Codex Specifications (see Appendix XVII).

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX STANDARDS (Agenda Item 11)³²

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

112. The Committee noted that no Maximum Levels for contaminants had been submitted for endorsement since its 35th Session and, therefore, no action was required.

CONSIDERATION OF THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (Agenda Item 12)³³

REPORT OF THE *AD HOC* WORKING GROUP ON CONTAMINANTS AND TOXINS IN FOODS (Agenda Item 12a)³⁴

113. The Committee recalled that at its 37th Session decided to reconvene the *ad hoc* Working Group on Contaminants and Toxins in Foods prior to its 38th Session.³⁵ Mr Frans Verstraete (European Community) chaired the meeting. Dr Paul Brent (Australia), Dr Rob Theelen (the Netherlands) and Dr Maria Cecilia Toledo (Brazil) acted as Rapporteurs.

114. The Chair of the Working Group briefly summarized the discussions and proposed several general recommendations for endorsement by the Committee. In addition to recommendations related to specific Agenda Items, the Committee discussed the following matters.

Availability of documents and needs of references

115. The Committee noted issues raised by the *ad hoc* Working Group regarding the late availability of documents and the use of scientific references. The Working Group stressed the need for the timely preparation and distribution of working documents to allow adequate time for the preparation of comments. It also emphasized the need to use scientific references to underpin statements and advisory measures when preparing discussion papers and codes of practices.

Working Document for Information and Use in Discussion on the GSCTF

116. The Committee thanked the Delegation of Japan and the Netherlands for having compiled a document that provides useful support to discussions on contaminants and toxins and endorsed the recommendation of the *ad hoc* Working Group that these two Delegations prepare an updated version of the document for use at its next Session.

³² ALINORM 06/38/17 (not issued).

³³ CX/FAC 06/38/18 (Working document for information and use in discussions on the GSCTF)

³⁴ CRD 5 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia).

³⁵ ALINORM 05/28/12, para. 122.

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

117. The Committee agreed to reconvene the *ad hoc* Working Group on Contaminants and Toxins in Foods prior to the next Session of the Committee under the Chairmanship of the European Community. It was also agreed that the Working Group meeting would be in English only.

GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS, INCLUDING SCHEDULE I (Agenda Item 12b)³⁶

118. The Committee was informed that the 28th Session of the Codex Alimentarius Commission had noted that Codex Maximum / Guideline Levels for Contaminants and Toxins were incorporated in Schedule I of the Codex *General Standard for Contaminants and Toxins in Foods* (GSCTF) which had not been officially forwarded for adoption and that the Commission had agreed to postpone the revocation of individual Codex Maximum/Guideline Levels as proposed by the Committee to its next session pending the submission by CCFAC of Schedule I of the GSCTF to the Commission.³⁷

119. The Committee agreed to the amendments recommended by the *ad hoc* Working Group and to re-order Schedule I into three main categories: mycotoxins, heavy metals and others and to have contaminants listed in each category in alphabetical order. The Committee endorsed the following recommendations of the *ad hoc* Working Group on Contaminants and Toxins in Foods:

- To forward, after inclusion of the agreed amendments, the General Standard for Contaminants and Toxins in Foods, including Schedule I to the Codex Alimentarius Commission for adoption (see Appendix XVIII);
- To recommend to the Codex Alimentarius Commission that specific reference to the GSCTF be included in the sections on contaminants of Codex commodity standards, e.g. “The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the CAC”;
- To forward to the Codex Alimentarius Commission a project document (see Appendix XIX) for new work to revise the Preamble of the GSCTF to remove the procedural provisions; to include them in the Procedural Manual; to update the provisions in the Procedural Manual as regard to contaminants; to amend “the complementary food categorization system for the GSCTF”; to align the language of the Preamble with the definitions contained in the Procedural Manual; and to establish an electronic Working Group, led by the European Community³⁸, to undertake this work, pending the approval of the Commission. It was agreed that the electronic Working Group would work in English only;
- To ask the Codex Committee on Pesticide Residues to treat the revision of the Codex Classification of Foods and Animal Feeds as a priority.

120. The Committee noted that after the adoption by the 29th Session of the Codex Alimentarius Commission, those Maximum and Guideline Levels advanced to Step 8 and Step 5/8 at the present session, would either be included in Schedule I or replace the existing levels.

³⁶ CX/FAC 06/38/19, CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia); CRD 25 (comments of Japan).

³⁷ ALINORM 05/28/41, para. 90.

³⁸ With the assistance of Australia, Belgium, Brazil, France, India, Japan, the Netherlands and Philippines.

MYCOTOXINS IN FOOD AND FEED (Agenda Item 13)**PROPOSED DRAFT APPENDIX TO THE CODEX CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN TREE NUTS (N08-2005) (Agenda Item 13a)³⁹**

121. The Committee noted that the 28th Session of the Codex Alimentarius Commission had approved the elaboration of an Appendix to the Codex *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts* (CAC/RCP 55-2004) to address additional measures for the prevention and reduction of aflatoxin contamination in Brazil Nuts as new work for the Committee (N08-2005)⁴⁰.

122. The Committee agreed to the amendments to the proposed draft Appendix to the Codex Code of Practice proposed by the *ad hoc* Working Group on Contaminants and Toxins in Foods, which took into account the comments submitted at Step 3. In addition, it revised the last paragraph of the Appendix to make it clearer.

Status of the proposed draft Appendix to the Codex Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts – Additional Measures for the Prevention and Reduction of Aflatoxin Contamination in Brazil Nuts (N08-2005)

123. The Committee agreed to forward the proposed draft Appendix to the Codex Alimentarius Commission for adoption at Step 5/8, with the omission of Steps 6 and 7 (see Appendix XX).

PROPOSED DRAFT SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN ALMONDS, BRAZIL NUTS, HAZELNUTS AND PISTACHIOS (N07-2004) (Agenda Item 13b)⁴¹

124. The Committee recalled that at its 37th Session it had returned the proposed draft Sampling Plan for Aflatoxin Contamination in Almonds, Brazil Nuts, Hazelnuts and Pistachios to Step 2 and had agreed to request an electronic Working Group to revise the document on the basis of new information becoming available in future, for circulation and comments at Step 3 and consideration at the current session.⁴²

125. The Committee agreed to further elaborate the proposed draft sampling plan once a maximum limit had been established by Committee and to include considerations on the draft sampling plan for almonds, brazil nuts, hazelnuts and pistachios in the discussion paper on total aflatoxin levels in processed tree-nuts (see Agenda Item 13c).

Status of the proposed draft Sampling Plan for Aflatoxin Contamination in Almonds, Brazil Nuts, Hazelnuts and Pistachios (N07-2004)

126. The Committee agreed to retain the proposed draft Sampling Plan at Step 4 awaiting outcome of the discussion paper on Maximum Levels of aflatoxins in tree nuts (see Appendix XXI).

³⁹ CX/FAC 06/38/20; CX/FAC 06/38/20, Add.1 (Comments at Step 3 of Brazil); CX/FAC 06/38/20, Add.2 (Comments at Step 3 of European Community and Kenya); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia).

⁴⁰ ALINORM 05/28/12, para. 93 and Appendix VIII).

⁴¹ CX/FAC 06/38/21; CX/FAC 06/38/21, Add.1 (Comments at Step 3 submitted of Brazil, Canada and European Community); CRD 5 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia).

⁴² ALINORM 05/28/12, para. 144.

DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN UNPROCESSED ALMONDS, HAZELNUTS AND PISTACHIOS AND PROPOSED DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN PROCESSED ALMONDS, HAZELNUTS AND PISTACHIOS (Agenda Item 13c)⁴³

127. The Committee noted that the 28th Session of the Codex Alimentarius Commission had adopted the proposed draft Maximum Level of 15 µg/kg for total aflatoxin level in unprocessed almonds, hazelnuts and pistachios at Step 5 and had advanced it to Step 6.⁴⁴ It was further recalled that, at its 37th Session, the Committee had decided to circulate for comments at Step 3 a proposed Maximum Level of 15 µg/kg for total aflatoxins in processed almonds, hazelnuts and pistachios and had established an electronic Working Group to prepare a discussion paper with a proposal for a Maximum Level, appropriate justification for aflatoxin levels in processed almonds, hazelnuts and pistachios, for circulation, comments and consideration at the current session.⁴⁵

128. A number of delegations suggested that a level of 8 µg/kg for total aflatoxins in processed almonds, hazelnuts and pistachios could be put forward for consideration. The Committee had a discussion on the Maximum Level and recognised the need for further information on health risks at different aflatoxin levels and on distribution of aflatoxins between lots. In light of the conclusion of the latest JECFA evaluation that it was unlikely that significant differences in health risks in a normal population would derive from Maximum Levels between 10 and 20 µg/kg for total aflatoxin in ground nuts, maize and their products, a number of countries proposed a Maximum Level of 15 µg/kg because it was safe and achievable, while others were of the opinion that the application of the Codex *Code of Practice for the Reduction and Prevention of Aflatoxin in Tree Nuts*, recently adopted, would have contributed to a reduction of aflatoxin levels and would make it possible to accept lower Maximum Levels.

129. The Committee decided to establish an electronic Working Group, led by the European Community⁴⁶, to expand the discussion paper on the aflatoxin level in ready-to-eat tree nuts, considering i) the detailed data on distribution of aflatoxins between lots, ii) consumer health risk assessment of different levels of aflatoxins in ready-to-eat tree nuts, iii) sampling plan for aflatoxin contamination in almonds, Brazil nuts, hazelnuts and pistachios, iv) effects of codes of practice, and v) terminology of “ready-to-eat” and “for further processing” for circulation, comments and consideration at the next session. The electronic Working Group will work in English.

130. The Committee agreed to request JECFA to conduct a dietary exposure assessment on tree nuts (ready-to-eat), in particular, almonds, hazelnuts, and pistachios, Brazil nuts, and impact on exposure taking into account hypothetical levels of 4, 8, 10 and 15 µg/kg, putting in the context of exposure from other sources and previous exposure assessments on maize and groundnuts (see para. 200).

131. The Committee clarified that “processed” and “unprocessed” tree nuts be referred to as “ready-to-eat” and tree nuts “for further processing”, respectively, and agreed to change the terminology accordingly. The Committee felt it important to show progress while awaiting further data on the impact of alternate levels and therefore put forward a proposed draft Maximum Level of 8 µg/kg for total aflatoxin for “ready-to-eat” almonds, hazelnuts and pistachios. The delegation of Iran expressed its reservation to this decision and gave its preference to a Maximum Level of 10 µg/kg for total aflatoxin for “ready-to-eat” almonds, hazelnuts and pistachios because it was of the opinion that it was necessary to await for the results of the JECFA evaluation.

⁴³ ALINORM 05/28/12, Appendix XXII; CL 2005/22-FAC (Request for comments at Step 3); CL 2005/36-FAC (Request for comments at Step 6); CX/FAC 06/38/22 (Comments at Step 3 of Argentina, Brazil and Canada; comments at Step 6 of Canada); CX/FAC 06/28/23 (Discussion paper with proposals for a Maximum level for Aflatoxins in processed almonds, hazelnuts and pistachios); CRD 5 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods); CRD 10 (Comments of Cuba); CRD 15 (Comments of European Community).

⁴⁴ ALINORM 05/28/41, para. 76 and Appendix VI.

⁴⁵ ALINORM 05/28/12, para. 141.

⁴⁶ With the assistance of Brazil, Iran, Indonesia, Sri Lanka Turkey, United Kingdom, United States (lead on Sampling Plan), WHO and INC

Status of the draft and proposed draft Maximum Levels for Total Aflatoxins in Unprocessed and Processed Almonds, Hazelnuts and Pistachios

132. The Committee agreed to the renamed categories of tree nuts (almonds, hazelnuts and pistachios) and to hold at Step 7 the Maximum Level of 15 µg/kg for total aflatoxins in tree nuts for further processing and to advance to Step 5 the proposed draft Maximum Level of 8 µg /kg for total aflatoxins in ready-to-eat tree nuts (see Appendix XXII). It was agreed that work on this matter would be completed by 2008.

DISCUSSION PAPER ON AFLATOXIN CONTAMINATION IN BRAZIL NUTS (Agenda Item 13d)⁴⁷

133. The Committee recalled that at its 37th Session it had agreed to continue work on aflatoxin contamination in Brazil nuts as new comprehensive data had become available. The Committee had established an electronic Working Group to prepare a revised discussion paper for consideration at the current session.⁴⁸

134. The Committee endorsed the recommendations of the *ad hoc* Working Group on Contaminants and Toxins in Foods to re-establish the electronic Working Group, led by Brazil⁴⁹, to revise the Discussion Paper for circulation and comments and discussion at the next Session of the Committee in view of additional data on the occurrence of aflatoxin in Brazil nuts, in particular, on the contribution of the shell portion to the aflatoxin content, as Maximum Levels apply to the edible part. It was agreed that the electronic Working Group would work in English only.

135. The Committee also agreed that discussion on a sampling plan for Brazil nuts should be performed as part of the ongoing discussion on a sampling plan for aflatoxin in tree nuts (see Agenda Item 13b) and that, preferably, one sampling plan for all tree nuts should be developed, unless the data indicated the need for a separate one.

136. The Committee decided that it was not appropriate to discuss a possible Maximum Level for aflatoxin in Brazil nuts at its present meeting.

DISCUSSION PAPER ON DEOXYNIVALENOL (DON) (Agenda Item 13e)⁵⁰

137. The Committee recalled that at its 37th Session it had decided to establish an electronic Working Group to develop a discussion paper to provide comprehensive relevant data, including the occurrence of deoxynivalenol and the effects of processing on the levels of DON, for consideration at the current session.⁵¹

138. The Committee agreed to endorse the recommendation of the *ad hoc* Working Group on Contaminants and Toxins in Foods to re-establish the electronic Working Group⁵² led by the United States to revise and update the Discussion Paper on DON with: more data from regions where data on DON levels are missing or inadequate; additional data, especially on DON levels in maize; information on the effect on levels of seasonal variation; and information on the effect of processing on DON levels in foods. In addition it was recommended that detailed indication on information that could become available in the near future, including the timing, should also be provided in order to expedite the possibility for JECFA to schedule an assessment on DON. The electronic Working Group would conduct its work in English.

DISCUSSION PAPER ON MAXIMUM LEVEL FOR OCHRATOXIN (OTA) IN WINE (Agenda Item 13f)⁵³

139. The Committee recalled that at its 37th Session it had agreed to establish an electronic Working Group to develop a discussion paper on Maximum Level for Ochratoxin A (OTA) in wine for consideration at the current session.⁵⁴

⁴⁷ CX/FAC 06/38/24; CRD 5 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia); CRD 18 (Comments of European Community).

⁴⁸ ALINORM 05/28/12, paras 146-147.

⁴⁹ With assistance of United Kingdom, United States and INC.

⁵⁰ CX/FAC 06/38/25; CRD 10 (Comments of Cuba); CRD 17 (Comments of European Community).

⁵¹ ALINORM 05/28/12, para. 150.

⁵² With assistance of Australia, Belgium, Canada, European Community, France, Germany, Japan, Netherlands, Republic of Korea, United Kingdom

⁵³ CX/FAC 06/38/26; CRD 10 (Comments of Cuba); CRD 15 (Comments of European Community).

⁵⁴ ALINORM 05/28/12, para. 228.

140. The Committee agreed to endorse the recommendation of the *ad hoc* Working Group on Contaminants and Toxins in Foods to start new work on the elaboration of a Code of Practice and clarified that the scope of this work should be limited to wine only. It was also agreed that the Code should include a specific statement that it would be used for regions only where OTA had been found at significant levels in wine. It was also agreed that Maximum Levels for OTA in wine might be considered in the future, pending collection of data on levels in wine and assessment of outcomes of the elaboration of the Code of Practice.

141. The Committee agreed to forward a project document for new work on the elaboration of a Code of Practice for the prevention and control of Ochratoxin A contamination in wine to the Codex Alimentarius Commission for approval as new work for the Committee (see Appendix XXIII).

142. Having ascertained its willingness, the Committee agreed to entrust to the OIV the initial drafting of the Code of Practice. It further agreed that, subject to the approval of the Commission, the proposed draft Code of Practice would be circulated for comments at Step 3 and considered at the next session of the Committee.

DISCUSSION PAPER ON OCHRATOXIN A CONTAMINATION IN COFFEE AND COCOA (Agenda Item 13g)⁵⁵

143. The Committee recalled that at its 37th Session it had agreed to establish an electronic Working Group to develop a discussion paper on Ochratoxin (OTA) contamination in coffee and cocoa, which would take into account the JECFA evaluation, the outputs of the FAO Coordinated Project “Enhancement of Coffee Quality through the Prevention of Mould Formation” and other relevant information, for consideration at the current session.⁵⁶

144. In noting the recommendation of the *ad hoc* Working Group on Contaminants and Toxins in Foods to develop separate discussion papers on OTA contamination in coffee and cocoa, one delegation observed that these products, compared to others, contribute little to the total PTWI and questioned if it was necessary for Codex to embark in work on OTA in coffee in view of the considerable amount of work already done by FAO in the development of a Code of Practice. It was also noted that recent exposure assessments had shown that coffee and wine are significant contributors to OTA exposure in the European Community and that there was some concern about OTA levels in cocoa and that this information, along with that developed by FAO, could provide a good basis for future elaboration of discussion papers.

145. The Committee agreed with the recommendations of the *ad hoc* Working Group to establish two electronic Working Groups, led by Brazil⁵⁷ and Ghana⁵⁸, to prepare separate discussion papers on OTA in coffee and OTA in cocoa, respectively, for circulation, comments and consideration at its next Session that might allow the Committee to decide if the development of Codes of Practice was appropriate. It was agreed that the above two electronic Working Groups would function in English only.

INDUSTRIAL AND ENVIRONMENTAL CONTAMINANTS IN FOODS (AGENDA ITEM 14)

DRAFT MAXIMUM LEVEL FOR LEAD IN FISH (Agenda Item 14a)⁵⁹

146. The Committee recalled that at its 37th Session it had agreed to retain the draft Maximum Level of 0.2 mg/kg for lead in fish at Step 7 and to decide the level at the current session, based on the information contained in a discussion paper, prepared by an electronic Working Group, that would compile the information necessary to develop an appropriate Maximum Level⁶⁰.

⁵⁵ CX/FAC 06/38/27 (Not issued); CRD5 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods); CRD16 (Discussion Paper on Ochratoxin A in Coffee and Cocoa, prepared by Ghana).

⁵⁶ ALINORM 05/28/12, para. 230.

⁵⁷ With the assistance of Canada, European Community, France, Ghana, Indonesia, Switzerland, the United Kingdom and Uganda and IFT.

⁵⁸ With the assistance of Brazil, European Community, Indonesia, Switzerland, the United Kingdom and the United States.

⁵⁹ ALINORM 05/28/12, App. XXIII; CX/FAC 06/38/28 (Discussion paper on Maximum Level for Lead in Fish); CRD 11 (Comments of Indonesia); CRD 19 (Comments of European Community and Philippines).

⁶⁰ ALINORM 05/28/12, paras 156-157.

147. The Delegation of the Philippines briefly introduced the discussion paper and highlighted that: i) analytical data on lead in fish had shown that most fish species could achieve a Maximum Level of 0.2 mg/kg but some other species required higher Maximum Levels of 0.4-0.5; ii) JECFA had conducted a quantitative risk assessment focusing specifically on infants and children and had concluded that the levels of lead found currently in foods would have negligible effects on the neurobehavioral development of infants and children; iii) changes of the Maximum Level from 0.2 mg/kg to 0.5mg/kg would have little effect on health; iv) trade problems at a Maximum Level of 0.2 mg/kg had occurred and a potential "violative rate" 7% for fish in trade had been estimated using the WHO GEMS/Food data base on lead levels in fish; and v) unless an investment was made in expensive equipment, lead was difficult to analyse accurately at a level of 0.2 mg/kg.

148. Concern was expressed that blood lead levels were near or at observed adverse effect level in certain vulnerable group, including some children and a level higher than 0.2 mg/kg in certain fish species might result in adverse health effects in such a group. It was also pointed out that analysis of lead in fish at a 0.2 mg/kg level could be carried out by using AOAC validated methods which could also be used by developing countries and that current sampling data indicated less than 1% exceeded 0.2 mg/kg, therefore this Maximum Level was feasible.

149. Other delegations, expressed their concern that a Maximum Level of 0.2 mg/kg in fish might exclude certain fish species from trade and stressed their difficulties to reach the limit of quantification required by this Maximum Level in routine laboratories and proposed establishment of a higher level for certain fish species.

150. As a way to make some progress, the suggestion was made to focus discussion on fish species which have impact on international food trade and to identify the circumstances that result in these species reaching and exceeding the proposed level of 0.2 mg/kg.

151. In response to a suggestion that the Committee might consider application of Maximum Level of 0.2 mg/kg to all fish, in combination with consumer advice for consumption of fish which could not meet 0.2 mg/kg, the JECFA Secretariat clarified that the major contributor of lead exposure was not fish and, therefore, it would not be appropriate to treat this issue in the same manner applied to other contaminants where fish is the main source of exposure contributor, such as methylmercury.

152. The Committee recalled that discussion on this matter had been in the agenda of the Committee for several years and that several options had been examined, including attempts to identify and classify various categories of species to which separate Maximum Levels could be assigned. The Committee considered a proposal of the Philippines of a Maximum Level of 0.3 mg/kg as a way to make progress in this work. In view of the JECFA evaluation, it agreed to put forward a draft Maximum Level of 0.3 mg/kg in fish. The Delegations of the European Community and the United States made reservations to this decision.

Status of the draft Maximum Level for Lead in Fish

153. The Committee agreed to forward the draft Maximum Level of 0.3 mg/kg for Lead in Fish to the 29th Session of the Codex Alimentarius Commission for adoption at Step 8 (see Appendix XXIV).

DRAFT MAXIMUM LEVELS FOR CADMIUM (Agenda Item 14b)⁶¹

154. The 28th Session of the Codex Alimentarius Commission adopted the proposed draft Maximum Levels of 0.4 mg/kg in rice polished, 1.0 mg/kg in marine bivalve molluscs (excluding oysters and scallops) and 1.0 mg/kg in cephalopods (without viscera) at Step 5 and advanced them to Step 6⁶².

⁶¹ ALINORM 05/28/12, Appendix XXIV; CL 2005/36-FAC (Request for comments at Step 6); CX/FAC 06/38/29 (Comments at Step 6 of Australia, Canada, Costa Rica, Japan and South Africa); CX/FAC 06/38/29, Add.1 (Comments at Step 6 of European Community); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia); CRD 20 (Comment of Thailand).

⁶² ALINORM 05/28/41, para. 77 and Appendix VI.

Draft Maximum Level for Cadmium in polished rice

155. The Delegation of Japan supported a Maximum Level of cadmium of 0.4 mg/kg based on the high background levels of cadmium in soils in their country, as well as in some other countries, and expressed the view that the draft Maximum Level was sufficiently protective for human health on the basis of the 64th JECFA dietary exposure assessment, which concluded that the effects of different Maximum Levels on overall intake of cadmium would be very small and of the exposure assessment conducted by Japan. . This Maximum Level was supported by many delegations, while others supported a lower level because rice is consumed at appreciable levels in the human diet and because the high background level appears to be a regional issue and only affects a small percentage of rice traded internationally.

156. The Committee decided to advance the Maximum Level of 0.4 mg/kg and noted the reservations of the Delegations of the European Community, Egypt and Norway to this decision.

Draft Maximum Level for Cadmium in molluscs

157. The Committee considered the proposed draft Maximum Level for cadmium in molluscs. Some delegations opposed to the proposed draft Maximum Levels of 1.0 mg/kg for Marine bivalve molluscs (excluding oysters and scallops) and Cephalopods (without viscera) because of the natural occurrence of cadmium in such commodities.

158. After some discussion, the Committee agreed to change the draft Maximum Level for marine bivalve molluscs (excluding oysters and scallops) and cephalopods (without viscera) to 2 mg./kg for adoption by the Commission. The delegation of the European Community expressed its reservation to this decision.

Status of the draft Maximum Levels for Cadmium

159. The Committee agreed to advance the draft Maximum Levels for cadmium in polished rice and in marine bivalve molluscs (excluding oysters and scallops) and cephalopods (without viscera) to the 29th Session of the Codex Alimentarius Commission for adoption at Step 8 (see Appendix XXV).

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXIN AND DIOXIN-LIKE PCB CONTAMINATION IN FOODS AND FEEDS (Agenda Item 14c)⁶³

160. The Committee recalled that at its 37th Session, it had agreed to return the proposed draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feeds to Step 2 for redrafting by an electronic Working Group for consideration at the current session.⁶⁴

161. The Committee considered the text revised by the *ad hoc* Working Group on Contaminants and Toxins in Foods, as contained in CRD 5, Appendix 5.

162. One delegation proposed deletion of the reference to Good Laboratory Practice (GLP) from the Code for consistency with other codes for the prevention and reduction of contaminants in foods. However, the proposal was not supported as methods of analysis and GLPs were considered to be critically important for dioxins and dioxin-like PCBs.

163. The Committee confirmed that while reference is made in the Code to the environmental sources of contamination, this Code focuses on measures applied to feed and food production, as these aspects are within the scope of the Committee.

164. The Committee noted the remark by one observer that levels of dioxins and dioxin-like PCBs in milk mainly originate from environmental sources, as supplemented feed is only a small part of the diet of lactating cows. The Committee noted that feed includes all feed as consumed by animals, but agreed to modify the fourth sentence of paragraph 28 to read “Measures to reduce the dioxin and dioxin-like PCBs levels in feed would have an immediate effect on contaminant levels in food of animal origin originating from farm animals, including farmed fish.”

⁶³ CX/FAC 06/38/30; CX/FAC 06/38/30, Add.1 (Comments at Step 3 of Canada, Japan, United States and CEFS); CX/FAC 06/38/30, Add.2 (Comments at Step 3 of European Community); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia); CRD 20 (Comment of Thailand).

⁶⁴ ALINORM 05/28/12, para. 180.

165. In response to the other concern raised by one delegation as to the difficulty for farmers, especially in developing countries, to carry out monitoring programmes as described in paragraph 66, the Committee, while acknowledging that this is not obligatory, agreed to replace “farmers, industrial feed and food manufacturers” with “operators in the feed and food chain to the extent feasible” in the first sentence of paragraph 58.

166. The Committee also agreed to make the following amendments in order to make the description clear and agreed to forward the Proposed Draft Code to the 29th Codex Alimentarius Commission for adoption.

- To add “according to national requirements” to the second bullet in paragraph 30.
- To replace “milk” with “feeds of animal origins” and “suckling animals” with “animals” in the second sentence of paragraph 32.

167. The representative of the WHO informed the Committee that the current mammalian toxic equivalency factors (TEFs) for dioxins and dioxin-like PCBs have recently been revised. The new WHO-TEFs would be published shortly and would be accessible from the website of the WHO International Program on Chemical Safety and the representative encouraged countries to use the new WHO-TEFs.

168. In response to the inquiry from the CCMAS on the method of analysis, the Committee decided to reply to the CCMAS that the work on methods of analysis was necessary for the screening of the presence of dioxin and dioxin-like PCBs in feed and food, and eventually for the development of performance criteria for screening and confirmatory methods.

Status of the proposed draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feeds

169. The Committee agreed to forward the proposed draft Code of Practice for adoption at Step 5/8, with the omission of Steps 6 and 7 (see Appendix XXVI).

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF CHLOROPROPANOLS DURING THE PRODUCTION OF ACID HYDROLYZED VEGETABLE PROTEIN (HVPs) AND PRODUCTS THAT CONTAIN ACID HVPs (N05-2005) (Agenda Item 14d)⁶⁵

170. The Committee noted that the 28th Session of the Codex Alimentarius Commission had approved the elaboration of a Code of Practice for the reduction of chloropropanols during the production of acid hydrolyzed vegetable proteins (HVPs) and products that contain acid-HVPs as new work for the Committee (N05-2005)⁶⁶ and that, pending the approval of the Commission, the 37th Session of the Committee had agreed that an electronic Working Group would elaborate the proposed draft Code of Practice for distribution, comments at Step 3 and further consideration at the current session.⁶⁷

171. It was noted by the Committee that most of the available data on reduction of chloropropanols referred to laboratory information and that only limited information was available on the reduction of chloropropanols under industrial conditions. It was also noted that industries had submitted data to JECFA and had contributed to this work. The difficulties of industries to provide certain types of data and to perform trials on an industrial scale were noted and the Observer from IHPC confirmed their willingness to continue to contribute to this work. It was explained by some delegations that in defining measures to reduce the presence of chloropropanols, effects on organoleptic properties needed to be considered.

172. The Committee agreed to endorse the recommendation of the *ad hoc* Working Group on Contaminants and Toxins in Foods to urge professional organisations and governments to provide additional data on measures to reduce the presence of chloropropanols in acid-HVP produced under industrial conditions, thereby considering, in particular, that which was feasible from an organoleptic point-of-view.

⁶⁵ CX/FAC 06/38/31; CX/FAC 06/38/31, Add.1 (Comments at Step 3 of Canada, European Community and IHPC); CX/FAC 06/38/31, Add.2 (Comments at Step 3 of Japan). CRD 5 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Food); CRD 10 (Comments of Cuba); CRD 20 (Comments of Thailand).

⁶⁶ ALINORM 05/28/12, para. 93 and Appendix VIII).

⁶⁷ ALINORM 05/28/12, para. 183.

173. The Committee also agreed to re-establish the electronic Working Group under the lead of the United Kingdom⁶⁸, to revise the proposed draft on the basis of the written comments submitted at the present meeting, the above discussion and the outcome of the 67th JECFA evaluation. In revising the Code of Practice, the electronic Working Group should consider revision of the title to specifically refer to 3-MCPD, on account of the co-occurrence of 3-MCPD and other chloropropanols. The electronic Working Group will work in English

Status of the proposed draft Code of Practice for the Reduction of Chloropropanols during the Production of Acid Hydrolyzed Vegetable Protein (HVPs) and Products that Contain acid HVPs (N05-2005)

174. The Committee agreed to return the draft Code of Practice to Step 2 for revision by the electronic Working Group, for circulation, comments at Step 3 and consideration at its next Session.

PROPOSED DRAFT MAXIMUM LEVELS FOR 3-MCPD IN LIQUID CONDIMENTS CONTAINING HVPs (Agenda Item 14e)⁶⁹

175. The Committee recalled that at its 37th Session, after a lengthy discussion on various Maximum Levels in an attempt to reach consensus, it had agreed to use as a starting point a Maximum Level of 0.4 mg/kg for 3-MCPD in liquid condiments containing acid HVP (excluding naturally fermented soya sauce) and to establish an electronic Working Group to prepare a discussion paper that would define the different acid HVP-containing products and collect information on other products that contain 3-MCPD.⁷⁰

176. The Committee endorsed the recommendation of the *ad hoc* Working Group on Contaminants and Toxins in Foods to re-establish the electronic Working Group, led by the United Kingdom⁷¹, to update the discussion paper in view of the results of the JECFA evaluation and other information relevant for discussions on the Maximum Levels, for circulation, comments and discussion at its next Session. It was agreed to reconsider the proposed Maximum Level in the light of the revised document.

Status of the proposed draft Maximum Levels for 3-MCPD in Liquid Condiments Containing HVPs (N08-2004)

177. The Committee agreed to maintain the proposed draft Maximum Level at Step 4 (see Appendix XXVII).

PROPOSED DRAFT MAXIMUM LEVELS FOR TIN (Agenda Item 14f)⁷²

178. The Committee recalled that at its 37th Session it had agreed to circulate the proposed draft Maximum Levels for tin for comments at Step 3 and further consideration at the current session.⁷³

⁶⁸ With assistance of Canada, European Community, Japan, Thailand, Republic of Korea, United States, AIIBP, ICGMA, IHPC.

⁶⁹ ALINORM 05/28/12, Appendix XXVIII.; CL 2005/22-FAC (Request for comments at Step 3 on the proposed draft Maximum Level for 3-MCPD in Liquid Condiments Containing HVPs); CX/FAC 06/38/32 (Comments at Step 3 of Brazil, Canada, European Community, Mexico, United States, AIIBP/FAIBP, IHPC); CX/FAC 06/38/32 (Comments at Step 3 of European Community, Japan and AIIBP/FAIBP); CX/FAC 06/38/33 (Discussion Paper on Acid-HVP Containing Products and other Products containing Chloropropanols); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia); CRD 20 (Comment of Thailand).

⁷⁰ ALINORM 05/28/12, paras 189-190. CRD 5 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia); CRD 20 (Comments of Thailand).

⁷¹ With assistance of Australia, Canada, China, European Community, Indonesia, Japan, Poland, Republic of Korea, Thailand, United States, AIIBP, ICGMA and IHPC.

⁷² ALINORM 05/28/12, Appendix XXIV; CL 2005/22-FAC (Request for comments at Step 3); CX/FAC 06/38/34 (Comments at Step 3 of Argentina, Brazil and Canada); CX/FAC 06/38/34, Add.1 (Comments at Step 3 of European Community, ICGMA and IFU); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia); CRD 20 (Comments of Thailand).

⁷³ ALINORM 05/28/12, para. 163.

179. The Delegation of the European Community, supported by Norway, reiterated its comments made at the 37th Session, referring to the JECFA opinion, that tin can cause gastric irritation in some individuals when present in beverages above 150 mg/kg and when present in other canned foods above 250 mg/kg and that the levels set must be in line with scientific advice to protect the safety of the consumer and, in particular, those individuals who may be sensitive to tin. It proposed that the Maximum Level should be 200 mg/kg in canned foods other than beverages and 100 mg/kg in canned beverages because data have shown that these levels are readily achievable and, in addition, implementation of the measures as outlined in the Code of Practice for the prevention and reduction of inorganic tin contamination in canned foods would further reduce these levels.

180. Many delegations supported the proposed draft Maximum Levels for tin of 250 mg/kg in canned foods other than beverages and 150 mg/kg in canned beverages, as these levels were in line with the objective of Codex to protect consumer health and facilitate international trade. Some delegations expressed the opinion that the reversible acute effects of gastric irritation in certain individuals were not severe enough to justify further reducing the levels and lower levels were not feasible. In addition, the important functional effects of tin, with respect to the organoleptic characteristics and shelf life of canned products were indicated.

181. The JECFA Secretariat clarified that the 64th meeting concluded that inorganic tin at concentrations higher than 150 mg/kg in canned beverages may produce acute effects of gastric irritation in certain individuals. Therefore, the proposed level of 150 mg/kg in canned beverages is compatible with the safety assessment.

182. The Committee agreed to maintain the Maximum Levels for tin of 150 mg/kg in canned beverages and 250 mg/kg in canned foods other than beverages. The European Community expressed its reservation to this decision.

Status of the proposed draft Maximum Levels for Tin

183. The Committee agreed to forward the proposed draft Maximum Levels to the 29th Session of the Codex Alimentarius Commission for adoption at Step 5 (see Appendix XXVIII). It was agreed that work on this matter would be completed by 2007/2008.

DISCUSSION PAPER ON ACRYLAMIDE (Agenda Item 14g)⁷⁴

184. The Committee recalled that at its 37th Session, it had agreed to establish a Working Group to revise this Discussion Paper, taking into account the 64th JECFA evaluation of acrylamide; national mitigation strategies; and the role of food processors, catering services, and consumers. In addition, the Committee agreed that the Discussion Paper should also include an outline of a Code of Practice and a project document for starting new work on the elaboration of the Code of Practice for circulation, comments and consideration at the current session.⁷⁵

185. The Committee endorsed the recommendation of the *ad hoc* Working Group on Contaminants and Toxins in Foods to forward to the Commission for approval as new work the project document on the elaboration of a Code of Practice for the Reduction of Acrylamide in Food (see Appendix XXIX). The Committee agreed that, subject to the approval of the Commission, an electronic Working Group⁷⁶ led by the United States and the United Kingdom and to work in English only, would elaborate an initial draft Code of Practice for circulation and comments at Step 3 and consideration at the next Session of the Committee. It was furthermore recognised that data were needed on levels of acrylamide from developing countries, in particular, on national foods.

⁷⁴ CX/FAC 06/38/35; CX/FAC 06/38/35, Add.1 (Comments of European Community, Japan, WHO and ICGMA): CRD 5 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods); CRD 10 (Comments of Cuba); CRD 11 (Comments of Indonesia).

⁷⁵ ALINORM 05/28/12, paras 194 and 196.

⁷⁶ With the assistance of Canada, China, Denmark, European Community, Germany, Indonesia, Japan, Netherlands, Republic of Korea, Sweden, Thailand, WHO, CIAA, ICGMA, IFT, INC

DISCUSSION PAPER ON POLYCYCLIC AROMATIC HYDROCARBONS (PAH) CONTAMINATION (Agenda Item 14h)⁷⁷

186. The Committee recalled that at its 37th Session it had agreed to establish a Working Group to revise this Discussion Paper with particular attention to the recent JECFA evaluation and to include an outline for a possible Code of Practice, mainly focusing on general advice addressing practices that may lead to high levels of PAH in foods, and a project document for starting new work on the elaboration of the Code of Practice, for circulation, comments and consideration at the current session⁷⁸

187. The Committee agreed with the recommendations of the *ad hoc* Working Group to start new work on the elaboration of a Code of Practice for the reduction of PAH contamination in food and to limit its scope to smoking and direct drying processes.

188. The Committee agreed to forward to the 29th Session of the Codex Alimentarius Commission, for approval as new work, the project document on the elaboration of a code of practice (see Appendix XXX). It agreed that, subject to the approval of the Commission, an electronic Working Group, led by Denmark⁷⁹, would elaborate an initial draft for circulation, comments at Step 3 and further consideration at its next session. The electronic Working Group would work in English only.

DISCUSSION PAPER ON THE GUIDELINES LEVELS FOR METHYLMERCURY IN FISH (Agenda Item 14i)⁸⁰

189. The Committee recalled that at its 37th Session it had agreed to establish a Working Group, to revise this Discussion Paper to consider: methods of analysis for methylmercury; elaboration of the Terms of Reference for an Expert Consultation on risks and benefits of fish consumption; and elaboration of a possible request to JECFA.⁸¹

190. The Committee discussed the difficulties of identifying a list of predatory fish on a global basis. It was recognised that there was a predominance of methylmercury over total mercury in most fish species, although some delegations noted that the ratio of methylmercury to total mercury in shell fish might be lower compared to fin fish.

191. Noting the issues raised by FAO and WHO on available data and the lack of resources, the Committee agreed to endorse the recommendation of the *ad hoc* Working Group on Contaminants and Toxins in Foods to forward a request to the Commission for a FAO/WHO Expert Consultation on health risks associated with methylmercury and dioxins and dioxin-like PCBs in fish and the health benefits of fish consumption, with the following terms of reference:

Assessment of the health risks associated with the consumption of fish and other seafood:

- To identify and to consider contaminants of possible concern present in fish (methylmercury and dioxins and dioxin-like PCBs).
- To describe the pattern of contamination of the different contaminants in the relevant fish species / fish groups, such as predatory fish, oily fish, etc.
- To identify vulnerable groups of the population who might be at higher risk than the average consumer (e.g. infants, young children, pregnant women, high consumers).
- To provide guidance to countries on ways to identify regions where people are more likely to be exposed to high levels of contaminants because of differences in nutritional behaviour or local contamination.

⁷⁷ CX/FAC 06/38/36; CX/FAC 06/38/36, Add.1 (Comments of Australia, Canada and United States); CX/FAC 06/38/36, Add.2 (Comments of European Community), CRD5 (Report of the *ad hoc* Working Group on Contaminants and Toxins in Foods), CRD 10 (Comment of Cuba), CRD 11 (Comment of Indonesia) and CRD 21 (Comments of Republic of Korea).

⁷⁸ ALINORM 05/28/12, paras 199-200.

⁷⁹ With the assistance of Australia, Belgium, Cuba, European Community, Ghana, India, Japan, Thailand, the Philippines, Poland, Spain, United Kingdom, IFT and INC.

⁸⁰ CX/FAC 06/38/37; CX/FAC 06/38/37, Add.1 (Not issued).

⁸¹ ALINORM 05/28/12, para. 203.

Assessment of the health benefits of fish and other seafood consumption:

- To consider and review the evidence on the beneficial nutritional factors of eating fish (e.g. as a source of protein and essential nutrients such as vitamin D, iodine, and omega-3 fatty acids).

Comparison of the health risks and health benefits of fish and other seafood consumption:

- To develop a methodology and identify the data necessary for carrying out quantitative assessments of risks and benefits related to fish and other seafood consumption.
- To compare nutritional benefits against the possibility of adverse effects, including the uncertainties, taking into consideration all groups in the population and, if possible, allowing quantitative comparisons of human health risks and benefits of fish and other seafood consumption.

192. The Committee also agreed to postpone consideration on the need to revise the guideline levels for methylmercury in fish pending the outcomes of the requested FAO/WHO Expert Consultation and to retain the current Codex guideline levels for the time-being.

193. In addition it was decided not to proceed with the development of a list of predatory fish and not to start compiling data on the ratio of methyl mercury to total mercury in different fish species and to possibly consider this at a later stage with a particular focus on the different ratios for shellfish.

194. The Committee also agreed to postpone discussion on the risk communication aspects of methylmercury in fish until a general discussion on this issue within Codex could give guidance on this matter. In this context the Committee noted the workshop on risk communication which was scheduled on 27 April 2006 in parallel with the Session of the Committee.

PROPOSED DRAFT REVISED GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS FOR USE IN INTERNATIONAL TRADE (Agenda Item 14j)⁸²

195. The 37th Session (April 2005) of the CCFAC returned⁸³ the draft revised Guideline Levels for Radionuclides in Foods for Use in International Trade⁸⁴ to Step 2 for revision by a Working Group led by the European Community and the IAEA for circulation, comments at Step 3 and consideration at its 38th Session. It was further agreed that the Working Group would consider the current draft text in its entirety, with a particular emphasis on:

- Revisions to the Scope of the guidelines to clarify that the guideline levels only apply in situations related to nuclear accidents or radiological events and do not apply to routine monitoring purposes.
- The separation of guideline levels specific to general and infant food categories.

196. The Representative of the IAEA noted that the *ad hoc* Working Group⁸⁵ on the proposed draft Revised Guideline Levels for Radionuclides in Foods for Use in International Trade met at IAEA Headquarters in Vienna, Austria from 8-9 September 2005. As requested by the 37th Session of the CCFAC, the Working Group reviewed and reached consensus on the draft text in its entirety, with particular emphasis on revisions to the scope of the guidelines to clarify that the guideline levels only apply in situations related to nuclear or radiological emergencies and do not apply to routine monitoring purposes, and to the separation of guideline levels specific to general and infant food categories. In reaching this consensus, the Working Group also made additional consequential amendments to the text, including a revision to the title and the text to specify that the guideline levels only apply to situations related to nuclear accidents or radiological events (i.e., not for routine monitoring purposes).

197. The Committee agreed with the suggestion to add a footnote to ³⁵S to read “This represents the value for organically-bound sulphur”.

⁸² CX/FAC 06/38/38; CX/FAC 06/38/38-Add. 1 (Comments of Canada, Lithuania (subsequently withdrawn), United States and Venezuela); CRD 10 (Comments of Cuba); CRD 22 (Comments of Japan and UNEP).

⁸³ ALINORM 05/28/12, paragraph 215.

⁸⁴ ALINORM 04/27/12, Appendix XXII.

⁸⁵ Led by the EC and IAEA, with the assistance of Belgium, Finland, France, Germany, Switzerland, the United Kingdom and the United States.

Status of the Proposed Draft Revised Guideline Levels for Radionuclides in Foods for Use in International Trade

198. The Committee agreed to forward the newly-named proposed draft Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency for Use in International Trade (see Appendix XXXI) to the 29th Session of the Codex Alimentarius Commission for adoption at Step 5/8 (with the omission of Steps 6 and 7) and inclusion in the Codex General Standard for Contaminants and Toxins in Foods.

PRIORITY LIST OF FOOD ADDITIVES, CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 15)⁸⁶

199. The 37th Session of the Committee agreed to ask the Codex Secretariat, in coordination with the Joint Secretariat to JECFA, to request, in a circular letter, new proposals for additions or amendments to the Priority List for consideration at the current session.

Report of the Working Group on the Priority List

200. Dr I. Pratt (Ireland), as rapporteur, introduced the report of the Working Group on the Priority List of substances for evaluation by JECFA. The Committee noted that the Working Group, chaired by Dr W. Tas (The Netherlands), had considered the comments received in response to CL 2005/31-FAC, the referral from the 7th Session of the Codex Committee on Milk and Milk Products, the recommendation of the *ad hoc* Working Group on the GSFA (see para. 73), and the recommendations of the *ad hoc* Working Group on Contaminants (see para. 130). Dr Pratt informed the Committee about the agenda of the forthcoming 67th JECFA meeting, which included many of the food additives and contaminants for which requests for evaluation had been made by the 37th Session of the Committee.

201. The Working Group recommended that the following compounds on the Priority List agreed to at the 37th session of the Committee, would remain on the Priority List: Flavours (around 325), acidified sodium chlorite, carrageenan, Processed Euchema Seaweed (PES), cyclotetraose, isoamylase from *Pseudomonas amyloxyloides*, sodium iron EDTA trihydrate.

202. The Working Group further agreed to propose the following additions to the Priority List of Food Additives: Carrageenan - safety for infants of 0-6 months of age (when used in infant formula); sunset yellow (revision of specification to include limit for Sudan Red); ligninsulfonate; phytosterols, phytostanols and their esters; nisin (revision of specification); lauric arginate ethyl ester; trisodium diphosphate (specification); monomagnesium phosphate (specification); paprika extract/paprika oleoresin for use as food colour; phospholipase A1 from *Fusarium venenatum* produced in *Aspergillus oryzae*; asparaginase expressed in *Aspergillus oryzae*; sodium aluminium sulfate; the food colours curcumin, amaranth, tartrazine, Sunset Yellow FCF, Fast Green FCF and carmine (exposure assessment); tartrazine, Sunset Yellow FCF, amaranth and Fast Green FCF (assessment of the potential for hypersensitivity response); and dietary exposure assessment to sulphites from all foods.

203. The Delegation of Brazil raised concern regarding the inclusion of phytosterols, phytostanols and their esters in this list on food additives, since they do comply with the definition of a food additive and their use might be as a food ingredients, and not as of food additives. The JECFA Secretariat noted that JECFA had in the past evaluated substances that could be used as food ingredients, in addition to uses as food additives. The Committee agreed that the JECFA Secretariat, together with the Codex Secretariat, will prepare for the next session of the Committee a discussion paper dealing with possible changes to the Procedural Manual, i.e. further explanations in the terms of reference of this Committee on the scope of requests to JECFA for scientific advice.

⁸⁶ CL 2005/31-FAC (Request for comments on the Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants proposed for Evaluation by JECFA); CX/FAC 06/38/39 (Comments of European Community, Switzerland, United States and IFAC); CX/FAC 06/38/39, Add. 1 (Comments of NATCOL); CRD 7 (Report of the Working Group on the Priority List); CRD 10 (Comments of Cuba); CRD 23 (Comments of Denmark and European Community).

204. In order to prioritize the numerous requests for evaluations by JECFA, the Working Group recommended to give the highest priority to the compounds on the Priority List agreed to at the 37th session of the Committee, but which have not yet been scheduled for evaluation by JECFA. In addition, it was recommended that the two enzymes proposed for evaluation be given high priority and be evaluated together with the pending request for evaluation of isoamylase. The additional request regarding the evaluation of carrageenan for safety of use in infant formulae was proposed to be added to the existing request for the safety assessment of carrageenans. The Working Group also recommended that the request, from the Codex Committee on Milk and Milk Products, on paprika oleoresin be considered as a high priority.

205. The Working Group recommended maintaining the contaminants and toxins deoxynivalenol, ochratoxin A, patulin, and phenylhydrazines (including agaritine) in the Priority List.

206. The Working Group recommended adding a question regarding the potential toxicity of 3-acetyl and 15-acetyl deoxynivalenol to the existing request for evaluation of deoxynivalenol; and requesting an exposure assessment to total aflatoxins from tree nuts, including an assessment of the impact on exposure of hypothetical limits of 4, 8, 10, 15 ppb. An assessment of exposure to total aflatoxins from dried figs was also recommended for evaluation by JECFA, when sufficient data can be provided.

207. The Working Group agreed to give the requests on OTA and aflatoxins higher priority than other contaminants, in line with the indicated availability of data.

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

209. The Committee agreed to ask the Codex Secretariat, in collaboration with the JECFA Secretariat, to request new proposals for additions or amendments to the Priority List for consideration at its next session in a separate Circular Letter, which would also include the questionnaire for submission.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 16)

FUTURE WORK (Agenda Item 16a)

DISCUSSION PAPER ON THE DEVELOPMENT OF A MAXIMUM LEVEL FOR AFLATOXINS IN DRIED FIGS⁸⁷

210. The Committee noted that this Agenda Item had been added to the agenda at the request of the Government of Turkey. In introducing the document, the Delegation of Turkey explained that aflatoxin contaminations in dried figs had become an increasingly important issue due to expansion of the production and consumption areas and proposed that the Committee consider new work on the development of a Maximum Level for aflatoxins in dried figs and of a Code of Practice for the prevention and reduction of aflatoxin contamination in dried figs.

211. The Committee agreed to establish an electronic Working Group, led by Turkey⁸⁸, which would work in English only, to revise the document and include additional information and data on the occurrence of aflatoxins in dried figs and better describe the difficulties in trade, for circulation and consideration at its next session. The Discussion Paper should also include an outline of a code of practice for the prevention and control of aflatoxin in dried figs and a project document for starting new work on the elaboration of a Code of Practice.

212. The Committee also agreed to request that aflatoxins in dried figs be added to the JECFA Priority List insofar as some data are already available and that, furthermore, a request could be taken up in a JECFA Call for Data.

DESCRIPTOR OF FOOD SUPPLEMENT IN THE FOOD CATEGORY SYSTEM OF GSFA⁸⁹

213. The Observer of the International Alliance of Dietary/Food Supplement Associations (IADSA) asked the Committee to amend food category 13.6 "Food supplements" of the Food Category System of the GSFA to align it with the Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005).

⁸⁷ CX/FAC 06/38/40

⁸⁸ With assistance of France, Greece, European Community, United Kingdom, United States, WHO and INC.

⁸⁹ CRD 13 (Comments of IADSA).

214. The Committee agreed to request the 29th Session of the Codex Alimentarius Commission to revise the GSFA descriptor of food category 13.6 “Food supplements”, as indicated Appendix XXXIII.

REVISION OF THE FOOD CATEGORY SYSTEM OF GSFA⁹⁰

215. In response to the request of the Delegation of Indonesia to revise the Food Category System (FCS) of the GSFA, the Committee agreed to establish an electronic Working Group, led by Indonesia⁹¹, to develop a discussion paper and, according to the procedure established at its 36th Session⁹², include a project document for the revision of the Food Category System of the GSFA (for circulation and consideration at its next Session). The Working Group would work in English only.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 17)

216. The Committee noted that date and place of the its next session would be subject to the discussion of the 29th Session of the Codex Alimentarius Commission regarding the split of the Codex Committee on Food Additives and Contaminants and, as appropriate, discussion between Codex and the Secretariats of designated host countries.

⁹⁰ CRD 11 (Comments of Indonesia).

⁹¹ With the assistance of China, Japan, Korea, Sri Lanka, Thailand, Tunisia and United States.

⁹² ALINORM 04/27/12, para. 66.

SUMMARY STATUS OF WORK

SUBJECT	STEP	FOR ACTION BY:	DOCUMENT REFERENCE (ALINORM 06/29/12)
Draft revision of the Preamble of the Codex General Standard for Food Additives	8	29 th CAC	Para. 55 and Appendix V
Draft Maximum Level for Lead in Fish	8	29 th CAC	Para. 153 and Appendix XXIV
Draft Maximum Levels for Cadmium in polished rice and in marine bivalve molluscs (excluding oysters and scallops) and in cephalopods (without viscera)	8	29 th CAC	Para. 159 and Appendix XXV
Draft and proposed draft Food Additive Provisions of the General Standard for Food Additives (GSFA)	8 and 5/8	29 th CAC	Paras 63 and 81 and Appendices VII and XI
Proposed draft amendments to the International Numbering System for Food Additives	5/8	29 th CAC	Para. 104 and Appendix XVI
Specifications for the Identity and Purity of Food Additives arising from the 65 th JECFA meeting	5/8	29 th CAC	Para. 110 and Appendix XVII
Proposed draft Appendix to the Codex Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts – Additional Measures for the Prevention and Reduction of Aflatoxin in Brazil nuts (N08-2005)	5/8	29 th CAC	Para. 123 and Appendix XX
Proposed draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feed	5/8	29 th CAC	Para. 169 and Appendix XXVI
Proposed draft revised Guideline Levels for Radionuclides in Foods Contaminated following a Nuclear or Radiological Emergency for Use in International Trade	5/8	29 th CAC	Para. 198 and Appendix XXXI
Codex General Standard for Contaminants and Toxins in Foods, including Schedule I	For adoption	29 th CAC	Para. 119 and Appendix XVIII
Revision of the Descriptor of Food Category 13.6 “Food supplements” of the GSFA	For adoption	29 th CAC	Para. 214 and Appendix XXXIII
Amended Annex to Table 3 of the GSFA	For adoption	29 th CAC	Para. 63 and Appendix VIII
Proposed Procedures for Consideration of Entry and Review of Food Additive Provisions in the GSFA	For adoption	CCGP and CAC	Para. 60 and Appendix VI
Draft Maximum Level for Ochratoxin A in raw wheat, barley, and rye	7	Next Session of the Committee	ALINORM 04/27/12, para. 136 and Appendix XVII
Draft Maximum Level for Total Aflatoxins in almonds, hazelnuts and pistachios for further processing	7	Next Session of the Committee	Para. 132 and Appendix XXII
Draft and proposed draft Food Additive Provisions of the GSFA	6 and 3	Codex Secretariat	Para. 81 and Appendix X
Proposed draft revision of the Codex Class Names and International Numbering System for Food Additives – CAC/GL 36-2003” (N07-2005)	5	29 th CAC	Para. 98 and Appendix XV
Proposed draft Maximum Level for Total Aflatoxins in almonds, hazelnuts and pistachios “ready-to-eat”	5	29 th CAC	Para. 132 and Appendix XXII

SUBJECT	STEP	FOR ACTION BY:	DOCUMENT REFERENCE (ALINORM 06/29/12)
Proposed draft Maximum Levels for Tin in canned food (other than beverages) and in canned beverages	5	29 th CAC	Para. 183 and Appendix XXVIII
Proposed draft Maximum Level for 3-MCPD in liquid condiments containing acid-HVP (excluding naturally fermented soya sauce) (N08-2004)	4	Next Session of the Committee	Para. 177 and Appendix XXVII
Proposed draft Sampling Plan for Aflatoxin Contamination in almonds, Brazil nuts, hazelnuts and Pistachios (N07-2004)	4	Next Session of the Committee	Para. 126 and Appendix XXI
Proposed draft Code of Practice for the Reduction of Chloropropanols during the Production of acid-Hydrolyzed Vegetable Proteins (HVPs) and Products that Contain acid-HVPs (N09-2005)	2/3	Working Group	Para. 174
Guidelines for the Use of Flavourings (new work)	1/2/3	29 th CAC	Para. 87 and Appendix XIV
Revision of the Preamble of the Codex General Standard for Contaminants and Toxins in Foods (new work)	1/2/3	29 th CAC	Para. 119 and Appendix XIX
Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine (new work)	1/2/3	29 th CAC	Para. 140 and Appendix XXIII
Code of Practice for the Reduction of Acrylamide in Food (new work)	1/2/3	29 th CAC	Para. 185 and Appendix XXIX
Code of Practice for the Reduction of Contamination of Food with PAH from Smoking and Direct Drying Processes (new work)	1/2/3	29 th CAC	Para. 188 and Appendix XXX
Revocation of Food Additives Provisions of the GSFA	---	29 th CAC	Paras 63 and 81 and Appendices VII and XII
Text to be included in Codex Commodity Standards (with a one-to-one relationship with GSFA food categories), which food additives list has been included in the GSFA	---	29 th CAC	Para. 63 and Appendix IX
Discontinuation of work on draft and proposed draft Food Additive Provisions of the GSFA	---	Codex Secretariat	Para. 81 and Appendix XIII
Discussion Paper on the impacts of the revisions of the food additive provisions in the relevant GSFA food category with a one-to-many relationship to a commodity standard	---	Electronic Working Group	Para. 64
Discussion Paper on Amendments to the Procedural Manual (Format of Codex Commodity Standards; relations between Commodity and General Committees; Terms of Reference of the Committee)	---	Electronic Working Group	Para. 68
Working Document for Information and Support to the Discussion on the GSFA	---	Codex Secretariat	Para. 72
Discussion Paper on Guidelines and Principles on the Use of Processing Aids	---	Electronic Working Group	Para. 92
Inventory of Processing Aids (updated list)	---	New Zealand	Para. 93
Working Document for Information and Use in Discussion on GSCTF	---	Netherlands and Japan	Para. 116
Discussion Paper on Maximum Levels in “ready-to-eat” almonds, hazelnuts and pistachios	---	Electronic Working Group	Para. 129

SUBJECT	STEP	FOR ACTION BY:	DOCUMENT REFERENCE (ALINORM 06/29/12)
Discussion Paper on Aflatoxin Contamination in Brazil nuts	---	Electronic Working Group	Para. 134
Discussion Paper on Deoxynivalenol (DON)	---	Electronic Working Group	Para. 138
Discussion Paper on Ochratoxin A in Coffee	---	Electronic Working Group	Para. 145
Discussion Paper on Ochratoxin A in Cacao	---	Electronic Working Group	Para. 145
Discussion Paper on Aflatoxin Contamination in Dried Figs	---	Electronic Working Group	Para. 211
Discussion Paper on Revision of the Food Category System of the GSFA	---	Electronic Working Group	Para. 215
Report of the Electronic Working Group on the GSFA	---	Electronic Working Group	Para. 79
Priority List of Food Additives, Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA	---	Codex Secretariat	Para. 229 and Appendix XXXII

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Appendix II**PROPOSED TIMEFRAME FOR COMPLETION OF WORK**

WORK TITLE	STEP	YEAR OF COMPLETION/SESSION
Draft Maximum Level for Lead in Fish	8	29 th CAC
Proposed draft revised Preamble of the GSFA, including the diagram	8	29 th CAC
Proposed draft Maximum Levels for Total Aflatoxins in Almonds, Hazelnuts and Pistachios “For Further Processing” and “Ready-To-Eat”	7 and 5	2008
Proposed draft Maximum Levels for Cadmium in Marine Bivalve Molluscs (excluding oysters and scallops) and in Cephalopods(without viscera) and in Polished Rice	8	29 th CAC
Proposed draft Maximum Levels for Tin in Canned Food (other than beverages) and in Canned Beverages	5	2007/2008
Proposed draft Maximum Level for 3-MCPD in Liquid Condiments containing acid-HVP(excluding naturally fermented soya sauce)	4	N08-2004
Proposed draft Sampling Plan for Aflatoxin contamination in Almonds, Brazil nuts, Hazelnuts and Pistachios	4	N07-2004
Proposed draft revised Guideline Levels for Radionuclides in Foods Contaminated following a Nuclear or Radiological Emergency for Use in International Trade	5/8	29 th CAC
Proposed draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feeds	5/8	29 th CAC
Proposed draft revision of the Codex “Class Names and International Numbering System for Food Additives - CAC/GL 36-2003”	5	N07-2005
Proposed draft Appendix to the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts - Additional Measures for the Prevention and Reduction of Aflatoxins in Brazil nuts	5/8	N08-2005
Proposed draft Code of Practice for the Reduction of Chloropropanols during the Production of acid-Hydrolysed Vegetable Proteins(HVPs) and Products that contain acid-HVPs	2/3	N09-2005

Appendix III

**ACTION REQUIRED AS THE RESULT OF CHANGES IN THE ACCEPTABLE DAILY INTAKE
(ADI) STATUS AND OTHER TOXICOLOGICAL
RECOMMENDATIONS ARISING FROM THE 65TH JECFA MEETING**

INS Number	Food additive	38 th CCFAC Recommendation
901	Beeswax	Forward the proposed food additive provision for the use of beeswax in food category 14.1.4 to the 29 th CAC for adoption at step 8.
902	Candelilla wax	Forward the proposed food additive provision for the use of Candelilla wax in food category 14.1.4 to the 29 th CAC for adoption at step 8.
-	Phospholipase A1 from <i>Fusarium venenatum</i> expressed in <i>Aspergillus oryzae</i>	No action
1204	Pullulan	Include Pullulan in Table 3 of the GSFA at Step 4 and request proposed maximum use levels in the food categories listed in the Annex to Table 3.
999 (i)	Quillaia extract Type 1	Assign INS number 999 (i)
999 (ii)	Quillaia extract Type 2	Assign INS number 999 (ii)

STATUS OF ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES AND PROCESSING AIDS IN CODEX STANDARDS

PART 1 – CODEX COMMITTEE ON NUTRITION AND FOOD FOR SPECIAL DIETARY USES

DRAFT REVISED STANDARD FOR PROCESSED CEREAL BASED FOODS FOR INFANTS AND YOUNG CHILDREN - (At Step 8 of the Procedure) ALINORM 06/29/26, Appendix II

4. FOOD ADDITIVES

Only the food additives listed in this Section or in the Codex Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
- b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995, Rev. 5 (2004)).

