

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 99/12A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-third Session
Rome, Italy, 28 June - 3 July 1999

**REPORT OF THE THIRTY-FIRST SESSION OF THE
CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**
The Hague, The Netherlands, 22-26 March 1999

NOTE: This report includes Codex Circular Letter CL 1999/4-FAC.

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CX 4/30.2

CL 1999/4-FAC
April 1999

TO: - Codex Contact Points
- Interested International Organizations

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

SUBJECT: **Distribution of the Report of the Thirty-first Session of the Codex Committee on Food Additives and Contaminants (ALINORM 99/12A)**

A. MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION

Draft Standards and Related Texts at Step 8

- 1. Draft General Standard for Food Additives: Revised Table 1** (paras. 46 and 56 , Appendix II)
- 2. Draft General Standard for Food Additives: Table 3 and Annex to Table 3** (paras. 52 and 56, Appendix III)
- 3. Draft Specifications for the Identity and Purity of Food Additives at Step 8** (paras. 65 and 68, Appendix VII)

Governments wishing to propose amendments or to comment on the above matters should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see Procedural Manual of the Codex Alimentarius Commission) to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, **before 30 May 1999**.

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

- 4. Proposed Draft Amendment to the General Standard for Food Additives: Preamble - Footnote** (paras. 33, 56, Appendix V) (see also section B.1 of the present CL)

For technical reasons and to avoid misinterpretation of the Standard, the Secretariat recommends that the Commission also consider adopting the amended Footnote to Section 1.1 of the Standard.

- 5. Draft Amendments to the Codex International Numbering System for Food Additives** (para. 74, Appendix VIII)