The following additives are permitted in the preparation of processed cereal-based foods for infants and young children, as described in Section 2.1 of this Standard (in 100 g of product, ready for consumption prepared following manufacturer's instructions unless otherwise indicated).

INS no.		Maximum level	38 th CCFAC Comments
Emulsifiers			
322	Lecithins	1500 mg	Endorsed by 38th CCFAC
471	Mono- and diglycerides	500 mg Singly or in combination	Endorsed by 37 th CCFAC Endorsed 38th CCFAC with revision; combination of ML of 471 with 472 a, b and c
472a	Acetic and fatty acid esters of glycerol		Endorsed by 37 th CCFAC
472b	Lactic and fatty acid esters of glycerol		Endorsed by 37 th CCFAC
472c	Citric and fatty acid esters of glycerol		Endorsed by 37 th CCFAC
Acidity Regulators			
500 ii	Sodium hydrogen carbonate	GMP	Endorsed by 38th CCFAC
501 ii	Potassium hydrogen carbonate	GMP	Endorsed by 38th CCFAC
170 i	Calcium carbonate	GMP	Endorsed by 38th CCFAC
270	L(+)-Lactic acid	GMP	Endorsed by 38th CCFAC
330	Citric acid	GMP	Endorsed by 38th CCFAC
260	Acetic acid	GMP	Endorsed by 38th CCFAC
261	Potassium acetates		Endorsed by 38th CCFAC
262 i	Sodium acetate		Endorsed by 38th CCFAC
263	Calcium acetate		Endorsed by 38th CCFAC
296	Malic acid (DL) – L(+)-form only		Endorsed by 37 th CCFAC
325	Sodium lactate (solution) – L(+)-form only		Endorsed by 38th CCFAC
326	Potassium lactate (solution) – L(+)-form only		Endorsed by 38th CCFAC
327	Calcium lactate – L(+)-form only		Endorsed by 38th CCFAC
331 i	Monosodium citrate		Endorsed by 38th CCFAC
331 ii	Trisodium citrate		Endorsed by 38th CCFAC
332 i	Monopotassium citrate		Endorsed by 38th CCFAC
332 ii	Tripotassium citrate		Endorsed by 38th CCFAC
333	Calcium citrate		Endorsed by 38th CCFAC
507	Hydrochloric acid		Endorsed by 38th CCFAC
524	Sodium hydroxide		Endorsed by 38th CCFAC
525	Potassium hydroxide		Endorsed by 38th CCFAC
526	Calcium hydroxide	Endorsed by 38th CCFAC	

INS no.			Maximum level	38 th CCFAC Comments
575	Glucono delta-lactone		GMP	Endorsed by 37 th CCFAC
334	L(+)-Tartaric acid – L(+)form only		500 mg Singly or in combination Tartrates as residue in biscuits and rusks	Endorsed by 37 th CCFAC
335 i	Monosodiumtartrate			Endorsed by 38th CCFAC
335 ii	Disodium tartrate			Endorsed by 38th CCFAC
336 i	Monopotassium tartrate –L(+)form only			Endorsed by 37 th CCFAC
336 ii	Dipotassium tartrate – L(+)form only			Endorsed by 37 th CCFAC
337	Potassium sodium L(+)tartrate L(+)form only			Endorsed by 37 th CCFAC
338	Orthophosphoric acid			} Only for pH adjustment 440 mg Singly or in combination as phosphorous
339 i	Monosodium orthophosphate	Endorsed by 38th CCFAC		
339 ii	Disodium orthophosphate	Endorsed by 38th CCFAC		
339 iii	Trisodium orthophosphate	Endorsed by 38th CCFAC		
340 i	Monopotassium orthophosphate	Endorsed by 38th CCFAC		
340 ii	Dipotassium orthophosphate	Endorsed by 38th CCFAC		
340 iii	Tripotassium orthophosphate	Endorsed by 38th CCFAC		
341 i	Monocalcium orthophosphate	Endorsed by 38th CCFAC		
341 ii	Dicalcium orthophosphate	Endorsed by 38th CCFAC		
341 iii	Tricalcium orthophosphate	Endorsed by 38th CCFAC		
Antioxidants				
306	Mixed tocopherols concentrate	}	300 mg/kg fat or oil basis , Singly or in combination	Endorsed by 37 th CCFAC
307	Alpha-tocopherol			Endorsed by 37 th CCFAC
304	L-Ascorbyl palmitate		200 mg/kg fat	Endorsed by 37 th CCFAC
300	L-Ascorbic acid	}	50 mg, expressed as ascorbic acid and within the limits for sodium	Endorsed by 37 th CCFAC
301	Sodium ascorbate			Endorsed by 37 th CCFAC
303	Potassium ascorbate			Endorsed by 37 th CCFAC
302	Calcium ascorbate		20 mg, expressed as ascorbic acid	Endorsed by 37 th CCFAC
Raising Agents				
503 i	Ammonium carbonate	}	Limited by GMP	Endorsed by 38th CCFAC
503 ii	Ammonium hydrogen carbonate			Endorsed by 38th CCFAC
500 i	Sodium carbonate			Endorsed by 38th CCFAC
500 ii	Sodium hydrogen carbonate			Endorsed by 38th CCFAC
Thickeners				
410	Carob bean gum	}	1000 mg singly or in combination	Endorsed by 38th CCFAC
412	Guar gum			Endorsed by 38th CCFAC
414	Gum arabic			Endorsed by 38th CCFAC
415	Xanthan gum			Endorsed by 38th CCFAC
440	Pectins (Amidated and Non-Amidated)			Endorsed by 38th CCFAC
1404	Oxidized starch	}	5000 mg Singly or in combination	Endorsed by 37 th CCFAC
1410	Monostarch phosphate			Endorsed by 37 th CCFAC
1412	Distarch phosphate			Endorsed by 37 th CCFAC
1413	Phosphated distarch phosphate			Endorsed by 37 th CCFAC
1414	Acetylated distarch phosphate			Endorsed by 37 th CCFAC
1422	Acetylated distarch adipate			Endorsed by 37 th CCFAC
1420	Starch acetate esterified with acetic anhydride			Endorsed by 37 th CCFAC
1450	Starch sodium octenyl succinate			Endorsed by 37 th CCFAC
1451	Acetylated oxidized starch			Endorsed by 37 th CCFAC

INS no.			Maximum level	38th CCFAC Comments
Anticaking Agents				
551	Silicon dioxide (amorphous)		200 mg for dry cereals only	Endorsed by 38th CCFAC
Packing Packaging Gases				
290	Carbon dioxide		GMP	Endorsed by 38th CCFAC
941	Nitrogen		GMP	Endorsed by 38th CCFAC

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**DRAFT STANDARD FOR A BLEND OF EVAPORATED SKIMMED MILK AND VEGETABLE FAT;
DRAFT STANDARD FOR A BLEND OF SWEETENED CONDENSED MILK AND VEGETABLE FAT (at
Step 8 of the Procedure) - ALINORM 06/29/11, Appendices III and V**

4. FOOD ADDITIVES

Only food additives listed below may be used and only within the limits specified.

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
322	Lecithins	Limited by GMP	Endorsed 38 th CCFAC
Stabilizers			
331(i)	Sodium Dihydrogen Citrate	Limited by GMP	Endorsed 37 CCFAC
331(iii)	Trisodium Citrate	Limited by GMP	Endorsed 37 CCFAC
332(i)	Potassium Dihydrogen Citrate	Limited by GMP	Endorsed 38 th CCFAC
332(ii)	Tripotassium Citrate	Limited by GMP	Endorsed 38 th CCFAC
333	Calcium Citrate	Limited by GMP	Endorsed 38 th CCFAC
508	Potassium Chloride	Limited by GMP	Endorsed 38 th CCFAC
509	Calcium Chloride	Limited by GMP	Endorsed 37CCFAC
170(i)	Calcium Carbonate	Limited by GMP	Endorsed 38 th CCFAC
339(i)	Monosodium Orthophosphate	4400 mg/kg Singly or in combination, as phosphorus 10 g/kg Combined Total expressed as P ₂ O ₅	Endorsed 38 th CCFAC
339(ii)	Disodium Orthophosphate		Endorsed 38 th CCFAC
339(iii)	Trisodium Orthophosphate		Endorsed 38 th CCFAC
340(i)	Monopotassium Orthophosphate		Endorsed 38 th CCFAC
340(ii)	Dipotassium Orthophosphate		Endorsed 38 th CCFAC
340(iii)	Tripotassium Orthophosphate		Endorsed 38 th CCFAC
341(i)	Monocalcium Orthophosphate		Endorsed 38 th CCFAC
341(ii)	Dicalcium Orthophosphate		Endorsed 38 th CCFAC
341(iii)	Tricalcium Orthophosphate		Endorsed 38 th CCFAC
450(i)	Disodium Diphosphate		Endorsed 38 th CCFAC
450(ii)	Trisodium Diphosphate		Endorsed 38 th CCFAC
450(iii)	Tetrasodium Diphosphate		Endorsed 38 th CCFAC
450(v)	Tetrapotassium Diphosphate		Endorsed 38 th CCFAC
450(vi)	Dicalcium Diphosphate		Endorsed 38 th CCFAC
450(vii)	Calcium Dihydrogen Diphosphate		Endorsed 38 th CCFAC
451(i)	Pentasodium Triphosphate		Endorsed 38 th CCFAC
451(ii)	Pentapotassium Triphosphate		Endorsed 38 th CCFAC
452(i)	Sodium Polyphosphate		Endorsed 38 th CCFAC
452(ii)	Potassium Polyphosphate		Endorsed 38 th CCFAC
452(iii)	Sodium Calcium Polyphosphate		Endorsed 38 th CCFAC
452(iv)	Calcium Polyphosphates	Endorsed 38 th CCFAC	
452(v)	Ammonium Polyphosphates	Endorsed 38 th CCFAC	
500(i)	Sodium Carbonate	Limited by GMP	Endorsed 38 th CCFAC
500(ii)	Sodium Hydrogen Carbonate	Limited by GMP	Endorsed 38 th CCFAC
500(iii)	Sodium Sesquicarbonate	Limited by GMP	Endorsed 38 th CCFAC
501(i)	Potassium Carbonates	Limited by GMP	Endorsed 38 th CCFAC
501(ii)	Potassium Hydrogen Carbonate	Limited by GMP	Endorsed 38 th CCFAC
Thickeners			
407	Carrageenan and its Na, K, NH ₄ , Ca and Mg salts (including furcelleran)	Limited by GMP	Endorsed 37 CCFAC Endorsed 38 th CCFAC
407a	Processed Eucheuma Seaweed	Limited by GMP	Endorsed 38 th CCFAC

**DRAFT STANDARD FOR A BLEND OF SKIMMED MILK AND VEGETABLE FAT IN POWDERED FORM
(at Step 8 of the Procedure) - ALINORM 06/29/11, Appendix IV**

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Only food additives listed below may be used and only within the limits specified.

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
Stabilizers			
331(i)	Sodium Dihydrogen citrate	Limited by GMP	Endorsed 38 th CCFAC
331(iii)	Trisodium citrate	Limited by GMP	Endorsed 38 th CCFAC
332(i)	Potassium Dihydrogen Citrate	Limited by GMP	Endorsed 38 th CCFAC
332(ii)	Tripotassium Citrate	Limited by GMP	Endorsed 38 th CCFAC
508	Potassium Chloride	Limited by GMP	Endorsed 38 th CCFAC
509	Calcium chloride	Limited by GMP	Endorsed 37 CCFAC
Acidity Regulators			
339(i)	Monosodium Orthophosphate	4400 mg/kg Singly or in combination, as phosphorus 10 g/kg singly or in combination to total expressed as P ₂ O ₅	Endorsed 38 th CCFAC
339(ii)	Disodium Orthophosphate		Endorsed 38 th CCFAC
339(iii)	Trisodium Orthophosphate		Endorsed 38 th CCFAC
340(i)	Monopotassium Orthophosphate		Endorsed 38 th CCFAC
340(ii)	Dipotassium Orthophosphate		Endorsed 38 th CCFAC
340(iii)	Tripotassium Orthophosphate		
341(i)	Monocalcium Orthophosphate		Endorsed 38 th CCFAC
341(ii)	Dicalcium Orthophosphate		Endorsed 38 th CCFAC
450(i)	Disodium Diphosphate		Endorsed 38 th CCFAC
450(ii)	Trisodium Diphosphate		Endorsed 38 th CCFAC
450(iii)	Tetrasodium Diphosphate,		Endorsed 38 th CCFAC
450(v)	Tetrapotassium Diphosphate		Endorsed 38 th CCFAC
450(vi)	Dicalcium Diphosphate		Endorsed 38 th CCFAC
450(vii)	Calcium Dihydrogen Diphosphate		Endorsed 38 th CCFAC
451(i)	Pentasodium Triphosphate		Endorsed 38 th CCFAC
451(ii)	Pentapotassium Triphosphate		Endorsed 38 th CCFAC
452(i)	Sodium Polyphosphate		Endorsed 38 th CCFAC
452(ii)	Potassium Polyphosphate		Endorsed 38 th CCFAC
452(iii)	Sodium Calcium Polyphosphate		Endorsed 38 th CCFAC
452(iv)	Calcium Polyphosphates		Endorsed 38 th CCFAC
452(v)	Ammonium Polyphosphates	Endorsed 38 th CCFAC	
500(i)	Sodium Carbonate	Limited by GMP	Endorsed 38 th CCFAC
500(ii)	Sodium Hydrogen Carbonate	Limited by GMP	Endorsed 38 th CCFAC
500(iii)	Sodium sesquicarbonate	Limited by GMP	Endorsed 38 th CCFAC
501(i)	Potassium Carbonates	Limited by GMP	Endorsed 38 th CCFAC
501(ii)	Potassium Hydrogen Carbonate	Limited by GMP	Endorsed 38 th CCFAC
Emulsifiers			
322	Lecithins	Limited by GMP	Endorsed 38 th CCFAC
471	Mono- and diglycerides of fatty acids	Limited by GMP	Endorsed 37 CCFAC
Anticaking Agents			
170(i)	Calcium carbonate	Limited by GMP	Endorsed 37 CCFAC
504(i)	Magnesium carbonate	Limited by GMP	Endorsed 37 CCFAC
530	Magnesium Oxide	Limited by GMP	Endorsed 37 CCFAC
551	Silicon Dioxide (Amorphous)	Limited by GMP	Endorsed 37 CCFAC
552	Calcium Silicate	Limited by GMP	
553(i)	Magnesium Silicate	Limited by GMP	Endorsed 37 CCFAC
553(iii)	Talc	Limited by GMP	Endorsed 37 CCFAC
554	Sodium Aluminosilicate	Limited by GMP	Endorsed 37 CCFAC
556	Calcium Aluminum Silicate	Limited by GMP	Endorsed 37 CCFAC
559	Aluminum Silicate	Limited by GMP	Endorsed 37 CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
341(iii)	Tricalcium orthophosphate	4400 mg/kg Singly or in combination, as phosphorus 10 g/kg singly or in combination to total expressed as P ₂ O ₅	Endorsed 38th CCFAC
343(iii)	Trimagnesium orthophosphate		Endorsed 38th CCFAC
Antioxidants			
300	Ascorbic Acid	500 mg/kg as ascorbic acid	Endorsed 37 CCFAC
301	Sodium Ascorbate		Endorsed 37 CCFAC
304	Ascorbyl Palmitate	80 mg/kg, Singly or in combination as ascorbyl stearate	Endorsed 38th CCFAC
305	Ascorbyl Stearate		Endorsed 38th CCFAC
320	BHA Butylated Hydroxyanisole	100 mg/kg Singly or in combination. Expressed on fat or oil basis	Endorsed 38th CCFAC
321	BHT Butylated Hydroxytoluene		Endorsed 38th CCFAC
319	TBHQ Tertiary Butylhydroquinone		Endorsed 38th CCFAC

**DRAFT REVISED STANDARD FOR CHEDDAR (C-1) / DRAFT REVISED STANDARD FOR DANBO (C-3)
(at Step 8 of the Procedure) - ALINORM 06/29/11, Appendices VI and VII**

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:	
	Cheese mass	Surface/rind treatment
Colours:	X ¹	-
Bleaching agents:	-	-
Acids:	-	-
Acidity regulators:	X	-
Stabilizers:	-	-
Thickeners:	-	-
Emulsifiers:	-	-
Antioxidants:	-	-
Preservatives:	X	X
Foaming agents:	-	-
Anti-caking agents:	-	X ²

¹) Only to obtain the colour characteristics, as described in Section 2

²) For the surface of sliced, cut, shredded or grated cheese, only

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38th CCFAC Comments
Colours			
101(i)	Riboflavin	300 mg/kg	Endorsed 38 th CCFAC
140	Chlorophyll	Limited by GMP	Endorsed 38 th CCFAC
160a(i),e,f	Carotenoids	35 mg/kg Singly or in combination	Endorsed 38 th CCFAC
160a(i)	Beta-Carotene (Synthetic)		
160a(ii)	Beta-Carotene (Blakeslea triaspora)		
160e	Beta-apo-carotenal		
160f	Beta-apo-8'-caroteinoic acid, methyl or ethyl ester		
160a(ii)	Carotenes, Vegetable	600 mg/kg	Endorsed 38 th CCFAC
160b	Annatto Extracts	25 mg/kg On bixin/norbixin basis	Endorsed 37 CCFAC Not endorsed, has temporary ADI
Preservatives			
1105	Lysozyme Hydrochloride	Limited by GMP	Endorsed 37 CCFAC
200	Sorbic Acid	1000 mg/kg based on sorbic acid. Surface Treatment only *.	Endorsed 38 th CCFAC
201	Sodium Sorbate		Endorsed 38 th CCFAC
202	Potassium Sorbate		Endorsed 38 th CCFAC
203	Calcium Sorbate		Endorsed 38 th CCFAC
234	Nisin		12.5 mg/kg
235	Pimaricin (Natamycin)	2 mg/dm ² Not present at a depth of 5 mm. Surface Treatment only *	Endorsed 38 th CCFAC
251	Sodium Nitrate	37 mg/kg Singly or in combination (expressed as nitrate ion). 50 mg/kg Singly or in combination (expressed as sodium nitrate)	Endorsed 37 CCFAC
252	Potassium Nitrate		Endorsed 37 CCFAC
280	Propionic Acid	3000 mg/kg Surface Treatment only *	Endorsed 38 th CCFAC
281	Sodium Propionate		Endorsed 38 th CCFAC
282	Potassium Propionate		Endorsed 38 th CCFAC
Acidity Regulators			
170(i)	Calcium Carbonate	Limited by GMP	Endorsed 38 th CCFAC
504(i)	Magnesium Carbonate	Limited by GMP	Endorsed 38 th CCFAC
575	Glucono Delta-Lactone	Limited by GMP	Endorsed 38 th CCFAC
Anticaking Agents			
460	Cellulose	Limited by GMP	Endorsed 38 th CCFAC
460(i)	Microcrystalline Cellulose	Limited by GMP	Endorsed 38 th CCFAC
460(ii)	Powdered Cellulose	Limited by GMP	
551	Silicon Dioxide, (amorphous)	10000 mg/kg Singly or in combination Silicates calculated as silicon dioxide	Endorsed 37 CCFAC
552	Calcium Silicate		Endorsed 37 CCFAC
553(i), (iii)	Magnesium Silicates		Endorsed 38 th CCFAC
553(i)	Magnesium Silicate		
553(iii)	Talc		
554	Sodium Aluminosilicate		Endorsed 37 CCFAC
556	Calcium Aluminium Silicate		Endorsed 37 CCFAC
559	Aluminium Silicate		Endorsed 37 CCFAC

(*) For the definition of cheese surface and rind see Appendix to the Codex General Standard for Cheese (Codex STAN A-6-1978, Rev. 1-1999)

PROPOSED DRAFT REVISED STANDARD FOR EDAM (C-4); PROPOSED DRAFT REVISED STANDARD FOR GOUDA (C-5); PROPOSED DRAFT REVISED STANDARD FOR HAVARTI (C-6) ; PROPOSED DRAFT REVISED STANDARD FOR SAMSO (C-7); PROPOSED DRAFT REVISED STANDARD FOR TILSITER (C-14); PROPOSED DRAFT REVISED STANDARD FOR SAINT-PAULIN (C-13): (AT STEP 5/8 OF THE PROCEDURE) (at Step 5/8 of the Procedure) - ALINORM 06/29/11, Appendices IX, X, XI, XII, XIV and XV

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:	
	Cheese mass	Surface/rind treatment
Colours:	X ¹	-
Bleaching agents:	-	-
Acids:	-	-
Acidity regulators:	X	-
Stabilizers:	-	-
Thickeners:	-	-
Emulsifiers:	-	-
Antioxidants:	-	-
Preservatives:	X	X
Foaming agents:	-	-
Anti-caking agents:	-	X ²

¹) Only to obtain the colour characteristics, as described in Section 2

²) For the surface of sliced, cut, shredded or grated cheese, only

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38th CCFAC Comments
Colours			
160a(i),e,f	Carotenoids	35 mg/kg Singly or in combination	Endorsed 38th CCFAC
160a(i)	Beta-Carotene (Synthetic)		
160a(ii)	Beta-Carotene (Blakeslea triaspora)		
160e	Beta-apo-carotenal		
160f	Beta-apo-8'-caroteinoic acid, methyl or ethyl ester		
160a(ii)	Carotenes, Vegetable	600 mg/kg	Endorsed 38th CCFAC
160b	Annatto Extracts	25 mg/kg On bixin/norbixin basis	Not endorsed, has temporary ADI
Preservatives			
1105	Lysozyme Hydrochloride	Limited by GMP	Endorsed 38th CCFAC
200	Sorbic Acid	1000 mg/kg based on sorbic acid. Surface Treatment only*	Endorsed 38th CCFAC
201	Sodium Sorbate		Endorsed 38th CCFAC
202	Potassium Sorbate		Endorsed 38th CCFAC
203	Calcium Sorbate		Endorsed 38th CCFAC
234	Nisin		12.5 mg/kg
235	Pimaricin (Natamycin)	2 mg/dm ² Not present at a depth of 5 mm. Surface Treatment Only *	Endorsed 38th CCFAC
251	Sodium Nitrate	35 mg/kg Singly or in combination (expressed as nitrate ion). 50 mg/kg Singly or in combination (expressed as sodium nitrate)	Endorsed 38th CCFAC
252	Potassium Nitrate		Endorsed 38th CCFAC
280	Propionic Acid	3000 mg/kg Surface Treatment only *	Endorsed 38th CCFAC
281	Sodium Propionate		Endorsed 38th CCFAC
282	Potassium Propionate		Endorsed 38th CCFAC
Acidity Regulators			
170(i)	Calcium Carbonate	Limited by GMP	Endorsed 38th CCFAC
504(i)	Magnesium Carbonate	Limited by GMP	Endorsed 38th CCFAC
575	Glucono delta-Lactone	Limited by GMP	Endorsed 38th CCFAC
Anticaking Agents			
460	Cellulose	Limited by GMP	Endorsed 38th CCFAC
460(i)	Microcrystalline Cellulose	Limited by GMP	Endorsed 38th CCFAC
460(ii)	Powdered Cellulose	Limited by GMP	Endorsed 38th CCFAC
551	Silicon Dioxide, (amorphous)	10000 mg/kg Singly or in combination Silicates calculated as silicon dioxide	Endorsed 38th CCFAC
552	Calcium Silicate		Endorsed 38th CCFAC
553(i), (iii)	Magnesium Silicates		Endorsed 38th CCFAC
553(i)	Magnesium Silicate		Endorsed 38th CCFAC
553(iii)	Talc		Endorsed 38th CCFAC
554	Sodium Aluminosilicate		Endorsed 38th CCFAC
556	Calcium Aluminium Silicate		Endorsed 38th CCFAC
559	Aluminium Silicate		Endorsed 38th CCFAC

(*) For the definition of cheese surface and rind see Appendix to the Codex General Standard for Cheese (Codex STAN A-6-1978, Rev. 1-1999)

PROPOSED DRAFT REVISED STANDARD FOR EMMENTAL (C-9) (at Step 5/8 of the Procedure) - ALINORM 06/29/11, Appendix XIII

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:	
	Cheese mass	Surface/rind treatment
Colours:	X ¹	-
Bleaching agents:	-	-
Acids:	-	-
Acidity regulators:	X	-
Stabilizers:	-	-
Thickeners:	-	-
Emulsifiers:	-	-
Antioxidants:	-	-
Preservatives:	X	X
Foaming agents:	-	-
Anti-caking agents:	-	X ²

¹) Only to obtain the colour characteristics, as described in Section 2

²) For the surface of sliced, cut, shredded or grated cheese, only

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
Colours			
160a(i),e f	Carotenoids	35 mg/kg Singly or in combination	
160a(i)	Beta-Carotene (Synthetic)		Endorsed 38th CCFAC
160a(ii)	Beta-Carotene (Blakeslea triaspora)		Endorsed 38th CCFAC
160e	Beta-apo-carotenal		Endorsed 38th CCFAC
160f	Beta-apo-8'-caroteinoic acid, methyl or ethyl ester		Endorsed 38th CCFAC
160a(ii)	Carotenes, Vegetable	600 mg/kg	Endorsed 38th CCFAC
160b	Annatto Extracts	25 mg/kg On bixin/norbixin basis	Not endorsed, has temporary ADI
Preservatives			
1105	Lysozyme Hydrochloride	Limited by GMP	Endorsed 38th CCFAC
200	Sorbic Acid	1000 mg/kg based on sorbic acid. Surface Treatment only*	Endorsed 38th CCFAC
201	Sodium Sorbate		Endorsed 38th CCFAC
202	Potassium Sorbate		Endorsed 38th CCFAC
203	Calcium Sorbate		Endorsed 38th CCFAC
234	Nisin		12.5 mg/kg
235	Pimaricin (Natamycin)	2 mg/dm ² Not present at a depth of 5 mm. Surface Treatment Only *	Endorsed 38th CCFAC
251	Sodium Nitrate	35 mg/kg Singly or in combination (expressed as nitrite ion) 50 mg/kg Singly or in combination (expressed as sodium nitrate)	Endorsed 38th CCFAC
252	Potassium Nitrate		Endorsed 38th CCFAC
Acidity Regulators			
170(i)	Calcium Carbonate	Limited by GMP	Endorsed 38th CCFAC
504(i)	Magnesium Carbonate	Limited by GMP	Endorsed 38th CCFAC
575	Glucono Delta-Lactone	Limited by GMP	Endorsed 38th CCFAC
Anticaking Agents			
460	Cellulose	Limited by GMP	
460(i)	Microcrystalline Cellulose	Limited by GMP	Endorsed 38th CCFAC
460(ii)	Powdered Cellulose	Limited by GMP	Endorsed 38th CCFAC
551	Silicon dioxide, (amorphous)	10000 mg/kg Singly or in combination Silicates calculated as silicon dioxide	Endorsed 38th CCFAC
552	Calcium Silicate		Endorsed 38th CCFAC
553(i), (iii)	Magnesium Silicates		
553(i)	Magnesium Silicate		Endorsed 38th CCFAC
553(iii)	Talc		Endorsed 38th CCFAC
554	Sodium Aluminosilicate		Endorsed 38th CCFAC
556	Calcium Aluminium Silicate		Endorsed 38th CCFAC
559	Aluminium Silicate		Endorsed 38th CCFAC

(*) For the definition of cheese surface and rind see Appendix to the Codex General Standard for Cheese (Codex STAN A-6-1978, Rev. 1-1999)

PROPOSED DRAFT REVISED STANDARD FOR PROVOLONE (C-15) (at Step 5/8 of the Procedure) - ALINORM 06/29/11, Appendix XVI

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:	
	Cheese mass	Surface/rind treatment
Colours:	X ¹	-
Bleaching agents:	-	-
Acids:	-	-
Acidity regulators:	X	-
Stabilizers:	-	-
Thickeners:	-	-
Emulsifiers:	-	-
Antioxidants:	-	-
Preservatives:	X	X
Foaming agents:	-	-
Anti-caking agents:	-	X ²

¹) Only to obtain the colour characteristics, as described in Section 2

²) For the surface of sliced, cut, shredded or grated cheese, only

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38th CCFAC Comments
Colours			
160a(i),e f	Carotenoids	35 mg/kg Singly or in combination	Endorsed 38th CCFAC
160a(i)	Beta-Carotene (Synthetic)		
160a(ii)	Beta-Carotene (Blakeslea triaspora)		
160e	Beta-apo-carotenal		
160f	Beta-apo-8'-caroteinoic acid, methyl or ethyl ester		
160a(ii)	Carotenes, Vegetable	600 mg/kg	
160b	Annatto Extracts	25 mg/kg On bixin/norbixin basis	Not endorsed, has temporary ADI
171	Titanium Dioxide	Limited by GMP	Endorsed 38th CCFAC
Preservatives			
1105	Lysozyme Hydrochloride	Limited by GMP	Endorsed 38th CCFAC
200	Sorbic Acid	1000 mg/kg based on sorbic acid. Surface Treatment only*	Endorsed 38th CCFAC
201	Sodium Sorbate		Endorsed 38th CCFAC
202	Potassium Sorbate		Endorsed 38th CCFAC
203	Calcium Sorbate		Endorsed 38th CCFAC
234	Nisin		12.5 mg/kg
235	Pimaricin (Natamycin)	2 mg/dm ² Not present at a depth of 5 mm. Surface Treatment Only *	Endorsed 38th CCFAC
239	Hexamethylene Tetramine	25 mg/kg Expressed as formaldehyde	Endorsed 38th CCFAC
251	Sodium Nitrate	35 mg/kg Singly or in combination (expressed as nitrate ion). 50 mg/kg Singly or in combination (expressed as sodium nitrate)	Endorsed 38th CCFAC
252	Potassium Nitrate		Endorsed 38th CCFAC
280	Propionic Acid	3000 mg/kg Surface Treatment only *	Endorsed 38th CCFAC
281	Sodium Propionate		Endorsed 38th CCFAC
282	Potassium Propionate		Endorsed 38th CCFAC
Acidity Regulators			
170(i)	Calcium Carbonate	Limited by GMP	Endorsed 38th CCFAC
504(i)	Magnesium Carbonate	Limited by GMP	Endorsed 38th CCFAC
575	Glucono delta-Lactone	Limited by GMP	Endorsed 38th CCFAC
Anticaking Agents			
460	Cellulose	Limited by GMP	Endorsed 38th CCFAC
460(i)	Microcrystalline Cellulose	Limited by GMP	Endorsed 38th CCFAC
460(ii)	Powdered Cellulose	Limited by GMP	Endorsed 38th CCFAC
551	Silicon dioxide, (amorphous)	10000 mg/kg Singly or in combination Silicates calculated as silicon dioxide	Endorsed 38th CCFAC
552	Calcium Silicate		Endorsed 38th CCFAC
553(i), (iii)	Magnesium Silicates		Endorsed 38th CCFAC
553(i)	Magnesium Silicate		
553(iii)	Talc		
554	Sodium Aluminosilicate		Endorsed 38th CCFAC
556	Calcium Aluminium Silicate		Endorsed 38th CCFAC
559	Aluminium Silicate		Endorsed 38th CCFAC

(*) For the definition of cheese surface and rind see Appendix to the Codex General Standard for Cheese (Codex STAN A-6-1978, Rev. 1-1999)

PROPOSED DRAFT REVISED STANDARD FOR COTTAGE CHEESE (C-16) (at Step 5/8 of the Procedure) -
ALINORM 06/29/11, Appendix XVII

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:	
	Cheese mass ²	Surface/rind treatment
Colours:	-	-
Bleaching agents:	-	-
Acids:	X	-
Acidity regulators:	X	-
Stabilizers:	X ¹	-
Thickeners:	-	-
Emulsifiers:	-	-
Antioxidants:	-	-
Preservatives:	X	-
Foaming agents:	-	-
Anti-caking agents:	-	-

¹) Stabilizers including modified starches may be used in compliance with the definition of milk products and only to the extent they are functionally necessary, taking into account any use of gelatine and starches as provided for in section 3.2.

²) Cheese mass ^{includes} creaming mixture

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38th CCFAC Comments
Preservatives			
200	Sorbic Acid	1000 mg/kg, Singly or in combination as sorbic acid	Endorsed 38th CCFAC
201	Sodium Sorbate		Endorsed 38th CCFAC
202	Potassium Sorbate		Endorsed 38th CCFAC
203	Calcium Sorbate		Endorsed 38th CCFAC
234	Nisin	12.5 mg/kg	Endorsed 38th CCFAC
280	Propionic Acid	Limited by GMP	Endorsed 38th CCFAC
281	Sodium Propionate		Endorsed 38th CCFAC
282	Calcium Propionate		Endorsed 38th CCFAC
283	Potassium Propionate		Endorsed 38th CCFAC
Acidity Regulators			
170(i)	Calcium Carbonate	Limited by GMP	Endorsed 38th CCFAC
261(i)	Potassium Acetate	Limited by GMP	Endorsed 38th CCFAC
261(ii)	Potassium Diacetate	Limited by GMP	Endorsed 38th CCFAC
262(i)	Sodium Acetate	Limited by GMP	Endorsed 38th CCFAC
263	Calcium Acetate	Limited by GMP	Endorsed 38th CCFAC
325	Sodium Lactate	Limited by GMP	Endorsed 38th CCFAC
326	Potassium Lactate	Limited by GMP	Endorsed 38th CCFAC
327	Calcium Lactate	Limited by GMP	Endorsed 38th CCFAC
350(i)	Sodium Hydrogen Malate	Limited by GMP	Endorsed 38th CCFAC
350(ii)	Sodium Malate	Limited by GMP	Endorsed 38th CCFAC
351(i)	Potassium Hydrogen Malate	Limited by GMP	Endorsed 38th CCFAC
351(ii)	Potassium Malate	Limited by GMP	Endorsed 38th CCFAC
352(ii)	Calcium Malate	Limited by GMP	Endorsed 38th CCFAC
500(i)	Sodium Carbonate	Limited by GMP	Endorsed 38th CCFAC
500(ii)	Sodium Hydrogen Carbonate	Limited by GMP	Endorsed 38th CCFAC
500(iii)	Sodium Sesquicarbonate	Limited by GMP	Endorsed 38th CCFAC
501(i)	Potassium Carbonate	Limited by GMP	Endorsed 38th CCFAC
501(ii)	Potassium Hydrogen Carbonate	Limited by GMP	Endorsed 38th CCFAC
504(i)	Magnesium Carbonate	Limited by GMP	Endorsed 38th CCFAC
504(ii)	Magnesium Hydrogen Carbonate	Limited by GMP	Endorsed 38th CCFAC

INS No.	Name of Additive	Maximum Level	38th CCFAC Comments
575	Glucono-Delta-Lactone	Limited by GMP	Endorsed 38 th CCFAC
577	Potassium Gluconate	Limited by GMP	Endorsed 38 th CCFAC
578	Calcium Gluconate	Limited by GMP	Endorsed 38 th CCFAC
Acids			
260	Acetic Acid	Limited by GMP	Endorsed 38 th CCFAC
270	Lactic Acid	Limited by GMP	Endorsed 38 th CCFAC
296	Malic Acid (DL-)	Limited by GMP	Endorsed 38 th CCFAC
330	Citric Acid	Limited by GMP	Endorsed 38 th CCFAC
338	Orthophosphoric Acid	880 mg/kg as phosphorus 2000 mg/kg as P ₂ O ₅	Endorsed 38 th CCFAC
507	Hydrochloric Acid	Limited by GMP	Endorsed 38 th CCFAC
574	Gluconic Acid	Limited by GMP	Not endorsed, does not have an ADI
Stabilizers			
331(i)	Sodium Dihydrogen Citrate	Limited by GMP	Endorsed 38 th CCFAC
332(i)	Potassium Dihydrogen Citrate	Limited by GMP	Endorsed 38 th CCFAC
333	Calcium Citrates	Limited by GMP	Endorsed 38 th CCFAC
339(i-iii); 340(i-iii); 341(i-iii); 342(i,ii); 343(ii,iii); 450(i,iii,v,vi); 451(i,ii); 452(i,ii,iv,v)	Phosphates	1300 mg/kg, Singly or in combination, as phosphorus. 3000 mg/kg, singly or in combination, expressed as P ₂ O ₅	
339(i)	Monosodium Orthophosphate		Endorsed 38 th CCFAC
339(ii)	Disodium Orthophosphate		Endorsed 38 th CCFAC
339(iii)	Trisodium Orthophosphate		Endorsed 38 th CCFAC
340(i)	Monopotassium Orthophosphate		Endorsed 38 th CCFAC
340(ii)	Dipotassium Orthophosphate		Endorsed 38 th CCFAC
340(iii)	Tripotassium Orthophosphate		Endorsed 38 th CCFAC
341(i)	Monocalcium Orthophosphate		Endorsed 38 th CCFAC
341(ii)	Dicalcium Orthophosphate		Endorsed 38 th CCFAC
341(iii)	Tricalcium Orthophosphate		Endorsed 38 th CCFAC
342(i)	Monoammonium Orthophosphate		Endorsed 38 th CCFAC
342(ii)	Diammonium Orthophosphate		Endorsed 38 th CCFAC
343(ii)	Dimagnesium Orthophosphate		Endorsed 38 th CCFAC
343(iii)	Trimagnesium Orthophosphate		Endorsed 38 th CCFAC
450(i)	Disodium Diphosphate		Endorsed 38 th CCFAC
450(iii)	Tetrasodium Diphosphate		Endorsed 38 th CCFAC
450(v)	Tetrapotassium Diphosphate		Endorsed 38 th CCFAC
450(vi)	Dicalcium Diphosphate		Endorsed 38 th CCFAC
451(i)	Pentasodium Triphosphate		Endorsed 38 th CCFAC
451(ii)	Pentapotassium Triphosphate		Endorsed 38 th CCFAC
452(i)	Sodium Polyphosphate	Endorsed 38 th CCFAC	
452(ii)	Potassium Polyphosphate	Endorsed 38 th CCFAC	
452(iv)	Calcium Polyphosphate	Endorsed 38 th CCFAC	
452(v)	Ammonium Polyphosphate	Endorsed 38 th CCFAC	
400	Alginate Acid	Limited by GMP	Endorsed 38 th CCFAC
401	Sodium Alginate	Limited by GMP	Endorsed 38 th CCFAC
402	Potassium Alginate	Limited by GMP	Endorsed 38 th CCFAC
403	Ammonium Alginate	Limited by GMP	Endorsed 38 th CCFAC
404	Calcium Alginate	Limited by GMP	Endorsed 38 th CCFAC
405	Propylene Glycol Alginate	5000 mg/kg, singly or in combination	Endorsed 38 th CCFAC
406	Agar	Limited by GMP	Endorsed 38 th CCFAC
407	Carrageenan or and its Na, K, NH ₄ , Ca and Mg Salts (includes	Limited by GMP	Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38th CCFAC Comments
	Furcelleran)		
407a	Processed Eucheama Seaweed	Limited by GMP	Endorsed 38th CCFAC
410	Carob Bean Gum	Limited by GMP	Endorsed 38th CCFAC
412	Guar Gum	Limited by GMP	Endorsed 38th CCFAC
413	Tragacanth Gum	Limited by GMP	Endorsed 38th CCFAC
415	Xanthan Gum	Limited by GMP	Endorsed 38th CCFAC
416	Karaya Gum	Limited by GMP	Endorsed 38th CCFAC
417	Tara Gum	Limited by GMP	Endorsed 38th CCFAC
440	Pectins	Limited by GMP	Endorsed 38th CCFAC
466	Sodium Carboxymethyl Cellulose	Limited by GMP	Endorsed 38th CCFAC
Stabilizers (Modified Starches)			
1400	Dextrins, Roasted Starch White and Yellow	Limited by GMP	Endorsed 38th CCFAC
1401	Acid-Treated Starch	Limited by GMP	Endorsed 38th CCFAC
1402	Alkaline-Treated Starch	Limited by GMP	Endorsed 38th CCFAC
1403	Bleached Starch	Limited by GMP	Endorsed 38th CCFAC
1404	Oxidized Starch	Limited by GMP	Endorsed 38th CCFAC
1405	Starches, Enzyme-Treated	Limited by GMP	Endorsed 38th CCFAC
1410	Monostarch Phosphate	Limited by GMP	Endorsed 38th CCFAC
1412	Distarch Phosphate Esterified with Sodium Trimetaphosphate; Esterified with Phosphorus-Oxychloride	Limited by GMP	Endorsed 38th CCFAC
1413	Phosphated Distarch Phosphate	Limited by GMP	Endorsed 38th CCFAC
1414	Acetylated Distarch Phosphate	Limited by GMP	Endorsed 38th CCFAC
1420	Starch Acetate Esterified with Acetic Anhydride	Limited by GMP	Endorsed 38th CCFAC
1421	Starch Acetate Esterified with Vinyl Acetate	Limited by GMP	Endorsed 38th CCFAC
1422	Acetylated Distarch Adipate	Limited by GMP	Endorsed 38th CCFAC
1440	Hydroxypropyl Starch	Limited by GMP	Endorsed 38th CCFAC
1442	Hydroxypropyl Distarch Phosphate	Limited by GMP	Endorsed 38th CCFAC

PROPOSED DRAFT REVISED STANDARD FOR COULOMMIERS (C-18) (at Step 5/8 of the Procedure) - ALINORM 06/29/11, Appendix XVIII

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:	
	Cheese mass	Surface/rind treatment
Colours:	X ¹	-
Bleaching agents:	-	-
Acids:	-	-
Acidity regulators:	X	-
Stabilizers:	-	-
Thickeners:	-	-
Emulsifiers:	-	-
Antioxidants:	-	-
Preservatives:	-	-
Foaming agents:	-	-
Anti-caking agents:	-	-

¹) Only to obtain the colour characteristics, as described in Section 2

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
Colours			
160a(i),e,f	Carotenoids	35 mg/kg Singly or in combination	Endorsed 38th CCFAC
160a(i)	Beta-Carotene (Synthetic)		
160a(ii)	Beta-Carotene (Blakeslea triaspora)		
160e	Beta-apo-carotenal		
160f	Beta-apo-8'-caroteinoic acid, methyl or ethyl ester		
160a(ii)	Carotenes, Vegetable	600 mg/kg	Endorsed 38th CCFAC
160b	Annatto Extracts	25 mg/kg On bixin/norbixin basis	Not endorsed, has temporary ADI
Acidity Regulators			
575	Glucono Delta-Lactone	GMP	Endorsed 38th CCFAC

PROPOSED DRAFT REVISED STANDARD FOR CREAM CHEESE (C-31) (at Step 5/8 of the Procedure) - ALINORM 06/29/11, Appendix XIX

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:	
	Cheese mass	Surface/rind treatment
Colours:	X ¹	-
Bleaching agents:	-	-
Acids:	X	-
Acidity regulators:	X	-
Stabilizers:	X ²	-
Thickeners:	X ²	-
Emulsifiers:	X	-
Antioxidants:	X	-
Preservatives:	X	-
Foaming agents:	X ³	-
Anti-caking agents:	-	-

¹) Only to obtain the colour characteristics, as described in Section 2

²) Stabilizers and thickeners including modified starches may be used in compliance with the definition of milk products and only to heat treated products to the extent they are functionally necessary, taking into account any use of gelatine and starches as provided for in section 3.2.

³) For whipped products, only

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
Preservatives			
200	Sorbic Acid	1000 mg/kg, Singly or in combination as sorbic acid	Endorsed 38 th CCFAC
201	Sodium Sorbate		Endorsed 38 th CCFAC
202	Potassium Sorbate		Endorsed 38 th CCFAC
203	Calcium Sorbate		Endorsed 38 th CCFAC
234	Nisin	12.5 mg/kg	Endorsed 38 th CCFAC
280	Propionic acid	Limited to GMP	Endorsed 38 th CCFAC
281	Sodium propionate		Endorsed 38 th CCFAC
282	Calcium propionate		Endorsed 38 th CCFAC
283	Potassium propionate		Endorsed 38 th CCFAC
Acidity Regulators			
170i	Calcium Carbonate	Limited to GMP	Endorsed 38 th CCFAC
261i	Potassium Acetate	Limited to GMP	Endorsed 38 th CCFAC
261(i) 261ii	Potassium Diacetate	Limited to GMP	Endorsed 38 th CCFAC
262i	Sodium Acetate	Limited to GMP	Endorsed 38 th CCFAC
263	Calcium Acetate	Limited to GMP	Endorsed 38 th CCFAC
325	Sodium Lactate	Limited to GMP	Endorsed 38 th CCFAC
326	Potassium Lactate	Limited to GMP	Endorsed 38 th CCFAC
327	Calcium Lactate	Limited to GMP	Endorsed 38 th CCFAC
350(i)	Sodium Hydrogen Malate	Limited to GMP	Endorsed 38 th CCFAC
350(ii)	Sodium Malate	Limited to GMP	Endorsed 38 th CCFAC
351(i)	Potassium Hydrogen Malate	Limited to GMP	Endorsed 38 th CCFAC
351(ii)	Potassium Malate	Limited to GMP	Endorsed 38 th CCFAC
352(ii)	Calcium Malate	Limited to GMP	Endorsed 38 th CCFAC
500(i)	Sodium Carbonate	Limited to GMP	Endorsed 38 th CCFAC
500(ii)	Sodium Hydrogen carbonate	Limited to GMP	Endorsed 38 th CCFAC
500(iii)	Sodium Sesquicarbonate	Limited to GMP	Endorsed 38 th CCFAC
501(i)	Potassium Carbonate	Limited to GMP	Endorsed 38 th CCFAC
501(ii)	Potassium Hydrogen Carbonate	Limited to GMP	Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
504(i)	Magnesium Carbonate	Limited to GMP	Endorsed 38 th CCFAC
504(ii)	Magnesium Hydrogen Carbonate	Limited to GMP	Endorsed 38 th CCFAC
575	Glucono-delta-Lactone	Limited to GMP	Endorsed 38 th CCFAC
577	Potassium Gluconate	Limited to GMP	Endorsed 38 th CCFAC
578	Calcium Gluconate	Limited to GMP	Endorsed 38 th CCFAC
Acids			
260	Acetic Acid	Limited to GMP	Endorsed 38 th CCFAC
270	Lactic Acid (L-, D-, and DL-)	Limited to GMP	Endorsed 38 th CCFAC
296	Malic Acid (DL-)	Limited to GMP	Endorsed 38 th CCFAC
330	Citric Acid	Limited to GMP	Endorsed 38 th CCFAC
338	Orthophosphoric acid	880 mg/kg as phosphorus 2000 mg/kg as P ₂ O ₅	Endorsed 38 th CCFAC
507	Hydrochloric Acid	Limited to GMP	Endorsed 38 th CCFAC
574	Gluconic Acid	Limited to GMP	Not endorsed, does not have an ADI
331(i)	Sodium Dihydrogen Citrate	Limited to GMP	Endorsed 38 th CCFAC
332(i)	Potassium Dihydrogen Citrate	Limited to GMP	Endorsed 38 th CCFAC
333	Calcium Citrates	Limited to GMP	Endorsed 38 th CCFAC
334, 335(i), 335(ii), 336(i), (ii), 337	Tartrates	1500 mg/kg Singly or in combination as tartaric acid	
334	Tartaric Acid (L(+)-)		Endorsed 38 th CCFAC
335(i)	Monosodium Tartrate		Endorsed 38 th CCFAC
335(ii)	Disodium Tartrate		Endorsed 38 th CCFAC
336(i)	Monopotassium Tartrate		Endorsed 38 th CCFAC
336(ii)	Dipotassium Tartrate		Endorsed 38 th CCFAC
337	Potassium Sodium Tartrate		Endorsed 38 th CCFAC
Stabilizers			
339(i-iii); 340(i-iii); 341(i-iii); 342(i,ii); 343(i,iii); 450(i,iii,v,vi); 451(i,ii); 452(i,ii,iv,v);	Phosphates	4400 mg/kg, Singly or in combination, as phosphorus 10000 mg/kg, singly or in combination, expressed as P ₂ O ₅	
339(i)	Monosodium Orthophosphate		Endorsed 38 th CCFAC
339(ii)	Disodium Orthophosphate		Endorsed 38 th CCFAC
339(iii)	Trisodium Orthophosphate		Endorsed 38 th CCFAC
340(i)	Monopotassium Orthophosphate		Endorsed 38 th CCFAC
340(ii)	Dipotassium Orthophosphate		Endorsed 38 th CCFAC
340(iii)	Tripotassium Orthophosphate		Endorsed 38 th CCFAC
341(i)	Monocalcium Orthophosphate		Endorsed 38 th CCFAC
341(ii)	Dicalcium Orthophosphate		Endorsed 38 th CCFAC
341(iii)	Tricalcium Orthophosphate		Endorsed 38 th CCFAC
342(i)	Monoammonium Orthophosphate		Endorsed 38 th CCFAC
342(ii)	Diammonium Orthophosphate		Endorsed 38 th CCFAC
343(ii)	Dimagnesium Orthophosphate		Endorsed 38 th CCFAC
343(iii)	Trimagnesium Orthophosphate		Endorsed 38 th CCFAC
450(i)	Disodium Diphosphate		Endorsed 38 th CCFAC
450(iii)	Tetrasodium Diphosphate		Endorsed 38 th CCFAC
450(v)	Tetrapotassium Diphosphate		Endorsed 38 th CCFAC
450(vi)	Dicalcium Diphosphate		Endorsed 38 th CCFAC
451(i)	Pentasodium Triphosphate		Endorsed 38 th CCFAC
451(ii)	Pentapotassium Triphosphate		Endorsed 38 th CCFAC
452(i)	Sodium Polyphosphate		Endorsed 38 th CCFAC
452(ii)	Potassium Polyphosphate		Endorsed 38 th CCFAC
452(iv)	Calcium Polyphosphate		Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
452(v)	Ammonium Polyphosphate		Endorsed 38th CCFAC
400	Alginic Acid	Limited to GMP	Endorsed 38th CCFAC
401	Sodium Alginate	Limited to GMP	Endorsed 38th CCFAC
402	Potassium Alginate	Limited to GMP	Endorsed 38th CCFAC
403	Ammonium Alginate	Limited to GMP	Endorsed 38th CCFAC
404	Calcium Alginate	Limited to GMP	Endorsed 38th CCFAC
405	Propylene Glycol Alginate	5000 mg/kg, singly or in combination	Endorsed 38th CCFAC
406	Agar	Limited to GMP	Endorsed 38th CCFAC
407	Carrageenan- or and its Na, K, NH ₄ , Ca and Mg salts (includes Furcelleran)	Limited to GMP	Endorsed 38th CCFAC
407a	Processed Eucheuma Seaweed	Limited to GMP	Endorsed 38th CCFAC
410	Carob Bean Gum	Limited to GMP	Endorsed 38th CCFAC
412	Guar Gum	Limited to GMP	Endorsed 38th CCFAC
413	Tragacanth Gum	Limited to GMP	Endorsed 38th CCFAC
415	Xanthan Gum	Limited to GMP	Endorsed 38th CCFAC
416	Karaya gum	Limited to GMP	Endorsed 38th CCFAC
417	Tara Gum	Limited to GMP	Endorsed 38th CCFAC
418	Gellan Gum	Limited to GMP	Endorsed 38th CCFAC
466	Sodium Carboxymethyl Cellulose	Limited to GMP	Endorsed 38th CCFAC
Stabilizers (Modified Starches)			
1400	Dextrins, Roasted Starch White and Yellow	Limited to GMP	Endorsed 38th CCFAC
1401	Acid-Treated Starch	Limited to GMP	Endorsed 38th CCFAC
1402	Alkaline Treated Starch	Limited to GMP	Endorsed 38th CCFAC
1403	Bleached Starch	Limited to GMP	Endorsed 38th CCFAC
1404	Oxidized Starch	Limited to GMP	Endorsed 38th CCFAC
1405	Starches, Enzyme-Treated	Limited to GMP	Endorsed 38th CCFAC
1410	Monostarch Phosphate	Limited to GMP	Endorsed 38th CCFAC
1412	Distarch Phosphate Esterified with Sodium Trimetaphosphate; Esterified with Phosphorus-Oxychloride	Limited to GMP	Endorsed 38th CCFAC
1413	Phosphated Distarch Phosphate	Limited to GMP	Endorsed 38th CCFAC
1414	Acetylated Distarch Phosphate	Limited to GMP	Endorsed 38th CCFAC
1420	Starch Acetate Esterified with Acetic Anhydride	Limited to GMP	Endorsed 38th CCFAC
1421	Starch Acetate Esterified with Vinyl Acetate	Limited to GMP	Endorsed 38th CCFAC
1422	Acetylated Distarch Adipate	Limited to GMP	Endorsed 38th CCFAC
1440	Hydroxypropyl Starch	Limited to GMP	Endorsed 38th CCFAC
1442	Hydroxypropyl Distarch Phosphate	Limited to GMP	Endorsed 38th CCFAC
Emulsifiers			
322	Lecithins	Limited to GMP	Endorsed 38th CCFAC
470	Salts of Fatty Acids (with Base Al, Ca, Na, Mg, K and NH₄)	Limited to GMP	Only the ones with ADI are endorsed
470(i)	Salt of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium	Limited to GMP	Endorsed 38th CCFAC
470(ii)	Salt of oleic acid with calcium, potassium and sodium	Limited to GMP	Endorsed 38th CCFAC
471	Mono- and Di-Glycerides of Fatty Acids	Limited to GMP	Endorsed 38th CCFAC
472a	Acetic and Fatty Acid Esters of Glycerol	Limited to GMP	Endorsed 38th CCFAC
472b	Lactic and Fatty Acid Esters of Glycerol	Limited to GMP	Endorsed 38th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
472c	Citric and Fatty Acid Esters of Glycerol	Limited to GMP	Endorsed 38 th CCFAC
472e	Diacetyltartaric and Fatty Acid Esters of Glycerol	10000 mg/kg Limited to GMP	Endorsed 38 th CCFAC with revision due to numeric ADI
Antioxidants			
300	Ascorbic Acid	Limited to GMP	Endorsed 38 th CCFAC
301	Sodium Ascorbate	Limited to GMP	Endorsed 38 th CCFAC
302	Calcium Ascorbate	Limited to GMP	Endorsed 38 th CCFAC
304	Ascorbyl Palmitate	500 mg/kg Singly or in combination as ascorbyl stearate	Endorsed 38 th CCFAC
305	Ascorbyl Stearate		Endorsed 38 th CCFAC
306	Mixed Tocopherols Concentrate	200 mg/kg Singly or in combination	Endorsed 38 th CCFAC
307	alpha-Tocopherol		Endorsed 38 th CCFAC
Colours			
160ai,e,f	Carotenoids	35 mg/kg	Endorsed 38 th CCFAC
160a(i)	Beta-Carotene (Synthetic)		
160a(ii)	Beta-Carotene (Blakeslea triaspora)		
160e	Beta-apo-carotenal		
160f	Beta-apo-8'-caroteinoic acid, methyl or ethyl ester		
160aia	Carotenes, Vegetable	600 mg/kg	
160b	Annatto Extracts	10 mg/kg On bixin/norbixin basis	Not endorsed, has temporary ADI
171	Titanium Dioxide	GMP	Endorsed 38 th CCFAC
Foaming Agent			
290	Carbon Dioxide	GMP	Endorsed 38 th CCFAC
941	Nitrogen	GMP	Endorsed 38 th CCFAC

PROPOSED DRAFT REVISED STANDARD FOR CAMEMBERT (C-33) (at Step 5/8 of the Procedure) - ALINORM 06/29/11, Appendix XX

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:	
	Cheese mass	Surface/rind treatment
Colours:	X ¹	-
Bleaching agents:	-	-
Acids:	-	-
Acidity regulators:	X	-
Stabilizers:	-	-
Thickeners:	-	-
Emulsifiers:	-	-
Antioxidants:	-	-
Preservatives:	-	-
Foaming agents:	-	-
Anti-caking agents:	-	-

¹) Only to obtain the colour characteristics, as described in Section 2

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
160a(ii)	Beta-Carotene (Blakeslea triaspora)	35 mg/kg Singly or in combination	Endorsed 38 th CCFAC
160e	Beta-apo-carotenal		
160f	Beta-apo-8'-caroteinoic acid, methyl or ethyl ester		
160a(i),e,f	Carotenoids		
160aia	Carotenes, Vegetable		
160a(i)	Beta-Carotene (Synthetic)	600 mg/kg	
160b	Annatto Extracts	25 mg/kg On bixin/norbixin basis	Not endorsed, has temporary ADI

		basis	ADI
Acidity Regulators			
575	Glucono Delta-Lactone	Limited to GMP	Endorsed 38th CCFAC

PROPOSED DRAFT REVISED STANDARD FOR BRIE (C-34) (at Step 5/8 of the Procedure) - ALINORM 06/29/11, Appendix XXI

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:	
	Cheese mass	Surface/rind treatment
Colours:	X ¹	-
Bleaching agents:	-	-
Acids:	-	-
Acidity regulators:	X	-
Stabilizers:	-	-
Thickeners:	-	-
Emulsifiers:	-	-
Antioxidants:	-	-
Preservatives:	-	-
Foaming agents:	-	-
Anti-caking agents:	-	-

¹) Only to obtain the colour characteristics, as described in Section 2

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
Colours			
160a(i),e,f	Carotenoids	35 mg/kg Singly or in combination	Endorsed 38th CCFAC
160a(i)	Beta-Carotene (Synthetic)		
160a(ii)	Beta-Carotene (<i>Blakeslea triasporea</i>)		
160e	Beta-apo-carotenal		
160f	Beta-apo-8'-caroteinoic acid, methyl or ethyl ester		
160a(ii)	Carotenes, Vegetable	600 mg/kg	
160b	Annatto Extracts	25 mg/kg On bixin/norbixin basis	Not endorsed, has temporary ADI
Acidity Regulators			
575	Glucono Delta-Lactone	Limited to GMP	Endorsed 38th CCFAC

PROPOSED DRAFT STANDARD FOR MOZZARELLA (at Step 5/8 of the Procedure) - ALINORM 06/29/11, Appendix XXII

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class:	Justified use:			
	Mozzarella with low moisture content		Mozzarella with high moisture content	
	Cheese mass	Surface treatment	Cheese mass	Surface treatment
Colours:	X ¹	-	X ¹	-
Bleaching agents:	-	-	-	-
Acids:	X	-	X	-
Acidity regulators:	X	-	X	-
Stabilizers:	X	-	X	-
Thickeners:	X	-	X	-
Emulsifiers:	-	-	-	-
Antioxidants:	-	-	-	-
Preservatives:	X	X	X	-
Foaming agents:	-	-	-	-
Anti-caking agents:	-	X ³	-	-

¹) Only to obtain the colour characteristics, as described in Section 2

²) For the surface of sliced, cut, shredded or grated cheese, only

³) “**Anticaking agents for use on the surface of sliced, cut, shredded or grated cheese only**”

X = The use of additives belonging to the class is technologically justified

- = The use of additives belonging to the class is not technologically justified

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
Preservatives			
200	Sorbic Acid	1000 mg/kg Singly or in combination as sorbic acid	Endorsed 38 th CCFAC
201	Sodium Sorbate		Endorsed 38 th CCFAC
202	Potassium Sorbate		Endorsed 38 th CCFAC
203	Calcium Sorbate		Endorsed 38 th CCFAC
234	Nisin	12.5 mg/kg	Endorsed 38 th CCFAC
235	Pimaricin (Natamycin)	Not exceeding 2 mg/dm ² and not present in a depth of 5 mm	Endorsed 38 th CCFAC
280	Propionic acid	Limited to GMP	Endorsed 38 th CCFAC
281	Sodium propionate		Endorsed 38 th CCFAC
282	Calcium propionate		Endorsed 38 th CCFAC
283	Potassium propionate		Endorsed 38 th CCFAC
Acidity Regulators			
170i	Calcium Carbonate	Limited to GMP	Endorsed 38 th CCFAC
261i	Potassium Acetate	Limited to GMP	Endorsed 38 th CCFAC
261ii	Potassium Diacetate	Limited to GMP	Endorsed 38 th CCFAC
262i	Sodium Acetate	Limited to GMP	Endorsed 38 th CCFAC
263	Calcium Acetate	Limited to GMP	Endorsed 38 th CCFAC
325	Sodium Lactate	Limited to GMP	Endorsed 38 th CCFAC
326	Potassium Lactate	Limited to GMP	Endorsed 38 th CCFAC
327	Calcium lactate	Limited to GMP	Endorsed 38 th CCFAC
350i	Sodium Hydrogen Malate	Limited to GMP	Endorsed 38 th CCFAC
350ii	Sodium Malate	Limited to GMP	Endorsed 38 th CCFAC
351i	Potassium Hydrogen Malate	Limited to GMP	Endorsed 38 th CCFAC
351ii	Potassium Malate	Limited to GMP	Endorsed 38 th CCFAC
352ii	Calcium Malate	Limited to GMP	Endorsed 38 th CCFAC
500i	Sodium carbonate	Limited to GMP	Endorsed 38 th CCFAC
500ii	Sodium Hydrogen carbonate	Limited to GMP	Endorsed 38 th CCFAC
500iii	Sodium sesquicarbonate	Limited to GMP	Endorsed 38 th CCFAC
501i	Potassium carbonate	Limited to GMP	Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
501ii	Potassium Hydrogen Carbonate	Limited to GMP	Endorsed 38 th CCFAC
504(i)	Magnesium carbonate	Limited to GMP	Endorsed 38 th CCFAC
504(ii)	Magnesium Hydrogen Carbonate	Limited to GMP	Endorsed 38 th CCFAC
575	Glucono-delta-lactone	Limited to GMP	Endorsed 38 th CCFAC
577	Potassium Gluconate	Limited to GMP	Endorsed 38 th CCFAC
578	Calcium Gluconate	Limited to GMP	Endorsed 38 th CCFAC
Acids			
260	Acetic Acid	Limited to GMP	Endorsed 38 th CCFAC
270	Lactic Acid (L-, D-, and DL-)	Limited to GMP	Endorsed 38 th CCFAC
296	Malic Acid (DL-)	Limited to GMP	Endorsed 38 th CCFAC
330	Citric Acid	Limited to GMP	Endorsed 38 th CCFAC
338	Orthophosphoric Acid	880 mg/kg as phosphorus 2000 mg/kg as P ₂ O ₅	Endorsed 38 th CCFAC
507	Hydrochloric Acid	Limited to GMP	Endorsed 38 th CCFAC
574	Gluconic Acid	Limited to GMP	Not endorsed, does not have an ADI
Stabilizers			
331i	Sodium Dihydrogen Citrate	Limited to GMP	Endorsed 38 th CCFAC
332i	Potassium Dihydrogen Citrate	Limited to GMP	Endorsed 38 th CCFAC
333	Calcium Citrates	Limited to GMP	Endorsed 38 th CCFAC
339(i-iii); 340(i-iii); 341(i-iii); 342(i,ii); 343(ii,iii); 450(i,iii,v, vi); 451(i,ii); 452(i,ii,iv, v);	Phosphates	4400 mg/kg, Singly or in combination, as phosphorus 10000 mg/kg singly or in combination, expressed as P ₂ O ₅	
339(i)	Monosodium Orthophosphate		Endorsed 38 th CCFAC
339(ii)	Disodium Orthophosphate		Endorsed 38 th CCFAC
339(iii)	Trisodium Orthophosphate		Endorsed 38 th CCFAC
340(i)	Monopotassium Orthophosphate		Endorsed 38 th CCFAC
340(ii)	Dipotassium Orthophosphate		Endorsed 38 th CCFAC
340(iii)	Tripotassium Orthophosphate		Endorsed 38 th CCFAC
341(i)	Monocalcium Orthophosphate		Endorsed 38 th CCFAC
341(ii)	Dicalcium Orthophosphate		Endorsed 38 th CCFAC
341(iii)	Tricalcium Orthophosphate		Endorsed 38 th CCFAC
342(i)	Monoammonium Orthophosphate		Endorsed 38 th CCFAC
342(ii)	Diammonium Orthophosphate		Endorsed 38 th CCFAC
343(ii)	Dimagnesium Orthophosphate		Endorsed 38 th CCFAC
343(iii)	Trimagnesium Orthophosphate		Endorsed 38 th CCFAC
450(i)	Disodium Diphosphate		Endorsed 38 th CCFAC
450(iii)	Tetrasodium Diphosphate		Endorsed 38 th CCFAC
450(v)	Tetrapotassium Diphosphate		Endorsed 38 th CCFAC
450(vi)	Dicalcium Diphosphate		Endorsed 38 th CCFAC
451(i)	Pentasodium Triphosphate		Endorsed 38 th CCFAC
451(ii)	Pentapotassium Triphosphate		Endorsed 38 th CCFAC
452(i)	Sodium Polyphosphate	Endorsed 38 th CCFAC	
452(ii)	Potassium Polyphosphate	Endorsed 38 th CCFAC	
452(iv)	Calcium Polyphosphate	Endorsed 38 th CCFAC	
452(v)	Ammonium Polyphosphate	Endorsed 38 th CCFAC	
406	Agar	Limited to GMP	Endorsed 38 th CCFAC
407	Carrageenan or and its Na, K, NH ₄ , Ca and Mg salts (includes furcelleran)	Limited to GMP	Endorsed 38 th CCFAC
407a	Processed Eucheuma Seaweed	Limited to GMP	Endorsed 38 th CCFAC
410	Carob bean gum	Limited to GMP	Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
412	Guar gum	Limited to GMP	Endorsed 38 th CCFAC
413	Tragacanth gum	Limited to GMP	Endorsed 38 th CCFAC
415	Xanthan gum	Limited to GMP	Endorsed 38 th CCFAC
416	Karaya gum	Limited to GMP	Endorsed 38 th CCFAC
417	Tara Gum	Limited to GMP	Endorsed 38 th CCFAC
440	Pectins	Limited to GMP	Endorsed 38 th CCFAC
466	Sodium carboxymethyl cellulose	Limited to GMP	Endorsed 38 th CCFAC
Colours			
140	Chlorophyll	Limited to GMP	Endorsed 38 th CCFAC
141i,ii	Chlorophylls, Copper Complexes	5 mg/kg	Endorsed 38 th CCFAC
141i	Chlorophyll copper complex		
141ii	Chlorophyllin copper complex, sodium and potassium salts		
171	Titanium Dioxide	Limited to GMP	Endorsed 38 th CCFAC
Anticaking Agents			
460	Cellulose	Limited to GMP	Endorsed 38 th CCFAC
460i	Microcrystalline Cellulose	Limited to GMP	Endorsed 38 th CCFAC
460ii	Powdered Cellulose	Limited to GMP	Endorsed 38 th CCFAC
551	Silicon dioxide, amorphous	10000 mg/kg Singly or in combination as silicon dioxide	Endorsed 38 th CCFAC
552	Calcium silicate		Endorsed 38 th CCFAC
553i	Magnesium silicate		Endorsed 38 th CCFAC
554	Sodium aluminosilicate		Endorsed 38 th CCFAC
556	Calcium aluminium silicate		Endorsed 38 th CCFAC
559	Aluminium silicate		Endorsed 38 th CCFAC

PROPOSED DRAFT STANDARD FOR DAIRY FAT SPREADS (at Step 5/8 of the Procedure) - ALINORM 06/29/11, Appendix XXIII

4. FOOD ADDITIVES

Only those additive functional classes indicated as technologically justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below the table may be used and only within the functions and limits specified.

Additive functional class:	Justified use in dairy fat spreads:	
	<70% milk fat content*	≥ 70% milk fat content
Acids	X	X
Acidity regulators	X	X
Anticaking agents	-	-
Antifoaming agents	X	X
Antioxidants	X	X
Bleaching agents	-	-
Bulking agents	-	-
Carbonating agents	-	-
Colours	X	X
Colour retention agents	-	-
Emulsifiers	X	-
Firming agents	-	-
Flavour enhancers	X	-
Foaming agents	-	-
Gelling agents	-	-
Humectants	-	-
Preservatives	X	X
Propellants	X	X
Raising agents	-	-
Sequestrants	-	-
Stabilizers	X	-
Thickeners	X	-

The application of GMP in the use of emulsifiers, stabilizers, thickeners and flavour enhancers includes consideration of the fact that the amount required to obtain the technological function in the product decreases with increasing fat content, fading out at fat content about 70%.

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
Colours			
100(i)	Curcumin	5 mg/kg	Endorsed 38 th CCFAC
160a(i)	Carotenes, beta- (Synthetic) Beta-Carotene (Synthetic)	35 mg/kg Singly or in combination	Endorsed 38 th CCFAC
160a(ii)	Beta-Carotene (Blakeslea triaspora)		Endorsed 38 th CCFAC
160e	Carotenal, beta apo-(C30) Beta-apo-carotenal		Endorsed 38 th CCFAC
160f	Carotenoic acid, methyl or ethylester, beta apo-8' Beta-apo-8'-carotenoic acid, methyl or ethyl ester		Endorsed 38 th CCFAC
160a(ii)	Carotene, beta-, Natural Extracts Carotenes, Vegetable	Limited by GMP	Endorsed 38 th CCFAC
160b	Annatto, Bixin, Norbixin Annatto Extracts	20 mg/kg (calculated as total bixin or norbixin)	Not endorsed, has temporary ADI
Emulsifiers			
432	Polyoxyethylene (20) sorbitan monolaurate	10000 mg/kg singly or in combination (Dairy fat spreads for baking purposes only)	Endorsed 38 th CCFAC
433	Polyoxyethylene (20) sorbitan monooleate		Endorsed 38 th CCFAC
434	Polyoxyethylene (20) sorbitan monopalmitate		Endorsed 38 th CCFAC
435	Polyoxyethylene (20) sorbitan monostearate		Endorsed 38 th CCFAC
436	Polyoxyethylene (20) sorbitan tristearate		Endorsed 38 th CCFAC
471	Mono- and diglycerides of fatty acids	Limited by GMP	Endorsed 38 th CCFAC
472(a) 472a	Acetic and fatty acid esters of glycerol	Limited by GMP	Endorsed 38 th CCFAC
472(b) 472b	Lactic and fatty acid esters of glycerol	Limited by GMP	Endorsed 38 th CCFAC
472(e) 472c	Citric and fatty acid esters of glycerol	Limited by GMP	Endorsed 38 th CCFAC
472(e) 472e	Diacyltartaric and fatty acid esters of glycerol	10000 mg/kg	Endorsed 38 th CCFAC
473	Sucrose esters of fatty acids	10000 mg/kg, Dairy fat spreads for baking purposes only.	Endorsed 38 th CCFAC
474	Sucroglycerides	10000 mg/kg, Dairy fat spreads for baking purposes only.	Endorsed 38 th CCFAC
475	Polyglycerol esters of fatty acids	5000 mg/kg	Endorsed 38 th CCFAC
476	Polyglycerol polyricinoleate esters of interesterified ricinoleic acid	4000 mg/kg	Endorsed 38 th CCFAC
481(i)	Sodium stearoyl lactylate	10000 mg/kg Singly or in combination	Endorsed 38 th CCFAC
482(i)	Calcium stearoyl lactylate		Endorsed 38 th CCFAC with revision. ML was missing Group ADI with 481 (i)
491	Sorbitan monostearate	10000 mg/kg, Singly or in combination	Endorsed 38 th CCFAC
492	Sorbitan tristearate		Endorsed 38 th CCFAC
493	Sorbitan monolaurate		Endorsed 38 th CCFAC
494	Sorbitan monooleate		Endorsed 38 th CCFAC
495	Sorbitan monopalmitate		Endorsed 38 th CCFAC
Preservatives			
200	Sorbic acid	2000 mg/kg Singly or in combination (as sorbic acid) for fat contents < 59% and	Endorsed 38 th CCFAC
201	Sodium Sorbate		Endorsed 38 th CCFAC
202	Potassium sorbate		Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
203	Calcium sorbate	1000 mg/kg singly or in combination (as sorbic acid) for fat contents \geq 59%	Endorsed 38 th CCFAC
Stabilizers/thickeners			
340—(i),(ii) (iii)	Potassium phosphates	880 mg/kg, Singly or in combination, as phosphorus 2000 mg/kg singly or in combination with other phosphates, expressed as P ₂ O ₅	Endorsed 38 th CCFAC
340(i)	Monopotassium Orthophosphate		Endorsed 38 th CCFAC
340(ii)	Dipotassium Orthophosphate		Endorsed 38 th CCFAC
340(iii)	Tripotassium Orthophosphate		Endorsed 38 th CCFAC
341 (i),(ii),(iii)	Calcium orthophosphate		Endorsed 38 th CCFAC
341(i)	Monocalcium Orthophosphate		Endorsed 38 th CCFAC
341(ii)	Dicalcium Orthophosphate		Endorsed 38 th CCFAC
341(iii)	Tricalcium Orthophosphate		Endorsed 38 th CCFAC
450(i)	Disodium Diphosphate		Endorsed 38 th CCFAC
400	Alginic acid	Limited by GMP	Endorsed 38 th CCFAC
401	Sodium alginate	Limited by GMP	Endorsed 38 th CCFAC
402	Potassium alginate	Limited by GMP	Endorsed 38 th CCFAC
403	Ammonium alginate	Limited by GMP	Endorsed 38 th CCFAC
404	Calcium alginate	Limited by GMP	Endorsed 38 th CCFAC
406	Agar	Limited by GMP	Endorsed 38 th CCFAC
405	Propylene glycol alginate	3000 mg/kg	Endorsed 38 th CCFAC
407	Carrageenan and its Na, K, NH ₄ , Ca and Mg salts (including furcellaran)	Limited by GMP	Endorsed 38 th CCFAC
407a	Processed eucheuma seaweed (PES)	Limited by GMP	Endorsed 38 th CCFAC
410	Carob bean gum	Limited by GMP	Endorsed 38 th CCFAC
412	Guar gum	Limited by GMP	Endorsed 38 th CCFAC
413	Tragacanth gum	Limited by GMP	Endorsed 38 th CCFAC
414	Gum arabic (Acacia gum)	Limited by GMP	Endorsed 38 th CCFAC
415	Xanthan gum	Limited by GMP	Endorsed 38 th CCFAC
418	Gellan gum	Limited by GMP	Endorsed 38 th CCFAC
422	Glycerol	Limited by GMP	Endorsed 38 th CCFAC
440	Pectins	Limited by GMP	Endorsed 38 th CCFAC
460 (i)	Microcrystalline Cellulose	Limited by GMP	Endorsed 38 th CCFAC
460 (ii)	Powdered Cellulose	Limited by GMP	Endorsed 38 th CCFAC
461	Methyl cellulose	Limited by GMP	Endorsed 38 th CCFAC
463	Hydroxypropyl cellulose	Limited by GMP	Endorsed 38 th CCFAC
464	Hydroxypropyl methyl cellulose	Limited by GMP	Endorsed 38 th CCFAC
465	Methyl ethyl cellulose	Limited by GMP	Endorsed 38 th CCFAC
466	Sodium carboxymethyl cellulose	Limited by GMP	Endorsed 38 th CCFAC
500 (i)	Sodium carbonate	Limited by GMP	Endorsed 38 th CCFAC
500(ii)	Sodium Hydrogen Carbonate	Limited by GMP	Endorsed 38 th CCFAC
500 (iii)	Sodium sesquicarbonate	Limited by GMP	Endorsed 38 th CCFAC
1400	Dextrin, roasted starch white and yellow	Limited by GMP	Endorsed 38 th CCFAC
1401	Acid-treated starch	Limited by GMP	Endorsed 38 th CCFAC
1402	Alkaline-treated starch	Limited by GMP	Endorsed 38 th CCFAC
1403	Bleached starch	Limited by GMP	Endorsed 38 th CCFAC
1404	Oxidised Oxidized starch	Limited by GMP	Endorsed 38 th CCFAC
1405	Starches, enzyme-treated	Limited by GMP	Endorsed 38 th CCFAC
1410	Monostarch phosphate	Limited by GMP	Endorsed 38 th CCFAC
1412	Distarch phosphate esterified with Sodium trimetaphosphate; esterified with phosphorous oxychloride	Limited by GMP	Endorsed 38 th CCFAC
1413	Phosphated distarch phosphate	Limited by GMP	Endorsed 38 th CCFAC
1414	Acetylated distarch phosphate	Limited by GMP	Endorsed 38 th CCFAC
1420	Starch acetate esterified with acetic anhydride	Limited by GMP	Endorsed 38 th CCFAC
1422	Acetylated distarch adipate	Limited by GMP	Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
1440	Hydroxypropyl starch	Limited by GMP	Endorsed 38 th CCFAC
1442	Hydroxypropyl distarch phosphate	Limited by GMP	Endorsed 38 th CCFAC
Acidity regulators			
325	Sodium lactate	Limited by GMP	Endorsed 38 th CCFAC
326	Potassium lactate	Limited by GMP	Endorsed 38 th CCFAC
327	Calcium lactate	Limited by GMP	Endorsed 38 th CCFAC
329	Magnesium lactate	Limited by GMP	Endorsed 38 th CCFAC
331(i)	Sodium dihydrogen citrate	Limited by GMP	Endorsed 38 th CCFAC
331(ii)	Disodium monohydrogen citrate	Limited by GMP	Endorsed 38 th CCFAC
334	Tartaric acid (L(+))	5000 mg/kg Singly or in combination as tartaric acid	Endorsed 38 th CCFAC
335 (i)	Monosodium tartrate		Endorsed 38 th CCFAC
335 (ii)	Disodium tartrate		Endorsed 38 th CCFAC
336 (i),(ii)	Potassium tartrates		Endorsed 38 th CCFAC
336(i)	Monopotassium tartrate		Endorsed 38 th CCFAC
336(ii)	Dipotassium tartrate		Endorsed 38 th CCFAC
337	Potassium sodium tartrate		Endorsed 38 th CCFAC
339 (i),(ii),(iii)	Sodium phosphates	880 mg/kg, Singly or in combination, as phosphorus 2000 mg/kg singly or in combination with other phosphates, expressed as P ₂ O ₅	Endorsed 38 th CCFAC
338	Orthophosphoric acid		Endorsed 38 th CCFAC
339(i)	Monosodium Orthophosphate		Endorsed 38 th CCFAC
339(ii)	Disodium Orthophosphate		Endorsed 38 th CCFAC
339(iii)	Trisodium Orthophosphate		
524	Sodium hydroxide	Limited by GMP	Endorsed 38 th CCFAC
526	Calcium hydroxide	Limited by GMP	Endorsed 38 th CCFAC
Antioxidants			
304	Ascorbyl palmitate palmitate	500 mg/kg as ascorbyl stearate	Endorsed 38 th CCFAC
305	Ascorbyl stearate		Endorsed 38 th CCFAC
306	Mixed tocopherols concentrate	500 mg/kg	Endorsed 38 th CCFAC
307	Alpha-Tocopherol, alpha		Endorsed 38 th CCFAC
310	Propyl gallate	200 mg/kg, Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), and Propyl Gallate (INS 310) at a combined maximum level of 200 mg/kg on a fat or oil basis. May be used only in dairy fat spreads intended for cooking purposes.	Endorsed 38 th CCFAC
320	Butylated hydroxyanisole (BHA)	200 mg/kg Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), and Propyl Gallate (INS 310) at a combined maximum level of 200 mg/kg on a fat or oil basis. May be used only in dairy fat spreads intended for cooking purposes.	Endorsed 38 th CCFAC
321	Butylated hydroxytoluene (BHT)	75 mg/kg Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), and Propyl Gallate	Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
		(INS 310) at a combined maximum level of 200 mg/kg on a fat or oil basis. May be used only in dairy fat spreads intended for cooking purposes.	
	Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), and Propyl Gallate (INS 310) at a combined maximum level of 200 mg/kg on a fat or oil basis. May be used only in dairy fat spreads intended for cooking purposes.		
Anti-foaming agents			
900a	Polydimethylsiloxane	10 mg/kg in dairy fat spreads for frying purposes, only	Endorsed 38 th CCFAC
Flavour enhancers			
627	Disodium 5'-Guanylate	Limited by GMP	Endorsed 38 th CCFAC
628	Dipotassium 5'-Guanylate	Limited by GMP	Endorsed 38 th CCFAC

PROPOSED DRAFT STANDARD FOR FERMENTED MILKS (ALINORM 06/29/11, Appendix XXV)

PART 1 - FERMENTED MILKS (PLAIN)

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
Stabilizers and Thickeners			
331(iii)	Trisodium Citrate	Limited to GMP	Endorsed 38 th CCFAC
334; 335(i,ii); 336(i,ii); 337	Tartrates	Limited to GMP	
334	Tartaric Acid (L(+)-)	Limited to GMP	Endorsed 38 th CCFAC
335(i)	Monosodium Tartrate	Limited to GMP	Endorsed 38 th CCFAC
335(ii)	Disodium Tartrate	Limited to GMP	Endorsed 38 th CCFAC
336(i)	Monopotassium Tartrate	Limited to GMP	Endorsed 38 th CCFAC
336(ii)	Dipotassium Tartrate	Limited to GMP	Endorsed 38 th CCFAC
337	Potassium Sodium Tartrate	Limited to GMP	Endorsed 38 th CCFAC
339(i-iii); 340(i-iii); 341(i-iii); 342(i,ii); 343(ii,iii); 450(i,iii,v,vi); 451(i,ii); 452(i,ii,iv,v)	Phosphates	2,200 mg/kg used singly or in combination expressed as P ₂ O ₅	
339(i)	Monosodium Orthophosphate	970 mg/kg, Singly or in combination, as phosphorus	Endorsed 38 th CCFAC
339(ii)	Disodium Orthophosphate		Endorsed 38 th CCFAC
339(iii)	Trisodium Orthophosphate	2,200 mg/kg used singly or in combination expressed as P ₂ O ₅	Endorsed 38 th CCFAC
340(i)	Monopotassium Orthophosphate		Endorsed 38 th CCFAC
340(ii)	Dipotassium Orthophosphate		Endorsed 38 th CCFAC
340(iii)	Tripotassium Orthophosphate		Endorsed 38 th CCFAC
341(i)	Monocalcium Orthophosphate		Endorsed 38 th CCFAC
341(ii)	Dicalcium Orthophosphate		Endorsed 38 th CCFAC
341(iii)	Tricalcium Orthophosphate		Endorsed 38 th CCFAC
342(i)	Monoammonium Orthophosphate		Endorsed 38 th CCFAC
342(ii)	Diammonium Orthophosphate		Endorsed 38 th CCFAC
343(ii)	Dimagnesium Orthophosphate		Endorsed 38 th CCFAC
343(iii)	Trimagnesium Orthophosphate		Endorsed 38 th CCFAC
450(i)	Disodium Diphosphate		Endorsed 38 th CCFAC
450(iii)	Tetrasodium Diphosphate		Endorsed 38 th CCFAC
450(v)	Tetrapotassium Diphosphate		Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
450(vi)	Dicalcium Diphosphate		Endorsed 38 th CCFAC
451(i)	Pentasodium Triphosphate		Endorsed 38 th CCFAC
451(ii)	Pentapotassium Triphosphate		Endorsed 38 th CCFAC
452(i)	Sodium Polyphosphate		Endorsed 38 th CCFAC
452(ii)	Potassium Polyphosphate		Endorsed 38 th CCFAC
452(iv)	Calcium Polyphosphate		Endorsed 38 th CCFAC
452(v)	Ammonium Polyphosphate		Endorsed 38 th CCFAC
401	Sodium Alginate	Limited to GMP	Endorsed 38 th CCFAC
405	Propylene Glycol Alginate	Limited to GMP	Endorsed 38 th CCFAC
406	Agar	Limited to GMP	Endorsed 38 th CCFAC
407	Carrageenan and its Na, K, NH ₄ , Ca and Mg salts (including furcelleran)	Limited to GMP	Endorsed 38 th CCFAC
407a	Processed Eucheuma Seaweed	Limited to GMP	Endorsed 38 th CCFAC
410	Carob Bean Gum	Limited to GMP	Endorsed 38 th CCFAC
412	Guar Gum	Limited to GMP	Endorsed 38 th CCFAC
415	Xanthan Gum	Limited to GMP	Endorsed 38 th CCFAC
416	Karaya Gum	Limited to GMP	Endorsed 38 th CCFAC
417	Tara Gum	Limited to GMP	Endorsed 38 th CCFAC
418	Gellan Gum	Limited to GMP	Endorsed 38 th CCFAC
425	Konjac Flour	Limited to GMP	Endorsed 38 th CCFAC
440	Pectins (Amidated and Non-Amidated)	Limited to GMP	Endorsed 38 th CCFAC
460(i)	Microcrystalline Cellulose	Limited to GMP	CCMMP consider if additives should be included
460(ii)	Powdered Cellulose	Limited to GMP	
466	Sodium Carboxymethyl Cellulose	Limited to GMP	Endorsed 38 th CCFAC
1400	Dextrins, White and Yellow, Roasted Starch	Limited to GMP	Endorsed 38 th CCFAC
1401	Acid Treated Starch	Limited to GMP	Endorsed 38 th CCFAC
1402	Alkaline Treated Starch	Limited to GMP	Endorsed 38 th CCFAC
1403	Bleached Starch	Limited to GMP	Endorsed 38 th CCFAC
1404	Oxidized Starch	Limited to GMP	Endorsed 38 th CCFAC
1405	Enzyme Treated Starch	Limited to GMP	Endorsed 38 th CCFAC
1410	Monostarch Phosphate	Limited to GMP	Endorsed 38 th CCFAC
1412	Distarch Phosphate	Limited to GMP	Endorsed 38 th CCFAC
1413	Phosphated Distarch Phosphate	Limited to GMP	Endorsed 38 th CCFAC
1414	Acetylated Distarch Phosphate	Limited to GMP	Endorsed 38 th CCFAC
1420	Starch Acetate	Limited to GMP	Endorsed 38 th CCFAC
1422	Acetylated Distarch Adipate	Limited to GMP	Endorsed 38 th CCFAC
1440	Hydroxypropyl Starch	Limited to GMP	Endorsed 38 th CCFAC
1442	Hydroxypropyl Distarch Phosphate	Limited to GMP	Endorsed 38 th CCFAC
1450	Starch Sodium Octenyl Succinate	Limited to GMP	Endorsed 38 th CCFAC

PART 2 - HEAT TREATED FERMENTED MILKS (PLAIN)

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
Acidity Regulators			
260	Acetic Acid, Glacial	Limited to GMP	Endorsed 38 th CCFAC
270	Lactic Acid (L-)	Limited to GMP	Endorsed 38 th CCFAC
296	Malic Acid (DL-)	Limited to GMP	Endorsed 38 th CCFAC
326	Potassium Lactate	Limited to GMP	Endorsed 38 th CCFAC
327	Calcium Lactate	Limited to GMP	Endorsed 38 th CCFAC
330	Citric Acid	Limited to GMP	Endorsed 38 th CCFAC
331i	Sodium Dihydrogen Citrate	Limited to GMP	Endorsed 38 th CCFAC
331(iii)	Trisodium Citrate	Limited to GMP	Endorsed 38 th CCFAC
332(i)	Potassium Dihydrogen Citrate	Limited to GMP	Endorsed 38 th CCFAC
332(ii)	Tripotassium Citrate	Limited to GMP	Endorsed 38 th CCFAC
355	Adipic Acid	1500 mg/kg, as adipic acid	Endorsed 38 th CCFAC
356	Sodium Adipate		Endorsed 38 th CCFAC
357	Potassium Adipate		Endorsed 38 th CCFAC
359	Ammonium Adipate		Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
500(i)	Sodium Carbonate	Limited to GMP	Endorsed 38 th CCFAC
500(ii)	Sodium Hydrogen Carbonate	Limited to GMP	Endorsed 38 th CCFAC
501(i)	Potassium Carbonate	Limited to GMP	Endorsed 38 th CCFAC
504(i)	Magnesium Carbonate	Limited to GMP	Endorsed 38 th CCFAC
504(ii)	Magnesium Hydrogen Carbonate	Limited to GMP	Endorsed 38 th CCFAC
507	Hydrochloric Acid	Limited to GMP	Endorsed 38 th CCFAC
524	Sodium Hydroxide	Limited to GMP	Endorsed 38 th CCFAC
526	Calcium Hydroxide	Limited to GMP	Endorsed 38 th CCFAC
527	Ammonium Hydroxide	Limited to GMP	Endorsed 38 th CCFAC
528	Magnesium Hydroxide	Limited to GMP	Endorsed 38 th CCFAC
529	Calcium Oxide	Limited to GMP	Endorsed 38 th CCFAC
574	Gluconic Acid	Limited to GMP	Not endorsed 38 th CCFAC. Has no ADI
575	Glucono Delta-Lactone	Limited to GMP	Endorsed 38 th CCFAC
Packing Packaging Gases			
290	Carbon Dioxide	Limited to GMP	Endorsed 38 th CCFAC
941	Nitrogen	Limited to GMP	Endorsed 38 th CCFAC
Stabilizers and Thickeners			
170i	Calcium Carbonate	Limited to GMP	Endorsed 38 th CCFAC
338;339(i-iii); 340(i-iii); 341(i-iii); 342(i,ii); 343(ii,iii); 450(i,iii,v,vi); 451(i,ii); 452(i,ii,iv,v)	Phosphates	2,200 mg/kg used singly or in combination expressed as P ₂ O ₅	
339(i)	Monosodium Orthophosphate	970 mg/kg, Singly or in combination, as phosphorus 2,200 mg/kg used singly or in combination expressed as P ₂ O ₅	Endorsed 38 th CCFAC
339(ii)	Disodium Orthophosphate		Endorsed 38 th CCFAC
339(iii)	Trisodium Orthophosphate		Endorsed 38 th CCFAC
340(i)	Monopotassium Orthophosphate		Endorsed 38 th CCFAC
340(ii)	Dipotassium Orthophosphate		Endorsed 38 th CCFAC
340(iii)	Tripotassium Orthophosphate		Endorsed 38 th CCFAC
341(i)	Monocalcium Orthophosphate		Endorsed 38 th CCFAC
341(ii)	Dicalcium Orthophosphate		Endorsed 38 th CCFAC
341(iii)	Tricalcium Orthophosphate		Endorsed 38 th CCFAC
342(i)	Monoammonium Orthophosphate		Endorsed 38 th CCFAC
342(ii)	Diammonium Orthophosphate		Endorsed 38 th CCFAC
343(ii)	Dimagnesium Orthophosphate		Endorsed 38 th CCFAC
343(iii)	Trimagnesium Orthophosphate		Endorsed 38 th CCFAC
450(i)	Disodium Diphosphate		Endorsed 38 th CCFAC
450(iii)	Tetrasodium Diphosphate		Endorsed 38 th CCFAC
450(v)	Tetrapotassium Diphosphate		Endorsed 38 th CCFAC
450(vi)	Dicalcium Diphosphate		Endorsed 38 th CCFAC
451(i)	Pentasodium Triphosphate		Endorsed 38 th CCFAC
451(ii)	Pentapotassium Triphosphate		Endorsed 38 th CCFAC
452(i)	Sodium Polyphosphate		Endorsed 38 th CCFAC
452(ii)	Potassium Polyphosphate		Endorsed 38 th CCFAC
452(iv)	Calcium Polyphosphate		Endorsed 38 th CCFAC
452(v)	Ammonium Polyphosphate		Endorsed 38 th CCFAC
400	Alginic Acid	Limited by GMP Singly or in combination.	Endorsed 38 th CCFAC
401	Sodium Alginate		Endorsed 38 th CCFAC
402	Potassium Alginate		Endorsed 38 th CCFAC
403	Ammonium Alginate		Endorsed 38 th CCFAC
404	Calcium Alginate		Endorsed 38 th CCFAC
406	Agar	Limited to GMP	Endorsed 38 th CCFAC
407	Carrageenan and its Na, K, NH ₄ , Ca and Mg salts (including	Limited to GMP	Endorsed 38 th CCFAC

INS No.	Name of Additive	Maximum Level	38 th CCFAC Comments
	furcelleran)		
407a	Processed Eucheuma Seaweed	Limited to GMP	Endorsed 38th CCFAC
410	Carob Bean Gum	Limited to GMP	Endorsed 38th CCFAC
412	Guar Gum	Limited to GMP	Endorsed 38th CCFAC
413	Tragacanth Gum	Limited to GMP	Endorsed 38th CCFAC
414	Gum Arabic	Limited to GMP	Endorsed 38th CCFAC
415	Xanthan Gum	Limited to GMP	Endorsed 38th CCFAC
416	Karaya Gum	Limited to GMP	Endorsed 38th CCFAC
417	Tara Gum	Limited to GMP	Endorsed 38th CCFAC
418	Gellan Gum	Limited to GMP	Endorsed 38th CCFAC
425	Konjac Flour	Limited to GMP	Endorsed 38th CCFAC
440	Pectins (Amidated and Non-Amidated)	Limited to GMP	Endorsed 38th CCFAC
460(i)	Microcrystalline Cellulose	Limited to GMP	CCMMP consider if additives should be included
460(ii)	Powdered Cellulose	Limited to GMP	
461	Methyl Cellulose	Limited to GMP	Endorsed 38th CCFAC
463	Hydroxypropyl Cellulose	Limited to GMP	Endorsed 38th CCFAC
464	Hydroxypropyl Methyl Cellulose	Limited to GMP	Endorsed 38th CCFAC
465	Methyl Ethyl Cellulose	Limited to GMP	Endorsed 38th CCFAC
466	Sodium Carboxymethyl Cellulose	Limited to GMP	Endorsed 38th CCFAC
470(ii)	Salts of Oleic Acid (Ca, K, Na) Salt of oleic acid with calcium, potassium and sodium	Limited to GMP	Endorsed 38th CCFAC
471	Mono- and Di- glycerides	Limited to GMP	Endorsed 38th CCFAC
472a	Acetic and Fatty Acid Esters of Glycerol	Limited to GMP	Endorsed 38th CCFAC
472b	Lactic and Fatty Acid Esters of Glycerol	Limited to GMP	Endorsed 38th CCFAC
472c	Citric and Fatty Acid Esters of Glycerol	Limited to GMP	Endorsed 38th CCFAC
1200	Polydextrose	Limited to GMP	Endorsed 38th CCFAC
1400	Dextrins, White and Yellow, Roasted Starch	Limited to GMP	Endorsed 38th CCFAC
1401	Acid Treated Starch	Limited to GMP	Endorsed 38th CCFAC
1402	Alkaline Treated Starch	Limited to GMP	Endorsed 38th CCFAC
1403	Bleached Starch	Limited to GMP	Endorsed 38th CCFAC
1404	Oxidized Starch	Limited to GMP	Endorsed 38th CCFAC
1405	Enzyme Treated Starch	Limited to GMP	Endorsed 38th CCFAC
1410	Mono Starch Phosphate	Limited to GMP	Endorsed 38th CCFAC
1412	Distarch Phosphate	Limited to GMP	Endorsed 38th CCFAC
1413	Phosphated Distarch Phosphate	Limited to GMP	Endorsed 38th CCFAC
1414	Acetylated Distarch Phosphate	Limited to GMP	Endorsed 38th CCFAC
1420	Starch Acetate	Limited to GMP	Endorsed 38th CCFAC
1422	Acetylated Distarch Adipate	Limited to GMP	Endorsed 38th CCFAC
1440	Hydroxypropyl Starch	Limited to GMP	Endorsed 38th CCFAC
1442	Hydroxypropyl Distarch Phosphate	Limited to GMP	Endorsed 38th CCFAC
1450	Starch Sodium Octenyl Succinate	Limited to GMP	Endorsed 38th CCFAC

PART 3 – CODEX COMMITTEE ON CEREALS, PULSES AND LEGUMES

Proposed Food Additive provision in the Draft Standard for Instant Noodles from the Codex Committee on Cereals, Pulses and Legumes (CCCPL)

4. FOOD ADDITIVES

The use of food additive(s) as well as food additive(s) carry-over shall comply with the maximum level permitted by the General Standard for Food Additives (GSFA), CODEX STAN 192-1995. However, until the food additive

provisions for the food category 06.4.3 “Pre-cooked pastas and noodles and like products” in the GSFA is finalised, the following listed food additives will apply¹.

INS No.	Food Additive	Maximum Level	38th CCFAC Comments
Acidity Regulators			
260	Acetic acid, glacial	GMP	Endorsed 38 th CCFAC
262(i)	Sodium acetate	GMP	Endorsed 38 th CCFAC
270	Lactic acid (L-, D-, and DL-)	GMP	Endorsed 38 th CCFAC
296	Malic acid (DL-)	GMP	Endorsed 38 th CCFAC
327	Calcium lactate	GMP	Endorsed 38 th CCFAC
330	Citric acid	GMP	Endorsed 38 th CCFAC
331(iii)	Trisodium citrate	GMP	Endorsed 38 th CCFAC
334	Tartaric acid (L(+)-)	7500mg/kg	Endorsed 38 th CCFAC
350(ii)	Sodium malate	GMP	Endorsed 38 th CCFAC
365	Sodium fumarates	GMP	Endorsed 38 th CCFAC
500(i)	Sodium carbonate	GMP	Endorsed 38 th CCFAC
500(ii)	Sodium hydrogen carbonate	GMP	Endorsed 38 th CCFAC
501(i)	Potassium carbonate	GMP	Endorsed 38 th CCFAC
516	Calcium sulphate	GMP	Endorsed 38 th CCFAC
529	Calcium oxide	GMP	Endorsed 38 th CCFAC
Antioxidants			
300	Ascorbic acid (L-)	GMP	Endorsed 38 th CCFAC
304	Ascorbyl palmitate	500 mg/kg Singly or in combination as ascorbyl stearate	Endorsed 38 th CCFAC
305	Ascorbyl stearate		Endorsed 38 th CCFAC
306	Mixed tocopherols concentrate		200 mg/kg Singly or in combination
307	Alpha-tocopherol	Endorsed 38 th CCFAC	
310	Propyl gallate	200 mg/kg Singly or in combination expressed as a fat or oil basis	Endorsed 38 th CCFAC
319	Tertiary butylhydroquinone (TBHQ)		Endorsed 38 th CCFAC
320	Butylated hydroxyanisole (BHA)		Endorsed 38 th CCFAC
321	Butylated hydroxytoluene (BHT)		Endorsed 38 th CCFAC
Colours			
100(i)	Curcumin	500 mg/kg	Endorsed 38 th CCFAC
101(i)	Riboflavin	200 mg/kg Singly or in combination as riboflavin	Endorsed 38 th CCFAC
101(ii)	Riboflavin 5'-phosphate, sodium		Endorsed 38 th CCFAC
102	Tartrazine	300 mg/kg	Endorsed 38 th CCFAC
110	Sunset yellow FCF	300 mg/kg	Endorsed 38 th CCFAC
120	Carmines	100 mg/kg	Endorsed 38 th CCFAC
123	Amaranth	100 mg/kg	Endorsed 38 th CCFAC)
141(i)	Chlorophyll copper complex	100 mg/kg	Endorsed 38 th CCFAC
141(ii)	Chlorophyllin copper complex, sodium and potassium salts	100 mg/kg	Endorsed 38 th CCFAC
143	Fast green FCF	290 mg/kg	Endorsed 38 th CCFAC
150a	Caramel I-plain	GMP	Endorsed 38 th CCFAC
150b	Caramel II-caustic sulphite process	50000 mg/kg	Endorsed 38 th CCFAC
150c	Caramel III-ammonia process	50000 mg/kg	Endorsed 38 th CCFAC
150d	Caramel IV-ammonia sulphite process	50000 mg/kg	Endorsed 38 th CCFAC
160a(i)	Beta carotene (synthetic)	1200 mg/kg	Endorsed 38 th CCFAC
160a(ii)	Carotenes, Natural extracts Vegetable	1000 mg/kg	Endorsed 38 th CCFAC
160a(ii)	Beta-carotene (Blakeslea trispora)	1000 mg/kg	Endorsed 38 th CCFAC
160b	Annatto extracts	100 mg/kg	Not endorse, has temporary ADI
160e	Beta-apo-carotenal	200 mg/kg	Endorsed 38 th CCFAC
160f	Beta-apo-8'-carotenic acid, methyl or ethyl ester	1000 mg/kg	Endorsed 38 th CCFAC

¹ This sentence and the food additive list which follows will be removed from the standard once the GSFA on the food category 06.4.3. “Pre-cooked pastas and noodles and like products” is completed.

INS No.	Food Additive	Maximum Level	38th CCFAC Comments
162	Beet red	GMP	Endorsed 38 th CCFAC
Flavour Enhancer			
620	Glutamic acid (L(+)-)	GMP	Endorsed 38 th CCFAC
621	Monosodium glutamate, L-	GMP	Endorsed 38 th CCFAC
631	Disodium 5'-inosinate,	GMP	Endorsed 38 th CCFAC
627	Disodium 5'-guanylate	GMP	Endorsed 38 th CCFAC
635	Disodium 5'-ribonucleotides	GMP	Endorsed 38 th CCFAC
Stabilizers			
170(i)	Calcium carbonate	GMP	Endorsed 38 th CCFAC
406	Agar	GMP	Endorsed 38 th CCFAC
459	Beta-cyclodextrin	1000 mg/kg	Endorsed 38 th CCFAC
Thickeners			
400	Alginic acid	GMP	Endorsed 38 th CCFAC
401	Sodium Alginate	GMP	Endorsed 38 th CCFAC
410	Carob Bean Gum	GMP	Endorsed 38 th CCFAC
407	Carrageenan and its Na, K, NH ₄ salts (includes furcellaran)	GMP	Endorsed 38 th CCFAC
407a	Processed Eucheuma Seaweed	GMP	Endorsed 38th CCFAC
412	Guar gum	GMP	Endorsed 38 th CCFAC
414	Gum Arabic (acacia gum)	GMP	Endorsed 38 th CCFAC
415	Xanthan gum	GMP	Endorsed 38 th CCFAC
416	Karaya Gum	GMP	Endorsed 38 th CCFAC
417	Tara Gum	GMP	Endorsed 38 th CCFAC
418	Gellan Gum	GMP	Endorsed 38 th CCFAC
424	Curdlan	GMP	Endorsed 38 th CCFAC
440	Pectins	GMP	Endorsed 38 th CCFAC
466	Sodium carboxymethyl cellulose	GMP	Endorsed 38 th CCFAC
508	Potassium chloride	GMP	Endorsed 38 th CCFAC
1401	Acid treated starch	GMP	Endorsed 38 th CCFAC
1402	Alkaline treated starch	GMP	Endorsed 38 th CCFAC
1403	Bleached starch	GMP	Endorsed 38 th CCFAC
1404	Oxidized Starch	GMP	Endorsed 38 th CCFAC
1405	Starches, enzyme-treated	GMP	Endorsed 38 th CCFAC
1410	Monostarch phosphate	GMP	Endorsed 38 th CCFAC
1412	Distarch phosphate esterified with sodium trimetaphosphate; esterified with phosphorous oxychloride	GMP	Endorsed 38 th CCFAC
1413	Phosphated distarch phosphate	GMP	Endorsed 38 th CCFAC
1414	Acetylated distarch phosphate	GMP	Endorsed 38 th CCFAC
1420	Starch acetate esterified with acetic anhydride	GMP	Endorsed 38 th CCFAC
1422	Acetylated distarch adipate	GMP	Endorsed 38 th CCFAC
1440	Hydroxypropyl starch	GMP	Endorsed 38 th CCFAC
1442	Hydroxypropyl distarch phosphate	GMP	Endorsed 38 th CCFAC
1450	Starch sodium octenyl succinate	GMP	Endorsed 38 th CCFAC
1451	Acetylated oxidized starch	GMP	Endorsed 38 th CCFAC
Humectants			
325	Sodium lactate	GMP	Endorsed 38 th CCFAC
339(i)	Monosodium orthophosphate	2000 mg/kg Singly or in combination as P phosphorus	Endorsed 38 th CCFAC
339(ii)	Disodium orthophosphate		
339(iii)	Trisodium orthophosphate		
340(i)	Monopotassium orthophosphate		
340(ii)	Dipotassium orthophosphate		
340(iii)	Tripotassium orthophosphate		
341(iii)	Tricalcium orthophosphate		
450(i)	Disodium diphosphate		
450(iii)	Tetrasodium diphosphate		
450(v)	Tetrapotassium diphosphate		

INS No.	Food Additive	Maximum Level	38th CCFAC Comments
450(vi)	Dicalcium diphosphate		
451(i)	Pentasodium triphosphate		
452(i)	Sodium polyphosphate		
452(ii)	Potassium polyphosphate		
452(iv)	Calcium polyphosphates		
452(v)	Ammonium polyphosphates		
420	Sorbitol and sorbitol syrop	GMP	Endorsed 38 th CCFAC
1520	Propylene glycol	10000 mg/kg	Endorsed 38 th CCFAC
Emulsifiers			
322	Lecthin	GMP	Endorsed 38 th CCFAC
405	Propylene glycol alginate	5000 mg/kg	Endorsed 38 th CCFAC
430	Polyoxyethylene (8)stearate	5000 mg/kg (dry basis) Singly or in combination	Endorsed 38 th CCFAC
431	Polyoxyethylene (40)stearate		Endorsed 38 th CCFAC
432	Polyoxyethylene (20)sorbitan monolaurate	5000 mg/kg Singly or in combination as total polyoxyethylene(20) sorbitan esters	Endorsed 38 th CCFAC
433	Polyoxyethylene (20)sorbitan monooleate		Endorsed 38 th CCFAC
434	Polyoxyethylene (20)sorbitan monopalmitate		Endorsed 38 th CCFAC
435	Polyoxyethylene (20)sorbitan monostearate		Endorsed 38 th CCFAC
436	Polyoxyethylene (20)sorbitan tristearate		Endorsed 38 th CCFAC
471	Mono and di-glycerides of fatty acids	GMP	Endorsed 38 th CCFAC
472e	Diacetyltartaric and fatty acid esters of glycerol	10000 mg/kg	Endorsed 38 th CCFAC
473	Sucrose esters of fatty acids	2000 mg/kg	Endorsed 38 th CCFAC
475	Polyglycerol esters of fatty acids	2000 mg/kg	Endorsed 38 th CCFAC
476	Polyglycerol esters of interesterified ricinoleic acids	500 mg/kg	Endorsed 38 th CCFAC
477	Propylene glycol esters of fatty acids	5000 mg/kg (dry basis)	Endorsed 38 th CCFAC
481(i)	Sodium stearyl lactylate	5000 mg/kg	Endorsed 38 th CCFAC
482(i)	Calcium stearyl lactylate	5000 mg/kg	Endorsed 38 th CCFAC
491	Sorbitan monostearate	5000 mg/kg (dry basis) singly or in combination	Endorsed 38 th CCFAC
492	Sorbitan tristearate		Endorsed 38 th CCFAC
493	Sorbitan monolaurate		Endorsed 38 th CCFAC
495	Sorbitan monopalmitate		Endorsed 38 th CCFAC
Flour Treatment Agents			
220	Sulphur dioxide	20 mg/kg Singly or in combination as Sulphur sulphur dioxide	Endorsed 38 th CCFAC
221	Sodium sulphite		Endorsed 38 th CCFAC
222	Sodium hydrogen sulphite		Endorsed 38 th CCFAC
223	Sodium metabisulphite		Endorsed 38 th CCFAC
224	Potassium metabisulphite		Endorsed 38 th CCFAC
225	Potassium sulphite		Endorsed 38 th CCFAC
227	Calcium hydrogen sulphite		Endorsed 38 th CCFAC
228	Potassium bisulphite		Endorsed 38 th CCFAC
539	Sodium thiosulphate		Endorsed 38 th CCFAC
Preservatives			
200	Sorbic acid	2000 mg/kg singly or in combination as Sorbic acid	Endorsed 38 th CCFAC
201	Sodium sorbate		Endorsed 38 th CCFAC
202	Potassium sorbate		Endorsed 38 th CCFAC
203	Calcium sorbate		Endorsed 38 th CCFAC
Anticaking Agent			
900a	Polydimethylsiloxane	50 mg/kg	Endorsed 38 th CCFAC

DRAFT REVISED PREAMBLE OF THE GENERAL STANDARD FOR FOOD ADDITIVES**CODEX STAN 192****(at Step 8 of the Procedure)****PREAMBLE****1. SCOPE****1.1 Food Additives Included in this Standard**

Only the food additives listed herein are recognized as suitable for use in foods in conformance with the provisions of this Standard.¹ Only food additives that have been assigned an Acceptable Daily Intake (ADI) or determined, on the basis of other criteria, to be safe² by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)³ and an International Numbering System (INS) designation by Codex will be considered for inclusion in this Standard. The use of additives in conformance with this standard is considered to be technologically justified.

1.2 Foods in Which Additives May Be Used

This Standard sets forth the conditions under which food additives may be used in all foods, whether or not they have previously been standardized by Codex. The use of additives in foods standardized by Codex is subject to the conditions of use established by the Codex commodity standards and this standard. The General Standard for Food Additives (GSFA) should be the single authoritative reference point for food additives. Codex commodity committees have the responsibility and expertise to appraise and justify the technological need for the use of additives in foods subject to a commodity standard. The information given by the commodity committees may also be taken into account by the Codex Committee on Food Additives and Contaminants when considering food additive provisions in similar non-standardized foods. When a food is not covered by a commodity committee, Codex Committee on Food Additives and Contaminants will appraise the technological need.

1.3 Foods in Which Additives May Not Be Used

Food categories or individual food items in which the use of food additives is not acceptable, or where use should be restricted, are defined by this Standard.

1.4 Maximum Use Levels for Food Additives

The primary objective of establishing maximum use levels for food additives in various food groups is to ensure that the intake of an additive from all its uses does not exceed its ADI.

The food additives covered by this Standard and their maximum use levels are based in part on the food additive provisions of previously established Codex commodity standards, or upon the request of governments after subjecting the requested maximum use levels to an appropriate method for verifying the compatibility of a proposed maximum level with the ADI.

Annex A of this Standard may be used as a first step in this regard. The evaluation of actual food consumption data is also encouraged.

¹ Notwithstanding the provisions of this Section of the General Standard, the lack of reference to a particular additive or to a particular use of an additive in a food in the General Standard as currently drafted, does not imply that the additive is unsafe or unsuitable for use in food. The Commission shall review the necessity for maintaining this footnote on a regular basis, with a view to its deletion once the General Standard is substantially complete.

² For the purpose of this standard “determined, on the basis of other criteria, to be safe” means that the use of a food additive does not pose a safety concern under conditions of use described by JECFA as being of no toxicological concern (e.g. use levels defined circumstances).

³ An data base of food additive specifications with their current ADI status, the year of their most recent JECFA evaluation, their assigned INS numbers, etc., are available in English at the JECFA website at FAO <http://www.fao.org/ag/agn/jecfa-additives/search.html?lang=en> . The database has a query page and background information in English, French, Spanish, Arabic and Chinese. The reports of JECFA are available at the JECFA website at WHO <http://www.who.int/ipcs/food/jecfa/en/>

2. DEFINITIONS

- a) **Food additive** means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.⁴
- b) **Acceptable Daily Intake (ADI)** is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk.⁵
- c) **Acceptable Daily Intake "Not Specified" (NS)**⁶ is a term applicable to a food substance of very low toxicity for which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background levels in food, does not, in the opinion of JECFA, represent a hazard to health.

For the above reason, and for reasons stated in individual JECFA evaluations, establishment of an acceptable daily intake expressed in numerical form is not deemed necessary by JECFA. An additive meeting the above criterion must be used within the bounds of good manufacturing practice as defined in section 3.3 below.

- d) **Maximum Use Level** of an additive is the highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe by the Codex Alimentarius Commission. It is generally expressed as mg additive/kg of food.

The maximum use level will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.

3. GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES⁷

The use of food additives in conformance with this Standard requires adherence to all the principles set forth in Sections 3.1 – 3.4.

3.1 Food Additive Safety

- a) Only those food additives shall be endorsed and included in this Standard that, so far as can be judged on the evidence presently available from JECFA, present no appreciable health risk to consumers at the use levels proposed.

⁴ Codex Alimentarius Procedural Manual.

⁵ Principles for the Safety Assessment of Food Additives and Contaminants in Food, World Health Organization, (WHO Environmental Health Criteria, No. 70), p. 111 (1987). For the purposes of this Standard, the phrase “without appreciable health risk” means that there is a reasonable certainty of no harm to consumers if an additive is used at levels that do not exceed those in this Standard. The provisions of this Standard do not sanction the use of an additive in a manner that would adversely affect consumer health.

⁶ For purposes of this Standard, the phrase acceptable daily intake (ADI) “not limited” (NL) has the same meaning as ADI “not specified”. The phrase “acceptable ADI” refers to an evaluation by JECFA, which established safety on the basis of an acceptable level of treatment of food, limited numerically or by GMP, rather than on a toxicologically established ADI.

⁷ General Principles for the Use of Food Additives were originally adopted by the Ninth Session of the Codex Alimentarius as a Codex Advisory Text (para. 295, ALINORM 72/35). Pertinent portions of the Text are incorporated as an integral part of this Standard, suitable modifications having been made as necessary with respect to the present context.

- b) The inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake⁸ from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily intake of the food additive by those consumers.
- c) The quantity of an additive added to food is at or below the maximum use level and is the lowest level necessary to achieve the intended technical effect. The maximum use level may be based on the application of the procedures of Annex A, the intake assessment of Codex members or upon a request by the CCFAC to JECFA for an independent evaluation of national intake assessments.

3.2 Justification for the Use of Additives

The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable:

- a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;
- b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
- c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;
- d) to provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

3.3 Good Manufacturing Practice (GMP)⁹

All food additives subject to the provisions of this Standard shall be used under conditions of good manufacturing practice, which include the following:

- a) the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;
- b) the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible; and,
- c) the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.

⁸ Codex members may provide the Codex Committee on Food Additives and Contaminants (CCFAC) with intake information that may be used by the CCFAC in establishing maximum use levels. Additionally, the JECFA, at the request of the CCFAC, will evaluate intakes of additives based on intake assessments submitted by Codex members responding to a call for data. The CCFAC will consider the JECFA evaluations when establishing the maximum use levels for additives.

⁹ For additional information, see the Codex Alimentarius Commission Procedural Manual. Relations Between Commodity Committees and General Committees- Food Additives and Contaminants.

3.4 Specifications for the Identity and Purity of Food Additives

Food additives used in accordance with this Standard should be of appropriate food grade quality and should at all times conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission¹⁰ or, in the absence of such specifications, with appropriate specifications developed by responsible national or international bodies. In terms of safety, food grade quality is achieved by conformance of additives to their specifications as a whole (not merely with individual criteria) and through their production, storage, transport, and handling in accordance with GMP.

4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS¹¹

4.1 Conditions Applying to Carry-Over of Food Additives

Other than by direct addition, an additive may be present in a food as a result of carry-over from a raw material or ingredient used to produce the food, provided that:

- a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this Standard;
- b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in this Standard;
- c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of raw materials, or ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of this standard.

An additive may be used in a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of this standard.

4.2 Foods for Which the Carry-over of Food Additives is Unacceptable

Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard.

- a) 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants.
- b) 13.2 - Complementary foods for infants and young children.

5. FOOD CATEGORY SYSTEM¹²

The food category system is a tool for assigning food additive uses in this Standard. The food category system applies to all foodstuffs.

The food category descriptors are not to be legal product designations nor are they intended for labelling purposes.

The food category system is based on the following principles:

- a) The food category system is hierarchical, meaning that when an additive is recognized for use in a general category, it is recognized for use in all its sub-categories, unless otherwise stated. Similarly, when an additive is recognized for use in a sub-category, its use is recognized in any further sub-categories or individual foodstuffs mentioned in a sub-category.

¹⁰ An index (CAC/MISC 6) of all specifications adopted by the Codex Alimentarius Commission, as well as the year of adoption, is available at the Codex website (http://www.codexalimentarius.net/web/standard_list.do?lang=en). These specifications, prepared by the JECFA, are also being published in 2006 in the "Combined Compendium of Food Additive Specifications," FAO JECFA Monographs No. 1, which consists of four volumes and in subsequent JECFA Monographs. The specifications are also available at the JECFA website (<http://www.fao.org/ag/agn/jecfa-additives/search.html?lang=en>). Although specifications for flavouring agents are not included in the printed compendium, with the exception of those few which have an additional non-flavour technological function, they are included in an online searchable database at the JECFA website at FAO. http://apps3.fao.org/jecfa/flav_agents/flavag-q.jsp?language=en.

¹¹ The principle relating to the carry-over of food additives into foods (the "Carry-Over Principle") addresses the presence of additives in food as a result of the use of raw materials or other ingredients in which these additives are used. The Codex Alimentarius Commission at its 17th Session (1987) adopted a revised statement of the principle as a Codex Advisory Text. The Carry-Over Principle applies to all foods covered by Codex standards, unless otherwise specified in such standards.

¹² Annex B to this Standard.

- b) The food category system is based on product descriptors of foodstuffs as marketed, unless otherwise stated.
- c) The food category system takes into consideration the carry-over principle. By doing so, the food category system does not need to specifically mention compound foodstuffs (e.g., prepared meals, such as pizza, because they may contain, *pro rata*, all the additives endorsed for use in their components), unless the compound foodstuff needs an additive that is not endorsed for use in any of its components.
- d) The food category system is used to simplify the reporting of food additive uses for assembling and constructing this Standard.

6. DESCRIPTION OF THE STANDARD

This Standard consists of three main components:

- a) Preamble
- b) Annexes
 - i. Annex A is a guideline for considering maximum use levels for additives with numerical JECFA ADIs.
 - ii. Annex B is a listing of the food category system used to develop and organize Tables 1, 2, and 3 of the standard. Descriptors for each food category and sub-category are also provided.
 - iii. Annex C is a cross-reference of the food category system and Codex commodity standards.
- c) Food Additive Provisions
 - i. Table 1 specifies, for each food additive or food additive group (in alphabetical order) with a numerical JECFA ADI, the food categories (or foods) in which the additive is recognized for use, the maximum use levels for each food or food category, and its technological function. Table 1 also includes the uses of those additives with non-numerical ADIs for which a maximum use level is specified.
 - ii. Table 2 contains the same information as Table 1, but the information is arranged by food category number.
 - iii. Table 3 lists additives with Not Specified or Not Limited JECFA ADIs that are acceptable for use in foods in general when used at *quantum satis* levels and in accordance with the principles of good manufacturing practice described in Section 3.3 of this preamble.

The Annex to Table 3 lists food categories and individual food items excluded from the general conditions of Table 3. The provisions in Tables 1 and 2 govern the use of additives in the food categories listed in the Annex to Table 3.

Unless otherwise specified, maximum use levels for additives in Tables 1 and 2 are set on the final product as consumed.

Tables 1, 2, and 3 do not include references to the use of substances as processing aids.¹³

¹³ Processing Aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product: Codex Alimentarius Commission Procedural Manual.

Appendix VI**Procedures for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives**

(for inclusion in the Codex Procedural Manual)

Scope

The Codex General Standard for Food Additives (GSFA) is intended to include food additive provisions for standardised and non-standardised foods in the Codex Alimentarius.

The following text describes the data and information that should be submitted to CCFAC when requesting the Committee to initiate work to add or revise food additive provisions in the Codex General Standard for Food Additives. The decisions required to establish acceptance or rejection of new proposals are also elaborated.

Provisions for the use of processing aids (e.g., most enzyme preparations, clarifying and filtering aids, extraction solvents) are not included in the General Standard for Food Additives.

Initiation of Work**Revision**

The food additive provisions of the GSFA may be revised by CCFAC after requests submitted by Codex Committees, Codex members, or the Codex Alimentarius Commission. Information to support amendment of the GSFA shall be provided by the proposing body. Supporting information provided to the CCFAC should include, as appropriate:

- Specifications for the food additive;
- A summary of the JECFA safety evaluation of the food additive;
- The food categories or sub-categories in which the additive is intended to be used;
- An indication of the technological need / justification for the additive, referencing one or more of the General Principles for the Use of Food Additives of the GSFA (Section 3);
- Maximum use levels for the food additive in the specified food categories:
 - For additives with a numerical ADI, a numerical maximum use level for each specified use although for certain cases, a level of GMP may be appropriate;
 - For additives with an ADI Not Specified or Not Limited, a recommendation to list the additive in Table 3 accompanied by additional proposals for inclusion in Tables 1 and 2 for use in the food categories listed in the Annex to Table 3, as appropriate;
 - For additives with an “acceptable” ADI, either a numerical maximum use level for the acceptable level of treatment of a food or a level of GMP, consistent with the JECFA evaluation.
- A justification of the maximum use levels from a technological point-of-view; and an indication, by means of the procedure indicated in Annex A of the GSFA or an exposure assessment, that this level meets the safety requirements enumerated in Section 3.1 of the GSFA.
- A reasoned statement that consumers will not be misled by the use of the additive.

The Codex Committee for Food Additives and Contaminants shall consider all amendments to the GSFA proposed by Codex Committees, Codex members, or the Codex Alimentarius Commission.

Review

The food additive provisions for the GSFA shall be reviewed by CCFAC on a regular basis and revised as necessary in light of revisions of the risk assessment by JECFA or of changing technological need and justification for use.

- If JECFA changes an ADI to a Temporary ADI, the food additive provisions of the GSFA may remain unchanged until the ADI has been withdrawn or the full status has been restored by JECFA.

- If JECFA withdraws an ADI the food additive provisions of the GSFA shall be amended by removing all provision for the use of the additive.

The following additional guidance is provided regarding the information to be submitted:

- Identity of the food additive
 - Food additives shall have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives and either assigned a full numerical or non-numerical (“not specified” or “not limited”) Acceptable Daily Intake, or deemed to be acceptable for a particular use.
 - Food additives shall have been assigned an International Numbering System Number.
- Functional effect of the food additive
 - The functional class list used in the International Numbering System (CAC/GL 36) should be used.
- Proposed use of the food additive
 - The appropriate food categories from the food category system (Annex B of the General Standard for Food Additives) and maximum use levels should be specified.
 - With regard to the acceptable maximum use level:
 - A numerical use level should be provided for a food additive assigned a numerical Acceptable Daily Intake. However, in some cases, reporting the use level as good manufacturing practice (“GMP”) may be appropriate.
 - For a food additive assigned a non-numerical (“not specified” or “not limited”) Acceptable Daily Intake that is listed in Table 3 of the General Standard for Food Additives, a numerical or good manufacturing practice (“GMP”) use level should be provided for any request to list the additive in a food category in the Annex to Table 3.
 - For some food additives, the Acceptable Daily Intake has been reported on a specific basis (e.g., “as phosphorus” for phosphates; “as benzoic acid” for benzoates). For consistency, the maximum use level for these additives should be reported on the same basis as the Acceptable Daily Intake.
- Justification for the use and technological need of the food additive
 - Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives should be included.
- Safe use of the food additive
 - An intake assessment of the proposed use of the food additive, in accordance with Section 3.1 of the Preamble of the General Standard for Food Additives, should be included as appropriate.
- Justification that the use does not mislead the consumer
 - A reasoned statement that consumers will not be misled by the use of the additive should be provided.

Does the food additive use meet the criteria of Section 3.2 of the Preamble of the General Standard for Food Additives?

Section 3.2 of the Preamble of the General Standard for Food Additives establishes the criteria for justifying the use of a food additive. Adherence to these criteria is necessary for the inclusion of the food additive in the General Standard for Food Additives. If the use of the additive does not meet these criteria, it is not considered further and the work is discontinued. If the information provided to justify the use of the additive is inadequate for the Codex Commodity on Food Additives and Contaminants to reach a decision, further information on the use and technological justification and need for the food additive will be requested for consideration at the Committee’s next Session. If this information is not provided by the next Session, work on the provision is discontinued.

Is the food additive used in standardized food?

The Codex Committee on Food Additives and Contaminants, asks the relevant Codex commodity committee to consider the functional classes of additives, additives, and their technological justification for the commodity and to refer back this information by the next available session.. In light of this information, the Codex Committee on Food Additives and Contaminants recommends appropriate conditions of use based on proposals of the commodity committee.

In certain cases, however, it may be appropriate for the Codex commodity committee to develop a list of food additives with associated functional classes and acceptable maximum use levels that would be forwarded to the Codex Committee on Food Additives and Contaminants for endorsement and, ultimately, incorporation into the General Standard for Food Additives. The development of such food additive lists should be consistent with the principles used in the development of the General Standard for Food Additives. However, the development of food additive lists in commodity standards should be restricted as much as possible. For example, an additive may be listed in a commodity standard if it is needed to achieve a technical effect that is not achievable by the use of other additives of the same functional class. Additives may also be listed in a commodity standard if there is a need, based on a safety assessment, to limit the use of the additive. Justification for such exceptions should be provided by the Codex commodity committees to the Codex Committee on Food Additives and Contaminants for consideration.

If the Codex commodity committee has been adjourned, the Codex Committee on Food Additives and Contaminants may revise the food additive provisions in commodity standards under the purview of the adjourned committee, as necessary.

The Codex Committee on Food Additives and Contaminants would consider any proposed revision in light of the principles of technological justification for the use of additives as indicated in Section 3.2 of the Preamble of the General Standard for Food Additives. These revisions, once adopted by the Commission, would be incorporated into the General Standard for Food Additives.

Has a non-numerical (“Not Specified” or “Not Limited”) Acceptable Daily Intake been assigned?

Yes - Non-Numerical (“Not Specified” or “Not Limited”) Acceptable Daily Intake:

Food additives assigned a non-numerical Acceptable Daily Intake are proposed for inclusion in Table 3 of the General Standard for Food Additives. Requests for the use of these additives in the food categories listed in the Annex to Table 3 are made by proposing provisions for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives and Contaminants according to the criteria described under “*Consideration of Conditions of Use in the Specific Food Categories,*” below.

No - Numerical Acceptable Daily Intake or Acceptable for Limited Use:

Food additives assigned a numerical Acceptable Daily Intake or evaluated to be acceptable for one or more particular uses are proposed for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives and Contaminants according to the criteria described under “*Consideration of Conditions of Use in the Specific Food Categories,*” below.

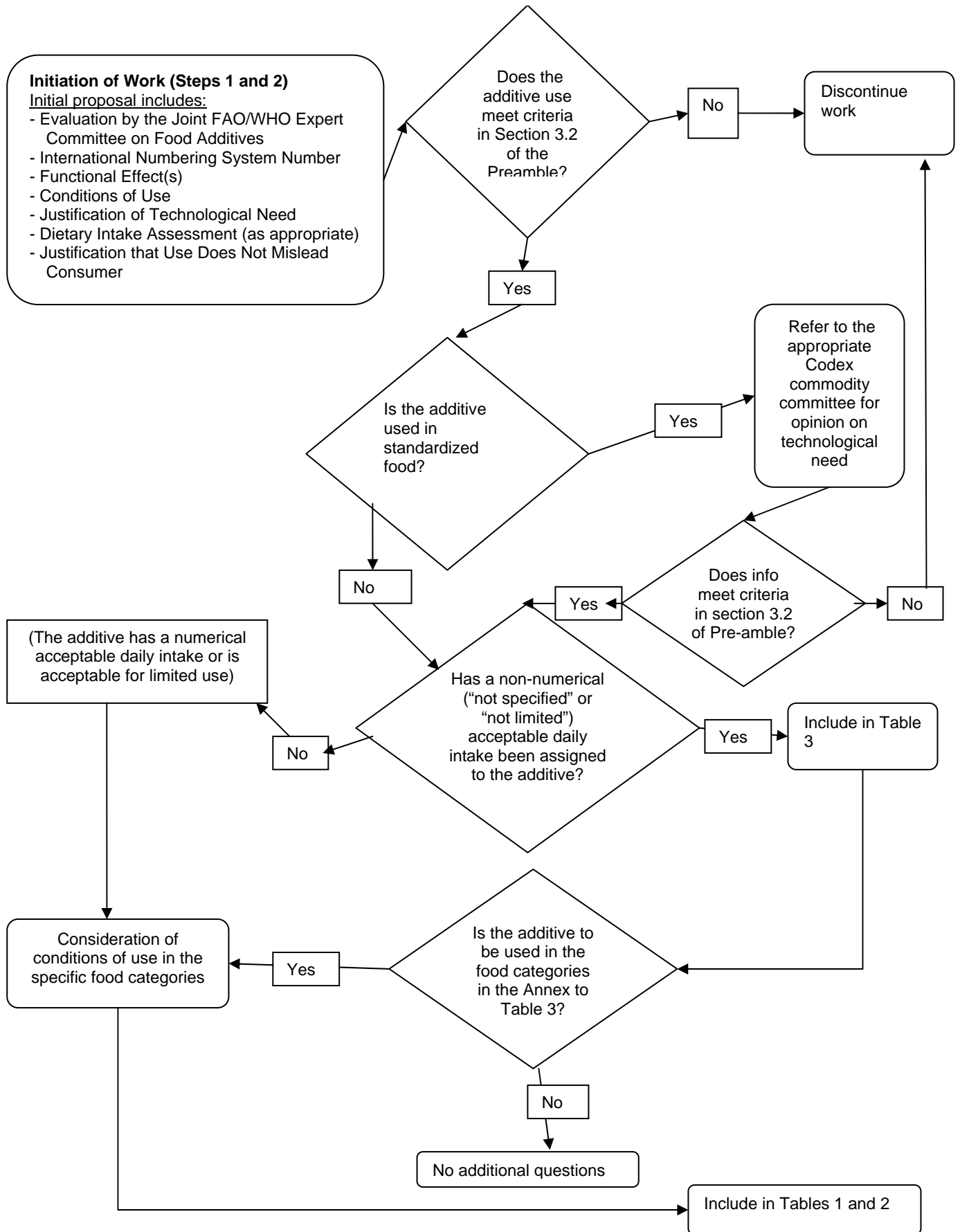
Consideration of Conditions of Use in the Specific Food Categories

The Codex Committee on Food Additives and Contaminants identifies and recommends appropriate food categories and use levels for inclusion in Tables 1 and 2 of the General Standard for Food Additives. For this purpose, the Committee will consider the following general principles for the inclusion of a food additive provision in Tables 1 and 2 of the General Standard for Food Additives:

1. Food additives that share a numerical group Acceptable Daily Intake will be considered as a group without further restrictions on the use of individual additives in that group. However, in some cases, restrictions on the use of individual additives in that group could be appropriate (e.g., because of public health concerns).
2. Food additives that have multiple functional classes will be considered without further restrictions to their functional class.

3. In general, a numerical use level for a proposed use of a food additive in a food category is given preference over a use level reported as good manufacturing practice (“GMP”). However, exceptions, as noted under “*Initiation of Work*,” shall also be taken into account by the Codex Committee on Food Additives and Contaminants on a case-by-case basis.
4. When establishing the acceptable maximum level of use for an additive in a specified food category, the Codex Committee on Food Additives and Contaminants considers the technological justification for the proposed level and the exposure assessment in accordance with Sections 3.1 and 3.2 of the Preamble of the General Standard for Food Additives. If more than one maximum use level is proposed, and the Committee cannot reach consensus on the appropriate maximum use level, the delegations supporting and the delegations opposing the proposed maximum use level should provide additional justification for their proposed levels to address any specific concerns raised by the Committee, by the next available session. to the Codex Committee on Food Additives and Contaminants, for consideration in its next Session. Proposals lacking justification will no longer be considered, and the proposed level for which justification has been provided will be forwarded for adoption.
5. To resolve questions related to dietary exposure of food additives, the Codex Committee on Food Additives and Contaminants may request the Joint FAO/WHO Expert Committee on Food Additives to perform exposure assessments for the additives based on the acceptable maximum use levels under consideration by the Codex Committee on Food Additives and Contaminants.
6. Acceptable maximum use levels are established as described in the previous sections and the food additive provisions are entered in the General Standard for Food Additives. Each use level represents the highest acceptable maximum use level in the broadest food category for which the use is technologically justified. To the extent possible, the hierarchical structure of the food category system will be used to simplify the listing of the food additive provisions in Tables 1 and 2 of the General Standard of Food Additives. In this regard:
 - If the new use of a food additive is for a broader food category and at a maximum use level that is higher than or equal to those in the sub-categories of the broad food category that are already listed in the General Standard for Food Additives, then the new use in the broader food category supersedes the already-listed provisions. These provisions are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).
 - If the new use of a food additive is for a broader food category and at a lower maximum use level than for the sub-categories of the broad food category that already exist in the General Standard for Food Additives, then the provisions listed in the General Standard for Food Additives are determined according to the hierarchy of the food category system. The highest maximum use level in each food sub-category, whether from an existing provision or from the new use in the broader food category, is entered into the General Standard for Food Additives. Any existing provisions that are superseded by the new use are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).
 - If the new use of a food additive, together with the already-listed provisions in the General Standard for Food Additives, represents use in all of the sub-categories of a broader food category at the same maximum use level, then the use in the broader food category will be listed in the General Standard for Food Additives. The already-listed provisions in the sub-categories are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the provision in the broader food category at Step 8 (if adopted provision at Step 8).

Diagram of procedure for consideration of the entry and review of food additives in the GSFA



**GSFA PROVISIONS TO BE ADOPTED AND TO BE REVOKED
TO ADDRESS GSFA FOOD CATEGORIES WITH A ONE-TO-ONE CORRESPONDENCE TO A
SINGLE CODEX COMMODITY STANDARD**

In addition to the below provisions, there will be consequential changes to other food categories in order to align the additive provisions in the food category that has a one-to-one correspondence to a single Codex commodity standard, as indicated in Appendix IV of CX/FAC 06/38/7.

Food Category No. 01.6.3 Whey cheese						
Additive	INS	Step	Max	Level	Comments	Action
Caramel Colour, Class III	150c	8		GMP	Note 3	Revoke
Caramel Colour, Class IV	150d	8		GMP	Note 3	Revoke
Sorbates	200-203	8	1000	mg/kg	Note 42	Adopt

Food Category No. 01.6.6 Whey protein cheese						
Additive	INS	Step	Max	Level	Comments	Action
Acetic Acid, Glacial	260	8		GMP		Adopt
Calcium Propionate	282	8	3000	mg/kg	Note 70	Adopt
Citric Acid	330	8		GMP		Adopt
Glucono Delta-Lactone	575	8		GMP		Adopt
Lactic Acid	270	8		GMP		Adopt
Malic Acid (DL-)	296	8		GMP		Adopt
Nisin	234	8	12.5	mg/kg	Notes 28	Adopt
Pimaricin	235	8	40	mg/kg	Notes 3 & 80	Adopt
Propionic Acid	280	8	3000	mg/kg	Note 70	Adopt
Sodium Propionate	281	8	3000	mg/kg	Note 70	Adopt
Sorbates	200-203	8	3000	mg/kg	Note 42	Adopt

Food Category No. 01.8.2 Dried whey and whey products, excluding whey cheeses						
Additive	INS	Step	Max	Level	Comments	Action
Aluminium Silicate	559	8	10000	mg/kg		Adopt
Benzoyl Peroxide	928	8	100	mg/kg	Note 160	Adopt
Calcium Aluminium Silicate (Synthetic)	556	8	10000	mg/kg		Adopt
Calcium Carbonate	170i	8	10000	mg/kg		Adopt
Calcium Chloride	509	8		GMP		Adopt
Calcium Hydroxide	526	8		GMP		Adopt
Calcium Silicate	552	8	10000	mg/kg		Adopt
Hydroxypropyl Distarch Phosphate	1442	8	10000	mg/kg		Adopt
Magnesium Carbonate	504i	8	10000	mg/kg		Adopt
Magnesium Oxide	530	8	10000	mg/kg		Adopt
Magnesium Silicate (Synthetic)	553i	8	10000	mg/kg		Adopt
Microcrystalline Cellulose	460i	8	10000	mg/kg		Adopt
Phosphates	338; 339i-iii; 340i-iii; 341i-iii; 342i,ii; 343i-iii; 450i-iii,v-vii; 451i,ii; 452i-v; 542	8	4400	mg/kg	Note 33	Adopt
Potassium Carbonate	501i	8		GMP		Adopt
Potassium Chloride	508	8		GMP		Adopt
Potassium Dihydrogen Citrate	332i	8		GMP		Adopt
Potassium Hydrogen Carbonate	501ii	8		GMP		Adopt
Potassium Hydroxide	525	8		GMP		Adopt
Powdered Cellulose	460ii	8	10000	mg/kg		Adopt
Silicon Dioxide (Amorphous)	551	8	10000	mg/kg		Adopt
Sodium Aluminosilicate	554	8	10000	mg/kg		Adopt
Sodium Carbonate	500i	8		GMP		Adopt
Sodium Dihydrogen Citrate	331i	8		GMP		Adopt
Sodium Hydrogen Carbonate	500ii	8		GMP		Adopt
Sodium Hydroxide	524	8		GMP		Adopt

Food Category No. 01.8.2 Dried whey and whey products, excluding whey cheeses						
Additive	INS	Step	Max	Level	Comments	Action
Sodium Sesquicarbonate	500iii	8		GMP		Adopt
Talc	553iii	8	10000	mg/kg		Adopt
Tripotassium Citrate	332ii	8		GMP		Adopt
Trisodium Citrate	331iii	8		GMP		Adopt

Food Category No. 02.1.1 Butter oil, anhydrous milkfat, ghee						
Additive	INS	Step	Max	Level	Comments	Action
Ascorbyl Esters	304, 305	8	500	mg/kg	Note 10	Adopt
BHA	320	8	175	mg/kg	Notes 15 & 133	Adopt
BHT	321	8	75	mg/kg	Notes 15 & 133	Adopt
Citric Acid	330	8		GMP		Adopt
Isopropyl Citrates	384	8	100	mg/kg	Note 77	Revoke
Propyl Gallate	310	8	100	mg/kg	Notes 15 & 133	Adopt
Sodium Dihydrogen Citrate	331i	8		GMP		Adopt
Tocopherols	306, 307	8	500	mg/kg		Adopt
Trisodium Citrate	331iii	8		GMP		Adopt

Food Category No. 02.2.1.1 Butter and concentrated butter						
Additive	INS	Step	Max	Level	Comments	Action
Annatto Extracts	160b	8	20	mg/kg	Note 9	Adopt
Calcium Hydroxide	526	8		GMP		Adopt
Carotenoids	160ai, e, f	8	25	mg/kg	Note 146	Adopt
Phosphates	338; 339i-iii; 340i-iii; 341i-iii; 342i,ii; 343i-iii; 450i-iii,v-vii; 451i,ii; 452i-v; 542	8	880	mg/kg	Notes 33 & 34	Adopt
Sodium Carbonate	500i	8		GMP		Adopt
Sodium Hydrogen Carbonate	500ii	8		GMP		Adopt
Sodium Hydroxide	524	8		GMP		Adopt

Food Category No. 02.2.1.2 Margarine and similar products						
Additive	INS	Step	Max	Level	Comments	Action
Acetic and Fatty Acid Esters of Glycerol	472a	5/8	10000	mg/kg		Adopt
Annatto Extracts	160b	8	20	mg/kg	Note 9	Adopt
Ascorbyl Esters	304, 305	8	500	mg/kg	Note 10	Adopt
BHA	320	8	175	mg/kg	Notes 15 & 133	Adopt
BHA	320	8	200	mg/kg	Notes 15 & 130	Revoke
BHT	321	8	75	mg/kg	Notes 15 & 133	Adopt
Carotenes, Vegetable	160aai	8	26	mg/kg		Revoke
Carotenoids	160ai, e, f	8	25	mg/kg		Adopt
Citric Acid	330	5/8		GMP		Adopt
Citric and Fatty Acid Esters of Glycerol	472c	5/8	10000	mg/kg		Adopt
Curcumin	100i	8	5	mg/kg		Adopt
EDTAs	385, 386	8	75	mg/kg	Note 21	Revoke
Isopropyl Citrates	384	8	100	mg/kg	Note 161	Adopt
Isopropyl Citrates	384	8	200	mg/kg		Revoke
Lactic Acid (L-, D- and DL-)	270	5/8		GMP		Adopt
Lactic and Fatty Acid Esters of Glycerol	472b	5/8	10000	mg/kg		Adopt
Lecithins	322	5/8		GMP		Adopt
Mono- and Diglycerides	471	5/8	10000	mg/kg		Adopt
Phosphates	338; 339i-iii; 340i-iii; 341i-iii; 342i,ii; 343i-iii; 450i-iii,v-vii; 451i,ii; 452i-v; 542	8	40	mg/kg	Notes 33 & 161	Adopt
Polyglycerol Esters of Fatty Acids	475	8	5000	mg/kg		Adopt
Potassium Dihydrogen Citrate	332i	5/8		GMP		Adopt

Food Category No. 02.2.1.2 Margarine and similar products						
Additive	INS	Step	Max	Level	Comments	Action
Potassium Lactate	326	5/8		GMP		Adopt
Propyl Gallate	310	8	100	mg/kg	Notes 15 & 133	Adopt
Propyl Gallate	310	8	200	mg/kg	Notes 15 & 130	Revoke
Silicon Dioxide (Amorphous)	551	5/8	10	mg/kg		Adopt
Sodium Dihydrogen Citrate	331i	5/8		GMP		Adopt
Sodium Lactate	325	5/8		GMP		Adopt
Sorbates	200-203	8	1000	mg/kg	Note 42	Adopt
Sorbitan Esters of Fatty Acids	491-495	8	10000	mg/kg		Adopt
Stearyl Citrate	484	8	100	mg/kg	Note 15	Revoke
Sucroglycerides	474	8	10000	mg/kg		Adopt
Sucrose Esters of Fatty Acids	473	8	10000	mg/kg		Adopt
Tartrates	334; 335i,ii; 336i,ii; 337	8		GMP	Note 45	Adopt
TBHQ	319	8	200	mg/kg	Notes 15 & 130	Revoke
Tocopherols	306, 307	8	500	mg/kg		Adopt
TOSOM	479	8	5000	mg/kg		Revoke
Tripotassium Citrate	332ii	5/8		GMP		Adopt
Trisodium Citrate	331iii	5/8		GMP		Adopt

Food Category No. 11.1.2 Powdered sugar, powdered dextrose						
Additive	INS	Step	Max	Level	Comments	Action
Calcium Aluminium Silicate (Synthetic)	556	8	15000	mg/kg	Note 56	Adopt
Calcium Silicate	552	8	15000	mg/kg	Note 56	Adopt
Caramel Colour, Class III	150c	8		GMP		Revoke
Caramel Colour, Class IV	150d	8		GMP		Revoke
Magnesium Carbonate	504i	8	15000	mg/kg	Note 56	Adopt
Magnesium Silicate (Synthetic)	553i	8	15000	mg/kg	Note 56	Adopt
Phosphates	338; 339i-iii; 340i-iii; 341i-iii; 342i,ii; 343i-iii; 450i-iii,v-vii; 451i,ii; 452i-v; 542	8	6600	mg/kg	Notes 33 & 56	Adopt
Silicon Dioxide (Amorphous)	551	8	15000	mg/kg	Note 56	Adopt
Sodium Aluminosilicate	554	8	15000	mg/kg	Note 56	Adopt

Food Category No. 11.1.3 Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar						
Additive	INS	Step	Max	Level	Comments	Action
Sulphites	220-225, 227, 228, 539	8	20	mg/kg	Notes 44 & 111	Adopt

Food Category No 12.1.1 Salt						
Additive	INS	Step	Max	Level	Comments	Action
Calcium Aluminium Silicate (Synthetic)	556	8		GMP		Adopt
Calcium Carbonate	170i	8		GMP		Adopt
Calcium Silicate	552	8		GMP		Adopt
Ferric Ammonium Citrate	381	8	25	Mg/kg	Note 23	Revoke
Ferrocyanides	535, 536, 538	8	14	Mg/kg	Notes 24 & 107	Adopt
Magnesium Carbonate	504i	8		GMP		Adopt
Magnesium Oxide	530	8		GMP		Adopt
Magnesium Silicate (Synthetic)	553i	8		GMP		Adopt
Phosphates	338; 339i-iii; 340i-iii; 341i-iii; 342i,ii; 343i-iii; 450i-iii,v-vii; 451i,ii; 452i-v; 542	8	8800	Mg/kg	Note 33	Adopt

Food Category No 12.1.1 Salt						
Additive	INS	Step	Max	Level	Comments	Action
Polysorbates	432-436	8	10	mg/kg		Adopt
Salts of Myristic, Palmitic & Stearic Acids (NH ₄ , Ca, K, Na)	470	8	GMP	Note 71		Adopt
Silicon Dioxide (Amorphous)	551	7		GMP		Adopt
Sodium Aluminosilicate	554	8		GMP		Adopt

Food Category No 13.1.1 Infant formulae						
Additive	INS	Step	Max	Level	Comments	Action
Acetylated Distarch Phosphate	1414	8	5000	mg/kg	Notes 72 & 163	Adopt
Ascorbyl Esters	304, 305	8	10	mg/kg	Notes 10 & 72	Adopt
Calcium Hydroxide	526	8		GMP	Note 72	Adopt
Carob Bean Gum	410	8	1000	mg/kg	Notes 72 & 162	Adopt
Carrageenan	407	8	300	mg/kg	Notes 72 & 164	Adopt
Citric Acid	330	8		GMP	Note 72	Adopt
Distarch Phosphate	1412	8	5000	mg/kg	Notes 72 & 163	Adopt
Guar Gum	412	8	1000	mg/kg	Note 72	Adopt
Hydroxypropyl Starch	1440	8	5000	mg/kg	Notes 72 & 163	Adopt
Lactic Acid (L-, D- and DL-)	270	8		GMP	Note 72	Adopt
Lecithins	322	8	5000	mg/kg	Note 72	Adopt
Mono- and Diglycerides	471	8	4000	mg/kg	Note 72	Adopt
Phosphated Distarch Phosphate	1413	8	5000	mg/kg	Notes 72 & 163	Adopt
Potassium Carbonate	501i	8		GMP	Note 72	Adopt
Potassium Dihydrogen Citrate	332i	8		GMP	Note 72	Adopt
Potassium Hydrogen Carbonate	501ii	8		GMP	Note 72	Adopt
Potassium Hydroxide	525	8		GMP	Note 72	Adopt
Sodium Carbonate	500i	8		GMP	Note 72	Adopt
Sodium Dihydrogen Citrate	331i	5/8		GMP	Note 72	Adopt
Sodium Hydrogen Carbonate	500ii	8		GMP	Note 72	Adopt
Sodium Hydroxide	524	8		GMP	Note 72	Adopt
Tocopherols	306	8	10	mg/kg	Note 72	Adopt
Tripotassium Citrate	332ii	8		GMP	Note 72	Adopt
Trisodium Citrate	331iii	8		GMP	Note 72	Adopt

Food Category No 13.1.2 Follow-up formulae						
Additive	INS	Step	Max	Level	Comments	Action
Acetylated Distarch Adipate	1422	8	5000	mg/kg	Notes 72 & 163	Adopt
Acetylated Distarch Phosphate	1414	8	5000	mg/kg	Notes 72 & 163	Adopt
Ascorbic Acid	300	8	50	mg/kg	Note 72	Adopt
Ascorbyl Esters	304, 305	8	50	mg/kg	Notes 10 & 72	Adopt
Calcium Ascorbate	302	8	50	mg/kg	Notes 70 & 72	Adopt
Calcium Hydroxide	526	8		GMP	Note 72	Adopt
Carob Bean Gum	410	8	1000	mg/kg	Note 72	Adopt
Carrageenan	407	8	300	mg/kg	Notes 72 & 164	Adopt
Citric Acid	330	8		GMP	Note 72	Adopt
Distarch Phosphate	1412	8	5000	mg/kg	Notes 72 & 163	Adopt
Guar Gum	412	8	1000	mg/kg	Note 72	Adopt
Lactic Acid (L-, D- and DL-)	270	8		GMP	Note 72	Adopt
Lecithins	322	8	5000	mg/kg	Note 72	Adopt
Mono- and Diglycerides	471	8	4000	mg/kg	Note 72	Adopt
Pectins	440	8	10000	mg/kg	Note 72	Adopt
Phosphated Distarch Phosphate	1413	8	5000	mg/kg	Notes 72 & 163	Adopt
Potassium Carbonate	501i	8		GMP	Note 72	Adopt
Potassium Dihydrogen Citrate	332i	5/8		GMP	Note 72	Adopt
Potassium Hydrogen Carbonate	501ii	8		GMP	Note 72	Adopt
Potassium Hydroxide	525	8		GMP	Note 72	Adopt
Sodium Ascorbate	301	8	50	mg/kg	Notes 70 & 72	Adopt
Sodium Carbonate	500i	8		GMP	Note 72	Adopt
Sodium Dihydrogen Citrate	331i	5/8		GMP	Note 72	Adopt
Sodium Hydrogen Carbonate	500ii	8		GMP	Note 72	Adopt

Food Category No 13.1.2 Follow-up formulae						
Additive	INS	Step	Max	Level	Comments	Action
Sodium Hydroxide	524	8		GMP	Note 72	Adopt
Tocopherols	306, 307	8	30	mg/kg	Note 72	Adopt
Tripotassium Citrate	332ii	8		GMP	Note 72	Adopt
Trisodium Citrate	331iii	8		GMP	Note 72	Adopt

Notes

Note 3: Surface treatment.

Note 9: As total bixin or norbixin.

Note 10: As ascorbyl stearate.

Note 15: Fat or oil basis.

Note 21: As anhydrous calcium disodium EDTA.

Note 23: As iron.

Note 24: As anhydrous sodium ferrocyanide.

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 33: As phosphorus.

Note 34: Anhydrous basis.

Note 42: As sorbic acid.

Note 44: As residual SO₂.

Note 45: As tartaric acid.

Note 56: Provided starch is not present.

Note 70: As the acid.

Note 72: Ready-to-eat basis.

Note 77: As mono-isopropyl citrate.

Note 80: Equivalent to 2 mg/dm² surface application to a maximum depth of 5 mm.

Note 107: Except for use of sodium ferrocyanide (INS 535) and potassium ferrocyanide (INS 536) in food-grade dendridic salt at 29 mg/kg as anhydrous sodium ferrocyanide.

Note 111: Excluding dried glucose syrup used in the manufacture of sugar confectionery at 150 mg/kg and glucose syrup used in the manufacture of sugar confectionery at 400 mg/kg.

Note 130: Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), Tertiary Butylated Hydroquinone (TBHQ, INS 319), and Propyl Gallate (INS 310).

Note 133: Any combination of Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), and Propyl Gallate (INS 310) at 200 mg/kg, provided that single use limits are not exceeded.

Note 146: Use level for synthetic β-Carotene (INS 160ai); 35 mg/kg for β-Apo-8-carotenal (INS 160e) and β-Apo-8-carotenoic acid, methyl or ethyl ester (INS 160f).

Note 160: Excluding whey powders for infant food.

Note 161: Use as an antioxidant synergist.

Note 162: Use temporarily endorsed.

Note 163: Use level for soy-based formula; 25,000 mg/kg for hydrolyzed protein and/or amino acid-based formula.

Note 164: Use level for soy-based formula; 1,000 mg/kg for hydrolyzed protein and/or amino acid-based formula.

PROPOSED REVISION TO THE ANNEX TO TABLE 3**FOOD CATEGORIES OR INDIVIDUAL FOOD ITEMS EXCLUDED FROM THE GENERAL
CONDITIONS OF TABLE THREE - AMENDED**

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

Category Number	Food Category
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
01.6.3	Whey cheese
01.6.6	Whey protein cheese
01.8.2	Dried whey and whey products, excluding whey cheese
02.1	Fats and oils essentially free from water
02.2.1.1	Butter and concentrated butter
02.2.1.2	Margarine
04.1.1	Fresh fruit
04.2.1	Fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10
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 and salt substitutes
12.2.1	Herbs and spices (<u>Only</u> herbs)
13.1	Infant formulae, follow-up formulae, and formulae for special medical purposes for infants
13.2	Complementary foods for infants and young children
14.1.1	Waters
14.1.2	Fruit and vegetable juices

**Category
Number** **Food Category**

14.1.3	Fruit and vegetable nectars
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal beverages, excluding cocoa
14.2.3	Grape wines

PROPOSALS TO REVISE COMMODITY STANDARDS WITH A ONE TO ONE RELATIONSHIP WITH A GSFA FOOD CATEGORY

(text that refers to the provision of the relevant GSFA food categories)

(The text is in the form of “Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in food category x.x.x.x (food category name) may be used in foods subject to this standard”.)

032-1981 Rev. 1-1989 Margarine

Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Category 02.2.1.2 (Margarine and similar products) may be used in foods subject to this standard.

072-1981 (4th Amendment 1997) Infant Formula

Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Category 13.1.1 (Infant formulae) may be used in foods subject to this standard.

150-1985 Food Grade Salt

Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Category 12.1.1 (Salt) may be used in foods subject to this standard.

156-1987 (Amended 1989) Follow-up Formula

Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Category 13.1.2 (Follow-up formulae) may be used in foods subject to this standard.

212-1999 (Amended 2001) Sugars

Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Category 11.1.1 (White sugar, dextrose anhydrous, dextrose monohydrate, fructose), 11.1.2 (Powdered sugar, powdered dextrose), 11.1.3 (Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar), 11.1.4 (lactose), and 11.1.5 (Plantation or mill white sugar) may be used in foods subject to this standard.

A-01-1971 Ref. 1-1989 Butter

Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Category 02.2.1.1 (Butter and concentrated butter) may be used in foods subject to this standard.

A-02-1973 Rev.1 – 1989 Milkfat Products

Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Category 02.1.1 (Butter oil, anhydrous milkfat, ghee) may be used in foods subject to this standard.

A-07-1971 Rev. 1-1999 Whey Cheeses

Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Category 01.6.3 (Whey cheese) and 01.6.6 (Whey protein cheese) may be used in foods subject to this standard.

A-15-1995 Rev.1-2003 Whey Powders

Food additives listed in Tables 1 and 2 of the Codex General Standard for Food Additives in Food Category 01.8.2 (Dried whey and whey products, excluding whey cheese) may be used in foods subject to this standard.

Appendix X

CODEX GENERAL STANDARD FOR FOOD ADDITIVES
REQUEST FOR ADDITIONAL INFORMATION

EDTAs						
Calcium Disodium Ethylene Diamine		INS: 385	Disodium Ethylene Diamine Tetra Acetate		INS: 386	
Tetra Acetate						
Function: Antioxidant, Preservative, Sequestrant						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	25	mg/kg	Note 21	6	Technological need and safety issues

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	Information Requested
04.1.2.5	jams, jellies and marmelades	1500	mg/kg	Note 13	3	Justification for use level: is it carry over from ingredient?

QUILLAIA EXTRACT						
Quillaia Extract		INS: 999				
Function: Foaming Agent						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	200	mg/kg	Note 132	6	Quillaia Type 1 or 2? Use level on saponin basis

BHA						
Butylated Hydroxyanisole		INS: 320				
Function: Antioxidant						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	200	mg/kg	Notes 15 & 130	6	Information to address intake by children
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	200	mg/kg	Notes 15 & 130	6	

BHT Butylated Hydroxytoluene Function: Adjuvant, Antioxidant INS: 321						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	200	mg/kg	Notes 15 & 130	6	Information to address intake by children
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	200	mg/kg	Notes 15 & 130	6	
08.2	processed meat, poultry, and game products in whole pieces or cuts	100	mg/kg	Notes 15 & 130	6	Information on limiting to dehydrated products
08.3	processed comminuted meat, poultry, and game products	100	mg/kg	Notes 15 & 130	6	

TBHQ Tertiary Butylhydroquinone Function: Antioxidant INS: 319						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
08.2	processed meat, poultry, and game products in whole pieces or cuts	100	mg/kg	Notes 15 & 130	6	Information regarding limiting to dehydrated products
08.3	processed comminuted meat, poultry, and game products	100	mg/kg	Notes 15 & 130	6	

DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL Diacetyltartaric and Fatty Acid Esters of Glycerol Function: Emulsifier, Sequestrant, Stabilizer INS: 472e						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.4	cream (plain) and the like	5000	mg/kg		6	Technological need
06.2	flours and starches (including soybean powder)	5000	mg/kg		6	
06.4.2	dried pastas and noodles and like products	5000	mg/kg		6	
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	10000	mg/kg	Note 16	3	
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	10000	mg/kg	Note 16	3	
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	5000	mg/kg		3	

POLYDIMETHYLSILOXANE Polydimethylsiloxane Function: Anticaking Agent, Antifoaming Agent INS: 900a						
Food Cat No.	Food Category	Max	Level	Comments	Step	Comments
12.9.1.3	other soybean products (including non-fermented soy sauce)	50	mg/kg		3	Technological need

SULPHITES						
Sulphur Dioxide		INS: 220	Sodium Sulphite		INS: 221	
Sodium Hydrogen Sulphite		INS: 222	Sodium Metabisulphite		INS: 223	
Potassium Metabisulphite		INS: 224	Potassium Sulphite		INS: 225	
Calcium Hydrogen Sulphite		INS: 227	Potassium Bisulphite		INS: 228	
Sodium Thiosulphate		INS: 539				
Function: Acidity Regulator, Adjuvant, Antioxidant, Bleaching Agent (Not for Flour), Flour Treatment Agent, Firming Agent, Preservative, Sequestrant, Stabilizer						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
04.1.2.1	frozen fruit	500	mg/kg	Note 44	6	Technological need
04.1.2.4	canned or bottled (pasteurized) fruit	350	mg/kg	Note 44	6	
04.1.2.5	jams, jellies and marmelades	500	mg/kg	Note 44	6	
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	750	mg/kg	Note 44	6	
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	50	mg/kg	Note 44	6	
07.1.1	bread and rolls	50	mg/kg	Note 44	6	
07.1.3	other ordinary bakery products (e.g., bagels, pita, English muffins)	50	mg/kg	Note 44	6	
07.1.4	bread-type products, including bread stuffing and bread crumbs	50	mg/kg	Note 44	6	
09.2.4.2	cooked mollusks, crustaceans, and echinoderms	30	mg/kg	Note 44	6	Technological need in cooked products; is it carry over from raw products? Clarification whether treatment reduces level.
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	30	mg/kg	Note 44	6	
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	300	mg/kg	Notes 44 & 140	6	
11.3	<u>Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3</u>	70	mg/kg	Note 44	6	Technological need
12.4	mustards	250	mg/kg	Notes 44 & 106	6	
12.5	soups and broths	1000	mg/kg	Note 44	6	
12.6	sauces and like products	300	mg/kg	Note 44	6	
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	350	mg/kg	Note 44	6	
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	500	mg/kg	Note 44	6	
16.0	composite foods - foods that could not be placed in categories 01 – 15	350	mg/kg	Note 44	6	

CANTHAXANTHIN						
Canthaxanthin		INS: 161g				
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms		GMP		6	Technological need (incl. numerical use level)
09.2.4.1	<u>cooked fish and fish products</u>	200	mg/kg		6	Technological need
14.1.4.3	concentrates (liquid or solid) for water-based flavoured drinks	100	mg/kg		6	
14.2.6	distilled spirituous beverages containing more than 15% alcohol	5	mg/kg		6	
15.1	<u>snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)</u>		GMP		6	

ERYTHROSINE						
Erythrosine		INS: 127				
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	300	mg/kg		6	Technological need
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	300	mg/kg		6	
02.1.3	lard, tallow, fish oil, and other animal fats	300	mg/kg		3	
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	300	mg/kg		6	
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	300	mg/kg		6	
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	300	mg/kg		6	
05.3	chewing gum	200	mg/kg		6	
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	300	mg/kg		6	
06.3	breakfast cereals, including rolled oats	300	mg/kg		6	
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	300	mg/kg		6	
08.2	processed meat, poultry, and game products in whole pieces or cuts	30	mg/kg		6	
08.3	processed comminuted meat, poultry, and game products	30	mg/kg		6	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	300	mg/kg		6	
12.2	herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	300	mg/kg		6	
13.6	food supplements	300	mg/kg		6	
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	300	mg/kg		6	

IRON OXIDES						
Iron Oxide, Black		INS: 172i		Iron Oxide, Red		INS: 172ii
Iron Oxide, Yellow		INS: 172iii				
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.4	cream (plain) and the like		GMP		6	Technological need (incl. numerical use level)
01.6.1	unripened cheese		GMP		6	
04.2.2.6	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5		GMP		6	
05.1.3	cocoa-based spreads, including fillings		GMP		6	
05.3	chewing gum	10000	mg/kg		6	Technological need
08.3.1.3	fermented non-heat treated processed comminuted meat, poultry, and game		GMP	Note 16	6	Technological need (incl.

IRON OXIDES						
Iron Oxide, Black Iron Oxide, Yellow Function: Colour		INS: 172i INS: 172iii	Iron Oxide, Red		INS: 172ii	
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
	products					numerical use level)
08.3.2	heat-treated processed comminuted meat, poultry, and game products		GMP	Note 16	6	
08.3.3	frozen processed comminuted meat, poultry, and game products		GMP	Note 16	6	
09.1.1	fresh fish		GMP	Note 50	6	
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms		GMP	Note 95	6	
09.2.4.2	cooked mollusks, crustaceans, and echinoderms		GMP		6	
10.4	egg-based desserts (e.g., custard)		GMP		6	
12.4	mustards		GMP		6	
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		GMP		6	
12.9.5	other protein products		GMP		6	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)		GMP		6	
13.4	dietetic formulae for slimming purposes and weight reduction		GMP		6	
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6		GMP		6	
13.6	food supplements		GMP		6	
14.1.3.2	vegetable nectar		GMP		6	
14.1.3.4	concentrates for vegetable nectar		GMP		6	
14.2.2	cider and perry		GMP		6	
14.2.3.2	sparkling and semi-sparkling grape wines		GMP		6	
14.2.4	wines (other than grape)		GMP		6	
14.2.6	distilled spirituous beverages containing more than 15% alcohol		GMP		6	
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)		GMP		6	

BRILLIANT BLUE FCF						
Brilliant Blue FCF Function: Colour		INS: 133				
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
04.1.1.2	surface-treated fresh fruit	500	mg/kg	Note 16	6	Technological need

CARMINES						
Carmines Function: Colour		INS: 120				
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.6.5	cheese analogues		GMP	Note 3	6	Technological need
07.1	bread and ordinary bakery wares		GMP		6	

CAROTENES, VEGETABLE						
Carotenes, Natural Extracts, (Vegetable) INS: 160aii						
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
04.1.1.2	surface-treated fresh fruit		GMP	Note 16	6	Technological need (incl. numerical use level)
05.1.3	cocoa-based spreads, including fillings	1000	mg/kg		3	Technological need
05.1.4	cocoa and chocolate products	1000	mg/kg		3	
05.1.4	cocoa and chocolate products	500	mg/kg		6	
09.1.2	fresh mollusks, crustaceans, and echinoderms		GMP	Note 16	6	Technological need (incl. numerical use level)
12.10.3	fermented soybean paste (e.g., miso)		GMP		6	Technological need
13.1.3	formulae for special medical purposes for infants	30	mg/kg	Note 84	3	
14.1.2.2	vegetable juice	2000	mg/kg		3	
14.1.2.4	Concentrates for vegetable juice	2000	mg/kg		3	
15.1	snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	25	mg/kg		6	
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	20000	mg/kg		3	
16.0	composite foods - foods that could not be placed in categories 01 – 15	1000	mg/kg		3	

CASTOR OIL						
Castor Oil INS: 1503						
Function: Anticaking Agent, Carrier Solvent, Glazing Agent, Release Agent						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
05.1	cocoa products and chocolate products including imitations and chocolate substitutes		GMP		6	Technological need (incl. numerical use level)
13.6	food supplements		GMP		6	

CHLOROPHYLLS, COPPER COMPLEXES						
Chlorophylls, Copper Complex INS: 141i Chlorophyllin Copper Complex, Sodium and Potassium Salts INS: 141ii						
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.6.2.1	ripened cheese, includes rind	15	mg/kg		6	Technological need
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	200	mg/kg		6	
04.1.1.2	surface-treated fresh fruit		GMP	Note 16	6	Technological need (incl. numerical use level)
04.1.2.5	jams, jellies and marmelades	200	mg/kg		6	Technological need
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	150	mg/kg		6	
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	150	mg/kg	Note 62	6	
05.1.2	cocoa mixes (syrups)	6.4	mg/kg	Note 62	3	
05.1.3	cocoa-based spreads, including fillings	6.4	mg/kg	Note 62	3	
05.1.4	cocoa and chocolate products	700	mg/kg		6	
05.1.5	imitation chocolate, chocolate substitute products	700	mg/kg		6	

CHLOROPHYLLS, COPPER COMPLEXES						
Chlorophylls, Copper Complex		INS: 141i		Chlorophyllin Copper Complex, Sodium and Potassium Salts		INS: 141ii
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms		GMP	Note 95	6	Technological need (incl. numerical use level)
13.6	food supplements		GMP		6	

GRAPE SKIN EXTRACT						
Grape Skin Extract		INS: 163ii				
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.3.2	beverage whiteners	1500	mg/kg		3	Technological need
01.4	cream (plain) and the like	1500	mg/kg		3	
01.5.2	milk and cream powder analogues	1500	mg/kg		3	
01.6.1	unripened cheese	1000	mg/kg		3	
01.6.2.1	ripened cheese, includes rind	125	mg/kg		6	
03.0	edible ices, including sherbet and sorbet	1000	mg/kg		3	
04.2.2.5	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	1500	mg/kg		3	
04.2.2.6	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	1500	mg/kg		3	
04.2.2.7	fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10	1500	mg/kg		3	
07.0	bakery wares	1500	mg/kg		3	
08.2	processed meat, poultry, and game products in whole pieces or cuts	5000	mg/kg		3	
08.3.1.1	cured (including salted) non-heat treated processed comminuted meat, poultry, and game products	5000	mg/kg		3	
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg		3	
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms		GMP	Note 16	6	Technological need (incl. numerical use level)
09.2.4.1	cooked fish and fish products	500	mg/kg		3	Technological need
12.4	mustards	500	mg/kg		3	
13.1.3	formulae for special medical purposes for infants	20	mg/kg	Note 84	3	
16.0	composite foods - foods that could not be placed in categories 01 – 15	1500	mg/kg		3	

POLYSORBATES						
Polyoxyethylene (20) Sorbitan Monolaurate		INS: 432	Polyoxyethylene (20) Sorbitan Monooleate		INS: 433	
Polyoxyethylene (20) Sorbitan Monopalmitate		INS: 434	Polyoxyethylene (20) Sorbitan Monostearate		INS: 435	
Polyoxyethylene (20) Sorbitan Tristearate		INS: 436				
Function: Antifoaming Agent, Adjuvant, Emulsifier, Foaming Agent, Flour Treatment Agent, Stabilizer						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
07.1.1	bread and rolls	3000	mg/kg		6	Technological need
07.1.2	crackers, excluding sweet crackers	5000	mg/kg	Note 11	6	
07.1.3	other ordinary bakery products (e.g., bagels, pita, English muffins)	10000	mg/kg	Note 11	6	
07.1.4	bread-type products, including bread stuffing and bread crumbs	5000	mg/kg	Note 11	6	
07.1.5	steamed breads and buns	5000	mg/kg	Note 11	6	
07.1.6	mixes for breads and ordinary bakery wares	5000	mg/kg	Note 11	6	
07.2	fine bakery wares (sweet, salty, savoury) and mixes	5000	mg/kg		6	
14.1.4	water-based flavoured drinks, including "sport," "energy" or "electrolyte" drinks and particulated drinks	10000	mg/kg		3	

RIBOFLAVINS						
Riboflavin 5'-Phosphate, Sodium		INS: 101i	Riboflavin 5'-Phosphate		INS: 101ii	
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	300	mg/kg		3	Technological Need
08.0	meat and meat products, including poultry and game	1000	mg/kg		6	
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms		GMP	Note 95	6	Technological need (incl. numerical use level)

CARAMEL COLOUR, CLASS III						
Caramel Colour, Class III - Ammonia		INS: 150c				
Process						
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.6.1	unripened cheese	50000	mg/kg		3	Technological need
01.6.2	ripened cheese	50000	mg/kg		3	
01.6.4	processed cheese	50000	mg/kg		3	
01.6.5	Cheese analogues	50000	mg/kg		3	
02.1.2	vegetable oils and fats	20000	mg/kg		3	
02.1.3	lard, tallow, fish oil, and other animal fats	20000	mg/kg		3	
02.2.1.3	Blends of butter and margarine	20000	mg/kg		3	
02.2.2	emulsions containing less than 80% fat	20000	mg/kg		3	
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	20000	mg/kg		3	
04.1.2	processed fruit	80000	mg/kg		3	
04.2.2	processed vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	80000	mg/kg		3	
04.2.2.2	dried vegetables (including mushrooms and		GMP	Note 76	6	Technological

CARAMEL COLOUR, CLASS III						
Caramel Colour, Class III - Ammonia INS: 150c						
Process						
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
	fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds					need (incl. numerical use level)
04.2.2.7	fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10		GMP		6	
05.0	Confectionery	50000	mg/kg		3	Technological need
05.1.1	cocoa mixes (powders) and cocoa mass/cake		GMP		6	Technological need (incl. numerical use level)
05.1.4	cocoa and chocolate products		GMP		6	
06.4.2	dried pastas and noodles and like products	50000	mg/kg		3	Technological need
06.4.3	pre-cooked pastas and noodles and like products	50000	mg/kg		3	
07.1.2	crackers, excluding sweet crackers	50000	mg/kg		3	
07.1.3	other ordinary bakery products (e.g., bagels, pita, English muffins)	50000	mg/kg		3	
07.1.4	bread-type products, including bread stuffing and bread crumbs	50000	mg/kg		3	
07.1.5	steamed breads and buns	50000	mg/kg		3	
07.1.6	mixes for breads and ordinary bakery wares	50000	mg/kg		3	
08.0	meat and meat products, including poultry and game	200000	mg/kg	Note 16	3	
09.1	fresh fish and fish products, including mollusks, crustaceans, and echinoderms	30000	mg/kg	Note 16	3	
09.2	processed fish and fish products, including mollusks, crustaceans, and echinoderms	30000	mg/kg		3	
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	30000	mg/kg		3	
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	30000	mg/kg		3	Technological need; should Note 50 be added?
10.2	egg products	20000	mg/kg		3	Technological need
10.3	dried and/or heat coagulated egg products	20000	mg/kg		3	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	50000	mg/kg		3	
12.2.2	seasonings and condiments		GMP			Technological need (incl. numerical use level)
14.1.2.2	vegetable juice	50000	mg/kg		3	Justification for use level
14.1.2.4	concentrates for vegetable juice	50000	mg/kg		3	
14.1.5	coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	100000	mg/kg		3	Technological need
14.2	alcoholic beverages, including alcohol-free and low-alcoholic counterparts	50000	mg/kg		3	
16.0	composite foods - foods that could not be placed in categories 01 – 15	20000	mg/kg		3	Justification for level; is carry over sufficient?

CARAMEL COLOUR, CLASS IV						
Caramel Colour, Class IV - Ammonia INS: 150d Sulphite Process Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.6.1	unripened cheese	50000	mg/kg		3	Technological need
01.6.2	ripened cheese	50000	mg/kg		3	
01.6.4	processed cheese	50000	mg/kg		3	
01.6.5	cheese analogues	50000	mg/kg		3	
04.1.2	processed fruit	80000	mg/kg		3	
04.2.2	processed vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	80000	mg/kg		3	Justification for high use level
05.0	confectionery	50000	mg/kg		3	Technological need
05.1.1	cocoa mixes (powders) and cocoa mass/cake		GMP		6	Technological need (incl. numerical use level)
05.1.4	cocoa and chocolate products		GMP		6	
08.0	meat and meat products, including poultry and game	200000	mg/kg	Note 16	3	Technological need
09.1	fresh fish and fish products, including mollusks, crustaceans, and echinoderms	30000	mg/kg	Note 16	3	
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	30000	mg/kg		3	Technological need; should Note 50 be added?
14.1.2.2	vegetable juice	50000	mg/kg		3	Justification for use level
14.2	alcoholic beverages, including alcohol-free and low-alcoholic counterparts	50000	mg/kg		3	Technological need
16.0	composite foods - foods that could not be placed in categories 01 - 15	20000	mg/kg		3	Justification for level; is carry over sufficient?

FAST GREEN FCF						
Fast Green FCF INS: 143 Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
04.2.2.7	fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10	300	mg/kg		3	Technological need
06.4.2	dried pastas and noodles and like products	100	mg/kg		6	
06.4.3	pre-cooked pastas and noodles and like products	100	mg/kg		6	
07.0	bakery wares	100	mg/kg		6	
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	100	mg/kg		6	
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms	100	mg/kg	Note 16	6	

ALLURA RED AC						
Allura Red AC		INS: 129				
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.6.1	unripened cheese	200	mg/kg	Note 3	3	Is the colour application on the cheese or only in the coating?
01.6.5	cheese analogues	300	mg/kg	Note 3	3	
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions		GMP		6	Technological need (incl. numerical use level)
04.1.2.5	jams, jellies and marmelades	500	mg/kg		6	Technological need
04.1.2.7	candied fruit	300	mg/kg		6	
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	800	mg/kg		6	
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	300	mg/kg		6	
04.1.2.11	fruit fillings for pastries	800	mg/kg		6	
04.2.2.4	canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	200	mg/kg		6	
04.2.2.6	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	200	mg/kg		6	
05.1.3	cocoa-based spreads, including fillings	300	mg/kg		6	Technological need
05.1.4	cocoa and chocolate products	300	mg/kg		6	
06.2	Flours and starches (including soybean powder)	500	mg/kg		6	
07.1.2	Crackers, excluding sweet crackers	300	mg/kg		6	
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	300	mg/kg		6	
08.1.1	fresh meat, poultry, and game, whole pieces or cuts	500	mg/kg	Note 16	6	
08.1.1	fresh meat, poultry, and game, whole pieces or cuts		GMP	Note 4	6	
08.1.2	fresh meat, poultry, and game, comminuted	25	mg/kg		6	Technological need
08.3.2	heat-treated processed comminuted meat, poultry, and game products	25	mg/kg		6	
08.4	edible casings (e.g., sausage casings)	500	mg/kg	Note 16	6	Technological need (incl. numerical use level)
08.4	edible casings (e.g., sausage casings)		GMP		6	
14.2.2	cider and perry	200	mg/kg		6	Technological need
14.2.4	wines (other than grape)	200	mg/kg		6	
16.0	composite foods - foods that could not be placed in categories 01 – 15	500	mg/kg		6	

CAROTENOIDS						
Beta-Carotene (Synthetic)		INS: 160ai	Beta-Carotene (<i>Blakeslea trispora</i>)		INS: 160aii	
Beta-Apo-8'-Carotenal		INS: 160e	Beta-Apo-8'-Carotenoic Acid, Methyl or Ethyl Ester		INS: 160f	
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.3.2	beverage whiteners	1000	mg/kg		3	Technological need
01.4	cream (plain) and the like	1000	mg/kg		3	
02.2.1.3	blends of butter and margarine		GMP		6	Numerical use level
02.2.2	emulsions containing less than 80% fat	1000	mg/kg		6	Technological need
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	1000	mg/kg		6	
05.1.1	cocoa mixes (powders) and cocoa mass/cake	300	mg/kg		6	Technological need
05.1.2	cocoa mixes (syrops)	300	mg/kg		6	
05.1.3	cocoa-based spreads, including fillings	300	mg/kg		6	
05.1.4	cocoa and chocolate products	500	mg/kg		6	
05.1.5	imitation chocolate, chocolate substitute products	500	mg/kg		6	
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	500	mg/kg		6	
09.1.1	fresh fish	300	mg/kg		6	
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg		3	
09.3.3	salmon substitutes, caviar, and other fish roe products	500	mg/kg		6	
09.3.4	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	500	mg/kg		6	
10.2	egg products	1000	mg/kg		3	
10.4	egg-based desserts (e.g., custard)	150	mg/kg		6	
12.2.2	seasonings and condiments	500	mg/kg		6	
12.9.5	other protein products	100	mg/kg		6	
14.1.3.2	vegetable nectar	100	mg/kg		6	
14.1.3.4	concentrates for vegetable nectar	100	mg/kg		6	
14.2.2	cider and perry	200	mg/kg		6	
14.2.4	wines (other than grape)	200	mg/kg		6	
14.2.6	distilled spirituous beverages containing more than 15% alcohol	200	mg/kg		6	
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	200	mg/kg		6	

INDIGOTINE						
Indigotine		INS: 132				
Function: Colour						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
02.1.3	lard, tallow, fish oil, and other animal fats	200	mg/kg		3	Justification for use level
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	300	mg/kg		6	Technological need
05.1.3	cocoa-based spreads, including fillings	100	mg/kg		6	
05.1.4	cocoa and chocolate products	450	mg/kg		6	
11.3	sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	300	mg/kg		6	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	300	mg/kg		6	

INDIGOTINE Indigotine Function: Colour INS: 132						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
11.6	table-top sweeteners, including those containing high-intensity sweeteners	300	mg/kg		6	
14.2.2	cider and perry	200	mg/kg		6	
14.2.4	wines (other than grape)	200	mg/kg		6	

PONCEAU 4R Ponceau 4R Function: Colour INS: 124						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
11.6	table-top sweeteners, including those containing high-intensity sweeteners	200	mg/kg		6	Justification of use level
14.2.4	wines (other than grape)	200	mg/kg		6	
14.2.6	distilled spirituous beverages containing more than 15% alcohol	200	mg/kg		6	

SUNSET YELLOW FCF Sunset Yellow FCF Function: Colour INS: 110						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.6.1	unripened cheese		GMP	Note 3	6	Numerical use level
01.6.5	cheese analogues		GMP	Note 3	6	
02.1.3	lard, tallow, fish oil, and other animal fats		GMP		6	Technological need (incl. numerical use level)
14.1.2.2	vegetable juice		GMP		6	Numerical use level

ASPARTAME Aspartame Function: Flavor Enhancer, Sweetener INS: 951						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.2	fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy based drinks)	2000	mg/kg		6	Technological need
01.4.1	pasteurized cream (plain)	6000	mg/kg		3	
01.4.2	sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	6000	mg/kg		3	
01.4.3	clotted cream (plain)	6000	mg/kg		3	
01.5.1	milk powder and cream powder (plain)	5000	mg/kg		3	
01.6.1	unripened cheese	1000	mg/kg		3	
07.1	bread and ordinary bakery wares	4000	mg/kg		6	
08.2	processed meat, poultry, and game products in whole pieces or cuts	300	mg/kg		6	
08.3	processed comminuted meat, poultry, and game products	300	mg/kg		6	
09.2	processed fish and fish products, including mollusks, crustaceans, and echinoderms	300	mg/kg		6	
10.2.3	dried and/or heat coagulated egg products	1000	mg/kg		6	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	3000	mg/kg		6	
12.6.1	emulsified sauces (e.g., mayonnaise, salad	500	mg/kg		6	

ASPARTAME						
Aspartame		INS: 951				
Function: Flavor Enhancer, Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
	dressing)					
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	350	mg/kg		6	
12.6.3	mixes for sauces and gravies	350	mg/kg		6	
12.6.4	clear sauces (e.g., fish sauce)	350	mg/kg		6	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	1000	mg/kg		6	
14.2.4	wines (other than grape)	700	mg/kg		6	
14.2.5	Mead	700	mg/kg		6	
14.2.6	distilled spirituous beverages containing more than 15% alcohol	700	mg/kg		6	

ACESULFAME POTASSIUM						
Acesulfame Potassium		INS: 950				
Function: Flavour Enhancer, Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.2	fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy based drinks)	500	mg/kg		3	Technological need
01.4	cream (plain) and the like	1000	mg/kg		3	
01.5	milk powder and cream powder and powder analogues (plain)	3000	mg/kg		3	
01.6.1	unripened cheese	500	mg/kg		3	
06.1	whole, broken, or flaked grain, including rice	300	mg/kg		3	
06.4.2	dried pastas and noodles and like products	200	mg/kg		3	
06.4.3	pre-cooked pastas and noodles and like products	200	mg/kg		3	
07.1	bread and ordinary bakery wares	1000	mg/kg		3	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1000	mg/kg		6	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	1000	mg/kg		6	
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	500	mg/kg		6	
12.6.3	mixes for sauces and gravies	1000	mg/kg		6	
12.6.4	clear sauces (e.g., fish sauce)	500	mg/kg		6	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	450	mg/kg		6	
14.2.3	grape wines	500	mg/kg		3	
14.2.4	wines (other than grape)	500	mg/kg		3	
14.2.5	Mead	500	mg/kg		3	
14.2.6	distilled spirituous beverages containing more than 15% alcohol	350	mg/kg		3	
16.0	composite foods - foods that could not be placed in categories 01 – 15	350	mg/kg		3	

SUCRALOSE						
Sucralose		INS: 955				
Function: Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.2.1	fermented milks (plain)	400	mg/kg		3	Technological

SUCRALOSE						
Sucralose		INS: 955				
Function: Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.2.1.2	fermented milks (plain), heat-treated after fermentation	250	mg/kg		6	need
01.2.2	Renneted milk (plain)		GMP		6	Technological need (incl. numerical use level)
01.3.1	Condensed milk (plain)		GMP		6	
01.4	cream (plain) and the like	580	mg/kg		3	Technological need
01.5	Milk powder and cream powder and powder analogues (plain)		GMP		6	Technological need (incl. numerical use level)
01.6	Cheese and analogues		GMP		6	Technological need excl. 01.6.3, 01.6.6 & 01.8.2 (incl. numerical use level)
01.8	Whey and whey products, excluding whey cheeses		GMP		6	
06.6	batters (e.g., for breading or batters for fish or poultry)	600	mg/kg		6	Technological need
06.7	pre-cooked or processed rice products, including rice cakes (Oriental type only)	600	mg/kg		6	
07.1	bread and ordinary bakery wares	750	mg/kg		6	
11.3	sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	1500	mg/kg		6	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1500	mg/kg		6	
12.2.1	herbs and spices	400	mg/kg		3	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	450	mg/kg		6	
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	450	mg/kg		6	
12.6.3	mixes for sauces and gravies	450	mg/kg	Note 127	6	
12.6.4	clear sauces (e.g., fish sauce)	450	mg/kg		6	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	400	mg/kg		6	
14.2	alcoholic beverages, including alcohol-free and low-alcoholic counterparts	700	mg/kg		6	

SACCHARIN						
Saccharin		INS: 954		Saccharin (and Sodium, Potassium, Calcium Salts)		INS: 954
Function: Flavour Enhancer, Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.2.1	fermented milks (plain)	200	mg/kg		6	Technological need
01.2.2	renneted milk (plain)	100	mg/kg		6	
01.6.1	unripened cheese	100	mg/kg		6	
07.1.3	other ordinary bakery products (e.g., bagels, pita, English muffins)	15	mg/kg		6	
08.2.1.1	cured (including salted) non-heat treated processed meat, poultry, and game products in whole pieces or cuts	2000	mg/kg		6	
08.2.2	heat-treated processed meat, poultry, and game products in whole pieces or cuts	500	mg/kg		6	
08.3.2	heat-treated processed comminuted meat, poultry, and game products	500	mg/kg		6	

SACCHARIN						
Saccharin		INS: 954	Saccharin (and Sodium, Potassium, Calcium Salts)		INS: 954	
Function: Flavour Enhancer, Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
09.2.4.1	cooked fish and fish products	500	mg/kg		6	
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	1200	mg/kg		6	
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	160	mg/kg	Note 144	6	
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	160	mg/kg	Note 144	6	
09.3.3	salmon substitutes, caviar, and other fish roe products	160	mg/kg		6	
09.3.4	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	160	mg/kg	Note 144	6	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	300	mg/kg		6	
12.9.1.3	other soybean products (including non-fermented soy sauce)	500	mg/kg		6	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	400	mg/kg		6	
16.0	composite foods - foods that could not be placed in categories 01 – 15	200	mg/kg		6	

ALITAME						
Alitame		INS: 956				
Function: Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.2	fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy based drinks)	60	mg/kg		6	Technological need
01.4	cream (plain) and the like	100	mg/kg		6	
05.0	Confectionery	300	mg/kg		6	
07.0	bakery wares	200	mg/kg		6	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)		GMP		6	Technological need (incl. numerical use level)

NEOTAME						
Neotame		INS: 961				
Function: Flavour Enhancer, Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.2	fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy based drinks)	65	mg/kg		3	Technological need
01.4.1	pasteurized cream (plain)		GMP		3	
01.4.2	sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)		GMP		3	Technological need (incl. numerical use level)
01.4.3	clotted cream (plain)		GMP		3	
01.5.1	milk powder and cream powder (plain)		GMP		3	

NEOTAME						
Neotame		INS: 961				
Function: Flavour Enhancer, Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.6.1	unripened cheese	33	mg/kg		3	Technological need
07.1	bread and ordinary bakery wares	70	mg/kg		3	
08.2	processed meat, poultry, and game products in whole pieces or cuts	10	mg/kg		3	
08.3	processed comminuted meat, poultry, and game products	10	mg/kg		3	
09.2	processed fish and fish products, including mollusks, crustaceans, and echinoderms	10	mg/kg		3	
10.2.3	dried and/or heat coagulated egg products	33	mg/kg		3	
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	100	mg/kg		3	
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	65	mg/kg		3	
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	70	mg/kg		3	
12.6.3	mixes for sauces and gravies	12	mg/kg		3	
12.6.4	clear sauces (e.g., fish sauce)	12	mg/kg		3	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	33	mg/kg		3	
14.2.4	wines (other than grape)	23	mg/kg		3	
14.2.5	Mead	23	mg/kg		3	
14.2.6	distilled spirituous beverages containing more than 15% alcohol	23	mg/kg		3	

POLYVINYL ALCOHOL						
Polyvinyl Alcohol		INS: 1203				
Function: Glazing Agent, Stabilizer						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	2000	mg/kg		3	Justification for the use as glazing agent
05.1.4	cocoa and chocolate products	15000	mg/kg		3	
06.3	breakfast cereals, including rolled oats	5000	mg/kg		3	
15.2	processed nuts, including covered nuts and nut mixtures (with e.g., dried fruit)	15000	mg/kg		3	

CYCLAMATES						
Cyclamic Acid (and Sodium, Potassium, Calcium Salts)		INS: 952				
Function: Flavour Enhancer, Sweetener						
Food Cat No.	Food Category	Max	Level	Comments	Step	Information Requested
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	500	mg/kg	Note 17	6	Technological need
12.6.1	emulsified sauces (e.g., mayonnaise, salad dressing)	500	mg/kg	Note 17	6	
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)	400	mg/kg	Note 17	6	

Notes to the Comments for the Revised Draft General Standard for Food Additives (38th CCFAC)

Note 3: Surface treatment.

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

Note 11: Flour basis.

Note 13: As benzoic acid.

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 21: As anhydrous calcium disodium EDTA.

Note 44: As residual SO₂.

Note 50: For use in fish roe only.

Note 62: As copper.

Note 76: Use in potatoes only.

Note 84: For infants over 1 year of age only.

Note 95: For use in surimi and fish roe products only.

Note 106: Except for use in Dijon mustard at 500 mg/kg.

Note 127: As served to the consumer.

Note 130: Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), Tertiary Butylated Hydroquinone (TBHQ, INS 319), and Propyl Gallate (INS 310).

Note 132: Except for use at 500 mg/kg (dried basis) in semi-frozen beverages.

Note 140: Except for use in canned abalone (PAUA) at 1000 mg/kg.

Note 144: For use in sweet and sour products only.

Appendix XI

**DRAFT (AT STEP 8) AND PROPOSED DRAFT (AT STEP 5/8) FOOD ADDITIVE PROVISIONS
FOR INCLUSION IN THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES**

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
05.1.4	cocoa and chocolate products	5000	mg/kg	Note 3	5/8
05.1.5	imitation chocolate, chocolate substitute products	5000	mg/kg	Note 3	5/8
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	5000	mg/kg	Note 3	5/8
13.6	food supplements	5000	mg/kg	Note 3	5/8
14.1.5	coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	200	mg/kg	Note 108	5/8
15.0	ready-to-eat savouries	200	mg/kg	Note 3	5/8

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
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	200	mg/kg	Note 131	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
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	200	mg/kg	Note 131	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
12.9.1.3	other soybean products (including non-fermented soy sauce)	1000	mg/kg	Note 13	5/8

POLYDIMETHYLSILOXANE Polydimethylsiloxane INS: 900a Function: Anticaking Agent, Antifoaming Agent					
Food Cat No.	Food Category	Max	Level	Comments	Step
02.1.2	vegetable oils and fats	10	mg/kg		8
02.1.3	lard, tallow, fish oil, and other animal fats	10	mg/kg		8

PROPYLENE GLYCOL ESTERS OF FATTY ACIDS					
Propylene Glycol Esters of Fatty Acids INS: 477 Function: Emulsifier, Stabilizer					
Food Cat No.	Food Category	Max	Level	Comments	Step
02.2.1.3	blends of butter and margarine	10000	mg/kg	Note 134	5/8
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	40000	mg/kg		8
05.1.1	cocoa mixes (powders) and cocoa mass/cake	5000	mg/kg		5/8

EDTAs					
Calcium Disodium Ethylene Diamine INS: 385 Disodium Ethylene Diamine Tetra Acetate INS: 386 Tetra Acetate Function: Antioxidant, Preservative, Sequestrant					
Food Cat No.	Food Category	Max	Level	Comments	Step
04.2.2.1	frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	100	mg/kg	Notes 21 & 110	8

BHA					
Butylated Hydroxyanisole INS: 320 Function: Antioxidant					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.5.1	milk powder and cream powder (plain)	100	mg/kg	Notes 15 & 130	8
02.1.1	butter oil, anhydrous milkfat, ghee	175	mg/kg	Notes 15 & 133	8
02.1.2	vegetable oils and fats	200	mg/kg	Notes 15 & 130	8
02.1.3	lard, tallow, fish oil, and other animal fats	200	mg/kg	Notes 15 & 130	8
02.2.1.2	margarine and similar products	175	mg/kg	Notes 15 & 133	8
02.2.1.3	blends of butter and margarine	200	mg/kg	Notes 15 & 130	8
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	200	mg/kg	Notes 15 & 130	8
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	200	mg/kg	Notes 15 & 130	8
03.0	edible ices, including sherbet and sorbet	200	mg/kg	Notes 15 & 130	8
05.1.4	cocoa and chocolate products	200	mg/kg	Notes 15, 130 & 141	8
05.3	chewing gum	400	mg/kg	Note 130	8
06.4.3	pre-cooked pastas and noodles and like products	200	mg/kg	Notes 15 & 130	5/8
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	200	mg/kg	Notes 15 & 130	8
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
12.5	soups and broths	200	mg/kg	Notes 15 & 130	8
12.8	yeast and like products	200	mg/kg	Notes 15 & 130	8
13.6	food supplements	400	mg/kg	Notes 15 & 130	8

BHT					
Butylated Hydroxytoluene		INS: 321			
Function: Adjuvant, Antioxidant					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.5.1	milk powder and cream powder (plain)	200	mg/kg	Notes 15 & 130	8
02.1.1	butter oil, anhydrous milkfat, ghee	75	mg/kg	Notes 15 & 133	8
02.1.2	vegetable oils and fats	200	mg/kg	Notes 15 & 130	8
02.1.3	lard, tallow, fish oil, and other animal fats	200	mg/kg	Notes 15 & 130	8
02.2.1.2	margarine and similar products	75	mg/kg	Notes 15 & 133	8
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	200	mg/kg	Notes 15 & 130	8
02.4	fat-based desserts excluding dairy-based dessert products of food category 01.7	200	mg/kg	Notes 15 & 130	8
03.0	edible ices, including sherbet and sorbet	100	mg/kg	Notes 15 & 130	8
05.1.4	cocoa and chocolate products	200	mg/kg	Notes 15, 130 & 141	8
05.1.5	imitation chocolate, chocolate substitute products	200	mg/kg	Notes 15 & 130	8
05.3	chewing gum	400	mg/kg	Note 130	8
06.3	breakfast cereals, including rolled oats	100	mg/kg	Notes 15 & 130	8
06.4.3	pre-cooked pastas and noodles and like products	200	mg/kg	Notes 15 & 130	8
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	100	mg/kg	Notes 15 & 130	8
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg	Notes 15 & 130	8
12.2	herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	200	mg/kg	Notes 15 & 130	8
12.5	soups and broths	100	mg/kg	Notes 15 & 130	8
12.6	sauces and like products	100	mg/kg	Notes 15 & 130	8
13.6	food supplements	400	mg/kg	Notes 15 & 130	8
15.0	ready-to-eat savouries	200	mg/kg	Notes 15 & 130	8

TBHQ					
Tertiary Butylhydroquinone		INS: 319			
Function: Antioxidant					
Food Cat No.	Food Category	Max	Level	Comments	Step
02.1.2	vegetable oils and fats	200	mg/kg	Notes 15 & 130	8
02.1.3	lard, tallow, fish oil, and other animal fats	200	mg/kg	Notes 15 & 130	8
03.0	edible ices, including sherbet and sorbet	200	mg/kg	Notes 15 & 130	8
05.1.4	cocoa and chocolate products	200	mg/kg	Notes 15, 130 & 141	8
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	200	mg/kg	Notes 15 & 130	8
05.3	chewing gum	400	mg/kg	Note 130	8
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	200	mg/kg	Notes 15 & 130	8
06.4.3	pre-cooked pastas and noodles and like products	200	mg/kg	Notes 15 & 130	5/8
07.1.1	breads and rolls	200	mg/kg	Notes 15 & 130	8
07.1.2	crackers, excluding sweet crackers	200	mg/kg	Notes 15 & 130	8
07.1.3	other ordinary bakery products (e.g., bagels, pita, English muffins)	200	mg/kg	Notes 15 & 130	8

TBHQ					
Tertiary Butylhydroquinone		INS: 319			
Function: Antioxidant					
Food Cat No.	Food Category	Max	Level	Comments	Step
07.1.4	bread-type products, including bread stuffing and bread crumbs	200	mg/kg	Notes 15 & 130	8
12.4	mustards	200	mg/kg	Notes 15 & 130	8
12.5	soups and broths	200	mg/kg	Notes 15 & 130	8

DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL					
Diacetyltartaric and Fatty Acid Esters of Glycerol		INS: 472e			
Function: Emulsifier, Sequestrant, Stabilizer					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	5000	mg/kg		8
01.4.3	Clotted cream (plain)	5000	mg/kg		8
01.4.4	Cream analogues	5000	mg/kg		8
01.5.1	milk powder and cream powder (plain)	10000	mg/kg		8
02.1.2	vegetable oils and fats	10000	mg/kg		8
02.1.3	lard, tallow, fish oil, and other animal fats	10000	mg/kg		8
02.2.1.3	Blends of butter and margarine	10000	mg/kg		8
03.0	edible ices, including sherbet and sorbet	1000	mg/kg		8
07.1	bread and ordinary bakery wares and mixes	6000	mg/kg		5/8
07.2	fine bakery wares (sweet, salty, savoury) and mixes	20000	mg/kg		5/8
12.1.2	Salt substitutes	16000	mg/kg		8
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	500	mg/kg	Note 142	5/8

SULPHITES					
Sulphur Dioxide		INS: 220		Sodium Sulphite	
Sodium Hydrogen Sulphite		INS: 222		INS: 221	
Potassium Metabisulphite		INS: 224		Sodium Metabisulphite	
Calcium Hydrogen Sulphite		INS: 227		INS: 223	
Sodium Thiosulphate		INS: 539		Potassium Sulphite	
Function: Acidity Regulator, Adjuvant, Antioxidant, Bleaching Agent (Not for Flour), Flour Treatment Agent, Firming Agent, Preservative, Sequestrant, Stabilizer				INS: 225	
				INS: 228	
Food Cat No.	Food Category	Max	Level	Comments	Step
04.1.1.2	surface-treated fresh fruit	50	mg/kg	Note 44	8
04.1.2.2	dried fruit	1000	mg/kg	Notes 44 & 135	8
04.1.2.3	fruit in vinegar, oil, or brine	100	mg/kg	Note 44	8
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	500	mg/kg	Note 44	8
04.1.2.7	candied fruit	100	mg/kg	Note 44	8
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk	500	mg/kg	Note 44	8
04.1.2.11	fruit fillings for pastries	100	mg/kg	Note 44	8
04.2.1.3	peeled, cut or shredded fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	50	mg/kg	Notes 44, 76 & 136	8
04.2.2.1	frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	50	mg/kg	Notes 44, 76, 136 & 137	8
04.2.2.2	dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	500	mg/kg	Notes 44 & 105	8
04.2.2.3	vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds in vinegar, oil, brine, or soy sauce	100	mg/kg	Note 44	8

SULPHITES					
Sulphur Dioxide		INS: 220	Sodium Sulphite	INS: 221	
Sodium Hydrogen Sulphite		INS: 222	Sodium Metabisulphite	INS: 223	
Potassium Metabisulphite		INS: 224	Potassium Sulphite	INS: 225	
Calcium Hydrogen Sulphite		INS: 227	Potassium Bisulphite	INS: 228	
Sodium Thiosulphate		INS: 539			
Function: Acidity Regulator, Adjuvant, Antioxidant, Bleaching Agent (Not for Flour), Flour Treatment Agent, Firming Agent, Preservative, Sequestrant, Stabilizer					
Food Cat No.	Food Category	Max	Level	Comments	Step
04.2.2.4	canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	50	mg/kg	Note 44	8
04.2.2.5	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	500	mg/kg	Notes 44 & 138	8
04.2.2.6	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	500	mg/kg	Note 44	8
04.2.2.7	fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10	500	mg/kg	Note 44	8
06.2.1	Flours	200	mg/kg	Note 44	8
06.2.2	starches	50	mg/kg	Note 44	8
06.4.3	pre-cooked pastas and noodles and like products	20	mg/kg	Note 44	8
07.2	fine bakery wares (sweet, salty, savoury) and mixes	50	mg/kg	Note 44	8
09.1.2	fresh mollusks, crustaceans, and echinoderms	100	mg/kg	Note 44	8
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	100	mg/kg	Notes 44 & 139	8
11.1.3	soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar	20	mg/kg	Notes 44 & 111	8
11.2	Brown sugar excluding products of food category 11.1.3	40	mg/kg	Note 44	5/8
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	40	mg/kg	Note 44	8
12.2.1	Herbs and spices	150	mg/kg	Note 44	5/8
12.2.2	seasonings and condiments	200	mg/kg	Note 44	8
12.3	vinegars	100	mg/kg	Note 44	8
14.1.2.2	vegetable juice	50	mg/kg	Notes 44 & 122	8
14.1.2.4	concentrates for vegetable juice	50	mg/kg	Notes 44, 122 & 127	8
14.1.3.2	vegetable nectar	50	mg/kg	Notes 44 & 122	8
14.1.3.4	concentrates for vegetable nectar	50	mg/kg	Notes 44, 122 & 127	8
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	70	mg/kg	Notes 44, 127 & 143	8
14.2.1	beer and malt beverages	50	mg/kg	Note 44	8
14.2.2	cider and perry	200	mg/kg	Note 44	8
14.2.3	Grape wines	350	mg/kg	Notes 44 & 103	8
14.2.4	Wines (other than grape)	200	mg/kg	Note 44	8
14.2.5	Mead	200	mg/kg	Note 44	8
14.2.6	distilled spirituous beverages containing more than 15% alcohol	200	mg/kg	Note 44	8
15.1	snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	50	mg/kg	Note 44	8

Notes**Note 3:** Surface treatment.**Note 13:** As benzoic acid.**Note 15:** Fat or oil basis.

Note 21: As anhydrous calcium disodium EDTA.

Note 44: As residual SO₂.

Note 76: Use in potatoes only.

Note 103: Except for use in special white wines at 400 mg/kg.

Note 105: Except for use in dried gourd strips (KAMPYO) at 5000 mg/kg.

Note 108: For use on coffee beans only.

Note 110: For use in frozen French fried potatoes only.

Note 111: Excluding dried glucose syrup used in the manufacture of sugar confectionery at 150 mg/kg and glucose syrup used in the manufacture of sugar confectionery at 400 mg/kg.

Note 122: Subject to national legislation of the importing country.

Note 127: As served to the consumer.

Note 130: Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), Tertiary Butylated Hydroquinone (TBHQ, INS 319), and Propyl Gallate (INS 310).

Note 131: As a result of use as a flavor carrier.

Note 133: Any combination of Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), and Propyl Gallate (INS 310) at 200 mg/kg, provided that single use limits are not exceeded.

Note 134: For baking purposes only.

Note 135: Except for use in dried apricots at 2000 mg/kg, bleached raisins at 1500 mg/kg, and desiccated coconut at 50 mg/kg.

Note 136: For use in white vegetables only.

Note 137: Except for use in frozen avocado at 300 mg/kg.

Note 138: For use in energy-reduced products only.

Note 139: For use in mollusks, crustaceans, and echinoderms only.

Note 141: For use in white chocolate only.

Note 142: Excluding coffee and tea.

Note 143: For use in fruit juice-based drinks and dry ginger ale only.

TBHQ Tertiary Butylhydroquinone INS: 319 Function: Antioxidant					
Food Cat No.	Food Category	Max	Level	Comments	Step
02.1	fats and oils essentially free from water	200	mg/kg	Notes 15 & 130	8
02.2.1.2	margarine and similar products	200	mg/kg	Notes 15 & 130	8

CAROTENES, VEGETABLE Carotenes, Natural Extracts, (Vegetable) INS: 160aii Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
02.1	fats and oils, and fat emulsions	1000	mg/kg		8
02.2.1.2	margarine and similar products	26	mg/kg		8

FAST GREEN FCF Fast Green FCF INS: 143 Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
08.1	fresh meat, poultry, and game		GMP	Notes 3 & 4	8
08.2	processed meat, poultry, and game products in whole pieces or cuts		GMP	Notes 3 & 4	8
08.4	edible casings (e.g., sausage casings)		GMP	Notes 3 & 4	8

Notes

Note 3: Surface treatment.

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

Note 15: Fat or oil basis.

Note 21: As anhydrous calcium disodium EDTA.

Note 108: For use on coffee beans only.

Note 130: Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), Tertiary Butylated Hydroquinone (TBHQ, INS 319), and Propyl Gallate (INS 310).

Appendix XIII

DISCONTINUATION OF WORK ON PROPOSED DRAFT AND DRAFT FOOD ADDITIVE PROVISIONS IN THE GENERAL STANDARD FOR FOOD ADDITIVES

Highlighted entries refer to provisions identified by the GSFA-WG for further discussion but should be recommended for discontinuation as a consequence of endorsing the recommendations of the CCFAC's ad hoc Working on the General Principles for the GSFA (CRD 1) for consistency to accommodate commodity standards with a one-to-one correspondence with a food category, pending the outcome of the discussion regarding the one-to-one correspondence in the plenary.

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
12.5.1	Ready-to-eat soups and broths, including canned, bottled, and frozen	1000	mg/kg	Note 13	6

POLYDIMETHYLSILOXANE					
Polydimethylsiloxane		INS: 900a			
Function: Anticaking Agent, Antifoaming Agent					
Food Cat No.	Food Category	Max	Level	Comments	Step
12.10.3	fermented soybean paste (e.g., miso)	50	mg/kg		6

QUILLAIA EXTRACT					
Quillaia Extract		INS: 999			
Function: Foaming Agent					
Food Cat No.	Food Category	Max	Level	Comments	Step
14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	500	mg/kg		7

BHA					
Butylated Hydroxyanisole		INS: 320			
Function: Antioxidant					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	200	mg/kg	Notes 15, 88 & 130	3
01.3.1	condensed milk (plain)	200	mg/kg	Notes 15, 88 & 130	3
01.3.1	condensed milk (plain)	100	mg/kg	Notes 15, 88 & 130	6
01.5.2	milk and cream powder analogues	100	mg/kg	Notes 15 & 130	6
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	2	mg/kg	Notes 15 & 130	6
02.0	fats and oils, and fat emulsions	200	mg/kg	Notes 15 & 130	6
04.1.2.2	dried fruit	200	mg/kg	Notes 15 & 130	6
04.1.2.7	candied fruit	32	mg/kg	Notes 15 & 130	6
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	2	mg/kg	Notes 15 & 130	6
04.1.2.12	cooked fruit	100	mg/kg	Notes 15 & 130	6

BHA Butylated Hydroxyanisole Function: Antioxidant INS: 320					
Food Cat No.	Food Category	Max	Level	Comments	Step
04.2.2.5	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	200	mg/kg	Notes 15 & 130	6
05.1.5	imitation chocolate, chocolate substitute products	200	mg/kg	Notes 15 & 130	6
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	2	mg/kg	Notes 15 & 130	6
10.4	egg-based desserts (e.g., custard)	2	mg/kg	Notes 15 & 130	6
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	20	mg/kg	Notes 15 & 130	6
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	1000	mg/kg	Notes 15 & 130	6

BHT Butylated Hydroxytoluene Function: Adjuvant, Antioxidant INS: 321					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.1.2	dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	200	mg/kg	Notes 15, 88 & 130	3
01.3.1	condensed milk (plain)	200	mg/kg	Notes 15, 88 & 130	3
01.3.1	condensed milk (plain)	100	mg/kg	Notes 15, 88 & 130	6
01.5.2	milk and cream powder analogues	100	mg/kg	Notes 15 & 130	6
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	90	mg/kg	Notes 2, 15 & 130	6
02.1	fats and oils essentially free from water	200	mg/kg	Notes 15 & 130	6
02.2.1.1	butter and concentrated butter	200	mg/kg	Notes 15 & 130	6
02.2.1.2	margarine and similar products	500	mg/kg	Notes 15 & 130	6
04.1.2.9	fruit-based desserts, including fruit-flavoured water-based desserts	90	mg/kg	Notes 2, 15 & 130	6
04.1.2.12	cooked fruit	100	mg/kg	Notes 15 & 130	6
04.2.2.5	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	200	mg/kg	Notes 15 & 130	6
06.1	whole, broken, or flaked grain, including rice	200	mg/kg	Notes 15 & 130	6
06.5	cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	90	mg/kg	Notes 2, 15 & 130	6
10.4	egg-based desserts (e.g., custard)	90	mg/kg	Notes 2, 15 & 130	6
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	20	mg/kg	Notes 15 & 130	6
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	1000	mg/kg	Notes 15 & 130	6

TBHQ Tertiary Butylhydroquinone Function: Antioxidant INS: 319					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.3.1	condensed milk (plain)	200	mg/kg	Notes 15 & 130	3
01.3.1	condensed milk (plain)	100	mg/kg	Notes 15, 88 & 130	6
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	90	mg/kg	Notes 2, 15 & 130	6
02.0	fats and oils, and fat emulsions	200	mg/kg	Notes 15 & 130	6
04.1.2.2	dried fruit	200	mg/kg	Notes 15 & 130	6

TBHQ					
Tertiary Butylhydroquinone		INS: 319			
Function: Antioxidant					
Food Cat No.	Food Category	Max	Level	Comments	Step
04.2.2.5	vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	200	mg/kg	Notes 15 & 130	6
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	1000	mg/kg	Notes 15 & 130	6
14.1.4	Water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks	200	mg/kg	Notes 15 & 130	6

DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL					
Diacetyltartaric and Fatty Acid Esters of Glycerol		INS: 472e			
Function: Emulsifier, Sequestrant, Stabilizer					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.1.1.2	buttermilk (plain)	5000	mg/kg		3
01.6.1	unripened cheese	10000	mg/kg		3
02.1	fats and oils essentially free from water	10000	mg/kg		6
02.2	fat emulsions mainly of type water-in-oil	10000	mg/kg		6
03.0	edible ices, including sherbet and sorbet	10000	mg/kg		3
04.1.1.2	surface-treated fresh fruit	10000	mg/kg	Note 16	3
04.1.2.12	cooked fruit	2500	mg/kg		3
04.2.1.2	surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	10000	mg/kg	Note 16	3
07.0	bakery wares	20000	mg/kg		3
07.0	bakery wares	10000	mg/kg		6
08.1.1	fresh meat, poultry, and game, whole pieces or cuts	10000	mg/kg	Note 16	3
08.1.2	fresh meat, poultry, and game, comminuted	10000	mg/kg		3
08.2.1	non-heat treated processed meat, poultry, and game products in whole pieces or cuts	10000	mg/kg		3
08.2.2	heat-treated processed meat, poultry, and game products in whole pieces or cuts	10000	mg/kg		3
08.2.3	frozen processed meat, poultry, and game products in whole pieces or cuts	10000	mg/kg	Note 16	3
08.3.1	non-heat treated processed comminuted meat, poultry, and game products	10000	mg/kg		3
08.3.2	heat-treated processed comminuted meat, poultry, and game products	10000	mg/kg		3
08.3.3	frozen processed comminuted meat, poultry, and game products	10000	mg/kg	Note 16	3
08.4	edible casings (e.g., sausage casings)	10000	mg/kg		3
09.1	fresh fish and fish products, including mollusks, crustaceans, and echinoderms	10000	mg/kg	Note 16	3
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	10000	mg/kg		3
09.2.4	cooked and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms	10000	mg/kg		3
09.2.5	smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	10000	mg/kg		3
09.3	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	10000	mg/kg		3
11.4	other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1000	mg/kg		3
12.2.1	herbs and spices		GMP		6
12.3	vinegars	1000	mg/kg		3
13.1.1	infant formulae	5000	mg/kg		3

DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL					
Diacetyltartaric and Fatty Acid Esters of Glycerol INS: 472e					
Function: Emulsifier, Sequestrant, Stabilizer					
Food Cat No.	Food Category	Max	Level	Comments	Step
13.1.2	follow-up formulae	5000	mg/kg		3
14.1.2.2	vegetable juice	5000	mg/kg		3
14.1.2.4	concentrates for vegetable juice	5000	mg/kg		3

SULPHITES					
Sulphur Dioxide INS: 220 Sodium Sulphite INS: 221					
Sodium Hydrogen Sulphite INS: 222 Sodium Metabisulphite INS: 223					
Potassium Metabisulphite INS: 224 Potassium Sulphite INS: 225					
Calcium Hydrogen Sulphite INS: 227 Potassium Bisulphite INS: 228					
Sodium Thiosulphate INS: 539					
Function: Acidity Regulator, Adjuvant, Antioxidant, Bleaching Agent (Not for Flour), Flour Treatment Agent, Firming Agent, Preservative, Sequestrant, Stabilizer					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.4.1	Plain processed cheese	300	mg/kg	Note 44	6
01.7	dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	100	mg/kg	Note 44	6
02.3	fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	50	mg/kg	Note 44	6
03.0	Edible ices, including sherbet and sorbet	25	mg/kg	Note 44	6
04.1.1.2	surface-treated fresh fruit	1000	mg/kg	Note 44	3
04.1.2.10	fermented fruit products	350	mg/kg	Note 44	6
04.2.2.8	cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	750	mg/kg	Note 44	6
05.2	confectionery including hard and soft candy, nougat, etc. other than food categories 05.1, 05.3 and 05.4	100	mg/kg	Note 44	6
05.3	chewing gum	150	mg/kg	Note 44	6
06.2.1	flours	900	mg/kg	Note 44	6
08.1.2	fresh meat, poultry, and game, comminuted	450	mg/kg	Note 44	6
08.3	Processed comminuted meat, poultry, and game products	500	mg/kg	Note 44	6
08.4	Edible casings (e.g., sausage casings)	500	mg/kg	Notes 44 & 72	6
11.1.4	Lactose	20	mg/kg	Note 44	6
12.1.1	Salt	1000	mg/kg	Note 29	6
12.2.2	seasonings and condiments	500	mg/kg	Note 44	3
12.9.5	Other protein products	200	mg/kg	Note 44	6
14.1.4.1	Carbonated water-based flavoured drinks	115	mg/kg	Note 44	6
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades	115	mg/kg	Note 44	6
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	115	mg/kg	Notes 44 & 127	6

CANTHAXANTHIN					
Canthaxanthin INS: 161g					
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6	cheese and analogues		GMP		6
02.0	fats and oils, and fat emulsions		GMP		6
08.1.1	fresh meat, poultry, and game, whole pieces or cuts	100	mg/kg		6
08.3.2	heat-treated processed comminuted meat, poultry, and game products	15	mg/kg		6
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms		GMP		6

CANTHAXANTHIN					
Canthaxanthin		INS: 161g			
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
12.9.5	other protein products	100	mg/kg		6
14.2.1	beer and malt beverages	5	mg/kg		6
14.2.3	grape wines	5	mg/kg		6

ERYTHROSINE					
Erythrosine		INS: 127			
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.2.2	rind of ripened cheese	100	mg/kg		6
01.6.4.2	flavoured processed cheese, including containing fruit, vegetables, meat, etc.	100	mg/kg	Notes 5 & 72	6
05.1.3	cocoa-based spreads, including fillings	100	mg/kg		6
07.0	bakery wares	300	mg/kg		6
08.1	fresh meat, poultry, and game	30	mg/kg	Notes 3 & 4	3
08.4	edible casings (e.g., sausage casings)	3000	mg/kg		3
09.2.1	frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	300	mg/kg		6
09.2.4.1	cooked fish and fish products	300	mg/kg		6
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms	300	mg/kg		6
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	1500	mg/kg		3
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	300	mg/kg		6
10.1	fresh eggs	300	mg/kg	Note 4	3
10.4	egg-based desserts (e.g., custard)	300	mg/kg		6
11.3	sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	300	mg/kg		6
11.6	table-top sweeteners, including those containing high-intensity sweeteners	300	mg/kg		6
12.6.2	non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	300	mg/kg		6
12.9.5	other protein products	100	mg/kg	Note 92	6
14.2.6	distilled spirituous beverages containing more than 15% alcohol	300	mg/kg		6
14.2.7	aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)		GMP		6

IRON OXIDES					
Iron Oxide, Black		INS: 172i		Iron Oxide, Red	
Iron Oxide, Yellow		INS: 172iii		INS: 172ii	
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.3.2	beverage whiteners		GMP		6
01.5.2	milk and cream powder analogues		GMP		6
01.6.3	whey cheese		GMP	Note 3	6
01.6.5	cheese analogues		GMP		6
04.1.2.8	fruit preparations, including pulp, purees, fruit toppings and coconut milk		GMP		6
06.2	flours and starches (including soybean powder)	300	mg/kg		3

IRON OXIDES					
Iron Oxide, Black Iron Oxide, Yellow Function: Colour		INS: 172i INS: 172iii	Iron Oxide, Red		INS: 172ii
Food Cat No.	Food Category	Max	Level	Comments	Step
08.2	processed meat, poultry, and game products in whole pieces or cuts		GMP	Note 16	6
08.3.1.2	cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products		GMP	Note 16	6
09.1.2	fresh mollusks, crustaceans, and echinoderms		GMP	Note 16	6
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms		GMP	Note 16	6
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms		GMP	Note 16	6
09.2.4.1	cooked fish and fish products		GMP		6
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms		GMP	Note 16	6
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly		GMP	Note 16	6
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine		GMP	Note 16	6

BRILLIANT BLUE FCF					
Brilliant Blue FCF Function: Colour		INS: 133			
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.3	whey cheese	200	mg/kg	Note 3	3
01.6.4	processed cheese	200	mg/kg		6
02.1.3	lard, tallow, fish oil, and other animal fats	200	mg/kg		3
04.2.1.2	surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	500	mg/kg	Note 16	6
05.1.3	cocoa-based spreads, including fillings	300	mg/kg		3
05.1.4	cocoa and chocolate products	300	mg/kg		3
05.1.5	imitation chocolate, chocolate substitute products	300	mg/kg		3
09.3.4	semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	500	mg/kg		6
14.2.1	beer and malt beverages	200	mg/kg		3

CARMINES					
Carmines Function: Colour		INS: 120			
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.1	unripened cheese		GMP	Note 3	6
01.6.2.2	rind of ripened cheese		GMP		6
01.6.3	whey cheese		GMP	Note 3	6

CAROTENES, VEGETABLE					
Carotenes, Natural Extracts, (Vegetable) Function: Colour		INS: 160aii			
Food Cat No.	Food Category	Max	Level	Comments	Step
01.4	cream (plain) and the like	1000	mg/kg		3
01.6.3	whey cheese	1000	mg/kg	Note 3	3
02.2.1.2	margarine and similar products	1000	mg/kg		3

CAROTENES, VEGETABLE					
Carotenes, Natural Extracts, (Vegetable) INS: 160aii					
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
04.2.1.2	surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds		GMP	Note 16	6
05.1.5	imitation chocolate, chocolate substitute products	1000	mg/kg		3
05.1.5	imitation chocolate, chocolate substitute products	500	mg/kg		6
08.1.1	fresh meat, poultry, and game, whole pieces or cuts	5000	mg/kg	Note 16	3

CASTOR OIL					
Castor Oil INS: 1503					
Function: Anticaking Agent, Carrier Solvent, Glazing Agent, Release Agent					
Food Cat No.	Food Category	Max	Level	Comments	Step
05.4	decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces		GMP		6
14.1.4	water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	500	mg/kg		6

CHLOROPHYLLS, COPPER COMPLEXES					
Chlorophylls, Copper Complex INS: 141i Chlorophyllin Copper Complex, Sodium and Potassium Salts INS: 141ii					
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.3	whey cheese	50	mg/kg		3
02.0	fats and oils, and fat emulsions		GMP		6
03.0	edible ices, including sherbet and sorbet	200	mg/kg		6
04.1.2.1	frozen fruit	100	mg/kg	Note 62	6
04.1.2.2	dried fruit	100	mg/kg	Note 62	6
04.1.2.7	candied fruit	100	mg/kg	Note 62	6
04.2.1.2	surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds		GMP	Note 16	6
04.2.2.1	frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	100	mg/kg	Note 62	6
07.2.2	other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)		GMP		6
07.2.3	mixes for fine bakery wares (e.g., cakes, pancakes)		GMP		6
12.5.2	mixes for soups and broths	30	mg/kg	Note 127	6
12.9.5	other protein products		GMP		6
13.1.3	formulae for special medical purposes for infants	20	mg/kg	Note 84	3
13.3	dietetic foods intended for special medical purposes (excluding products of food category 13.1)		GMP		6
13.4	dietetic formulae for slimming purposes and weight reduction		GMP		6
13.5	dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6		GMP		6
14.1.3.2	vegetable nectar		GMP		6
14.1.3.4	concentrates for vegetable nectar		GMP		6
14.2.2	cider and perry		GMP		6
14.2.4	wines (other than grape)		GMP		6
14.2.6	distilled spirituous beverages containing more than 15% alcohol		GMP		6

GRAPE SKIN EXTRACT					
Grape Skin Extract		INS: 163ii			
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.3	whey cheese	1000	mg/kg		3

POLYSORBATES					
Polyoxyethylene (20) Sorbitan Monolaurate		INS: 432	Polyoxyethylene (20) Sorbitan		INS: 433
Polyoxyethylene (20) Sorbitan Monopalmitate		INS: 434	Polyoxyethylene (20) Sorbitan Monostearate		INS: 435
Polyoxyethylene (20) Sorbitan Tristearate		INS: 436			
Function: Antifoaming Agent, Adjuvant, Emulsifier, Foaming Agent, Flour Treatment Agent, Stabilizer					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.4.2	sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	3000	mg/kg		6
02.0	fats and oils, and fat emulsions	10000	mg/kg		6
05.2.1	hard candy	10000	mg/kg		6
05.2.2	soft candy	1000	mg/kg		6
05.2.3	nougats and marzipans	1000	mg/kg		6
12.2	herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	10000	mg/kg		3

RIBOFLAVINS					
Riboflavin 5'-Phosphate, Sodium		INS: 101i	Riboflavin 5'-Phosphate		INS: 101ii
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.4	cream (plain) and the like	300	mg/kg		3
01.6.3	whey cheese	300	mg/kg	Note 3	3
05.1.2	cocoa mixes (syrops)	1000	mg/kg		3
05.1.3	cocoa-based spreads, including fillings	1000	mg/kg		3
05.1.4	cocoa and chocolate products	1000	mg/kg		3
14.2.6	distilled spirituous beverages containing more than 15% alcohol		GMP		6

BENZOYL PEROXIDE					
Benzoyl Peroxide		INS: 928			
Function: Bleaching Agent (Not for Flour), Flour Treatment Agent					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.8	whey and whey products, excluding whey cheeses		GMP		6

CARMEL COLOUR, CLASS III					
Caramel Colour, Class III - Ammonia Process		INS: 150c			
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6	cheese and analogues	50000	mg/kg		3
01.8	whey and whey products, excluding whey cheeses	50000	mg/kg		3
02.1	fats and oils essentially free from water	20000	mg/kg		3
02.2.1.2	margarine and similar products	20000	mg/kg		3
11.1.2	powdered sugar, powdered dextrose	50000	mg/kg		3

CARAMEL COLOUR, CLASS IV					
Caramel Colour, Class IV - Ammonia INS: 150d					
Sulphite Process					
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6	cheese and analogues	50000	mg/kg		3
01.8	whey and whey products, excluding whey cheeses	50000	mg/kg		3
02.1	fats and oils essentially free from water	20000	mg/kg		3
02.2.1.2	margarine and similar products	20000	mg/kg		3
11.1.2	powdered sugar, powdered dextrose	50000	mg/kg		3

ALLURA RED AC					
Allura Red AC INS: 129					
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.3	whey cheese	300	mg/kg	Note 3	3
02.1.3	lard, tallow, fish oil, and other animal fats	500	mg/kg		3
02.2.1.1	butter and concentrated butter	300	mg/kg		6
02.2.1.2	margarine and similar products	300	mg/kg		3
04.1.1.2	surface-treated fresh fruit	500	mg/kg	Note 16	6
04.1.2.6	fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	500	mg/kg		6
04.2.1.2	surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	500	mg/kg	Note 16	6
04.2.1.2	surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds		GMP	Note 145	6
06.3	breakfast cereals, including rolled oats	300	mg/kg		6
07.1	bread and ordinary bakery wares	300	mg/kg		6
07.1.1	Breads and rolls	500	mg/kg		6
07.1.4	Bread-type products, including bread stuffing and bread crumbs	300	mg/kg		6
07.1.5	Steamed breads and buns	300	mg/kg		6
07.1.6	Mixes for bread and ordinary bakery wares	300	mg/kg		6
08.2	processed meat, poultry, and game products in whole pieces or cuts	500	mg/kg	Note 16	6
08.3.1	non-heat treated processed comminuted meat, poultry, and game products	500	mg/kg	Note 16	6
08.3.3	frozen processed comminuted meat, poultry, and game products	500	mg/kg	Note 16	6
09.1.2	fresh mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	500	mg/kg	Note 16	6
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	500	mg/kg	Note 16	6
09.4	fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg		6
11.3	sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	300	mg/kg		6
14.2.1	beer and malt beverages	200	mg/kg		3

CAROTENOIDS					
Beta-Carotene (Synthetic)		INS: 160ai	Beta-Carotene (Blakeslea trispora)		INS: 160aii
Beta-Apo-8'-Carotenal		INS: 160e	Beta-Apo-8'-Carotenoic Acid, Methyl or Ethyl Ester		INS: 160f
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.3	wey cheese	1000	mg/kg	Note 3	3
02.1	fats and oils essentially free from water	1000	mg/kg		6
02.2.1.1	butter and concentrated butter	100	mg/kg		6
02.2.1.2	margarine and similar products	1000	mg/kg		6
04.1.1.2	surface-treated fresh fruit	500	mg/kg	Note 16	6
08.1.1	fresh meat, poultry, and game, whole pieces or cuts	500	mg/kg	Note 16	6
08.2	processed meat, poultry, and game products in whole pieces or cuts	500	mg/kg	Note 16	6
08.3.3	frozen processed comminuted meat, poultry, and game products	500	mg/kg	Note 16	6
08.4	edible casings (e.g., sausage casings)	500	mg/kg	Note 16	6
09.1.2	fresh mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	500	mg/kg	Note 16	6
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	500	mg/kg	Note 16	6
11.1.2	powdered sugar, powdered dextrose	35	mg/kg		6
14.2.3.2	sparkling and semi-sparkling grape wines	1000	mg/kg		3

INDIGOTINE					
Indigotine		INS: 132			
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.3	wey cheese	200	mg/kg	Note 3	
01.6.4	processed cheese	200	mg/kg		6
02.2.1.1	butter and concentrated butter	300	mg/kg		6
02.2.1.2	margarine and similar products	200	mg/kg		3
04.1.1.2	surface-treated fresh fruit	500	mg/kg	Note 16	6
04.2.1.2	surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	500	mg/kg	Note 16	6
05.1.1	cocoa mixes (powders) and cocoa mass/cake	300	mg/kg		6
05.1.2	cocoa mixes (syrups)	300	mg/kg		6
05.1.3	cocoa-based spreads, including fillings	300	mg/kg		6
08.0	meat and meat products, including poultry and game	500	mg/kg	Note 16	6
08.1	fresh meat, poultry and game		GMP	Note 4	6
08.2	processed meat, poultry, and game products in whole pieces or cuts		GMP	Note 4	6
09.1.2	fresh mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.2.2	frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.2.3	frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.2.4.3	fried fish and fish products, including mollusks, crustaceans, and echinoderms	500	mg/kg	Note 16	6
09.3.1	fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	500	mg/kg	Note 16	6
09.3.2	fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	500	mg/kg	Note 16	6
16.0	composite foods - foods that could not be placed in categories 01 – 15	500	mg/kg		6

PONCEAU 4R					
Ponceau 4R		INS: 124			
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.3	whey cheese	100	mg/kg	Note 3	3
12.10.3	fermented soybean paste (e.g., miso)	200	mg/kg		6
14.1.2.2	vegetable juice	300	mg/kg		3

SUNSET YELLOW FCF					
Sunset Yellow FCF		INS: 110			
Function: Colour					
Food Cat No.	Food Category	Max	Level	Comments	Step
01.6.3	whey cheese		GMP	Note 3	6
02.2.1.1	butter and concentrated butter	300	mg/kg		6
02.2.1.2	margarine and similar products		GMP		6

Notes

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 13: As benzoic acid.

Note 15: Fat or oil basis.

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

Note 29: Report basis not specified.

Note 44: As residual SO₂.

Note 62: As copper.

Note 72: Ready-to-eat basis.

Note 84: For infants over 1 year of age only.

Note 88: Carryover from the ingredient.

Note 92: On the weight of the protein before re-hydration.

Note 127: As served to the consumer.

Note 130: Singly or in combination: Butylated Hydroxyanisole (BHA, INS 320), Butylated Hydroxytoluene (BHT, INS 321), Tertiary Butylated Hydroquinone (TBHQ, INS 319), and Propyl Gallate (INS 310).

Note 145: Applied to outer shell of pistachio nuts only.

PROJECT DOCUMENT**PROPOSAL FOR NEW WORK ON THE ELABORATION OF GUIDELINES FOR THE USE OF FLAVOURINGS****1. The purpose and scope of the guideline;**

To integrate flavourings into the Codex system by elaborating a Codex Guideline for flavourings that establishes safe conditions of use, and practices that do not mislead consumers, similar to the Codex principles for the safe use of food additives described in the Preamble of the General Standard for Food Additives (GSFA; CODEX STAN 192-1995 Rev. 6-2005). The Guideline will reference the safety assessments completed by JECFA.

2. Its Relevance and timeliness;

Flavourings are a major category of ingredients intentionally added to food. Development of a guideline will provide a means for Codex to offer advice and information on the safe conditions of use for flavouring substances, and to facilitate fair trade of foods in international commerce.

JECFA has evaluated over 1600 flavouring substances and assigned them a status of "no safety concern at estimated levels of intake." It is appropriate to elaborate a guideline for the safe use of flavouring substances with reference to the evaluations completed by JECFA.

JECFA has also embarked on work to establish a method for evaluation of natural flavouring complexes. So far only a few natural flavouring complexes have been evaluated. Nevertheless, it would be prudent to include these in the guidelines for future reference.

3. The main aspects to be covered;

This Guideline would provide definitions, and principles for the safe use of flavourings similar to the Codex principles for the safe use of other food additives described in the Preamble of the GSFA. Appendix II contains a description of the changes to the "General Requirements for Natural Flavourings" Guideline (CAC/GL 29-1987) and the new proposed draft Codex Guideline for the Use of Flavourings. The main aspects to be covered by the proposed draft guideline are:

- i. Scope;
- ii. Definitions;
- iii. General Principles for the Use of Flavourings;
- iv. Flavouring Adjuvants;
- v. Substances of Toxicological Concern;
- vi. Methods of Analysis;
- vii. Hygiene;
- viii. Labeling;
- ix. Specifications of Identity and Purity; and,
- x. References to the Evaluations of Flavourings Completed by JECFA.

4. An assessment against the *Criteria for the establishment of work priorities*;

This proposal is consistent with the Criteria applicable to general subjects:

a. Consumer protection from the point of view of health and fraudulent practice.

By acknowledging the safety evaluations performed by JECFA, a Codex guideline will lead to more consistent protection of consumer health by ensuring the safe use of flavourings internationally.

b. Diversification of national legislations and apparent resultant or potential impediments to international trade.

The absence of a Codex guideline for flavourings contributes to inconsistencies in the regulation of flavouring substances among different countries. This may present non-tariff barriers to the free movement of foods and disruptions in international food trade.

c. Scope of work and establishment of priorities between the various sections of work.

The scope of work is provided in Item 1, above.

d. Work already undertaken by other international organizations in this field.

Other than the safety assessments performed by JECFA, other Codex Members including the European Community's European Food Safety Authority (EFSA), the Council of Europe and Korea's Food and Drug Administration have initiated their own evaluation of flavoring substances.

5. Relevance to the Codex Strategic objectives;

The new work contributes to the safety of human health and fair trade practices by satisfying the need for advice to governments on the safe use of flavouring substances in food.

6. Information on the relation between the proposal and other existing Codex documents;

In 1972, Codex published three definitions for flavouring substances in their "List of Food Additives Evaluated for Their Safety-in-Use in Food" (CAC/FAL 1-1973). In 1985, the Commission adopted the "General Requirements for Natural Flavourings," which was published as CAC/GL 29-1987, and contained revised definitions for natural flavourings. The proposed new work would incorporate CAC/GL 29-1987, and augment it with additional guidance on definitions, General Principles for the Safe Use of Flavourings, labeling, and specifications. In addition, it would provide a reference to the safety evaluations of flavouring substances completed by JECFA to augment Appendix A of CAC/GL 29-1987 (References to Lists of Raw Materials Suitable for the Preparation of Natural Flavors) which is retained as Appendix A in the proposed new guideline. It is proposed that CAC/GL 29-1987 be revoked upon completion of this new work.

7. Identification of any requirement for and availability of expert scientific advice;

JECFA has already conducted evaluations of the majority of the chemically-defined flavouring substances, and has embarked on work to establish a method to evaluate natural flavouring complexes. The conclusions are available on the JECFA website

8. Identification of any need for technical input to the guideline from external bodies so that plans may be made.

JECFA requests industries to provide updated poundage and use level data.**9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.**

The time-line for completing work on the proposed guideline is four years. Therefore, if the new work is approved by the Commission in 2006, a proposed draft guideline could be considered at Step 3 by the next session of the Committee in 2007, and adopted by the Commission at Step 5 and at Step 8 in 2008, and in 2009, respectively.

Appendix XV**PROPOSED DRAFT REVISION OF THE CODEX CLASS NAMES AND THE INTERNATIONAL NUMBERING SYSTEM****(at Step 5 of the Procedure)**

Functional Classes For LABELLING	Definition	Sub-classes For TECHNOLOGICAL USE
1 Acidity Regulator	A food additive, which controls the acidity or alkalinity of a food	acidity regulator, acid, acidifier, alkali, base, buffer, buffering agent, pH adjusting agent
2 Anticaking agent	A food additive, which reduces the tendency of components of food to adhere to one another	anticaking agent, anti-stick agent, drying agent, dusting agent
3 Antifoaming agent	A food additive, which prevents or reduces foaming	antifoaming agent, defoaming agent
4 Antioxidant	A food additive, which prolongs the shelf-life of foods by protecting against deterioration caused by oxidation	antioxidant, antioxidant synergist, antibrowning agent
5 Bleaching agent	A food additive (non-flour use) used to decolourize food. Bleaching agents do not include pigments	bleaching agent
6 Bulking agent	A food additive, which contributes to the bulk of a food without contributing significantly to its available energy value	bulking agent, filler
7 Carbonating agent	A food additive used to provide carbonation in a food	carbonating agent
8 [Carrier]	A food additive used to dissolve, dilute, disperse or otherwise physically modify a food additive or nutrient without altering its function (and without exerting any technological effect itself) in order to facilitate its handling, application or use	carrier, carrier solvent, nutrient carrier diluent for other food additives, encapsulating agent
9 Colour	A food additive, which adds or restores colour in a food	colour, decorative pigment, surface colourant
10 Colour retention agent	A food additive, which stabilizes, retains or intensifies the colour of a food	colour retention agent, colour fixative, colour stabilizer, colour adjunct
11 Emulsifier	A food additive, which forms or maintains a uniform emulsion of two or more phases in a food	emulsifier, plasticizer, dispersing agent, surface active agent, crystallization inhibitor, density adjustment (flavouring oils in beverages), suspension agent, clouding agent
12 Emulsifying salt	A food additive, which, in the manufacture of processed food, rearranges proteins in order to prevent fat separation	emulsifying salt, melding salt

Functional Classes For LABELLING	Definition	Sub-classes For TECHNOLOGICAL USE
13 Firming agent	A food additive, which makes or keeps tissues of fruit or vegetables firm and crisp, or interacts with gelling agents to produce or strengthen a gel	firming agent
14 Flavour enhancer	A food additive, which enhances the existing taste and/or odour of a food	flavour enhancer, flavour synergist
15 Flour treatment agent	A food additive, which is added to flour or dough to improve its baking quality or colour	flour treatment agent, flour bleaching agent, flour improver, dough conditioner, dough strengthening agent
16 Foaming agent	A food additive, which makes it possible to form or maintain a uniform dispersion of a gaseous phase in a liquid or solid food	foaming agent, whipping agent, aerating agent
17 Gelling agent	A food additive, which gives a food texture through formation of a gel	gelling agent
18 Glazing agent	A food additive, which when applied to the external surface of a food, imparts a shiny appearance or provides a protective coating	glazing agent, sealing agent, coating agent, surface-finishing agent, polishing agent, film-forming agent
19 Humectant	A food additive, which prevents food from drying out by counteracting the effect of a dry atmosphere	humectant, moisture-retention agent, wetting agent
20 [Packaging gas]	A food additive gas, which is introduced into a container before, during or after filling with food	packaging gas
21 Preservative	A food additive, which prolongs the shelf-life of a food by protecting against deterioration caused by microorganisms	preservative, antimicrobial preservative, antimycotic agent, bacteriophage control agent, fungistatic agent, antimould and antirope agent, antimicrobial synergist
22 Propellant	A food additive gas, which expels a food from a container	propellant
23 Raising agent	A food additive or a combination of food additives, which liberate(s) gas and thereby increase(s) the volume of a dough or batter	raising agent
24 Sequestrant	A food additive, which controls the availability of a cation	sequestrant
25 Stabilizer	A food additive, which makes it possible to maintain a uniform dispersion of two or more components	stabilizer, foam stabilizer, colloidal stabilizer, emulsion stabilizer
26 Sweetener	A food additive (other than a mono- or disaccharide sugar), which imparts a sweet taste to a food	sweetener, intense sweetener, bulk sweetener
27 Thickener	A food additive, which increases the viscosity of a food	thickener, bodying agent, binder, texturizing agent

**PROPOSED DRAFT AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM
FOR FOOD ADDITIVES**

(At Step 5/8 of the Procedure)

INS NUMBER	COMPOUND	TECHNOLOGICAL FUNCTION
161b	Luteins	Colour
161b (i)	Lutein from <i>Tagetes erecta</i>	Colour
161b (ii)	Tagetes extract	Colour
161h	Zeaxanthins	Colour
161h (i)	Zeaxanthin-(synthetic)	Colour
161h (ii)	Zeaxanthin-rich extract from <i>Tagetes erecta</i>	Colour
170 (i)	Calcium carbonate	Surface colourant, Anticaking agent, Stabilizer, Acidity regulator
325	Sodium lactate	Antioxidant synergist, Humectant, Bulking agent, Acidity regulator
333	Calcium citrates	Acidity regulators, Firming agents, Sequestrants , Stabilizers
335 (i)	Monosodium tartrate	Stabilizer, Sequestrant, Acidity regulator
335 (ii)	Disodium tartrate	Stabilizer, Sequestrant, Acidity regulator
336 (i)	Monopotassium tartrate	Stabilizer, Sequestrant, Acidity regulator
336 (ii)	Dipotassium tartrate	Stabilizer, Sequestrant, Acidity regulator
337	Potassium sodium tartrate	Stabilizer, Sequestrant, Acidity regulator
405	Propylene glycol alginate	Thickener, Emulsifier , Stabilizer
459	Cyclodextrin, beta-	Stabilizer, Binder, Carrier
470 (i)	Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium	Emulsifier, Stabilizer, Anticaking agent
470 (ii)	Salts of oleic acid with calcium, potassium and sodium	Emulsifier, Stabilizer, Anticaking agent
508	Potassium chloride	Gelling agent, Stabilizer
509	Calcium chloride	Firming agent, Stabilizer
901	Beeswax	Glazing agent, Release agent, Clouding agent
902	Candelilla wax	Glazing agent, Clouding agent
999 (i)	Quillaia extract Type 1	Foaming agent
999 (ii)	Quillaia extract Type 2	Foaming agent
1420	Starch acetate esterified with acetic anhydride	Stabilizer, Thickener
1421	Starch acetate esterified with vinyl acetate	Stabilizer, Thickener
1420	Starch acetate	Stabilizer, Thickener, Binder, Emulsifier
1451	Acetylated oxidised starch	Stabilizer, Thickener, Binder, Emulsifier
1452	Starch aluminium octenyl succinate	Anticaking agent, Carrier, Stabilizer

**SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM
THE SIXTY-FIFTH 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 4)

CATEGORY I (RECOMMENDED TO THE COMMISSION FOR ADOPTION)

ADDITIVES (6 entries)

- Aspartame-acesulfame salt
- Beeswax
- Candelilla Wax
- Laccase from *Myceliophthora thermophila* expressed in *Aspergillus oryzae*
- Phospholipase A1 from *Fusarium venenatum* expressed in *Aspergillus oryzae*
- Pullulan

FLAVOURING AGENTS (130 entries)

JECFA No	Name	JECFA No.	Name
1480	Maltol	1548	Isobutyl N-methylantranilate
1481	Ethyl maltol	1549	Methyl N-formylantranilate
1483	2-Methyl-3-(1-oxopropoxy)-4H-pyran-4-one	1550	Methyl N-acetylantranilate
1484	2-Butyl-5- or 6-keto-1,4-dioxane	1551	Methyl N,N-dimethylantranilate
1485	2-Amyl-5 or 6-keto-1,4-dioxane	1552	N-Benzoylantranilic acid
1486	2-Hexyl-5 or 6-keto-1,4-dioxane	1553	Trimethyloxazole
1487	2-Methylfuran	1554	2,5-Dimethyl-4-ethyloxazole
1488	2,5-Dimethylfuran	1555	2-Ethyl-4,5-dimethyloxazole
1489	2-Ethylfuran	1556	2-Isobutyl-4,5-dimethyloxazole
1490	2-Butylfuran	1557	2-Methyl-4,5-benzo-oxazole
1491	2-Pentylfuran	1558	2,4-Dimethyl-3-oxazoline
1492	2-Heptylfuran	1560	Allyl isothiocyanate
1493	2-Decylfuran	1561	Butyl isothiocyanate
1494	3-Methyl-2-(3-methylbut-2-enyl)-furan	1562	Benzyl isothiocyanate
1495	2,3-Dimethylbenzofuran	1563	Phenethyl isothiocyanate
1496	2,4-Difurfurylfuran	1564	3-Methylthiopropyl isothiocyanate
1497	3-(2-Furyl)acrolein	1565	4-Acetyl-2-methylpyrimidine
1498	2-Methyl-3(2-furyl)acrolein	1566	5,7-Dihydro-2-methylthieno(3,4-d)pyrimidine
1499	3-(5-Methyl-2-furyl)prop-2-enal	1568	1-Phenyl-3 or 5-propylpyrazole
1500	3-(5-Methyl-2-furyl)-butanal	1569	4,5-Dimethyl-2-propyloxazole
1501	2-Furfurylidenebutyraldehyde	1570	4,5-Epoxy-(E)-2-decenal
1502	2-Phenyl-3-(2-furyl)prop-2-enal	1571	beta-Ionone epoxide
1503	2-Furyl methyl ketone		
1504	2-Acetyl-5-methylfuran	1573	Epoxyoxophorone
1505	2-Acetyl-3,5-dimethylfuran	1574	Piperitenone oxide
1507	2-Butyrylfuran	1575	beta-Caryophyllene oxide
1508	(2-Furyl)-2-propanone	1576	Ethyl 3-phenylglycidate
1509	2-Pentanoylfuran	1577	Ethyl methylphenylglycidate
1510	1-(2-Furyl)butan-3-one	1578	Ethyl methyl-p-tolylglycidate
1511	4-(2-Furyl)-3-buten-2-one	1579	Ethylamine

<u>JECFA No</u>	<u>Name</u>	<u>JECFA No.</u>	<u>Name</u>
1512	Pentyl 2-furyl ketone	1580	Propylamine
1513	Ethyl 3-(2-furyl)propanoate	1581	Isopropylamine
1514	Isobutyl 3-(2-furan)propionate	1582	Butylamine
1515	Isoamyl 3-(2-furan)propionate	1583	Isobutylamine
1516	Isoamyl 4-(2-furan)butyrate	1584	sec-Butylamine
1517	Phenethyl 2-furoate	1585	Pentylamine
1518	Propyl 2-furanacrylate	1586	2-Methylbutylamine
1519	2,5-Dimethyl-3-oxo-(2H)-fur-4-yl butyrate	1587	Isopentylamine
1520	Furfuryl methyl ether	1588	Hexylamine
1521	Ethyl furfuryl ether	1589	Phenethylamine
1522	Difurfuryl ether	1590	2-(4-Hydroxyphenyl)ethylamine
1523	2,5-Dimethyl-3-furanthiol acetate	1591	1-Amino-2-propanol
1524	Furfuryl 2-methyl-3-furyl disulfide	1593	Butyramide
1525	3-[(2-Methyl-3-furyl)thio]-2-butanone	1594	1,6-Hexalactam
1526	O-Ethyl S-(2-furylmethyl)thiocarbonate	1595	2-Isopropyl-N,2,3-trimethylbutyramide
1527	4-Allylphenol	1596	N-Ethyl (E)-2,(Z)-6-nonadienamide
1528	2-Methoxy-6-(2-propenyl)phenol	1597	N-Cyclopropyl (E)-2,(Z)-6-nonadienamide
1529	Eugenol	1598	N-Isobutyl (E,E)-2,4-decadienamide
1530	Eugenyl formate	1599	Nonanoyl 4-hydroxy-3-methoxybenzylamide
1531	Eugenyl acetate	1600	Piperine
1532	Eugenyl isovalerate	1601	N-Ethyl-2-isopropyl-5-methylcyclohexanecarboxamide
1533	Eugenyl benzoate	1602	(+/-)-N,N-Dimethyl menthyl succinamide
1534	Methyl anthranilate	1603	1-Pyrroline
1535	Ethyl anthranilate	1604	2-Acetyl-1-pyrroline
1536	Butyl anthranilate	1605	2-Propionylpyrroline
1537	Isobutyl anthranilate	1606	Isopentylidene isopentylamine
1538	cis-3-Hexenyl anthranilate	1607	Piperidine
1539	Citronellyl anthranilate	1608	2-Methylpiperidine
1540	Linalyl anthranilate	1609	Pyrrolidine
1541	Cyclohexyl anthranilate	1610	Trimethylamine
1542	beta-Terpinyll anthranilate	1611	Triethylamine
1543	Phenylethyl anthranilate	1612	Tripropylamine
1544	beta-Naphthyl anthranilate	1613	N,N-Dimethylphenethylamine
1545	Methyl N-methylantranilate	1614	Trimethylamine oxide
1546	Ethyl N-methylantranilate	1615	Piperazine
1547	Ethyl N-ethylantranilate		

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

Food Additives

Quillaia extract (Type 2): Insert “INS no. 999 (ii)” under Synonyms.

Flavouring Agents

cis-Carvone-5,6-oxide (JECFA no. 1572) should be changed to *trans*-Carvone-5,6-oxide.

CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS*CODEX STAN 193-1995 (Rev.2-2005)***1. PREAMBLE****1.1 SCOPE**

This Standard contains the main principles and procedures which are used and recommended by the Codex Alimentarius in dealing with contaminants and toxins in foods and feeds, and lists the maximum levels of contaminants and natural toxicants in foods and feeds which are recommended by the CAC to be applied to commodities moving in international trade.

1.2 DEFINITION OF TERMS**1.2.1 General**

The definitions for the purpose of the Codex Alimentarius, as mentioned in Volume 1, are applicable to the General Standard for Contaminants and Toxins in Foods (GSCTF) and only the most important ones are repeated here. Some new definitions are introduced, where this seems warranted to obtain optimal clarity. When reference is made to foods, this also applies to animal feed, in those cases where this is appropriate.

1.2.2 Contaminant

Volume 1 of the Codex Alimentarius defines a contaminant as follows:

"Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter".

This standard applies to any substance that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, except:

- 1) Contaminants having only food quality significance, but no public health significance, in the food(s).
- 2) Pesticide residues, as defined by the Codex definition that are within the terms of reference of the Codex Committee on Pesticide Residues (CCPR). Pesticide residues arising from pesticide uses not associated with food production may be considered for inclusion in the GSCTF if not dealt with by the CCPR.
- 3) Residues of veterinary drugs, as defined by the Codex definition, that are within the terms of reference of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).
- 4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the Codex Committee on Food Hygiene (CCFH).
- 5) Processing aids (that by definition are intentionally added to foods).

1.2.3 Natural toxins included in this standard

The Codex definition of a contaminant implicitly includes naturally occurring toxicants such as are produced as toxic metabolites of certain microfungi that are not intentionally added to food (mycotoxins).

Microbial toxins that are produced by algae and that may be accumulated in edible aquatic organisms such as shellfish (phycotoxins) are also included in this standard. Mycotoxins and phycotoxins are both subclasses of contaminants.

Inherent natural toxicants that are implicit constituents of foods resulting from a genus, species or strain ordinarily producing hazardous levels of a toxic metabolite(s), i.e. phytotoxins are not generally considered within the scope of this standard. They are, however, within the terms of reference of the CCFAC and will be dealt with on a case by case basis.

1.2.4 Maximum level and related terms

The *Codex maximum level (ML)* for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the Codex Alimentarius Commission (CAC) to be legally permitted in that commodity.

A *Codex guideline level (GL)* is the maximum level of a substance in a food or feed commodity which is recommended by the CAC to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction.¹

1.3 GENERAL PRINCIPLES REGARDING CONTAMINANTS IN FOODS

1.3.1 General

Foods and feeds can become contaminated by various causes and processes. Contamination generally has a negative impact on the quality of the food or feed and may imply a risk to human or animal health.

Contaminant levels in foods shall be as low as reasonably achievable. The following actions may serve to prevent or to reduce contamination of foods and feeds:

- preventing food contamination at the source, e.g. by reducing environmental pollution.
- applying appropriate technology in food production, handling, storage, processing and packaging.
- applying measures aimed at decontamination of contaminated food or feed and measures to prevent contaminated food or feed to be marketed for consumption.

To ensure that adequate action is taken to reduce contamination of food and feed a Code of Practice shall be elaborated comprising source related measures and Good Manufacturing Practice as well as Good Agricultural Practice in relation to the specific contamination problem.

The degree of contamination of foods and feeds and the effect of actions to reduce contamination shall be assessed by monitoring, survey programs and more specialized research programs, where necessary.

When there are indications that health hazards may be involved with consumption of foods that are contaminated, it is necessary that a risk assessment is made. When health concerns can be substantiated, a risk management policy must be applied, based on a thorough evaluation of the situation. Depending on the assessment of the problems and the possible solutions, it may be necessary to establish maximum levels or other measures governing the contamination of foods. In special cases, it may also have to be considered to give dietary recommendations, when other measures are not sufficiently adequate to exclude the possibility of hazards to health.

National measures regarding food contamination should avoid the creation of unnecessary barriers to international trade in food or feed commodities. The purpose of the Codex General Standard for Contaminants and Toxins in Food is to provide guidance about the possible approach of the contamination problem and to promote international harmonization through recommendations which may help to avoid the creation of trade barriers.

For all contaminants, which may be present in more than one food or feed item, a broad approach shall be applied, taking into account all relevant information that is available, for the assessment of risks and for the development of recommendations and measures, including the setting of maximum levels.

¹ Because the CAC has decided that the preferred format of a Codex standard in food or feed is a maximum level, the present existing or proposed guideline levels shall be reviewed for their possible conversion to a maximum level.

1.3.2 Principles for establishing maximum levels in foods and feeds

Maximum levels shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They shall be set in such a way that the consumer is adequately protected. At the same time the technological possibilities to comply with maximum levels shall be taken into account. The principles of Good Manufacturing Practice, Good Veterinary Practice and Good Agricultural Practice shall be used. Maximum levels shall be based on sound scientific principles leading to levels which are acceptable worldwide, so that international trade in these foods is facilitated. Maximum levels shall be clearly defined with respect to status and intended use.

1.3.3 Specific criteria

The following criteria shall (not preventing the use of other relevant criteria) be considered when developing recommendations and making decisions in connection with the Codex General Standard for Contaminants and Toxins in Food: (Further details about these criteria are given in Annex I).

Toxicological information

- identification of the toxic substance(s);
- metabolism by humans and animals, as appropriate;
- toxicokinetics and toxicodynamics;
- information about acute and long term toxicity and other relevant toxicity;
- integrated toxicological expert advice regarding the acceptability and safety of intake levels of contaminants, including information on any population groups which are specially vulnerable.

Analytical data

- validated qualitative and quantitative data on representative samples;
- appropriate sampling procedures.

Intake data

- presence in foods of dietary significance for the contaminant intake;
- presence in foods that are widely consumed;
- food intake data for average and most exposed consumer groups;
- results from total diet studies;
- calculated contaminant intake data from food consumption models;
- data on intake by susceptible groups.

Fair trade considerations

- existing or potential problems in international trade;
- commodities concerned moving in international trade;
- information about national regulations, in particular on the data and considerations on which these regulations are based.

Technological considerations

- information about contamination processes, technological possibilities, production and manufacturing practices and economic aspects related to contaminant level management and control.

Risk assessment and risk management considerations

- risk assessment;
- risk management options and considerations;
- consideration of possible maximum levels in foods based on the criteria mentioned above;

- consideration of alternative solutions.

1.4 CODEX PROCEDURE FOR ESTABLISHING STANDARDS FOR CONTAMINANTS AND TOXINS IN FOODS

1.4.1 General

The Procedure for the elaboration of Codex Standards, as contained in the Procedural Manual, is applicable. Further details are mentioned here regarding the procedure to be followed and the criteria for decision making, in order to clarify and to facilitate the process of the elaboration of Codex Standards for Contaminants and Toxins in Foods.

1.4.2 Procedure for preliminary discussion about contaminants in the CCFAC

Suggestions for new contaminants or new contaminant/commodity combinations to be discussed in the Codex Committee on Food Additives and Contaminants (CCFAC) and to be included in the GSCTF may be raised by delegates or by the secretariat. An initial discussion may be held based on oral contributions, but preferably on the basis of a note containing relevant and adequate information. For a satisfactory preliminary review the following information is essential:

- 1) Identification of the contaminant and concise information about the background of the problem.
- 2) Indications about the availability of toxicological information and analytical and intake data, including references.
- 3) Indications about (potential) health problems.
- 4) Indications about existing and expected barriers to international trade.
- 5) Information about technological possibilities and economic aspects related to the management of the contaminant problem in food.
- 6) Preferably a proposal for action by the CCFAC.

When a delegation wishes that the CCFAC shall consider a request for action concerning a specific contaminant this delegation shall, as far as possible, supply information as stated above to serve as the basis for a preliminary review and request the Secretariat to include the matter on the agenda of the next meeting of the Committee.

1.4.3 Procedure for risk management decisions in the CCFAC regarding contaminants

An evaluation by JECFA of the toxicological and of other aspects of a contaminant and subsequent recommendations regarding the acceptable intake and regarding maximum levels in foods shall be the main basis for decisions to be discussed by the CCFAC. In the absence of recommendations by JECFA, decisions may be taken by CCFAC when sufficient information from other sources is available to the Committee and the matter is considered urgent.

The CCFAC procedure for risk management decisions is further described in Annex II.

1.5 FORMAT OF THE STANDARD FOR CONTAMINANTS IN FOODS

The General Standard for Contaminants and Toxins in Foods contains two types of presentation for the Standards: Schedule I in which the standards are listed per contaminant in the various food categories, and Schedule II (to be developed at a later stage) in which the contaminant standards are presented per food (category).

The format of the presentation is according to the provisions described in the Procedural Manual, in so far they are applicable. In order to obtain maximal clarity, explanatory notes shall be added where appropriate. The format contains all elements necessary for full understanding of the meaning, background, application and scope of the standards and contains references to the relevant documents and discussion reports on which the standard is based.

A full description of the format is given in Annex III.

For each session of the CCFAC, a working document shall be prepared in which the complete list of Codex Standards for contaminants in foods (both proposed and agreed) is presented in the form of Schedule I.

The list of Codex contaminant standards for individual foods or food categories shall be presented according to an agreed food categorization system. See Annex IV.

1.6 REVIEW AND REVISION OF THE STANDARD

The contaminant provisions for this Standard shall be reviewed on a regular basis and revised as necessary in the light of revisions of toxicological advice by JECFA or of changed risk management views, residue management possibilities, scientific knowledge or other important relevant developments.

Specific attention shall be given to the review of existing Maximum Levels and Guideline Levels and to their possible conversion to Maximum Levels.

ANNEX I

CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOODS

Introduction

In this Annex criteria are mentioned regarding information which is considered necessary for evaluating contaminant problems in foods and for the establishment of maximum levels. It is therefore important that these criteria are taken into account when information is supplied to JECFA and/or to the CCFAC.

The criteria mentioned here are elaborated in more detail than in section 1.3.3. of the Preamble. Only those aspects are mentioned that need further clarification, so criteria or aspects that are not mentioned here should not be ruled out in the evaluation process.

Toxicological information

Integrated toxicological expert advice regarding a safe/tolerable intake level of a contaminant is essential when decisions about maximum levels in foods are considered. A recommendation from JECFA regarding the maximum allowable or tolerable intake, based on a full evaluation of an adequate toxicological data base, shall be the main basis for decisions by CCFAC. In urgent cases, it may be possible to rely on less developed evaluations from JECFA or on toxicological expert advice from other international or national bodies.

When toxicological information is presented in relation to proposals for maximum levels for contaminants in foods, indications are desirable about the following aspects:

- identification of the toxic substance(s);
- metabolism in humans and animals, as appropriate;
- toxicokinetics and toxicodynamics;
- information about acute and long term toxicity in animals and humans, including epidemiological data on humans and other relevant toxicity data;
- conclusions and advice of toxicological expert(s) (groups), with references, including information on specially vulnerable population groups or animals.

Analytical data

Validated qualitative and quantitative analytical data on representative samples should be supplied. Information on the analytical and sampling methods used and on the validation of the results is desirable. A statement on the representativity of the samples for the contamination of the product in general (e.g. on a national basis) should be added. The portion of the commodity that was analyzed and to which the contaminant content is related should be clearly stated and preferably should be equivalent to the definition of the commodity for this purpose or to existing related residue regulation.

Appropriate sampling procedures should be applied. Special attention to this aspect is necessary in the case of contaminants that may be unequally distributed in the product (e.g. mycotoxins in some commodities).

Intake data

It is desirable to have information about the contaminant concentrations in those foods or food groups that (together) are responsible for at least half and preferably 80% or more of the total dietary intake of the contaminant, both for average consumers and for high consumers.

Information about the *presence of the contaminant in foods that are widely consumed* (staple foods) is desirable in order to be able to make a satisfactory assessment of the contaminant intake and of risks associated with food trade.

Food consumption data for average, most exposed and susceptible consumer groups are desirable for evaluations of (potential) intake of contaminants. This problem, however, has to be addressed differently on a national and on an international scale. It is therefore important to have information about both average and high consumption patterns regarding a wide scale of foodstuffs, so that for every contaminant the most exposed consumer groups may be identified. Detailed information about high consumption patterns is desirable, both regarding group identification criteria (e.g. age or sex differences, vegetarian or regional dietary customs, etc.) and statistical aspects.

Dietary intake of contaminants: Reference is made to the Guidelines for the study of dietary intake of chemical contaminants (WHO). It is important to supply all relevant details, such as the type of study (duplicate diet, total diet or market basket study, selective study), and statistical details. Calculated contaminant intake data from food consumption models may also be useful. When results about food groups and about effects of preparation and cooking etc. are available, these should also be supplied.

Fair trade considerations

Existing, expected or potential problems in international trade: In order to assess the urgency of a problem to be discussed by CCFAC it is important to have information about the magnitude of existing or expected problems, both regarding the amount and the source of the food or feed that is at stake and the concerned parties and economic aspects involved. Potential problems should also be indicated.

Foods concerned moving in international trade: The main exporting and importing countries for commodities which are involved in the issue should be identified and it is essential that information is available about contaminant concentrations in the commodities originating from the main exporting countries.

Information about national regulations: It is desirable that details are made available by countries (especially the main exporting and importing countries) about their national regulations regarding the contaminant in question, in particular on the data and the considerations on which these regulations are based. For a good evaluation of the problem it is essential that not only the data base is clear, but also the risk assessment and risk management policy which is used for making decisions regarding maximum levels in foods.

Technological considerations

Information about the source of the contaminant and the way in which the food is contaminated, possibly including information, if it is available, about contamination being present in parts only of the product, is essential for assessing the possibilities to control the contamination process and to be able to guarantee a desired product quality. Where possible **Source-related measures** should be proposed. **Good Manufacturing Practice (GMP)** and/or **Good Agricultural Practice (GAP)** should also be formulated to control a contamination problem. When this is possible, maximum levels may be based on GMP or GAP considerations and may thus be established at a level as low as reasonably achievable. Considerations regarding the technological possibilities to control a contamination problem, e.g. by cleaning, should also be taken into account when a primary risk assessment model (theoretical maximum daily intake) shows possible intakes exceeding the toxicological maximum intake recommendation. In such a case the possibilities of lower contamination levels need further careful examination. Then a detailed study about all the aspects involved is necessary, so that decisions about maximum limits can be based on a thorough evaluation of both the public health arguments and the possibilities and problems to comply with the proposed standard.

Risk assessment and risk management considerations

A tiered approach, involving risk assessment and risk management procedures, is recommended for developing a consistent policy regarding public health risks related to contaminants in foods.

Risk assessment is defined as the scientific evaluation of the probability of occurrence of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of the following steps: **hazard identification, hazard characterization, exposure assessment and risk characterization**. (The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties).

The first steps are *hazard identification* and *hazard characterization*. *Hazard identification* is the identification of known or potential health effects in humans, produced by a contaminant which may be present in a particular food or group of foods. *Hazard characterization* is the qualitative and, if possible, quantitative evaluation of the nature of the adverse effects associated with the food contaminant, including a dose/response assessment and, when possible, the establishment of a safety standard (ADI, TDI or comparable toxicological recommendation) for the intake of the contaminant. The *exposure assessment* is the qualitative and, when possible, quantitative evaluation of the likely intake of the contaminant via food, as well as exposure from other sources if relevant. In the *risk characterization* step, the hazard identification, hazard characterization and exposure assessment are combined into an estimation of the severity and occurrence of known or potential health effects likely to occur in a given population, including attendant uncertainties.

Potential public health risks can be considered to exist when there is evidence that the contaminant intake of (groups of) consumers may exceed (on a long term basis for long term recommendations) the toxicological recommendation about the maximum acceptable or tolerable intake level. More specific estimation and description of the risks will be necessary to deal adequately with cases when intakes exceeding the toxicological standard occur in practice and cannot easily be reduced. This also applies when it has not been possible to establish a safe dose level of the contaminant.

Risk management is defined as the process of weighing policy alternatives in the light of the risk assessment and, if required, to select and implement appropriate control options, including the establishment and enforcement of maximum levels of contaminants in foods. It is based on adequate risk assessment and on information about policy options and strategies to deal with contamination problems and involves **risk communication**.

Risk communication is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers and other interested parties. Responsible risk management is based on consistent application of an appropriate policy regarding the protection of public health, but also involves taking into account other relevant criteria, such as the available analytical data, the technological possibilities to control the contamination of products, economic factors and fair trade criteria.

In short, the risk assessment shall establish how many consumers possibly exceed the toxicological standard, and for how long time and how much, and what this implies as real health risks. Risk management involves, in a consistent way, deciding what is acceptable in this respect and what is not, to what extent other factors can be taken into account, and decisions and actions to achieve sufficient public health protection and control of the contamination.

Risk management decisions may lead to maximum levels for foods. In the process leading to such a decision, the consequences, costs and benefits should be presented and evaluated in relation to other policy options.

Establishment of maximum levels for contaminants

The *establishment of maximum levels of contaminants in foods* involves several principles, some of which have already been mentioned. Briefly stated, the following criteria will help in maintaining a consistent policy in this matter:

- MLs shall be set only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade.
- MLs shall be set only for those foods that are significant for the total exposure of the consumer to the contaminant. When identifying the significance of certain foods in the total exposure to the contaminant, the criteria contained in the CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups should be consulted (see para. 11 of the “CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods” in the Codex Alimentarius Commission Procedural Manual).

- MLs shall be set as low as reasonably achievable. Providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade. Where possible, MLs shall be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless a higher ML can be shown to be acceptable from a public health point of view and appreciable economic aspects are at stake.
- Proposals for MLs in products shall be based on data from at least various countries and sources, encompassing the main production areas/processes of those products, as far as they are engaged in international trade. When there is evidence that contamination patterns are sufficiently understood and will be comparable on a global scale, more limited data may be enough.
- MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group, or when there are other arguments that extrapolation is appropriate.
- Numerical values for MLs shall preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs.
- MLs shall apply to representative samples per lot. If necessary, appropriate methods of sampling shall be specified.
- MLs should not be lower than a level which can be analyzed with methods of analysis that can be readily applied in normal product control laboratories, unless public health considerations necessitate a lower detection limit which can only be controlled by means of a more elaborate method of analysis. In all cases, however, a validated method of analysis should be available with which a ML can be controlled.
- The contaminant as it should be analyzed and to which the ML applies should be clearly defined. The definition may include important metabolites when this is appropriate from an analytical or toxicological point of view. It may also be aimed at indicator substances which are chosen from a group of related contaminants.
- The product as it should be analyzed and to which the ML applies, should be clearly defined. In general, MLs are set on primary products. MLs shall in general preferably be expressed as a level of the contaminant related to the product as it is, on a fresh weight basis. In some cases, however, there may be valid arguments to prefer expression on a dry weight basis. Preferably the product shall be defined as it moves in trade, with provisions where necessary for the removal of inedible parts that might disturb the preparation of the sample and the analysis. The product definitions used by the CCPR and contained in the Classification of foods and feeds may serve as guidance on this subject; other product definitions should only be used for specified reasons. For contaminant purposes, however, analysis and consequently MLs will preferably be on the basis of the edible part of the product.

For fat soluble contaminants which may accumulate in animal products, provisions should be applied regarding the application of the ML to products with various fat content (comparable to the provisions for fat soluble pesticides).

- Guidance is desirable regarding the possible application of MLs established for primary products to processed products and multi-ingredient products. When products are concentrated, dried or diluted, use of the concentration or dilution factor is generally appropriate in order to be able to obtain a primary judgement of the contaminant levels in these processed products. The maximum contaminant concentration in a multi-ingredient food can likewise be calculated from the composition of the food. Information regarding the behaviour of the contaminant during processing (e.g. washing, peeling, extraction, cooking, drying etc.) is however desirable to give more adequate guidance here. When contaminant levels are consistently different in processed products related to the primary products from which they are derived, and sufficient information is available about the contamination pattern, it may be appropriate to establish separate maximum levels for these processed products. This also applies when contamination may occur during processing. In general however, maximum levels should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient foods by using appropriate factors. When these factors are sufficiently known, they should be added to the data base about the contaminant and mentioned in connection to the maximum level in a product.
- MLs shall preferably not be set higher than is acceptable in a primary (theoretical maximum intake and risk estimation) approach of their acceptability from a public health point of view. When this poses problems in relation to other criteria for establishing MLs, further evaluations are necessary regarding the possibilities to reduce the contaminant levels, e.g. by improving GAP and/or GMP conditions. When this does not bring a satisfactory solution, further refined risk assessment and contaminant risk management evaluations will have to be made in order to try to reach agreement about an acceptable ML.

Procedure for risk assessment in relation to (proposed) MLs for contaminants

It will be evident that in the case of contaminants, it is more difficult to control food contamination problems than in the case of food additives and pesticide residues. Proposed MLs will inevitably be influenced by this situation. In order to promote acceptance of Codex contaminant MLs, it is therefore important that assessments of the acceptability of those MLs are done in a consistent and realistic way. The procedure involves assessment of the dietary intake in relation to the proposed or existing MLs and the maximally acceptable intake from the toxicological point of view.

For pesticide residues, Guidelines (WHO, 1989, revised 1995) have been prepared for predicting the dietary intake, involving a two-tiered approach with increasingly realistic predictions of intake. In the crude estimate phase, hypothetical global and cultural diets are used to calculate the theoretical maximum daily intake (TMDI) (based on proposed or existing MRLs). The best estimate involves the national dietary pattern and corrections for residue losses during transport, storage, food preparation, for known residue level in foods as consumed, etc. It is recommended to be cautious in using other than average food consumption values, although it is considered appropriate to use relevant average food consumption data for identifiable subgroups of the population. The procedure is used to assess the acceptability of proposed MRLs and to promote international acceptance of Codex MRLs.

For contaminants and natural toxins in food, essentially the same procedure is used. Food consumption patterns with a higher intake of critical foods may be used in the intake calculations when this is part of an accepted national or international health protection and risk management policy. A harmonized approach using an appropriate intake estimation model that is as realistic as possible is recommended. Calculated data should where possible always be compared with measured intake data. Proposals for Codex MLs should be accompanied by intake calculations and risk assessment conclusions regarding their acceptability and use. The intake calculations should follow the methodology described in the CCFAC Policy for Exposure Assessment and, if appropriate, be accompanied by the generation of distribution curves for the concentration in specific foods/food groups (see paras 5-8 and 12-14 of the CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods in the Codex Alimentarius Commission Procedural Manual). Statements from Governments about the (non-acceptance of (proposed) Codex MLs should refer to specified intake calculations and risk management conclusions which support this position.

ANNEX II**PROCEDURE FOR RISK MANAGEMENT DECISIONS****Introduction**

The recommended procedure for risk management decisions in the CCFAC is presented here as a simple decision scheme based on the main criteria, mentioned in the Preamble, I.4.2. Criterion (1), basic information about the contaminant (problem) is not further mentioned, because it is considered a prerequisite, without which no sensible discussion can take place, hazard identification and characterization. Criterion (5), technological and economic aspects, is an essential tool for making recommendations about the risk management of the contaminant problem and for developing MLs, and when this information is not adequate, further data shall be requested. Bearing this in mind, it need not be further mentioned in the decision scheme, which is shown below. Decisions can be based on the availability of information (- or + or ?) on the following criteria:

- (2a) Tox toxicological information;
- (3) PHP potential health problems;,
- (2b) A/In analytical and intake data;,
- (4) TP international trade problems.

The question mark ? is used in the column PHP, to indicate that only toxicological information is sufficiently available, or only intake data, so that there is no sufficient basis to decide whether there are potential health problems. Obviously, in practice there will be many situations which are not so clear cut as it is presented in the scheme. Information may be considered sufficient by some, and inadequate by others. Decisions will have to be taken on a case by case basis, considering the criteria mentioned in Annex I. Further quantification of the criteria for the necessary data base for making decisions may become inevitable when serious problems are encountered in practice regarding this aspect.

Risk management decision scheme for CCFAC

Case	Criterion				CCFAC Action
	(2a) Tox	(2b) A/In	(3) PHP	(4) TP	
1.	-	+	?	-	Request Tox data/evaluation by JECFA
2.	-	+	?	+	Request Tox data/evaluation by JECFA, national risk assessment. In urgent cases, CCFAC statement
3.	+	-	?	-	Request analytical/intake data
4.	+	+	-	-	No further action
5.	+	+	-	+	Request national risk assessment. After evaluation (in urgent cases, after a preliminary assessment) a CCFAC statement
6.	+	+	+	-	Development of MLs by CCFAC
7.	+	+	+	+	Development of MLs by CCFAC, with priority (in urgent cases, if necessary, temporary MLs)

(-) insufficient information

(+) sufficient information

(?) only toxicological information is sufficiently available, or only intake data, so that there is no sufficient basis to decide whether there are potential health problems.

ANNEX III

FORMAT OF THE STANDARD

Introduction

The format for Schedule I shall contain the following elements:

- ***Name of the contaminant:*** symbols, synonyms, abbreviations, scientific descriptions and identification codes that are commonly used shall be mentioned, too.
- ***Codex number of the contaminant:*** number according to the list described in Schedule I.
- ***Reference to JECFA meetings*** (in which the contaminant was discussed).
- ***ADI, TDI, PTWI or similar toxicological intake recommendation:*** when the situation is complex a short statement and further references may be necessary here.
- ***Residue definition:*** definition of the contaminant as it shall be analyzed and to which the maximum level applies.
- ***List of Codex standards for the contaminant in foods:*** this list shall be composed of the following elements, in columns:
 - Classification number of food commodity or food category;
 - Name of food commodity/category;
 - Numerical value of maximum level;
 - Suffix accompanying a ML to specify the application of the ML;
 - Step in Codex procedure (only in CCFAC working documents);
 - References to documents, including references to source-directed measures or a code of practice, if appropriate;
 - References to standard criteria for methods of analysis and sampling;
 - Notes/remarks.

When appropriate, instead of a maximum level a (note referring to a) statement regarding the contaminant in the mentioned food (category) may be inserted.

The format of Schedule II shall contain the following elements:

- ***Name of food commodity/category;***
- ***Classification number of food commodity or food category;***
- ***List of Codex standards for contaminants in that food commodity/category:***

This list shall be composed of the following elements, in columns:

- Name of the contaminant;
 - Numerical value of maximum level;
 - Step in Codex procedure (only in CCFAC working documents);
 - References, remarks and notes (shorter than in Schedule I).
- ***Reference to a Code of practice for the food, if appropriate.***

ANNEX IV

FOOD CATEGORIZATION SYSTEM (GSCTF)

Introduction

The food categorization system of the Codex General Standard for Contaminants and Toxins in Foods is constructed to perform the following functions:

It has a logical structure which enables a clear and systematic presentation of the (proposed) MLs. It contains (references to) product definitions and definitions of the part of the product which is analyzed and to which the ML refers. It contains codes for the food categories and the individual foods, so that data can be stored and retrieved in a convenient way.

To achieve as much harmonization as possible, an existing agreed categorization system is used.

The GSCTF uses the system which is developed in the framework of the CCPR as it is also suitable for contaminants. It is adopted for characterizing the various food and feed groups and the individual commodities. This system is especially elaborated regarding primary agricultural commodities, but needs further extension regarding processed products. Where necessary, new (sub)group codes or commodity codes are therefore introduced. These are described in Annex IV-A. Annex IV-A will also contain product descriptions as far as they are different from those contained in the existing system described by the CCPR.

Where appropriate and possible, the descriptive texts accompanying the food categories do or should also contain indications about the concentration or dilution factor in the processed commodities mentioned, in relation to the primary product(s) involved. In that way a first estimate can be made of the possible carry-over of contaminants from primary products to the various processed products. It has to be borne in mind however that the specific distribution of a contaminant in the primary product and the behaviour during processing is a complicating factor here. Further advice may be necessary in those cases. See also the general indications in Annex I and possible specific information mentioned in relation to the contaminant.

Description of the food categorization system of the GSCTF

The first part contains the categorization system as developed and maintained by the CCPR. It consists of 5 classes, covering primary food commodities of plant, resp. animal origin, primary feed commodities and processed commodities of plant, resp. animal origin. The classes are subdivided in 19 types and 93 groups, which are identified by code numbers and letters.

Reference is made to Vol. 2 of the Codex Alimentarius, section 2 (1993), in which this system is described, and to CX/PR 92/6 (in which a different kind of group numbering was introduced).

Annex IV-A is the other part of the food categorization system for the GSCTF. It is developed and maintained by the CCFAC, and is complementary to the system described in the first part. It is mainly directed to processed, derived and multi-ingredient foods and encompasses all those types and groups and commodity descriptions that are necessary to assign food categorization codes to existing or planned Codex MLs for contaminants.

ANNEX IV-A**COMPLEMENTARY FOOD CATEGORIZATION SYSTEM FOR THE GSCTF****Introduction**

The additions to the food categorization system described in this Annex will serve the need of assigning a food code number to commodities that are not covered by this Annex. The commodities involved are mainly processed, derived and multi-ingredient foods.

The system has been designed as a comprehensive list (on a general level), in order to be able to accommodate possible future needs.

In this phase no individual product definitions and codes are given. It seems sufficient to go no further than a type or group level in judging the acceptability of the system. The classification can be developed in further detail as the need arises.

The system used in the Codex General Standard for Food Additives (GSFA) for food classification has been utilized as far as it is compatible with the existing Codex classification system described in this Annex.

See the following list of proposed new food categories. Some explanations (as shown in the list) and some existing related food categories, for a better insight in the proposed system.

Commodity descriptions can often be derived from existing Codex Standards.

Information regarding concentration and dilution factors, in relation to contaminant carry-over from primary products, will be added where appropriate and available.

Definitions for the part of the product that shall be analyzed and to which the ML of a contaminant will apply, that are different from existing definitions in this Annex, will also be added.

Class	Type	Group	Letter code	Product group description
D				PROCESSED FOODS OF PLANT ORIGIN (existing)
D	01			Secondary commodities of plant origin (5 existing groups)
D	01	06	TF	Treated fruit products (peeled, cut, frozen etc.) (New proposed group; commodity codes can be derived from existing fruit codes)
D	01	07	TV	Treated vegetable products (cleaned, cut, frozen etc.) (New proposed group; commodity codes can be derived from existing vegetable codes)
D	02			Derived products of plant origin (7 existing groups)
D	02	08	JV	Vegetable juices and purees (New proposed group; commodity codes can be derived from the existing vegetable codes)
D	02	09	SH	Sugars, syrups and honey (New proposed group; commodity codes to be developed)
D	03			Manufactured foods of plant origin (multi-ingredient) (1 existing group)
D	03	01	CP	Manufactured multi-ingredient cereal products (e.g. bread and other cooked cereal products) (existing group)

Class	Type	Group	Letter code	Product group description
D	03	02	CB	Beverages derived from cereals (e.g. beer) <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
D	03	03	NF	Fruit nectars <i>(New proposed group; commodity codes can be derived from the existing fruit codes)</i>
D	03	04	FF	Fermented fruit beverages (wine, cider) <i>(New proposed group; commodity codes can be derived from the existing fruit concerned)</i>
D	03	05	DA	Distilled alcoholic beverages <i>(New proposed group; commodity codes to be developed when the need arises)</i>
D	03	06	FJ	Fruit jams, jellies, marmalades etc. <i>(New proposed group; commodity codes to be derived from the existing fruit codes)</i>
D	03	07	SF	Fruit chutneys and comparable preparations <i>(New proposed group; commodity codes to be derived from the existing fruit codes)</i>
D	03	08	SV	Vegetable chutneys and comparable preparations <i>(New proposed group; commodity codes to be derived from the existing vegetable codes)</i>
D	03	09	PS	Preparations from nuts, oil seeds and other seeds <i>(New proposed group; commodity codes to be derived from the existing product codes)</i>
D	03	10	PP	Other manufactured plant products <i>(New proposed group; commodity codes to be developed when the need arises)</i>
E				PROCESSED FOODS OF ANIMAL ORIGIN <i>(existing class)</i>
E	01			Secondary commodities of animal origin <i>(2 existing groups)</i>
E	01	03	MS	Secondary meat products (e.g. cooked meat) <i>(New proposed group; commodity codes to be derived from the existing meat codes)</i>
E	01	04	ES	Secondary egg products (e.g. egg powder) <i>(New proposed group; commodity codes to be derived from the existing egg codes)</i>
E	01	05	WS	Secondary fishery products (e.g., smoked fish) <i>(New proposed group; commodity codes to be derived from the existing fish codes)</i>
E	02			Derived animal products of animal origin <i>(4 existing groups)</i>
E	02	05	MC	Derived meat products (e.g. meat extract) <i>(New proposed group; commodity codes to be derived from existing meat codes)</i>
E	02	06	ED	Derived egg products (e.g. egg white, yolk) <i>(New proposed group; commodity codes to be derived from existing egg codes)</i>

Class	Type	Group	Letter code	Product group description
E	02	07	WD	Derived fishery products <i>(New proposed group; commodity codes to be derived from the existing fish codes)</i>
E	03			Manufactured food (single ingredient), animal origin <i>(1 existing group)</i>
E	03	01	LI	Manufactured milk products (single ingredient) <i>(existing group)</i>
E	03	02	MT	Manufactured meat products (e.g. cured meat) <i>(New proposed group; commodity codes to be derived from existing meat codes)</i>
E	03	03	EM	Manufactured egg products (e.g. egg white powder) <i>(New proposed group; commodity codes to be derived from existing egg codes)</i>
E	03	04	WP	Manufactured fishery products <i>(New proposed group; commodity codes to be derived from existing fish codes)</i>
E	04			Manufactured food (multi-ingredient) of animal origin <i>(1 existing group)</i>
E	04	01	LM	Manufactured milk products (multi-ingredient) <i>(existing group)</i>
E	04	02	MP	Manufactured meat products (multi-ingredient) (e.g. sausage) <i>(New proposed group; commodity codes to be developed in relation to commodity description)</i>
E	04	03	EP	Manufactured egg products (multi-ingredient) <i>(New proposed groups; commodity codes to be developed in relation to commodity description)</i>
E	04	04	WI	Manufactured fishery products (multi-ingredient) <i>(New proposed group; commodity codes to be derived from existing fish codes)</i>
F				MULTI-INGREDIENT MANUFACTURED FOODS <i>(New proposed class)</i>
F	01			Beverages (multi-ingredient) <i>(New proposed type)</i>
F	01	01	BS	Beverages (soft drinks and comparable preparations) <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	01	02	BA	Alcoholic multi-ingredient beverages <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	02			Sauces, salad dressings, soups, bouillons etc. <i>(New proposed type)</i>
F	02	01	SP	Seasonings and condiments <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	02	02	PV	Vinegars (multi-ingredient) <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>

Class	Type	Group	Letter code	Product group description
F	02	03	PM	Mustards <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	02	04	BS	Soups and broths <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	02	05	ME	Sauces and comparable products <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	02	06	BC	Salads and sandwich spreads <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	03			Chocolate & other confectionery <i>(New proposed type)</i>
F	03	01	CC	Chocolate products <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	03	02	CS	Sugar confectionery, including nut based and comparable multi-ingredient confectionery <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	03	03	CG	Chewing gum <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	04			Margarines & other multi-ingredient fatty foods <i>(New proposed type)</i>
F	04	01	HF	Margarines > 80 % fat <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	04	02	LF	Margarines < 80 % fat <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	04	03	OF	Other products based on fat emulsions <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	05			Multi-ingredient bakery wares <i>(New proposed type)</i>
F	05	01	BF	Fine bakery wares <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	05	02	BS	Savoury snacks (potato, cereal or starch base) <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	05	03	NS	Savoury coated nuts, other nut snacks, nut mixtures <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06			Multi-ingredient foods for special dietary uses <i>(New proposed type)</i>

Class	Type	Group	Letter code	Product group description
F	06	01	ID	Infant and follow-on formulae <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	02	CD	Weaning foods <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	03	HD	Dietetic foods intended for special medical purposes <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	04	TD	Dietetic formulae for slimming purposes and weight reduction <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	05	SD	Supplementary foods for dietetic uses <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	06	AD	Food supplements <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
G				OTHER EDIBLE PRODUCTS <i>(New proposed class)</i>
G	01			Water, minerals and organic compounds <i>(New proposed type)</i>
G	01	01	DW	Drinking water, mineral water, table waters <i>(New proposed group, commodity codes to be developed when the necessity arises)</i>
G	01	02	SW	Salt, salt substitutes, mineral preparations <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>

**SCHEDULE I - MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS
AND TOXINS IN FOODS**

INDEX OF CONTAMINANTS IN ALPHABETIC ORDER

NAME	PAGE
Mycotoxins	
Aflatoxins, Total	
Aflatoxin M1	
Patulin	
Heavy Metals	
Arsenic	
Cadmium	
Lead	
Mercury	
Methylmercury	
Tin	
Others	
Acrylonitrile	
Radionuclides	
Vinylchloride monomer	

EXPLANATORY NOTES

Reference to JECFA:	References to JECFA meeting in which the contaminant was evaluated and the year of that meeting
Toxicological guidance value:	Toxicological advice about the tolerable intake level of the contaminant for humans, expressed in milligrammes (mg) per kg body weight (bw). The year of recommendations and additional explanation are included.
Residue definition:	Definition of the contaminant in the form of which the ML applies or which may or should be analyzed in commodities.
Synonyms:	Symbols, synonyms abbreviations, scientific descriptions and identification codes used to define the contaminant.
Commodity code:	The code for food commodities is according to the food and feed categorization system as contained in Annex V of the GSCTF. The food/feed categorization system also specifies the part of Commodity which should be analysed and to which the ML applies, unless a specific commodity definition is provided as an annex to the ML. For those maximum levels contained in Codex commodity standards, the relevant standard numbers are referred, if the code numbers are not readily available for these commodities.
Suffix:	A note accompanying an ML or GL, used to specify the application or the future revision of the ML, e.g., specific residue definitions can be mentioned by abbreviations here. See also "Qualification of MLs" below.
Type:	Indicates whether the value is Codex maximum level (ML) or Codex guideline level (GL). See also the definitions of these terms in the preamble of the GSCTF.

Qualification of MLs

C:	In canned products only
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Definitions of some toxicological terms

PMTDI:	<i>(Provisional Maximum Tolerable Daily Intake)</i> The endpoint used for contaminants with no cumulative properties. Its value represents permissible human exposure as a result of the natural occurrence of the substance in food and in drinking-water. In the case of trace elements that are both essential nutrients and
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	unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI.
PTWI:	<i>(Provisional Tolerable Weekly Intake)</i> An endpoint used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods.
PTMI:	<i>(Provisional Tolerable Monthly Intake)</i> An endpoint used for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods

AFLATOXINS, TOTAL

Reference to JECFA:	31 (1987), 46 (1996), 49 (1997)
Toxicological guidance:	Carcinogenic potency estimates for aflatoxins B, G, M (1997, Intake should be reduced to levels as low as reasonably possible.)
Residue definition:	Aflatoxins total (B1 +B2 + G1 + G2)
Synonyms:	Abbreviations, AFB, AFG, with numbers, to designate specific compounds
Related Code of Practice:	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CAC/RCP 55-2004) Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005)

Commodity/Product Code	Product Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
SO 0697	Peanut	15		ML	CS 209-199, Rev.1-2001	The ML applies to peanuts intended for further processing. For sampling plan, see Annex 2.

Aflatoxins are a group of highly toxic mycotoxins produced by fungi of the genus *Aspergillus*. The four main aflatoxins found in contaminated plant products are B1, B2, G1 and G2 and are a group of structurally related difuranocoumarin derivatives that usually occur together in varying ratios, AFB1 usually being the most important one. These compounds pose a substantial hazard to human and animal health. IARC (1992) classified aflatoxin B1 in Group 1 (human carcinogen) and AFM in Group 2B (probable human carcinogen). The liver is the primary target organ.

AFLATOXIN M1

Reference to JECFA:	56 (2001)
Toxicological guidance:	Cancer potency estimates at specified residue levels (2001, Using worst-case assumptions, the additional risks for liver cancer predicted with use of proposed maximum levels of aflatoxin M1 of 0.05 and 0.5 µg/kg are very small. The potency of aflatoxin M1 appears to be so low in HBsAg- individuals that a carcinogenic effect of M1 intake in those who consume large quantities of milk and milk products in comparison with non-consumers of these products would be impossible to demonstrate. Hepatitis B virus carriers might benefit from a reduction in the aflatoxin concentration in their diet, and the reduction might also offer some protection in hepatitis C virus carriers.)
Residue definition:	Aflatoxin M1
Synonyms:	AFM1

Commodity/Product Code	Product Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
ML 0106	Milk	0.5		ML	CS 232-2001	

PATULIN

Reference to JECFA: 35 (1989), 44 (1995)

Toxicological guidance: PMTDI 0.0004 mg/kg bw (1995)

Residue definition: patulin

Related Code of Practice: Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages (CAC/RCP 50-2003)

Commodity/Product Code	Product Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
JF 0226	Apple juice	50		ML	CS 235-2003	The ML also covers apple juice as ingredient in other beverages.

Patulin is a low molecular weight hemiacetal lactone mycotoxin produced by species of the genera *Aspergillus*, *Penicillium* and *Byssoschlamys*.

ARSENIC

Reference to JECFA:	5 (1960), 10 (1967), 27 (1983), 33 (1988)
Toxicological guidance:	PTWI 0.015 mg/kg bw (1988, For inorganic arsenic)
Residue definition:	Arsenic: total (As-tot) when not otherwise mentioned; inorganic arsenic (As-in); or other specification
Synonyms:	As
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Edible fats and oils	0.1		ML	CS 19-1981, Rev.2-1999	Edible fats and oils not covered by individual standards
	Margarine	0.1		ML	CS 32-1981, Rev.1-1989	
	Minarine	0.1		ML	CS 135-1981, Rev.1-1989	
	Named animal fats	0.1		ML	CS 211-1999	Lard, rendered pork fat, premier jus and edible tallow.
OR 0305	Olive oil, refined	0.1		ML	CS 33-1981, Rev.2-2003	
OC 0305	Olive oil, virgin	0.1		ML	CS 33-1981, Rev.2-2003	
OR 5330	Olive, residue oil	0.1		ML	CS 33-1981, Rev.2-2003	Olive pomace oil
OC 0172	Vegetable oils, Crude	0.1		ML	CS 210-1999, Rev.1-2001	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.
OR 0172	Vegetable oils, Edible	0.1		ML	CS 210-1999, Rev.1-2001	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.
	Natural mineral waters	0.01		ML	CS 108-1981, Rev.1-1997	Expressed in total As mg/l
	Salt, food grade	0.5		ML	CS 150-1985, Rev.1-1997	

Arsenic is a metalloid element which is normally occurring in mineral bound form in the earth's crust and which can become more easily available by natural sources such as volcanic activity and weathering of minerals, and by anthropogenic activity causing emissions in the environment, such as ore smelting, burning of coal and specific uses, such as arsenic-based wood preservatives, pesticides or veterinary or human medicinal drugs. As a result of naturally occurring metabolic processes in the biosphere arsenic occurs as a large number of organic or inorganic chemical forms in food (species). Especially in the marine environment arsenic is often found in high concentrations of organic forms, up to 50 mg/kg of arsenic on a wet weight basis in some seafood including seaweed, fish, shellfish and crustaceans. In fresh water and in the terrestrial environments arsenic is normally found in much lower levels (typically 0-20 ug/kg) in crop plants and in livestock. Higher levels may be found in rice, mushrooms and sometimes in poultry which is fed fish meal containing arsenic. The most toxic forms of arsenic are the inorganic arsenic (III) and (V) compounds; the inorganic arsenic trioxide is well known as a rat poison, which was also sometimes used for homicide. Methylated forms of arsenic have a low acute toxicity; arsenobetaine which is the principal arsenic form in fish and crustaceans is considered non-toxic. In shellfish, molluscs and seaweed dimethylarsinyriboside derivatives occur ("arsenosugars"), the possible toxicity of which is not known in detail. Only a few percent of the total arsenic in fish is present in inorganic form, which is the only form about which a PTWI has been developed by JECFA. The human epidemiological data used for this risk assessment is based on exposure to inorganic arsenic in drinking water. IARC has classified inorganic arsenic as a human carcinogen, and the estimated lifetime risk for arsenic-induced skin cancer which may be caused by drinking water at or in excess of the WHO guideline for arsenic in drinking water is estimated at 6×10^{-4} .

CADMIUM

Reference to JECFA:	16 (1972), 33 (1988), 41 (1993), 55 (2000), 61 (2003), 64 (2005)
Toxicological guidance:	PTWI 0.007 mg/kg bw (1988 (maintained in 2000 & 2003), The 64th JECFA concluded that the effect of different MLs on overall intake of cadmium would be very small. At the proposed Codex MLs, mean intake of cadmium would be reduced by approximately 1% of the PTWI. The imposition of MLs one level lower would result in potential reductions in intake of cadmium of no more than 6% (wheat grain, potatoes) of the PTWI. At the proposed Codex MLs, no more than 9% of a commodity would be violative (oysters). MLs one level below those proposed would result in approximately 25% of molluscs, potatoes, and other vegetables being violative.)
Residue definition:	Cadmium, total
Synonyms:	Cd
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
VB 0040	Brassica vegetables	0.05		ML	CS 248-2005	
VA 0035	Bulb vegetables	0.05		ML	CS 248-2005	
VC 0045	Fruiting vegetables, cucurbits	0.05		ML	CS 248-2005	
VO 0050	Fruiting vegetables, other than cucurbits	0.05		ML	CS 248-2005	Excluding tomatoes and edible fungi.
VL 0053	Leafy vegetables	0.2		ML	CS 248-2005	
VP 0060	Legume vegetables	0.1		ML	CAC/GL 39-2001	
VR 0589	Potato	0.1		ML	CS 248-2005	Peeled
VD 0070	Pulses	0.1		ML	CAC/GL 39-2001	Excluding soya bean (dry)
VR 0075	Root and tuber vegetables	0.1		ML	CS 248-2005	Excluding potato and celeriac
VS 0078	Stalk and stem vegetables	0.1		ML	CS 248-2005	
GC 0081	Cereal grains, except buckwheat, cañihua and quinoa	0.1		ML	CAC/GL 39-2001	Excluding wheat and rice; and bran and germ
GC 0654	Wheat	0.2		ML	CS 248-2005	
	Natural mineral waters	0.003		ML	CS 108-1981, Rev.1-1997	Expressed in mg/l
	Salt, food grade	0.5		ML	CS 150-1985, Rev.1-1999	

Cadmium is a relatively rare element, released to the air, land, and water by human activities. In general, the two major sources of contamination are the production and utilization of cadmium and the disposal of wastes containing cadmium. Increases in soil cadmium content will result in an increase in the uptake of cadmium by plants; the pathway of human exposure from agricultural crops is thus susceptible to increases in soil cadmium. The cadmium uptake by plants from soil is greater at low soil pH. Edible free-living food organisms such as shellfish, crustaceans, and fungi are natural accumulators of cadmium. Similar to humans, there are increased levels of cadmium in the liver and kidney of horses and some feral terrestrial animals. Regular consumption of these items can result in increased exposure. Tobacco is an important source of cadmium uptake in smokers. (Environmental health criteria for cadmium; International Programme on Chemical Safety (IPCS); 1992)

LEAD

Reference to JECFA:	10 (1966), 16 (1972), 22 (1978), 30 (1986), 41 (1993), 53 (1999)
Toxicological guidance:	PTWI 0.025 mg/kg bw (1987 for infants and young children, extended to all age groups in 1993, maintained 1999)
Residue definition:	Lead, total
Synonyms:	Pb
Related Code of Practice:	Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CAC/RCP 56-2004) Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
FT 0026	Assorted (sub)tropical fruits, edible peel	0.1		ML	CS 230-2001	
FI 0030	Assorted (sub)tropical fruits, inedible peel	0.1		ML	CS 230-2001	
FB 0018	Berries and other small fruits	0.2		ML	CS 230-2001	
FC 0001	Citrus fruits	0.1		ML	CS 230-2001	
FP 0009	Pome fruits	0.1		ML	CS 230-2001	
FS 0012	Stone fruits	0.1		ML	CS 230-2001	
VB 0040	Brassica vegetables	0.3		ML	CS 230-2001	Excluding kale
VA 0035	Bulb vegetables	0.1		ML	CS 230-2001	
VC 0045	Fruiting vegetables, Cucurbits	0.1		ML	CS 230-2001	
VO 0050	Fruiting vegetables, other than Cucurbits	0.1		ML	CS 230-2001	Excluding mushrooms
VL 0053	Leafy vegetables	0.3		ML	CS 230-2001	Including Brassica leafy vegetables but excluding spinach.
VP 0060	Legume vegetables	0.2		ML	CS 230-2001	
VD 0070	Pulses	0.2		ML	CS 230-2001	
VR 0075	Root and tuber vegetables	0.1		ML	CS 230-2001	Including peeled potatoes
	Canned fruit cocktail	1		ML	CS 78-1981	
	Canned grapefruit	1		ML	CS 15-1981	
	Canned mandarin oranges	1		ML	CS 68-1981	
	Canned mangoes	1		ML	CS 159-1987	
	Canned pineapple	1		ML	CS 42-1981	
	Canned raspberries	1		ML	CS 60-1981	
	Canned strawberries	1		ML	CS 62-1981	
	Canned tropical fruit salad	1		ML	CS 99-1981	
	Jams (fruit preserves) and jellies	1		ML	CS 79-1981	
	Mango chutney	1		ML	CS 160-1987	
	Table olives	1		ML	CS 66-1981, Rev.1-1987	
	Canned asparagus	1		ML	CS 56-1981	
	Canned carrots	1		ML	CS 116-1981	
	Canned green beans and canned wax beans	1		ML	CS 16-1981	

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Canned green peas	1		ML	CS 58-1981	
	Canned mature processed peas	1		ML	CS 81-1981	
	Canned mushrooms	1		ML	CS 55-1981	
	Canned palmito	1		ML	CS 144-1985	
	Canned sweet corn	1		ML	CS 18-1981	
	Canned tomatoes	1		ML	CS 13-1981	
	Pickled cucumbers (cucumber pickles)	1		ML	CS 115-1981	
	Processed tomato concentrates	1.5		ML	CS 57-1981	
JF 0175	Fruit juices	0.05		ML		Including nectars; Ready to drink
GC 0081	Cereal grains, except buckwheat, cañihua and quinoa	0.2		ML	CS 230-2001	
	Canned chestnuts and canned chestnuts puree	1		ML	CS 145-1985	
MM 0097	Meat of cattle, pigs and sheep	0.1		ML	CS 230-2001	Also applies to the fat from meat
PM 0110	Poultry meat	0.1		ML	CS 230-2001	
MO 0812	Cattle, Edible offal of	0.5		ML	CS 230-2001	
MO 0818	Pig, Edible offal of	0.5		ML	CS 230-2001	
PO 0111	Poultry, Edible offal of	0.5		ML	CS 230-2001	
	Edible fats and oils	0.1		ML	CS 19-1981, Rev.2-1999	Edible fats and oils not covered by individual standards
	Margarine	0.1		ML	CS 32-1981, Rev.1-1989	
	Minarine	0.1		ML	CS 135-1981, Rev.1-1989	
	Named animal fats	0.1		ML	CS 211-1999	Lard, rendered pork fat, premier jus and edible tallow.
OR 0305	Olive oil, refined	0.1		ML	CS 33-1981, Rev.2-2003	
OC 0305	Olive oil, virgin	0.1		ML	CS 33-1981, Rev.2-2003	
OR 5330	Olive, residue oil	0.1		ML	CS 33-1981, Rev.2-2003	Olive pomace oil
PF 0111	Poultry fats	0.1		ML	CS 230-2001	
OC 0172	Vegetable oils, Crude	0.1		ML	CS 230-2001, CS 210-1999, Rev.1-2001	Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter.
OR 0172	Vegetable oils, Edible	0.1		ML	CS 230-2001, CS 210-1999, Rev.1-2001	Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter.
ML 0106	Milks	0.02		ML	CS 230-2001, Rev.1-2003	A concentration factor applies to partially or wholly dehydrated milks.
LS	Secondary milk products	0.02		ML	CS 230-2001	As consumed
	Natural mineral waters	0.01		ML	CS 108-1981, Rev.1-1997	Expressed in mg/l
	Infant formula	0.02		ML	CS 230-2001	Ready to use
	Salt, food grade	2		ML	CS 150-1985, Rev.1-1997	

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Wine	0.2		ML	CS 230-2001	

MERCURY

Reference to JECFA:	10 (1966), 14 (1970), 16 (1972), 22 (1978)
Toxicological guidance:	PTWI 0.005 mg/kg bw (1978)
Residue definition:	Mercury, Total
Synonyms:	Hg
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Natural mineral waters	0.001		ML	CS 108-1981, Rev.1-1997	Expressed in mg/l
	Salt, food grade	0.1		ML	CS 150-1985, Rev.1-1997	

Mercury is a naturally occurring metallic element which can be present in foodstuffs by natural causes; elevated levels can also occur due to e.g. environmental contamination by industrial or other uses of mercury. Methylmercury and also total mercury levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher methyl mercury levels in other animal products.

METHYLMERCURY

Reference to JECFA:	22 (1978), 33 (1988), 53 (1999), 61 (2003)
Toxicological guidance:	PTWI 0.0016 mg/kg bw (2003)
Residue definition:	Methylmercury
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Fish	0.5		GL	CAC/GL 7-1991	Except predatory fish The Guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade. 1)
	Predatory fish	1		GL	CAC/GL 7-1991	Predatory fish such as shark (WS 0131), swordfish, tuna (WS 0132), pike (WF 0865) and others. The Guideline level for methylmercury in fresh or processed fish and fish products moving in international trade. 1)

Lots should be considered as being in compliance with the guideline levels if the level of methylmercury in the analytical sample, derived from the composite bulk sample, does not exceed the above levels. Where these Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction and what recommendations, if any, should be given as regards restrictions on consumption, especially by vulnerable groups such as pregnant women. Methylmercury is the most toxic form of mercury and is formed in aquatic environments. Methylmercury therefore is found mainly in aquatic organisms. It can accumulate in the food chain; the levels in large predatory fish species are therefore higher than in other species and fish is the predominant source of human exposure to methylmercury. Methylmercury and also total mercury levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher methylmercury levels in other animal products.

TIN	Reference to JECFA:	10 (1966), 14 (1970), 15 (1971), 19 (1975), 22 (1978), 26(1982), 33(1988), 55 (2000), 64 (2005)
	Toxicological guidance:	PTWI 14 mg/kg bw (1988, Expressed as Sn; includes tin from food additive uses; maintained in 2000.)
	Residue definition:	Tin, total (Sn-tot) when not otherwise mentioned; inorganic tin (Sn-in); or other specification
	Synonyms:	Sn
	Related Code of Practice:	Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods (CAC/RCP 60-2005) Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Canned fruit cocktail	250	C	ML	CS 78-1981	
	Canned grapefruit	250	C	ML	CS 15-1981	
	Canned mandarin oranges	250	C	ML	CS 68-1981	
	Canned mangoes	250	C	ML	CS 159-1987	
	Canned pineapple	250	C	ML	CS 42-1981	
	Canned raspberries	250	C	ML	CS 60-1981	
	Canned strawberries	200	C	ML	CS 62-1981	
	Canned tropical fruit salad	250	C	ML	CS 99-1981	
	Jams (fruit preserves) and jellies	250	C	ML	CS 79-1981	
	Mango chutney	250	C	ML	CS 160-1987	
	Table olives	250	C	ML	CS 66-1981, Rev.1-1987	
	Canned asparagus	250	C	ML	CS 56-1981	
	Canned carrots	250	C	ML	CS 116-1981	
	Canned green and wax beans	250	C	ML	CS 16-1981	
	Canned green peas	250	C	ML	CS 58-1981	
	Canned mature processed peas	250	C	ML	CS 81-1981	
	Canned mushrooms	250	C	ML	CS 55-1981	
	Canned palmito	250	C	ML	CS 144-1985	
	Canned sweet corn	250	C	ML	CS 18-1981	
	Canned tomatoes	250	C	ML	CS 13-1981	
	Pickled cucumber	250	C	ML	CS 115-1981	
	Processed tomato concentrates	250	C	ML	CS 57-1981	
	Canned chestnuts and chestnut purée	250	C	ML	CS 145-1985	
	Cooked cured chopped meat	200	C	ML	CS 98-1981, Rev.1-1991	For products in tinplate containers
	Cooked cured chopped meat	50		ML	CS 98-1981, Rev.1-1991	For products in other containers
	Cooked cured ham	50		ML	CS 96-1981, Rev.1-1991	For products in other containers
	Cooked cured ham	200	C	ML	CS 96-1981, Rev.1-1991	For products in tinplate containers
	Cooked cured pork shoulder	50		ML	CS 97-1981, Rev.1-1991	For products in other containers
	Cooked cured pork shoulder	200	C	ML	CS 97-1981, Rev.1-1991	For products in tinplate containers

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Corned beef	50		ML	CS 88-1981, Rev.1-1991	For products in other containers
	Corned beef	200	C	ML	CS 88-1981, Rev.1-1991	For products in tinfoil containers
	Luncheon meat	200	C	ML	CS 89-1981	For products in tinfoil containers
	Luncheon meat	50		ML	CS 89-1981	For products in other containers

Tin is mainly used in tinfoiled containers, but it is also extensively used in solders, in alloys including dental amalgams. Inorganic tin compounds, in which the element may be present in the oxidation states of +2 or +4, are used in a variety of industrial processes for the strengthening of glass, as a base for colours, as catalysts, as stabilizers in perfumes and soaps, and as dental anticariogenic agents. On the whole, contamination of the environment by tin is only slight. Food is the main source of tin for man. Small amounts are found in fresh meat, cereals, and vegetables. Larger amounts of tin may be found in foods stored in plain cans and, occasionally, in foods stored in lacquered cans. Some foods such as asparagus, tomatoes, fruits, and their juices tend to contain high concentrations of tin if stored in unlaquered cans (Environmental health criteria for tin; International Programme on Chemical Safety (IPCS); 1980). Inorganic tin is found in food in the +2 and +4 oxidation states; it may occur in a cationic form (stannous and stannic compounds) or as inorganic anions (stannites or stannates).

ACRYLONITRILE

Reference to JECFA:	28 (1984)
Toxicological guidance:	Provisional Acceptance (1984, the use of food-contact materials from which acrylonitrile may migrate is provisionally accepted on condition that the amount of the substance migrating into food is reduced to the lowest level technologically attainable.)
Residue definition:	acrylonitrile (monomer)
Synonyms:	2-Propenenitrile; vinyl cyanide (VCN); cyanoethylene; abbreviations, AN, CAN.
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Food	0.02		GL	CAC/GL 6-1991	

Acrylonitrile monomer is the starting substance for the manufacture of polymers which are used as fibres, resins, rubbers and also as packaging material for o.a. foods. Acrylonitrile is not known to occur as a natural product. Acrylonitrile is classified by IARC as possibly carcinogenic to humans (Group 2B). Polymers derived from acrylonitrile may still contain small amounts of free monomer. .

RADIONUCLIDES

Commodity/Product Code	Product Name	Representative radionuclides	Dose per unit intake factor in Sv/Bq	Level in Bq/kg	Type	Reference	Notes/Remarks for Codex Alimentarius
	Foods destined for general consumption	^{241}Am , ^{239}Pu	10^{-6}	10	GL	CAC/GL 5-1989	
	Foods destined for general consumption	^{90}Sr	10^{-7}	100	GL	CAC/GL 5-1989	
	Foods destined for general consumption	^{131}I , ^{134}Cs , ^{137}Cs	10^{-8}	1000	GL	CAC/GL 5-1989	
ML 0106	Milks	^{241}Am , ^{239}Pu	10^{-6}	1	GL	CAC/GL 5-1989	
ML 0106	Milks	^{131}I , ^{90}Sr	10^{-7}	100	GL	CAC/GL 5-1989	
ML 0106	Milks	^{134}Cs , ^{137}Cs	10^{-8}	1000	GL	CAC/GL 5-1989	
	Infant foods	^{241}Am , ^{239}Pu	10^{-6}	1	GL	CAC/GL 5-1989	
	Infant foods	^{131}I , ^{90}Sr	10^{-7}	100	GL	CAC/GL 5-1989	
	Infant foods	^{134}Cs , ^{137}Cs	10^{-8}	1000	GL	CAC/GL 5-1989	

These levels are designed to be applied only to radionuclides contaminating food moving in international trade following an accident and not to naturally occurring radionuclides which have always been present in the diet. The Guideline Levels remain applicable for one year following a nuclear accident. By an accident is meant a situation where the uncontrolled release of radionuclides to the environment results in the contamination of food offered in international trade.

As the proposed levels have extensive conservative assumptions built-in, there is no need to add contributions between dose per unit intake groups, and each of the three groups should be treated independently. However, the activity of the accidentally contaminating radionuclides within a dose per unit intake group should be added together if more than one radionuclide is present. Thus the 100 Bq/kg level for the 10^{-8} Sv/Bq dose per unit intake group is the total of all contaminants assigned to that group. For example, following a power reactor accident, ^{134}Cs and ^{137}Cs could be contaminants of food, and the 1000 Bq/kg refers to the summed activity of both these radionuclides.

These levels are intended to be applied to food prepared for consumption. They would be unnecessarily restrictive if applied to dried or concentrated foods prior to dilution or reconstitution.

Both FAO and WHO have called attention in the expert meeting reports to special consideration which might apply to certain classes of food which are consumed in small quantities, such as spices. Some of the foods grown in the areas affected by the Chernobyl accident fall-out contained very high levels of radionuclides following the accident. Because they represent a very small percentage of total diets and hence would be very small additions to the total dose, application of the Guideline Levels to products of this type may be unnecessarily restrictive. FAO and WHO are aware that policies vary at present in different countries regarding such classes of food.

See Appendix 1 for "Derivation of the Codex Guidelines in Foods Following Accidental Nuclear Contamination."

VINYL CHLORIDE MONOMER

Reference to JECFA:	28 (1984)
Toxicological guidance:	Provisional Acceptance (1984, the use of food-contact materials from which vinyl chloride may migrate is provisionally accepted, on condition that the amount of the substance migrating into food is reduced to the lowest level technologically)
Residue definition:	Vinylchloride monomer
Synonyms:	Monochloroethene, chloroethylene; abbreviation VC or VCM
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Food	0.01		GL	CAC/GL 6-1991	The GL in food packaging material is 1.0 mg/kg.

Vinylchloride monomer is the main starting substance for the manufacture of polymers which are used as resins, as packaging material for foods. Vinyl chloride is not known to occur as a natural product. Residues of VCM may be still present in the polymer. Vinyl chloride is considered by IARC to be a human carcinogen (as has been shown in occupational exposure situations).

APPENDIX 1 (of Annex 2 to Schedule 1)**DERIVATION OF THE CODEX GUIDELINES IN FOODS FOLLOWING ACCIDENTAL NUCLEAR CONTAMINATION**

The approach taken by WHO and FAO in recommending the Guideline Levels to the Codex Alimentarius Commission assumes a reference level of dose (5 mSv), a total average food consumption rate, a dose per unit intake factor for various radionuclides and a pattern of food consumption, and calculates the levels by the following formula:

$$\text{Level} = \frac{\text{RLD}}{m \times d}$$

where: RLD = Reference Level of Dose (Sv)

m = mass of food consumed (kg)

d = dose per unit intake factor (Sv/Bq)

Controlling radionuclide contamination of foods moving in international trade requires simple, uniform and easily applied values. This approach is one that can be uniformly applied by government authorities and yet one that achieves a level of public health protection to individuals that is considered more than adequate in the event of a nuclear accident.

In making these joint FAO/WHO recommendations the following assumptions were made in calculating the levels:

1. 5 mSv was adopted as the reference level of dose for an accident. This value, for most radionuclides, is the committed effective dose equivalent resulting from ingestion in the first year after an accident. Owing to the extremely conservative assumptions adopted, it is most unlikely that the application of the following levels will result in a dose to an individual greater than a small fraction of 1 mSv.
2. 550 kg of food is consumed in a year, all of which is contaminated.
3. Dose per unit intake factors for the radionuclides of concern (^{131}I , ^{137}Cs , ^{134}Cs , ^{90}Sr , ^{239}Pu) can be conveniently divided into three classes and applied to the general population:
 - a) those with a dose per unit intake of 10^{-6} Sv/Bq such as ^{239}Pu and other actinides;
 - b) those with a dose per unit intake factor of 10^{-7} Sv/Bq such as ^{90}Sr , and other beta emitters; and
 - c) those with a dose per unit intake factor of 10^{-8} Sv/Bq such as ^{134}Cs , ^{137}Cs , ^{131}I .

For infant foods and milk a dose per unit intake factor of 10^{-5} Sv/Bq was used instead of the 10^{-6} Sv/Bq value and ^{131}I was assigned to the 10^{-7} Sv/Bq class of radionuclides.

Applying these assumptions to the above formula, the level for the general population for the radionuclides in the 10^{-8} Sv/Bq group is:

$$\frac{5 \times 10^{-3}}{550 \times 10^{-8}} = 909 \text{ Bq/kg}$$

which can then be rounded 1000 Bq/kg. For the actinides this value of 10 Bq/kg, as the dose per unit intake factor is 100 times larger, and for the radionuclides in the 10^{-7} Sv/Bq class (such as ^{90}Sr), it is 100 Bq/kg.

It is recognized that the sensitivity of infants may pose a problem if the dose conversion factor for the general population were applied to them indiscriminately. WHO, in its document *Derived Intervention Levels for Radionuclides in Food*,² proposed separate guidelines for infants. The values were based on an infant consumption of milk of 275 L/y and the specific dose conversion factors for infants for ⁹⁰Sr, ¹³¹I, ¹³⁷Cs.

The resulting WHO Guideline values were:

⁹⁰Sr 160 Bq/L

¹³¹I* 1600 Bq/L

¹³⁷Cs 1800 Bq/L

* The value for ¹³¹I was based on a dose of 50 mSv to the thyroid and a mean life of ingested ¹³¹I of 11.5 days.

However, the dose per unit intake factors for infants ingesting alpha-emitting actinides have recently been revised upward and as a prudent measure, a dose per unit intake factor of 10^{-5} Sv/Bq for these radionuclides was applied to infants consuming milk and infant foods.

To reflect the infants' sensitivity, ¹³¹I was assigned a dose per unit intake factor of 10^{-7} Sv/Bq, putting it in the same class as ⁹⁰Sr.

For infant foods and milk the application of these dose per unit intake factors result in a level of 1 Bq/kg for the alpha emitters of the actinide series and any other radionuclide with a dose unit intake factor of 10^{-5} Sv/Bq, and 100 Bq/kg for ⁹⁰Sr and ¹³¹I or any other radionuclides assigned a dose per unit intake of 10^{-7} Sv/Bq.

By infant foods is meant a food prepared specifically for consumption by infants in the first year of life. Such foods are packaged and identified as being for this purpose.

² DERIVED INTERVENTION LEVELS FOR RADIONUCLIDES IN FOOD. Guidelines for application after widespread radioactive contamination resulting from a major radiation accident. WHO, Geneva, 1988.

APPENDIX 2 (of Annex 2 to Schedule 1)**SAMPLING PLAN FOR TOTAL AFLATOXINS IN PEANUTS INTENDED FOR FURTHER PROCESSING****INTRODUCTION**

1. The sampling plan calls for a single 20 kg laboratory sample of shelled peanuts (27 kg of unshelled peanuts) to be taken from a peanut lot (sub-lot) and tested against a maximum level of 15 micrograms per kilogram ($\mu\text{g}/\text{kg}$) total aflatoxins.
2. This sampling plan has been designed for enforcement and controls concerning total aflatoxins in bulk consignments of peanuts traded in the export market. To assist member countries in implementing the Codex sampling plan, sample selection methods, sample preparation methods and analytical methods required to quantify aflatoxin in bulk peanut lots are described in this document.

A. Definitions

- Lot:** an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings.
- Sublot:** designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
- Sampling plan:** is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the Codex maximum limit.
- Incremental sample:** a quantity of material taken from a single random place in the lot or sublot.
- Aggregate sample:** the combined total of all the incremental samples taken from the lot or sublot. The aggregate sample has to be at least as large as the 20 kg laboratory sample.
- Laboratory sample:** smallest quantity of peanuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than 20 kg, a 20 kg laboratory sample should be removed in a random manner from the aggregate sample. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenisation as possible.
- Test portion:** portion of the comminuted laboratory sample. The entire 20 kg laboratory sample should be comminuted in a mill. A portion of the comminuted 20 kg sample is randomly removed for the extraction of the aflatoxin for chemical analysis. Based upon grinder capacity, the 20 kg aggregate sample can be divided into several equal sized samples, if all results are averaged.

B. Sampling**Material to be Sampled**

3. Each lot which is to be examined must be sampled separately. Large lots should be subdivided into sublots to be sampled separately. The subdivision can be done following provisions laid down in Table 1 below.
4. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

Table 1: Subdivision of Large Lots into Sublots for Sampling

Commodity	Lot weight – tonne (T)	Weight or number of sublots	Number of incremental samples	Laboratory Sample Weight (kg)
Peanuts	≥ 500	100 tonnes	100	20
	>100 and <500	5 sublots	100	20
	≥ 25 and ≤ 100	25 tonnes	100	20
	>15 and ≤ 25	--1 subplot	100	20

Number of Incremental Samples for Lots of Less than 15 Tonnes

5. The number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100. The figures in the following Table 2 may be used to determine the number of incremental samples to be taken. It is necessary that the total sample weight of 20 kg is achieved.

Table 2: Number of Incremental Samples to be Taken Depending on the Weight of the Lot

Lot weight tonnes – (T)	N° of incremental samples
T ≤ 1	10
1 < T ≤ 5	40
5 < T ≤ 10	60
10 < T < 15	80

Incremental Sample Selection

6. Procedures used to take incremental samples from a peanut lot are extremely important. Every individual peanut in the lot should have an equal chance of being chosen. Biases will be introduced by the sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

7. Since there is no way to know if the contaminated peanut kernels are uniformly dispersed throughout the lot, it is essential that the aggregate sample be the accumulation of many small portions or increments of the product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

Static Lots

8. A static lot can be defined as a large mass of peanuts contained either in a single large container such as a wagon, truck, or railcar or in many small containers such as sacks or boxes and the peanuts are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because the container may not allow access to all peanuts.

9. Taking an aggregate sample from a static lot usually requires the use of probing devices to select product from the lot. The probing devices used should be specially designed for the type of container. The probe should (1) be long enough to reach all product, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small increments of product taken from many different locations throughout the lot.

10. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows :

Equation 1 : $SF = (LT \times IS) / (AS \times IP)$. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic Lots

11. True random sampling can be more nearly achieved when selecting an aggregate sample from a moving stream of peanuts as the lot is transferred, for example, by a conveyor belt from one location to another. When sampling from a moving stream, take small increments of product from the entire length of the moving stream; composite the peanuts to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample, then blend and subdivide the aggregate sample to obtain the desired size laboratory sample.

12. Automatic sampling equipment such as cross-cut samplers are commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, small increments of peanuts should be collected and composited at frequent and uniform intervals throughout the entire time peanuts flow past the sampling point.

13. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about three times the largest dimensions of the items in the lot.

14. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is :

Equation 2 : $S = (D \times LT) / (T \times V)$. D is the width of the diverter cup opening (in cm), LT is the lot size (in kg), T is interval or time between cup movement through the stream (in seconds), and V is cup velocity (in cm/sec).

15. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup is :

Equation 3 : $SF = (S \times V) / (D \times MR)$.

16. Equation 2 can also be used to compute other terms of interest such as the time between cuts (T). For example, the required time (T) between cuts of the diverter cup to obtain a 20 kg aggregate sample from a 30,000 kg lot where the diverter cup width is 5.08 cm (2 inches), and the cup velocity through the stream 30 cm/sec. Solving for T in Equation 2,

$$T = (5.08 \text{ cm} \times 30,000 \text{ kg}) / (20 \text{ kg} \times 30 \text{ cm/sec}) = 254 \text{ sec}$$

17. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 60 minutes and only 14 cuts (14 incremental samples) will be made by the cup through the lot. This may be considered too infrequent, in that too much product passes through the sampler between the time the cup cuts through the stream.

Weight of the Incremental Sample

18. The weight of the incremental sample should be approximately 200 grams or greater, depending on the total number of increments, to obtain an aggregate sample of 20kg.

Packaging and transmission of samples

19. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample which might arise during transportation or storage.

Sealing and labelling of samples

20. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

C. Sample Preparation

Precautions

21. Daylight should be excluded as much as possible during the procedure, since aflatoxin gradually breaks down under the influence of ultra-violet light.

Homogenisation – Grinding

22. As the distribution of aflatoxin is extremely non-homogeneous, samples should be prepared - and especially homogenised - with extreme care. All laboratory sample obtained from aggregate sample is to be used for the homogenisation/grinding of the sample.

23. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenisation as possible.

24. The use of a hammer mill with a #14 screen (3.1 mm diameter hole in the screen) has been proven to represent a compromise in terms of cost and precision. A better homogenisation (finer grind – slurry) can be obtained by more sophisticated equipment, resulting in a lower sample preparation variance.

Test portion

25. A minimum test portion size of 100 g taken from the laboratory sample.

D. Analytical Methods

Background

26. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specified method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation, reproducibility coefficient of variation, and the percent recovery necessary for various statutory limits. Utilising this approach, laboratories would be free to use the analytical method most appropriate for their facilities. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

Performance Criteria for Methods of Analysis

Table 3: Specific Requirements with which Methods of Analysis Should Comply

Criterion	Concentration Range	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	-
Recovery-Aflatoxins Total	1 - 15 µg/kg	70 to 110 %	
	> 15 µg/kg	80 to 110 %	
Precision RSD _R	All	As derived from Horwitz Equation	2 x value derived from Horwitz Equation
Precision RSD _F may be calculated as 0.66 times Precision RSD _R at the concentration of interest			

- The detection limits of the methods used are not stated as the precision values are given at the concentrations of interest;
- The precision values are calculated from the Horwitz equation, i.e.:

$$RSD_R = 2^{(1-0.5\log C)}$$

where:

- * RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions $[(s_R / \bar{x}) \times 100]$
- * C is the concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1,000 mg/kg)

27. This is a generalised precision equation which has been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

SCHEDULE II – MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS AND TOXINS IN FOODS

(to be developed after finalisation of the Food Category System)

Project document**PROPOSAL FOR NEW WORK ON THE REVISION OF THE PREAMBLE OF THE CODEX
GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS AND THE
PROCEDURAL MANUAL****1. The purpose and scope of the revision**

The current preamble to the General Standard for Contaminants and Toxins in Food (GSCTF) contains several references to procedural issues, which are addressed to Codex. As the GSCTF is addressed to Codex Members, it is proposed as future work to revise the preamble deleting the procedural provisions from the preamble of the GSCTF and to include these in the Procedural Manual.

The “Complementary food categorisation system for the GSCTF” requires some revision.

As some of the provisions in the Procedural Manual as regards the contaminants are outdated, it is appropriate to update this part of the Procedural Manual.

2. Its relevance and timeliness

The proposed revision is relevant as it will improve consistency and update current provisions in the Procedural Manual.

3. The main aspects to be covered

- extracting the procedural provisions from the preamble to GSCTF to include them in the Procedural Manual;
- revising of the “Complementary food categorisation system for the GSCTF”;
- updating of the provisions on the Procedural Manual as regards the contaminants;
- align the language of the Preamble with the language contained in the Procedural Manual.

4. An assessment against the Criteria for the establishment of work priorities

This proposal is consistent with the following criteria for the establishment of Work priorities:

Consumer protection fro; the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

5. Relevance to Codex Strategic objectives

This proposal is consistent with the Strategic Vision statement of the strategic Framework 2003-2007.

6. Information on the relationship between the proposal and other existing Codex documents

This new work is recommended by the 38th session of the CCFAC.

7. Identification of any requirement for and availability of expert scientific advice

None

8. Identification of any need for technical input to the standard from external bodies.

None

9. The proposed time line for completion of the new work, including the start date, proposed date for adoption at Step 5/8, and the proposed date for adoption by the Commission.

If the Commission accepts, in 2006, that the proposal for new work should proceed, the foreseen revisions will be circulated for consideration at Step 3 at the next Session of the Committee. Adoption at Step 5 is planned for 2008 and adoption at Step 8 can be expected in 2009.

Appendix XX**CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN
CONTAMINATION IN TREE NUTS****PROPOSED DRAFT APPENDIX ON ADDITIONAL MEASURES FOR THE PREVENTION AND
REDUCTION OF AFLATOXINS CONTAMINATION IN BRAZIL NUTS****(N08-2005)****(At Step 5/8 of the Procedure)****INTRODUCTION**

1. The formulation and acceptance of an appendix to the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts will provide uniform guidelines for producing countries to consider in attempting to control and manage contamination of Brazil nuts by aflatoxins. In order for these measures to be effective, it will be necessary for collectors, processors and other members of the production chain to consider the general principles established by the Code, while taking into account the fact that Brazil nut tree (*Bertholletia excelsa*) is not cultivated. This specie exists all over the Amazon Region, however the largest concentrations of trees are in the Brazilian Amazon.
2. This appendix applies only to Brazil nuts, given the very specific conditions related to their collection and processing.

RECOMMENDED PRACTICES BASED ON GOOD EXTRACTIVISTIC PRACTICES (GEP)**PRE-COLLECTION**

3. Before the crop season starts extractivists should clear the area under the Brazil nut trees, removing residual pods and nuts from the former crop. Pods left from the last crop season should never be mixed with pods from the present crop season, as they represent a potential source of contamination with *Aspergillus*.

COLLECTION

4. Collection of Brazil nuts should begin as soon as most of the pods have fallen from the trees to minimize problems involving *Aspergillus* contamination. A certain delay in the collection is expected because during the crop season remaining pods may fall, posing a risk to the lives of the collectors.

POST-COLLECTION

5. The pods should be sorted to remove broken and damaged ones, and gathered in piles or preferentially in thin layers, for only a short period of time.
6. Pods should be opened as soon as possible after collection, with the nuts being removed and separated from the pods and placed on clean and dry floor or hygienic plastic canvas in good condition, to avoid contact with the soil. During the opening of the pods care should be taken to avoid damage to the nuts as much as possible. The nuts should be sorted to remove damaged, rotten, empty, and rancid ones.
7. Initial transportation of the nuts, from the forest to a storage facility, should occur as soon as possible, using containers that are clean, dry and protected against rain and insects, to the greatest extent possible.
8. At the location of the primary storage, nuts should be dried to a safe moisture content to prevent mould growth and possible aflatoxin contamination during storage. For this purpose nuts should be spread out in thin layers, in open air, on clean surfaces, above ground level, and exposed to sun drying and/or to a natural air circulation, with a regular turn. The nuts should be protected against rain and pests, such as birds, rodents and insects and any other contamination.

9. After drying, the nuts should be placed in a storage facility that has floors that are at least 50 cm above ground level; protected against rain and pests and allow good air circulation. For the purpose of identification and traceability, nuts, in bulk or in bags, from different origins and/or days of collection should be handled separately and kept separated until the final processing and packaging.

10. During the transportation of the nuts from the primary storage facility, in bulk or in bags, either to an intermediate location or to a processing facility, the nuts should be separated from other goods, in containers that are clean, dry, protected against humidity and free from insects and visible fungal growth. Conveyances for transporting nuts should be made of material that will permit thorough cleaning and maintenance so as not to constitute a potential source of contamination for the Brazil nuts.

11. If the nuts are stored at an intermediate location, before reaching the processing facility, the storage facility should have the following:

- a) protection from rain and pests;
- b) a washable and impermeable floor;
- c) drainage of ground water;
- d) good air circulation;
- e) sufficient area and proper divisions to allow separation of lots .

GENERAL RECOMMENDATIONS

12. National, State and local governments, as well as Non Governmental Organizations – NGOs and trade associations and cooperatives should provide basic education and update information on the hazards associated with aflatoxin contamination to the extractivists and other agents involved in the Brazil nuts production chain.

13. Personnel involved in collecting pods should be regularly trained in personal hygienic and sanitary practices that must be implemented at all stages of production including the pre-collection, collection, post-collection and processing.

**PROPOSED DRAFT SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN ALMONDS,
BRAZIL NUTS, HAZELNUTS AND PISTACHIOS**

(N07-2004)

(At Step 4 of the Elaboration Procedure)

Introduction

1. An aflatoxin-sampling plan is defined by an aflatoxin test procedure and a accept/reject limit. The aflatoxin test procedure generally consists of three steps: sampling, sample preparation, and quantification. Aflatoxin sampling plan designs can vary tremendously depending on the objectives of an industry or regulatory agency. For aflatoxin sampling plans, sample size is usually the key issue. Generally, the sampling step is the largest source of uncertainty and large samples (or a large number of samples of a given size) are required to reduce the uncertainty associated with the aflatoxin test procedure (and thus reduce the exporters' and importers' risks) to acceptable levels. Examples of several aflatoxin sampling plan designs are described below.

- 1) The EU specifies a single 30 kg sample for raw shelled peanuts destined for further processing. The sample test results must be less than or equal to an accept/reject limits of 15 total ng/g and 8 ng/g B1 for the lot to be accepted.
- 2) The EU specifies a single 30 kg sample for tree nuts destined for further processing. The sample test results must be less than or equal to an accept/reject limits of 10 total ng/g and 5 ng/g B1 for the lot to be accepted.
- 3) The EU specifies three 10 kg samples for consumer-ready peanuts and tree nuts. All three 10 kg samples test results must be less than or equal to 4 ng/g total and 2 ng/g B1 for the lot to be accepted.
- 4) Codex specifies a single 20 kg sample for raw shelled peanuts. The sample test results must be less than or equal to an accept/reject limits of 15 total ng/g for the lot to be accepted.
- 5) The U.S. Department of Agriculture specifies a sequential type plan consisting of three 22 kg samples for raw shelled peanuts destined for further processing. The accept/reject limits vary for each sample tested, but the final accept/reject limit for the average of all three-sample test results is 15 total ng/g.
- 6) The U.S. Pistachio Industry is currently considering a sequential type-sampling plan consisting of three 10 kg samples for pistachio nuts. The accept/reject limits vary for each sample tested, but the final accept/reject limit for the average of all three-sample test results is 15 total ng/g.

Performance Evaluation

2. From research studies, methods have been developed to evaluate the performance of mycotoxin-sampling plan designs using operating characteristic (OC) curves. An OC curve describes the performance or the level of miss-classifications associated with an aflatoxin-sampling plan for tree nuts. An example of an OC curve is shown in Figure 1. The OC curve estimates the probability of accepting (or rejecting) lots at a given lot aflatoxin concentration by a specific aflatoxin-sampling plan design (sample size, sample preparation method, analytical method, and accept/reject limit). The shape (accept probabilities) of the OC curve is uniquely defined by the sampling plan design. The OC curve also gives an indication of the importers' risk (bad lots accepted) and the exporters' risk (good lots rejected) associated with a sampling plan design. The importers' and exporters' risks are shown in Figure 1. The evaluation method has been reviewed and sanctioned by an FAO/WHO Expert Consultation. Results of the review can be found in FAO/WHO Food and Nutrition Paper 55. The OC curve for a specific sampling plan is constructed knowing the variability and distributional characteristics among replicated sample test results taken from a contaminated lot. The evaluation method was used by CCFAC to design and predict the performance of the aflatoxin-sampling plan for raw shelled peanuts destined for further processing. The evaluation method assumes that no biases are associated with the aflatoxin test procedure. Biases are considered to be minimal when using the Codex guidelines established for sample selection, sample preparation, and analytical performance when sampling raw shelled peanuts for aflatoxin.

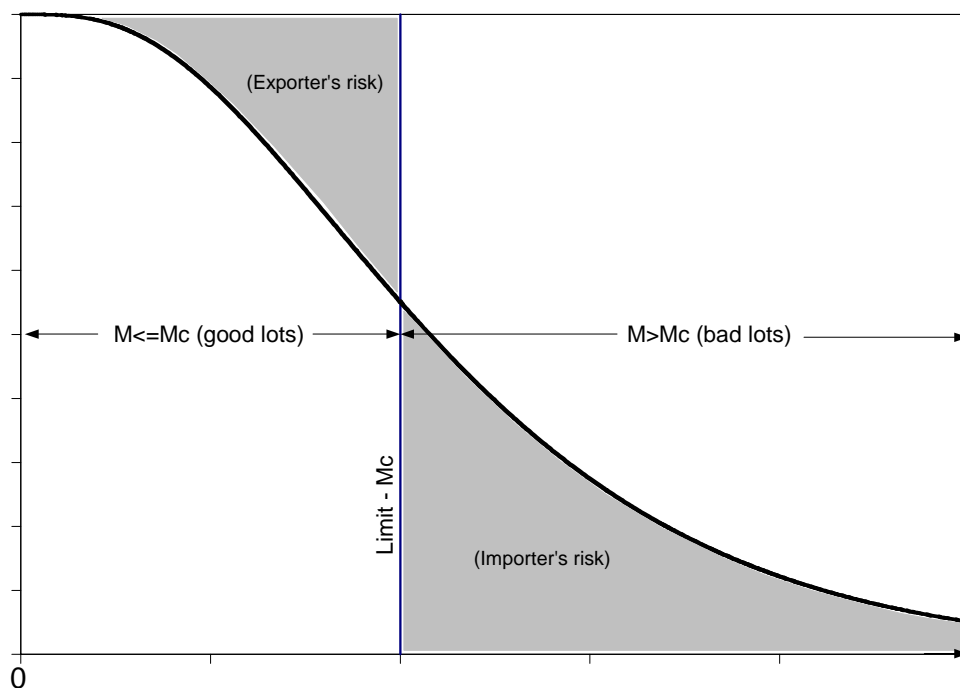


Figure 1. Example of an operating characteristic (OC) curve showing the importers' and exporters' risks associated with a sampling plan design.

Proposed Aflatoxin Sampling Plan Design for Tree Nuts

3. The proposed aflatoxin sampling plan for tree nuts can be described as follows:

- 1) a single 20 kg sample of shelled kernels is taken from the lot,
- 2) a VCM type mill is used to comminute the sample into a paste,
- 3) a 100 g analytical subsample is taken from the comminuted sample, *
- 4) HPLC analytical methods are used to quantify the aflatoxin in the analytical subsample, and

5) an accept/reject limit of 15 total ng/g aflatoxin is used to classify lots.

The sampling plan design is simple and easy to implement. If the sample test result is 15 ng/g total aflatoxin or less, the lot is accepted, else the lot is rejected.

* The performance characteristics of this plan may change if a subsample other than 100 g is taken.

Figure 2 shows two OC curves that describe the performance of the proposed sampling plan when sampling shelled almond and shelled hazelnut lots for aflatoxin. The OC curves were calculated using variability and distributional data specific to sampling shelled almonds and shelled hazelnuts for aflatoxin.

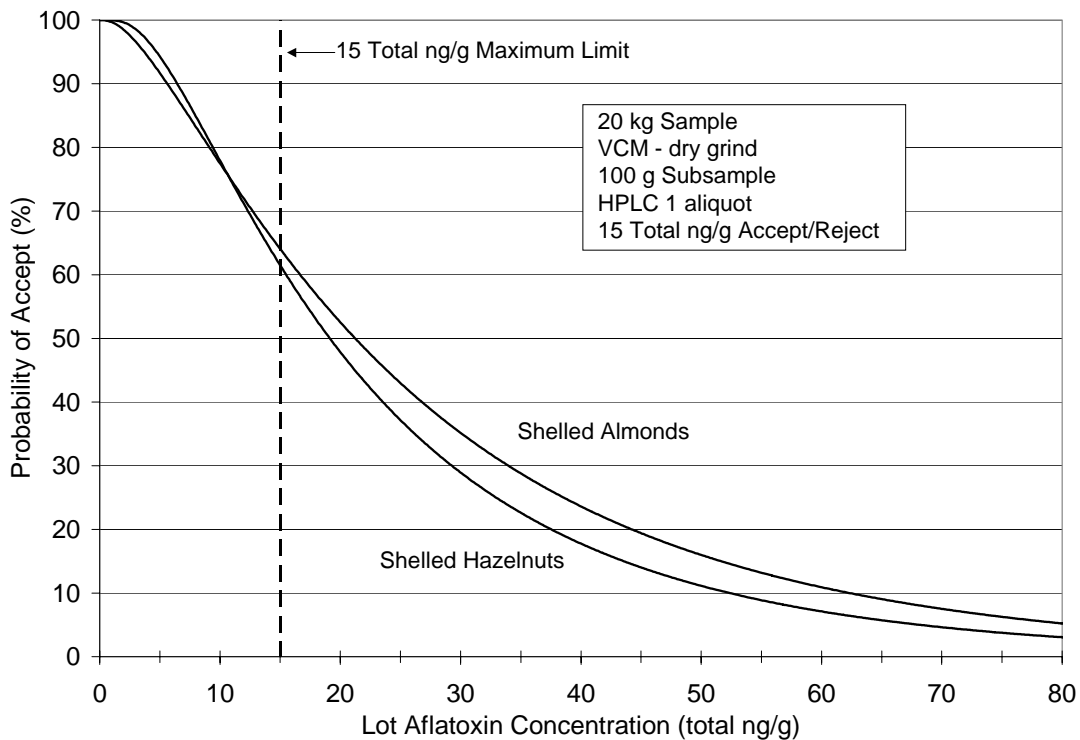


Figure 2. Operating characteristic curves that describe the performance of an aflatoxin sampling plan for almonds and hazelnuts that uses one 20 kg sample and a 15 ng/g accept/reject limit.

4. The two OC curves in Figure 2 are similar reflecting the fact that the variability and distributional data for shelled almond and shelled hazel nuts are similar. The OC curves for almonds and hazelnuts in Figure 2 shows that about 65 and 62%, respectively of the lots at 15 ng/g are accepted (35 and 38%, respectively are rejected) by the sampling plan and is based on an assumption that there is an equal probability of occurrence of any specific contamination level among lots tested with the sampling plan. However, actual contamination levels among lots sampled are usually skewed to the low concentrations. The sampling plan will reject most all lots above 80 ng/g. The chances of accepting lots at other concentrations by the proposed sampling plan can be determined from the OC curves in Figure 2.

5. Sample size has been expressed as sample mass or kg for convenience. Because the four tree nuts are physically different, the kernel count per unit mass will differ among the four tree nuts. For shelled almonds, a 20 kg sample contains about 15500 raw shelled kernels (77.5 kernels per 100 g). For shelled hazelnuts, a 20 kg sample contains about 20000 raw shelled kernels (100 kernels per 100 g). It is much easier to specify sample size and select a sample based upon mass instead of kernel count. However, sample-to-sample variability is dependent upon the number of kernels in the sample. As a result, the performance of the sampling plans depends on the number of kernels in the sample. If performance of a sampling plan that uses a 20 kg sample is significantly different among the four tree nuts, the mass of the sample associated with each tree nut may have to be adjusted so that the performance of the sampling plan for the four tree nuts is approximately the same. A simple conversion between mass and kernel count can be made knowing the count per unit mass for each type tree nut.

6. Codex's philosophy, when it adopted the aflatoxin-sampling plan for peanuts, was for the exporter and importer to share the risks associated with the sampling plan (Figure 1). The exporters' risk is defined as good lots rejected and the importers' risk is defined as bad lots accepted by the sampling plan. Risk sharing is usually accomplished by setting the accept/reject limit equal to the maximum limit. This approach (used by the Codex aflatoxin-sampling plan for peanuts) was also used in designing the proposed aflatoxin-sampling plan for tree nuts. If either or both risks are considered too large, more samples of a given size or larger sample sizes can be used to reduce uncertainty. Increasing the size of the sample will reduce both risks. Choosing the appropriate sampling plan design requires balancing risk reduction and costs related to the sampling plan.

**DRAFT AND PROPOSED DRAFT MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN
ALMONDS, HAZELNUTS AND PISTACHIOS “FOR FURTHER PROCESSING”
AND “READY-TO-EAT”**

Code No.	Food	ML($\mu\text{g}/\text{kg}$)	Step	Remarks
	Almonds, Hazelnuts and Pistachios for further processing	15	7	
	Almonds, Hazelnuts and Pistachios, ready-to-eat	8	5	

Project document**PROPOSAL FOR NEW WORK ON A “CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF OCHRATOXIN A CONTAMINATION IN WINE”****1. The purpose and scope of the Standard**

To develop a draft Code of practice for the prevention and reduction of ochratoxin A contamination in wine. The Code will cover cultivation practices in vineyards, practices at harvest and treatments at the winery.

2. Its relevance and timeliness

Measures can be taken to prevent and reduce the presence of ochratoxin A in wine products. Ochratoxin A is a hazard to human health. JECFA concluded in its assessment in 2001 that efforts are needed to ensure that intakes of ochratoxin A do not exceed the PTWI, and this could best be achieved by lowering overall contamination by appropriate agricultural, storage and processing practices. From different dietary exposure studies, it can be observed that wine is a significant contributor to the overall dietary human exposure of ochratoxin A. A code of Practice will provide a means of preventing and reducing the presence of OTA in wine.

3. The main aspects to be covered

The draft Code of Practice will cover all possible measures that have been proven to prevent and reduce ochratoxin A in wine. The Code will cover all stages of the production chain (cultivation practices in the vineyard, harvest, transport, pre-fermentation treatments, fermentation treatments, maturing and clarification treatments).

4. An assessment against the Criteria for the establishment of work priorities

This proposal is consistent with the following criteria for the establishment of Work priorities.

(a) Consumer protection from the point of view of health (by minimizing consumer dietary exposure to ochratoxin A from wine).

5. Relevance to Codex Strategic objectives

This proposal is consistent with the Strategic Vision statement of the strategic Framework 2003-2007.

6. Information on the relationship between the proposal and other existing Codex documents

This new work is recommended in the Discussion paper on ochratoxin A in wine to be presented and discussed at the 38th Session of CCFAC.

7. Identification of any requirement for and availability of expert scientific advice

- Availability of information.

* Resolution VITI-OENO 1/2005 – “Code of sound vitivinicultural practices in order to minimise levels of ochratoxin A in wine-based products” adopted by the General Assembly of the International Organization of Vine and Wine (OIV) in October 2005.

In accordance with the guidelines on co-operation between the Codex Alimentarius Commission and international intergovernmental organisations in the elaboration of standards and related texts, adopted by the Codex Alimentarius Commission at its 28th session in July 2005, this Code adopted by the OIV can be used as a basis for preparing the proposed draft Code, subject to concurrence of the cooperating organisation.

8. Identification of any need for technical input to the standard from external bodies.

As the International Organization of Vine and Wine (OIV) and the International Federation of Wines and Spirits (FIVS) have “Observer Status” in the Codex Alimentarius Commission and as the OIV and FIVS participate in the activities of Codex Alimentarius Commission in general and of the Committee in particular, there is no need for additional technical input from external bodies.

9. The proposed time line for completion of the new work, including the start date, proposed date for adoption at Step 5/8, and the proposed date for adoption by the Commission.

If the Commission accepts, in 2006, that the proposal for new work should proceed, the draft Code of Practice will be drafted based on “Code of sound vitivincultural practices in order to minimise levels of ochratoxin A in wine” and will be circulated for consideration at Step 3 at the next Session of the Committee. Adoption at Step 5 is planned for 2008 and adoption at Step 8 can be expected in 2009.

Appendix XXIV**DRAFT MAXIMUM LEVEL FOR LEAD IN FISH****At Step 8 of the Procedure**

Code No.	Food	ML(mg/kg)	Step	Remarks
	Fish	0.3 mg/kg	8	

Appendix XXV**DRAFT MAXIMUM LEVELS FOR CADMIUM****(At Step 8 of the Procedure)**

Code No.	Food	ML (mg/kg)	Step	Remarks
CM 0649	Rice, Polished	0.4	8	
IM 0151	Marine bivalve molluscs	2	8	Excluding oysters and scallops
IM 0152	Cephalopods	2	8	Without viscera

**PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF
DIOXIN AND DIOXIN-LIKE PCB CONTAMINATION IN FOODS AND FEEDS**

(at Step 5/8 of the Elaboration Procedure)

INTRODUCTION

GENERAL REMARKS

1. Dioxins, including polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (PCBs) are pervasive in the environment. Although dioxins and dioxin-like PCBs show similarities in their toxicological and chemical behaviour, their sources are different.
2. Current sources of dioxins and dioxin-like PCBs entering the food chain include new emissions and remobilisation of deposits or reservoirs in the environment. New emissions are mainly via the air route. Dioxins and dioxin-like PCBs decompose very slowly in the environment and remain there for very long periods of time. Therefore, a large part of current exposure is due to releases of dioxin and dioxin-like PCBs that occurred in the past.
3. PCBs, including dioxin-like PCBs, were produced intentionally and in considerable amounts between the 1930s and 1970s and were used in a wide range of applications. PCBs are still in use in existing closed systems and contained in solid matrices (e.g., sealing materials and electrical capacitors). Certain commercial PCBs are known to be contaminated with PCDFs and could therefore be regarded as a potential source for dioxin contamination.
4. Today release of dioxin-like PCBs occurs from leakages, accidental spills and illegal disposal and through emissions via air from thermal processes. Migration from sealants and other old matrix applications are of minor importance. The remobilisation of dioxin-like PCBs from environmental reservoirs is similar to dioxins.
5. Dioxins are formed as unwanted by-products from a number of human activities including certain industrial processes (e.g., production of chemicals, metallurgical industry) and combustion processes (e.g., waste incineration). Accidents at chemical factories have been shown to result in high emissions and contamination of local areas. Other dioxin sources include domestic heaters, agricultural and backyard burning of household wastes. Natural processes such as volcanic eruptions and forest fires can also produce dioxins.
6. When released into the air, dioxins can deposit locally on plants and on soil contaminating both food and feed. Dioxins can also be widely distributed by long-range atmospheric transport. The amount of deposition varies with proximity to the source, plant species, weather conditions and other specific conditions (e.g. altitude, latitude, temperature).
7. Sources of dioxins in soil include deposition from atmospheric dioxins, application of contaminated sewage sludge to farm land, flooding of pastures with contaminated sludge, and prior use of contaminated pesticides (e.g., 2,4,5-trichlorophenoxy acetic acid) and fertilizers (e.g., certain compost). Other sources of dioxins in soil may be of natural origin (e.g., ball clay).
8. Dioxins and dioxin-like PCBs are poorly soluble in water. However, they are adsorbed onto mineral and organic particles suspended in water. The surfaces of oceans, lakes and rivers are exposed to aerial deposition of these compounds which are consequently concentrated along the aquatic food chain. The entry of waste water or contaminated effluents from certain processes, such as chlorine bleaching of paper or pulp or metallurgical processes, can lead to contamination of water and sediment of coastal ocean areas, lakes and rivers.

9. The uptake of dioxins and dioxin-like PCBs by fish occurs via gills and diet. Fish accumulate dioxins and dioxin-like PCBs in their fatty tissue and liver. Bottom dwelling/bottom feeding fish species are more exposed to contaminated sediments than pelagic fish species. However, levels of dioxins and dioxin-like PCBs in bottom dwelling/bottom feeding fish are not always higher than those in pelagic fish depending on the size, diet and physiological characteristics of the fish. In general, fish show an age-dependent accumulation of dioxins and dioxin-like PCBs.

10. Food of animal origin is the predominant route of human exposure to dioxins and dioxin-like PCBs with approximately 80 - 90 % of the total exposure via fats in fish, meat and dairy products. Levels of dioxins and dioxin-like PCBs in animal fat may be related to contamination of the local environment and to contamination of feed (e.g., fish-oil and fish-meal) or, to certain production processes (e.g., artificial drying).

11. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the European Union Scientific Committee on Food (EU SCF) derived tolerable intakes and compared these with calculated intakes. They concluded that a considerable proportion of the population may exceed the tolerable intake of dioxins and dioxin-like PCBs.

12. In order to reduce the contamination of food, control measures at the feed level should be considered. These may involve developing Good Agricultural Practice, Good Animal Feeding Practice (see Codex Alimentarius Commission: Code of Practice on Good Animal Feeding), and Good Manufacturing Practice guidance and measures to effectively reduce dioxins and dioxin-like PCBs in feed, including:

- Identification of agricultural areas with increased dioxin and dioxin-like PCB contamination due to local emission, accidents or illegal disposal of contaminated materials, and monitoring of feed and feed ingredients derived from these areas,
- Setting guidance values for soil and recommendation for special agricultural use (e.g., limitation of grazing or use of appropriate agricultural techniques),
- Identification of possibly contaminated feed and feed ingredients,
- Monitoring compliance with nationally-established guideline levels or maximum limits, if available, and minimizing or decontaminating (e.g., refining of fish oil) non-complying feed and feed ingredients, and
- Identification and control of critical feed manufacturing processes (e.g., artificial drying by direct heating).

13. Similar control measures, where applicable, should be considered for reducing dioxins and dioxin-like PCBs in food.

SOURCE DIRECTED MEASURES

14. Reducing sources of dioxins and dioxin-like PCBs is an essential prerequisite for a further reduction of contamination. Measures to reduce dioxin emission sources should be directed to reducing the formation of dioxin during thermal processes as well as the application of destruction techniques. Measures to reduce dioxin-like PCBs emission sources should be directed to minimizing releases from existing equipment (e.g. transformers, capacitors), prevention of accidents and better control of the disposal of dioxin-like PCBs containing oils and wastes.

15. The Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention) is a global treaty to protect human health and the environment from persistent organic pollutants (POPs) including dioxins and dioxin-like PCBs.

16. Part II of Annex C of the Stockholm Convention lists the following industrial source categories, that have the potential for comparatively high formation and release of dioxins, and dioxin-like PCBs to the environment

- a. Waste incinerators, including co-incinerators of municipal, hazardous or medical waste or of sewage sludge;
- b. Cement kilns firing hazardous waste;

- c. Production of pulp using elemental chlorine or chemicals generating elemental chlorine for bleaching;
- d. Thermal processes in the metallurgical industry, i.e. secondary copper production; sinter plants in the iron and steel industry; secondary aluminium production; secondary zinc production.

17. Part III of Annex C also lists the following source categories that may unintentionally form and release dioxins, and dioxin-like PCBs, to the environment:

- a. Open burning of waste, including burning of landfill sites;
- b. Thermal processes in the metallurgical industry not mentioned in Part II, Annex C;
- c. Residential combustion sources;
- d. Fossil fuel-fired utility and industrial boilers;
- e. Firing installations for wood and other biomass fuels;
- f. Specific chemical production processes releasing unintentionally formed persistent organic pollutants, especially production of chlorophenols and chloranil;
- g. Crematoria;
- h. Motor vehicles, particularly those burning leaded gasoline;
- i. Destruction of animal carcasses;
- j. Textile and leather dyeing (with chloranil) and finishing (with alkaline extraction);
- k. Shredder plants for the treatment of end of life vehicles;
- l. Smouldering of copper cables;
- m. Waste of oil refineries.

18. Adopting technologies to minimize formation and release of dioxins and dioxin-like PCBs from these sources categories should be considered by national authorities when developing national measures to reduce dioxin and dioxin-like PCBs.

SCOPE

19. This Code of Practice focuses on measures (e.g., Good Agricultural Practices, Good Manufacturing Practices, Good Storage Practices, Good Animal Feeding Practices, and Good Laboratory Practices) for national authorities, farmers, and feed and food manufacturers to prevent or reduce dioxin and dioxin-like PCB contamination in foods and feeds.

20. This Code of Practice applies to the production and use of all materials destined for feed (including grazing or free-range feeding, forage crop production and aquaculture) and food at all levels whether produced industrially or on farm.

21. Since the global limitation and reduction of dioxins and dioxin-like PCBs from non food / feed related industrial and environmental sources may lie outside of the responsibility of CCFAC, these measures will not be considered within this Code of Practice.

RECOMMENDED PRACTICES

BASED ON GOOD AGRICULTURAL PRACTICES (GAPs), GOOD MANUFACTURING PRACTICES (GMPs), GOOD STORAGE PRACTICES (GSPs), GOOD ANIMAL FEEDING PRACTICES (GAFPs), AND GOOD LABORATORY PRACTICES (GLPs)

CONTROL MEASURES WITHIN THE FOOD CHAIN

Air, Soil, Water

22. To reduce dioxin and dioxin-like PCB contamination in the air, national food authorities should consider recommending to their national authorities responsible for air pollution measures to prevent uncontrolled burning of wastes, including the burning of landfill sites or backyard burning, and the use of PCB treated wood for domestic heaters.

23. Control measures to prevent or reduce contamination of the environment by dioxins and dioxin-like PCBs are important. To reduce possible contamination of feed or food, agricultural land with unacceptable dioxin and dioxin-like PCB contamination due to local emission, accidents, or illegal disposal of contaminated materials should be identified.

24. Agricultural production on contaminated areas should be avoided or should be restricted if a significant transfer of dioxins and dioxin-like PCBs to feed or food produced on these areas is anticipated. If possible, contaminated soil should be treated and detoxified or removed and stored under environmentally sound conditions.

25. The spreading of sewage sludge contaminated with dioxins and dioxin-like PCBs can lead to adhering of contaminants on the vegetation which can increase livestock exposure. Sewage sludge used in agriculture should be monitored, as necessary for dioxins and dioxin-like PCBs. Additionally, sewage sludge should be treated, as necessary, to render it inert or to detoxify it. National guidelines should be adhered to where applicable.

26. Livestock, game, and poultry, exposed to contaminated soil, may accumulate dioxins and dioxin like PCBs by consumption of contaminated soil or plants. These areas should be identified and controlled. If necessary, the production in these areas should be restricted.

27. Source-reduction measures will take many years to reduce contamination levels in wild caught fish due to the long half-lives of dioxins and dioxin-like PCBs in the environment. To reduce exposure to dioxins and dioxin-like PCBs, highly contaminated areas (e.g., lakes and rivers) and relevant fish species should be identified and fishing in these areas should be controlled and, if necessary, restricted.

Feed

28. The bulk of human dietary intake of dioxins and dioxin-like PCBs is due to the deposition of these substances in the lipid component of animal derived foods (e.g., poultry, fish, eggs, meat and milk). In lactating animals dioxins and dioxin-like PCBs are excreted partly with milk fat, and in laying hens the contaminants are concentrated in fat content of the yolk in laid eggs. To reduce this transfer, control measures at the feed and feed ingredients level should be considered. Measures to reduce the dioxin and dioxin-like PCB levels in feed would have an immediate effect on contaminant levels in food of animal origin originating from farm animals, including farmed fish. These measures should involve developing Codes of Good Agricultural Practices, Good Animal Feeding Practices (see, Good Manufacturing Practices, Good Storage Practices, and other control measures e.g., HACCP-like principles) which may reduce levels of dioxins and dioxin-like PCBs. Such measures may include:

- identification of possibly contaminated areas in the feed supply ecosystem,
- identification of the origin of frequently contaminated feed or feed ingredients, and
- monitoring the compliance of feed and feed ingredients with nationally-established guideline levels or maximum limits, if available. Threshold violating commodities should be investigated by the competent national authority, to determine whether those commodities should be excluded from further feeding.

29. Competent national authorities should periodically sample and analyse, using recognized international methods, suspect feed and feed ingredients to verify dioxin and dioxin-like PCB levels. This information will determine actions, if needed, to minimize dioxin and dioxin-like PCB levels and allow alternative feed and feed ingredients to be located, if necessary.

30. The purchaser and user should pay attention to:

- origin of feed and feed ingredients to ensure that producers and/or companies have certified production facilities, production processes and quality assurance programmes (e.g., HACCP-like principles);
- accompanying documents confirming compliance with nationally-established guideline levels or maximum limits, if available, according to national requirements.

Feed of animal origin

31. Due to the position of their precursors in the food chain, animal derived feed has a higher risk for dioxin and dioxin-like PCB contamination compared to plant derived feed. Attention should be paid to avoid these contaminants from entering the food chain through the feeding of animal derived feed to food producing animals. Animal derived feed should be monitored, as necessary, for dioxins and dioxin-like PCBs.

32. Accumulation of dioxins and dioxin-like PCBs in adipose tissues of livestock, with possible resultant violations of nationally-established guideline levels or maximum limits, if available, for meat and milk or their derived products should be prevented. Therefore, feed of animal origin that exceeds nationally-established guideline levels or maximum limits, if available, or contains elevated levels of dioxins or dioxin-like PCBs should not be fed to animals unless the fat has been removed.

33. If intended for use in feed, fish-oil and other products derived from fish, milk and milk substitutes, and animal fats should be monitored to the extent practicable for dioxins and dioxin-like PCBs. If there are nationally-established guideline levels or maximum limits, the feed manufacturer should ensure that the products are in compliance with these provisions.

Feed of plant origin

34. If potential sources of dioxins and dioxin-like PCBs are anticipated in the vicinity of fields, attention should be paid to monitor these areas, as necessary.

35. Cultivation sites irrigated with water or treated with sewage sludge or municipal compost that may contain elevated dioxin and dioxin-like PCB levels should be monitored, as necessary, for contamination.

36. Prior treatment of crops with herbicides from the chlorinated phenoxyalkanoic acid type or chlorinated products like pentachlorophenol should be considered as a potential source for dioxin contamination. Dioxin levels in soil and forage plants from sites treated previously with dioxin-contaminated herbicides should be monitored as necessary. This information will enable competent national authorities, if necessary, to take appropriate management measures in order to prevent the transfer of dioxins (and dioxin-like PCBs) into the food chain.

37. Typically, oilseeds and vegetable oil are not significantly contaminated with dioxins and dioxin-like PCBs. This also applies to other by-products of oilseed processing (e.g., oilseed cakes) used as feed ingredients. However, certain oil refining by-products (e.g., fatty acid distillates) may contain increased levels of dioxins and dioxin-like PCBs and should be analysed, as necessary, if used for feed.

Feed and Food Processing

Drying Processes

38. Certain processes for the artificial drying of feed and food (and feed or food ingredients) and the heating of indoor growing facilities (e.g. hothouses) requires a flow of heated gases, either a flue gas-air mix (direct drying or heating) or heated air alone (indirect drying or heating). Accordingly, fuels which are not generating dioxins and dioxin-like compounds and other harmful contaminants at unacceptable levels should be used. Feed, food and feed or food ingredients that are dried or subjected to heated air should be monitored as necessary to ensure that drying or heating processes do not result in elevated levels of dioxins and dioxin-like PCBs.

39. The quality of commercial dried feed materials, in particular green fodder and commercially dried foods depends on the selection of the raw material and the drying process. The purchaser should consider requiring a certificate from the manufacturer/supplier, that the dried goods are produced according to Good Manufacturing Practice, especially in the choice of the fuel and are in compliance with nationally-established guideline levels or maximum limits, if available.

Smoking

40. Depending on the technology used, smoking can be a critical processing step for increased dioxin content in foods, especially if the products show a very dark surface with particles of soot. Such processed products should be monitored, as necessary, by the manufacturer.

Milling / Disposal of Contaminated Milling Fractions

41. In agricultural land in the vicinity of dioxin and dioxin-like PCB emission sources, the air borne external deposition of dioxins and dioxin-like PCBs on the surface of all parts of the grain plants as well as the adherent dust fraction from the standing crop is widely removed during the milling process and before the final grinding process. If present, most particle-bound contamination is removed in the loading chute with the remaining dust. Further external contaminations are significantly reduced during aspiration and sieving. Certain grain fractions, especially dust, can have increased dioxin and dioxin-like PCB levels and should be monitored, as necessary. If there is evidence for elevated contamination, such fractions should not be used in food or feed and treated as waste.

Substances added to Feed and Food

Minerals and Trace Elements

42. Some minerals and trace elements are obtained from natural sources. However, experience has shown, that geogenic dioxins may be present in certain prehistoric sediments. Therefore, dioxin levels in minerals and trace elements added to feed or food should be monitored as necessary.

43. Reclaimed mineral products or by-products from certain industrial processes may contain elevated levels of dioxins and dioxin-like PCBs. The user of such feed ingredients should verify that dioxin and dioxin-like PCBs are within nationally-established guideline levels or maximum limits, if available, through certification by the manufacturer or supplier.

44. Elevated levels of dioxins have been found in ball clay used as an anticaking agent in soybean meal in feed. Attention should be paid to minerals used as binders or anticaking agents (e.g., bentonite, montmorillonite, kaolinitic clay) and carriers (e.g., calcium carbonate) used as feed ingredients. As assurance to the user that these substances do not contain minerals with elevated levels (e.g., exceeding nationally-established guideline levels or maximum limits, if available) of dioxins and dioxin-like PCBs, the distributor should provide appropriate certification to the user of such feed ingredients.

45. The supplementation of food producing animals with trace elements (e.g., copper or zinc) depends on the species, age and performance. Minerals, including trace elements, which are by-products or co-products of industrial metal production have been shown to contain elevated levels of dioxins. Such products should be monitored for dioxins and dioxin-like PCBs, as necessary.

Ingredients

46. Feed and food manufacturers should ensure that all ingredients in feed and food have minimal levels of dioxins and dioxin-like PCBs to reduce possible contamination and to comply with nationally-established guideline levels or maximum limits, if available.

Harvesting, Transport, Storage of Feed and Food

47. To the extent feasible, it should be ensured that minimal contamination with dioxins and dioxin-like PCBs occurs during the harvest of feed and food. This can be achieved in possibly contaminated areas by minimizing soil deposition on feed and food during harvest by using appropriate techniques and tools according to Good Agricultural Practice. Roots and tubers, grown on contaminated soil, should be washed to reduce soil contamination. If roots and tubers are washed, they should be sufficiently dried before storage or be stored following techniques (e.g. ensilage) aiming to prevent mould formation.

48. After flooding, crops harvested for feed and food should be monitored, as necessary, for dioxins and dioxin-like PCBs, if there is evidence for flood water contamination by these contaminants.

49. To avoid cross-contamination, the transport of feed and food should only be performed in vehicles (including ships) or in containers not contaminated with dioxins and dioxin-like PCBs. Storage containers for feed and food should be painted only with dioxin and dioxin-like PCB-free paint.

50. Storage sites for feed or food should be free from contamination with dioxins and dioxin-like PCBs. Surfaces (e.g., walls, floors) treated with tar-based paints may result in transfer of dioxins and dioxin-like PCBs to food and feed. Surfaces that come in contact with smoke and soot from fires always bear a risk of contamination with dioxins and dioxin-like PCBs. These sites should be monitored as necessary for contamination before use for storage of feed and food.

Special Problems of Animal Keeping (Housing)

51. Food producing animals may be exposed to dioxins and dioxin-like PCBs found in certain treated wood used in buildings, farm equipment and bedding material. To reduce exposure, animal contact with treated wood containing dioxins and dioxin-like PCBs should be minimized. In addition, sawdust from treated wood containing dioxins and dioxin-like PCBs should not be used as bedding material.

52. Due to contamination in certain soil, eggs from free living or free-range hens (e.g., organic farming) may have elevated levels of dioxins and dioxin-like PCBs compared to eggs from caged hens and should be monitored, as necessary.

53. Attention should be paid to older buildings as they may have building materials and varnishes that may contain dioxin and dioxin-like PCBs. If they have caught fire, measures should be taken to avoid contamination of the feed and feed chain by dioxins and dioxin-like PCBs.

54. In housings without a floor covering, the animals normally will take up soil particles from the ground. If there are indications of increased levels of dioxins and dioxin-like PCBs, the contamination of the soil should be controlled as necessary. If needed, the soil should be exchanged.

55. Pentachlorophenol-treated wood in animal facilities has been associated with elevated levels of dioxins in beef. Wood (e.g., railroad ties, utility poles) treated with chemicals such as pentachlorophenol or other unsuitable materials should not be used as fence posts for enclosures of free-range animals or feed lines. Hay racks should not be constructed from such treated wood. In addition, the preservation of wood with waste oils should also be avoided.

Monitoring

56. Farmers and industrial feed and food manufacturers have the primary responsibility for feed and food safety. Testing could be conducted within the framework of a food safety programme (e.g. Good Manufacturing Practices, On-Farm Safety programmes, Hazard Analysis and Critical Control Point programmes, etc.) In previous sections of this Code, it is mentioned where it could be appropriate to perform monitoring. Competent authorities should enforce the primary responsibility of farmers, feed and food manufacturers for feed and food safety through the operation of surveillance and control systems at appropriate points throughout the food chain, from the primary production to the retail level. In addition competent authorities should set up own monitoring programmes.

57. As analyses for dioxins are quite expensive in comparison to determination of other chemical contaminants, periodic tests should be performed to the extent feasible at least by industrial feed and food manufacturers including both incoming raw materials and final products and data should be kept (see para. 66). The frequency of sampling should consider results from previous analysis (by individual companies and/or via a pool of industry results within the same sector). If there are indications of elevated levels of dioxins and dioxin-like PCBs, farmers and other primary producers should be informed about the contamination and the source should be identified.

58. Monitoring programmes dealing with contaminations originating from the environment, accidents or illegal disposals should be organized by operators in the feed and food chain to the extent feasible and competent national authorities in order to obtain additional information on food and feed contamination. Products or ingredients at risk or found with elevated contamination should be monitored more intensively. For example, monitoring programmes may include major fish species used in food or feed that have been shown to contain elevated levels of dioxins and dioxin-like PCBs.

SAMPLING, ANALYTICAL METHODS, DATA REPORTING AND LABORATORIES

59. Advice concerning analytical requirements and qualification of laboratories is given in the literature. These recommendations and conclusions form the basis of the evaluation by JECFA and others. Furthermore, consideration of methods of analysis of dioxins and dioxin-like PCBs is addressed by the Codex Committee of Methods of Analysis and Sampling.

60. Traditional methods for the analysis of dioxin and dioxin-like PCBs rely on high-resolution mass spectrometry which is time-consuming and expensive. Alternatively, bioassay techniques have been developed as high throughput screening methods which can be less expensive than traditional methods. However, the cost of analysis remains an impediment to data collection thus research priority should be given to the development of less costly analytical methods for the analysis of dioxin and dioxin-like PCBs.

Sampling

61. Important aspects of sampling for dioxin and dioxin-like PCB analysis are collecting representative samples, avoiding cross contamination and deterioration of samples and unambiguously identifying and tracing back samples. All relevant information on sampling, sample preparation and sample description (e.g., sampling period, geographic origin, fish species, fat content, size of fish) should be recorded in order to provide valuable information.

Analytical methods and data reporting

62. Analytical methods should be applied only if they are fit for purpose meeting a minimum of requirements. If nationally-established maximum limits are available, the limit of quantification (LOQ) of the method of analysis should be in the range of one fifth of this level of interest. For control of time trends of background contamination, the limit of quantification of the method of analysis should be clearly below the mean of the present background ranges for the different matrices.

63. Performance of a method of analysis should be demonstrated in the range of the level of interest, e.g. 0.5 x, 1 x and 2 x level of maximum limit with an acceptable coefficient of variation for repeated analysis. The difference between upper bound and lower bound levels (see next para.) should not exceed 20 % for feed and food with a dioxin contamination of about 1 pg WHO-PCDD/PCDF-TEQ/g fat. If needed, another calculation based on fresh weight or dry matter could be considered.

64. Except for bioassay techniques, the results of total dioxin and dioxin-like PCB levels in a given sample should be reported as lower bound, medium bound and upper bound concentration by multiplying each congener by their respective WHO Toxic Equivalency Factor (TEF) and subsequently summing them up to give the total concentration expressed as Toxic Equivalency (TEQ). The three different TEQ values should be generated reflecting assignment of zero (lower bound), half the limit of quantification (medium bound), and limit of quantification (upper bound) values to each non-quantified dioxin and dioxin-like PCB congener.

65. Depending on sample type, the report of the analytical results may include the lipid or dry matter content of the sample as well as the method used for lipid extraction and for determination of dry matter. This report should also include a specific description of the procedure used to determine the level of quantification (LOQ).

66. A high throughput screening method of analysis with proven acceptable validation could be used to screen the samples with significant levels of dioxins and dioxin-like PCBs. Screening methods should have less than 1 % false-negative results in the relevant range of interest for a particular matrix. Use of ¹³C-labelled internal standards for dioxins or dioxin-like PCBs allows for specific control of possible losses of the analytes in each sample. In this way, false-negative results can be avoided preventing contaminated food or feed being used or marketed. For confirmatory methods, use of these internal standards is mandatory. For screening methods without control of losses during the analytical procedure, information on correction of losses of compounds and the possible variability of results should be given. Levels of dioxins and dioxin-like PCBs in positive samples (above the level of interest) should be determined by a confirmatory method.

Laboratories

67. Laboratories involved in the analysis of dioxins and dioxin-like PCBs using screening as well as confirmatory methods of analysis should be accredited by a recognized body operating in accordance with ISO/IEC Guide 58: 1993 or have quality assurance programmes that address all critical elements of accrediting agencies to ensure that they are applying analytical quality assurance. Accredited laboratories should follow the ISO/IEC/17025:1999 standard “General requirements for the competence of testing and calibration laboratories” or other equivalent standards. .

68. The regular participation in interlaboratory studies or proficiency tests for the determination of dioxins and dioxin-like PCBs in the relevant feed and food matrices is recommended according to ISO/IEC/17025: 1999 standard.

QUALITY MANAGEMENT AND EDUCATION

69. Good Agricultural Practices, Good Manufacturing Practices, Good Storage Practices, Good Animal Feeding Practices and Good Laboratory Practices are valuable systems for further reduction of dioxin and dioxin-like PCB contamination in the food chain. Farmers and feed and food manufacturers should consider educating their co-workers on how to prevent contamination by the implementation of control measures.

Glossary of Terms
(for the purpose of this Code of Practice)

Term	Explanation
anticaking agent	substance that reduce the tendency of individual particles of a feed or food to adhere
binder	substance that increase the tendency of individual particles of a feed or food to adhere
coefficient of variation	statistical parameter expressing: 100 x standard deviation of a set of values/mean value of set
confirmatory method of analysis	method of analysis with high quality parameters capable to confirm analytical results produced from screening methods with lower quality parameters
congener	one of two or more compounds of the same kind with respect to classification
dioxins (PCDD/PCDF)	Includes 7 polychlorinated dibenzo-p-dioxins (PCDDs) and 10 dibenzofurans (PCDFs) that have dioxin-like activity which belong to a group of lipophilic and persistent organic substances. Depending on the degree of chlorination (1 -8 chlorine atoms) and the substitution patterns, 75 different PCDDs and 135 different PCDFs (“congeners”), can be distinguished.
dioxin-like PCBs	Includes 12 non-ortho and mono-ortho substituted polychlorinated biphenyls (PCBs) showing toxicological properties (dioxin-like activity) that are similar to dioxins (25)
fish	cold-blooded vertebrate animals including Pisces, Elasmobranches and Cyclostomes. For the purpose of this code of practice, molluscs and crustaceans are also included (41).
feed	any single or multiple materials, whether processed, semi-processed or raw which is intended to be fed directly to food producing animals (27)
food	any substance, whether processed, semi-processed or raw which is intended for direct human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture , preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.
feed or food ingredient	a component or constituent of any combination or mixture making up a feed or food, whether or not it has a nutritional value in the diet, including additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances.
guideline levels	not statutory but recommended maximum levels
HACCP	Hazard Analysis Critical Control Point (HACCP) is a system that identifies, evaluates and controls hazards which are significant for food safety
limit of quantification (LOQ) (valid for dioxins and dioxin-like PCBs only)	the limit of quantification of an individual congener is the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions to be monitored with an S/N (signal/noise) ratio of 3:1 for the less sensitive signal and fulfilment of the basic requirements such as e.g. retention time, isotope ratio according to the determination procedure as described in EPA method 1613 revision B (38, 54).
maximum limits	statutory maximum limits for contaminants

Term	Explanation
minerals	Inorganic compounds used in food and feed required for normal nutrition or used as processing aids
PCBs	polychlorinated biphenyls belonging to a group of chlorinated hydrocarbons, which are formed by direct chlorination of biphenyl. Depending on the number of chlorine atoms (1 – 10) and their position at the two rings, 209 different compounds (“congeners”) are theoretically possible (25).
pelagic fish species	fish species living in free water (e.g., ocean, lake) without contact to the sediment
persistent organic pollutant (POP)	chemical substance that persists in the environment, bioaccumulates through the food web, and poses a risk of causing adverse effects to human health and the environment
Stockholm Convention (POPs Convention)	The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from persistent organic pollutants (POPs) including dioxins and dioxin-like PCBs and entered into force on 17 th May 2004. In implementing the Stockholm Convention governments will take measures to eliminate or reduce the release of POPs into the environment.
screening method of analysis	method of analysis with lower quality parameters to select samples with significant levels of an analyte
trace elements	chemical elements essential for plant, animal and/or human nutrition in small amounts
Toxic Equivalency (TEQ)	relative value calculated by multiplying the concentration of a congener by the toxic equivalency factor (TEF)
WHO- -TEQ	TEQ value for dioxins and dioxin-like PCBs, established by WHO and based on established Toxic Equivalency Factors (TEFs) (37)
Toxic Equivalency Factor (TEF)	Estimates of the toxicity of dioxin-like compounds relative to the toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), which is assigned a TEF of 1.0

**PROPOSED DRAFT MAXIMUM LEVEL FOR 3-MCPD IN LIQUID CONDIMENTS
CONTAINING ACID-HYDROLYZED VEGETABLE PROTEIN (EXCLUDING NATURALLY
FERMENTED SOY SAUCE)**

(N08-2004)

(AT STEP 4 OF THE PROCEDURE)

Code No.	Food	ML (mg/kg)	Step	Remarks
	Liquid condiments containing acid-Hydrolyzed vegetable protein (excluding naturally fermented soy sauce)	0.4	4	

PROPOSED DRAFT MAXIMUM LEVELS FOR TIN**(At Step 5 of the Procedure)**

Code No.	Food	ML(mg/kg)	Step	Remarks
	Canned Beverages	150 mg/kg	5	
	Canned Foods other than Beverages	250 mg/kg	5	

Project document**PROPOSAL FOR NEW WORK ON A CODE OF PRACTICE FOR THE REDUCTION OF ACRYLAMIDE IN FOOD****The purposes and the scope of the standard**

To develop a draft Code of Practice for the reduction of acrylamide in food. The Code will cover major aspects of commercial production of food, including agricultural practices, storage, raw ingredients, and processing and preparation of food (thermal input, temperature profile, pH, recipe, etc.). The United Kingdom, in consultation with other member countries, will write a first draft of the Code of Practice.

Its relevance and timeliness

Conditions that can be controlled during the production of food, such as agricultural practices, storage conditions, thermal input, temperature profile, pH and recipe, can affect the concentration of acrylamide in the final product. JECFA (2005) has stated that acrylamide may be a human health concern at the levels found in food. A Code of Practice will provide a means of reducing the concentration of the process contaminant acrylamide.

The main aspects to be covered

The draft Code of Practice will cover the parameters that can be controlled and the conditions that have been shown to be effective for these parameters. It will present potential methods for reducing acrylamide in the areas of agronomics, product composition, process conditions and final preparation. It will include an assessment of the effect of these methods on finished product characteristics, both positive and negative. It will also emphasize previous successful and failed mitigation strategies. The Code of Practice will carry forward information included in previous discussion papers on acrylamide.

An assessment against the Criteria for the Establishment of Work Priorities

This proposal is consistent with the following Criteria for the Establishment of Work Priorities:

- a) Consumer protection from the point of view of health and fraudulent practices. (By reducing consumer dietary exposure to acrylamide from food).

Relevance to the Codex strategic objectives

This proposal is consistent with the Strategic Vision statement of the Strategic Framework 2003-2007

Information on the relation between the proposal and other existing Codex documents

This new work is recommended in the Discussion Paper on Acrylamide (CX/FAC 05/37/33), the Report of the 37th Session of the Codex Committee on Food Additives and Contaminants (ALINORM 05/28/12) and the revised Discussion Paper on Acrylamide presented at the 38th CCFAC Session.

Identification of any requirements for and availability of expert scientific advice

None.

Identification of any need for technical input to the standard from external bodies so that this can be planned for.

None.

The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at the Step 5, and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed five years.

If the Commission approves, in 2006, that the proposal for this New Work should proceed, the draft Code of Practice will be circulated for consideration at Step 3 at the next Session of the Committee. Advancement to Step 5 is planned for 2009 and an additional Session of the Committee might be necessary to finalise the revision for adoption at Step 8 by the subsequent Session of the Codex Alimentarius Commission.

Appendix XXX**Project Document****PROPOSAL FOR NEW WORK ON A CODE OF PRACTICE FOR THE REDUCTION OF CONTAMINATION OF FOOD WITH PAH FROM SMOKING AND DIRECT DRYING PROCESSES****The purpose and the scope of the standard.**

The scope is to develop Code of Good Manufacturing Practice for reduction of contamination of food with PAH from smoking and direct drying processes.

Its relevance and timeliness.

JECFA reviewed PAH in February 2005 (JECFA, summary report, 2005). The Committee concluded that the critical effect of PAH is carcinogenicity. As a number of PAH are also genotoxic, it is not possible to assume a threshold mechanism and a PTWI could not be established. JECFA used a margin of exposure approach to conclude that PAH are of low concern to human health. Efforts should be made to reduce contamination with PAH during drying and smoking processes, e.g. by replacing direct smoking (with smoke developed in the smoking chamber, traditionally in smokehouses) with indirect smoking.

The main aspects to be covered.

The draft Code of Practice will cover the parameters to be controlled during smoking and drying processes foodstuffs. In addition, it will support the advice given by JECFA on reduction of PAH in processed foods.

An assessment against criteria for the establishment of work priorities.

This proposal is consistent with the following criteria for the establishment of work priorities: Codex Alimentarius should protect consumers by ensuring food safety and e.g., reduce exposure to PAH.

Relevance to the Codex strategic objectives.

This proposal is consistent with the strategic vision statement of the strategic Framework 2003-2007.

Information on the relation between the proposal and other existing Codex documents.

This new work is recommended in the Discussion Paper on polycyclic aromatic hydrocarbons (PAH) and food processing (CX/FAC 06/38/36).

Identification of any requirements for and availability of expert scientific advice.

None

Identification of any need for technical input to the standard from external bodies so that this can be planned for.

None

The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at step 5, and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed five years.

If the Commission approves, in 2006, that the proposal for this new work should proceed, the draft Code of Practice will be circulated for comments at Step 3 and consideration at the next session of the Committee. Advancement to step 5 is planned for 2008 and additional session of the Committee might be necessary to finalise the revision for adoption at step 8 by the subsequent session of the CAC.

**PROPOSED DRAFT REVISED GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS
CONTAMINATED FOLLOWING A NUCLEAR OR RADIOLOGICAL EMERGENCY
FOR USE IN INTERNATIONAL TRADE**

(At Step 5/8 of the Procedure)

TABLE 1: GUIDELINE LEVELS (IN Bq/kg) FOR RADIONUCLIDES IN FOODS

Radionuclides in Foods	Guideline Level (Bq/kg)	
	Infant Foods*	Other Foods
²³⁸ Pu, ²³⁹ Pu, ²⁴⁰ Pu, ²⁴¹ Am	1	10
⁹⁰ Sr, ¹⁰⁶ Ru, ¹²⁹ I, ¹³¹ I, ²³⁵ U	100	100
³⁵ S**, ⁶⁰ Co, ⁸⁹ Sr, ¹⁰³ Ru, ¹³⁴ Cs, ¹³⁷ Cs, ¹⁴⁴ Ce, ¹⁹² Ir	1000	1000
³ H***, ¹⁴ C, ⁹⁹ Tc	1000	10000

* When intended for use as such.

** This represents the value for organically bound sulphur.

*** This represents the value for organically bound tritium.

Scope: The Guideline Levels apply to radionuclides contained in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency¹. These guideline levels apply to food after reconstitution or as prepared for consumption, i.e., not to dried or concentrated foods, and are based on an intervention exemption level of 1 mSv in a year.

Application: As far as generic radiological protection of food consumers is concerned, when radionuclide levels in food do not exceed the corresponding Guideline Levels, the food should be considered as safe for human consumption. When the Guideline Levels are exceeded, national governments shall decide whether and under what circumstances the food should be distributed within their territory or jurisdiction. National governments may wish to adopt different values for internal use within their own territories where the assumptions concerning food distribution that have been made to derive the Guideline Levels may not apply, e.g., in the case of wide-spread radioactive contamination. For foods that are consumed in small quantities, such as spices, that represent a small percentage of total diet and hence a small addition to the total dose, the Guideline Levels may be increased by a factor of 10.

Radionuclides: The Guideline Levels do not include all radionuclides. Radionuclides included are those important for uptake into the food chain; are usually contained in nuclear installations or used as a radiation source in large enough quantities to be significant potential contributors to levels in foods, and; could be accidentally released into the environment from typical installations or might be employed in malevolent actions. Radionuclides of natural origin are generally excluded from consideration in this document.

In Table 1, the radionuclides are grouped according to the guideline levels rounded logarithmically by orders of magnitude. Guideline levels are defined for two separate categories “infant foods” and “other foods”. This is because, for a number of radionuclides, the sensitivity of infants could pose a problem. The guideline levels have been checked against age-dependent ingestion dose coefficients defined as committed effective doses per unit intake for each radionuclide, which are taken from the "International Basic Safety Standards" (IAEA, 1996)².

¹ For the purposes of this document, the term “emergency” includes both accidents and malevolent actions.

² Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Office, OECD Nuclear Energy Agency, Pan American Health Organization, World Health Organization

Multiple radionuclides in foods: The guideline levels have been developed with the understanding that there is no need to add contributions from radionuclides in different groups. Each group should be treated independently. However, the activity concentrations of each radionuclide within the same group should be added together³.

(1996) International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA, Vienna.

³ For example, if ¹³⁴Cs and ¹³⁷Cs are contaminants in food, the guideline level of 1000 Bq/kg refers to the summed activity of both these radionuclides.

ANNEX 1

SCIENTIFIC JUSTIFICATION FOR PROPOSED DRAFT REVISED GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS CONTAMINATED FOLLOWING A NUCLEAR OR RADIOLOGICAL EMERGENCY

The proposed draft revised Guideline Levels for Radionuclides in Foods and specifically the values presented in Table 1 above are based on the following general radiological considerations and experience of application of the existing international and national standards for control of radionuclides in food.

Significant improvements in the assessment of radiation doses resulting from the human intake of radioactive substances have become available since the Guideline Levels were issued by the Codex Alimentarius Commission in 1989⁴ (CAC/GL 5-1989).

Infants and adults: The levels of human exposure resulting from consumption of foods containing radionuclides listed in Table 1 at the suggested guideline levels have been assessed both for infants and adults and checked for compliance with the appropriate dose criterion.

In order to assess public exposure and the associated health risks from intake of radionuclides in food, estimates of food consumption rates and ingestion dose coefficients are needed. According to Ref. (WHO, 1988) it is assumed that 550 kg of food is consumed by an adult in a year. The value of infant food and milk consumption during first year of life used for infant dose calculation equal to 200 kg is based on contemporary human habit assessments (F. Luykx, 1990⁵; US DoH, 1998⁶; NRPB, 2003⁷). The most conservative values of the radionuclide-specific and age-specific ingestion dose coefficients, i.e. relevant to the chemical forms of radionuclides which are most absorbed from the gastro-intestinal tract and retained in body tissues, are taken from the (IAEA, 1996).

Radiological criterion: The appropriate radiological criterion, which has been used for comparison with the dose assessment data below, is a generic intervention exemption level of around 1 mSv for individual annual dose from radionuclides in major commodities, e.g. food, recommended by the International Commission on Radiological Protection as safe for members of the public (ICRP, 1999)⁸.

Naturally occurring radionuclides: Radionuclides of natural origin are ubiquitous and as a consequence are present in all foodstuffs to varying degrees. Radiation doses from the consumption of foodstuffs typically range from a few tens to a few hundreds of microsieverts in a year. In essence, the doses from these radionuclides when naturally present in the diet are unamenable to control; the resources that would be required to affect exposures would be out of proportion to the benefits achieved for health. These radionuclides are excluded from consideration in this document as they are not associated with emergencies.

⁴ The Codex Alimentarius Commission at its 18th Session (Geneva 1989) adopted Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989) applicable for six radionuclides (⁹⁰Sr, ¹³¹I, ¹³⁷Cs, ¹³⁴Cs, ²³⁹Pu and ²⁴¹Am) during one year after the nuclear accident.

⁵ F. Luykx (1990) Response of the European Communities to environmental contamination following the Chernobyl accident. In: Environmental Contamination Following a Major Nuclear Accident, IAEA, Vienna, v.2, 269-287.

⁶ US DoHHS (1998) Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies. Food and Drug Administration, Rockville.

⁷ K. Smith and A. Jones (2003) Generalised Habit Data for Radiological Assessments. NRPB Report W41.

⁸ International Commission on Radiological Protection (1999). Principles for the Protection of the Public in Situations of Prolonged Exposure. ICRP Publication 82, Annals of the ICRP.

One-year exposure assessment: It is conservatively assumed that during the first year after major environmental radioactive contamination caused by a nuclear or radiological emergency it might be difficult to readily replace foods imported from contaminated regions with foods imported from unaffected areas. According to FAO statistical data the mean fraction of major foodstuff quantities imported by all the countries worldwide is 0.1. The values in Table 1 as regards foods consumed by infants and the general population have been derived to ensure that if a country continues to import major foods from areas contaminated with radionuclides, the mean annual internal dose of its inhabitants will not exceed around 1 mSv (see Annex 2). This conclusion might not apply for some radionuclides if the fraction of contaminated food is found to be higher than 0.1, as might be the case for infants who have a diet essentially based on milk with little variety.

Long-term exposure assessment: Beyond one year after the emergency the fraction of contaminated food placed on the market will generally decrease as a result of national restrictions (withdrawal from the market), changes to other produce, agricultural countermeasures and decay.

Experience has shown that in the long term the fraction of imported contaminated food will decrease by a factor of a hundred or more. Specific food categories, e.g. wild forest products, may show persistent or even increasing levels of contamination. Other categories of food may gradually be exempted from controls. Nevertheless, it must be anticipated that it may take many years before levels of individual exposure as a result of contaminated food could be qualified as negligible.

ANNEX 2

**ASSESSMENT OF HUMAN INTERNAL EXPOSURE WHEN
THE GUIDELINE LEVELS ARE APPLIED**

For the purpose of assessment of the mean public exposure level in a country caused by the import of food products from foreign areas with residual radioactivity, in implementing the present guideline levels the following data should be used: annual food consumption rates for infants and adults, radionuclide- and age-dependent ingestion dose coefficients and the import/production factors. When assessing the mean internal dose in infants and adults it is suggested that due to monitoring and inspection the radionuclide concentration in imported foods does not exceed the present guideline levels. Using cautious assessment approach it is considered that all the foodstuffs imported from foreign areas with residual radioactivity are contaminated with radionuclides at the present guideline levels.

Then, the mean internal dose of the public, E (mSv), due to annual consumption of imported foods containing radionuclides can be estimated using the following formula:

$$E = GL(A) \cdot M(A) \cdot e_{ing}(A) \cdot IPF$$

where:

$GL(A)$ is the Guideline Level (Bq/kg)

$M(A)$ is the age-dependent mass of food consumed per year (kg)

$e_{ing}(A)$ is the age-dependent ingestion dose coefficient (mSv/Bq)

IPF is the import/production factor⁹ (dimensionless).

Assessment results presented in Table 2 both for infants and adults demonstrate that for all the twenty radionuclides doses from consumption of imported foods during the 1st year after major radioactive contamination do not exceed 1 mSv. It should be noted that the doses were calculated on the basis of a value for the IPF equal to 0.1 and that this assumption may not always apply, in particular to infants who have a diet essentially based on milk with little variety.

It should be noted that for ²³⁹Pu as well as for a number of other radionuclides the dose estimate is conservative. This is because elevated gastro-intestinal tract absorption factors and associated ingestion dose coefficients are applied for the whole first year of life whereas this is valid mainly during suckling period recently estimated by ICRP to be as average first six months of life (ICRP, 2005¹⁰). For the subsequent six months of the first year of life the gut absorption factors are much lower. This is not the case for ³H, ¹⁴C, ³⁵S, iodine and caesium isotopes.

As an example, dose assessment for ¹³⁷Cs in foods is presented below for the first year after the area contamination with this nuclide.

For adults: $E = 1000 \text{ Bq/kg} \cdot 550 \text{ kg} \cdot 1.3 \cdot 10^{-5} \text{ mSv/Bq} \cdot 0.1 = 0.7 \text{ mSv}$;

For infants: $E = 1000 \text{ Bq/kg} \cdot 200 \text{ kg} \cdot 2.1 \cdot 10^{-5} \text{ mSv/Bq} \cdot 0.1 = 0.4 \text{ mSv}$

⁹ The import/production factor (IPF) is defined as the ratio of the amount of foodstuffs imported per year from areas contaminated with radionuclides to the total amount produced and imported annually in the region or country under consideration.

¹⁰ International Commission on Radiological Protection (2005) Doses to Infants from Radionuclides Ingested in Mothers Milk. To be published.

TABLE 2

**ASSESSMENT OF EFFECTIVE DOSE FOR INFANTS AND ADULTS FROM
INGESTION OF IMPORTED FOODS IN A YEAR**

Radionuclide	Guideline Level (Bq/kg)		Effective dose (mSv)	
	Infant foods	Other foods	1 st year after major contamination	
			Infants	Adults
²³⁸ Pu	1	10	0.08	0.1
²³⁹ Pu			0.08	0.1
²⁴⁰ Pu			0.08	0.1
²⁴¹ Am			0.07	0.1
⁹⁰ Sr	100	100	0.5	0.2
¹⁰⁶ Ru			0.2	0.04
¹²⁹ I			0.4	0.6
¹³¹ I			0.4	0.1
²³⁵ U			0.7	0.3
³⁵ S*	1000	1000	0.2	0.04
⁶⁰ Co			1	0.2
⁸⁹ Sr			0.7	0.1
¹⁰³ Ru			0.1	0.04
¹³⁴ Cs			0.5	1
¹³⁷ Cs			0.4	0.7
¹⁴⁴ Ce			1	0.3
¹⁹² Ir			0.3	0.08
³ H**	1000	10000	0.002	0.02
¹⁴ C			0.03	0.3
⁹⁹ Tc			0.2	0.4

* This represents the value for organically bound sulphur.

** This represents the value for organically bound tritium.

Appendix XXXII

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

	<i>Question(s) to be answered</i>	<i>Data availability (when, what)</i>	<i>Proposed by</i>
A. Food additives			
Flavours: 325 ¹	Risk assessment at current use patterns; establishment of specifications; additional compounds to already evaluated groups. Full details to be provided to JECFA secretariat, including use-level data	Available	US
Acidified Sodium chlorite ¹	Risk assessment for use in food contact (as processing aid)	Available from US	US
Carrageenan ¹	Toxicological re-evaluation and revision of specification Assessment of safety for infants 0-6 months of age (from infant formula use)	SCF evaluation and new toxicological data available	EC
Processed Euchema Seaweed (PES) ¹	Toxicological re-evaluation and revision of specification	new toxicological data available	EC
Cyclotetraose ¹	Safety evaluation (use as carrier and stabilizer)	Nov 2005	Switzerland
Isoamylase from <i>Pseudomonas amyloclavus</i> ¹	Safety evaluation and specification	Available	Switzerland
Phospholipase A1 from <i>Fusarium venenatum</i> produced by <i>Aspergillus oryzae</i> ¹	Safety assessment	Apr 2006	Denmark
Asparaginase expressed in <i>Aspergillus oryzae</i> ¹	Safety assessment and specification	Sep 2006	Denmark
Sodium iron EDTA trihydrate ¹	Safety evaluation, use for iron fortification (approved in US, China, Brazil, etc..)	Available	US
Sunset Yellow	Revision of specification (additional limit for Sudan I)	Available	EC

	<i>Question(s) to be answered</i>	<i>Data availability (when, what)</i>	<i>Proposed by</i>
Ligninsulfonate	Safety assessment and specification (Carrier for vitamins, carotenoids, other nutrients and additives formulations)	Nov 2006	Switzerland
Phytosterols, phytostanols and their esters	Safety assessment and specification	Dec 2006	Switzerland
Nisin	Revision of specification	Available	US
Lauric arginate ethyl ester	Assessment of safety and intake, specification	Available	US
Trisodium diphosphate	Specification	Available	IFAC/EC
Monomagnesium phosphate	Specification	Available	IFAC/EC
Paprika extract/paprika oleoresin ¹	Safety as food colour , specification and exposure assessment NOTE: can the existing safety assessment and specification for paprika oleoresin for use as spice be extended to the use as food colour.	Dec 2006	Switzerland
Food colours: Curcumin; amaranth; tartrazine, Sunset yellow FCF, Fast green, carmine	Dietary exposure assessment based on proposed draft (step 3) and draft (step 6) provisions, in addition use-level based exposure assessment	Available Korea: 2007 intake assessment from all food sources	CCFAC
Tartrazine, Sunset yellow FCF, Fast green, amaranth	Assessment of potential for hypersensitivity	Sweden: old data Korea: clinical study available in 2007	CCFAC
Sulphites	Dietary exposure assessment from all foods	Available	CCFAC
Sodium Aluminium Sulfate	Safety assessment and specification	Available	Switzerland

	<i>Question(s) to be answered</i>	<i>Data availability (when, what)</i>	<i>Proposed by</i>
B. Contaminants			
Deoxynivalenol (DON)	Exposure assessment on a more global basis taking new data into account, also review of toxicological data and considering the need for an acute reference dose (taking into account data also in finished products, but also in raw wheat and other commodities as they are traded internationally and consideration of processing factors)	(Not before end 2007-2008)	CCFAC
	Toxicity of 3-acetyl and the 15-acetyl DON (data availability unknown)	Info to be collected by the Committee	
Ochratoxin A ¹	Toxicological re-evaluation, exposure assessment (special consideration to developing countries), impact of different maximum levels for cereals (5 or 20 µg/kg), effects of processing on residual levels in foods	End 2004	UK/EC
Patulin	Exposure assessment (questions to be developed at future sessions based on available data)	2007	CCFAC
Phenyl hydrazines (including agaritine)	Full evaluation	2004 (available)	Denmark
Aflatoxins ¹	Dietary exposure assessment of total aflatoxins in tree nuts (ready-to-eat), in particular almonds, hazelnuts, pistachios, Brazil nuts, and impact on exposure taking into account hypothetical limits of 4, 8, 10, 15 µg/kg. And put in context of exposure from other sources and to the previous exposure assessment on maize and groundnuts. Dried figs possibly is included in this assessment, based on the availability of data.	Available EFSA assessment in process	CCFAC

¹ High priority for evaluation by JECFA

AMENDMENT TO THE DESCRIPTOR OF FOOD CATEGORY 13.6 OF ANNEX B (FOOD CATEGORY SYSTEM) OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

13.6 Food Supplements;

Includes vitamin and mineral supplements in ~~tablet and liquid form~~ unit dose forms such as capsules, tablets, powders, solutions, etc., where national jurisdictions regulate these products as food.*

* *Codex Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55-2005).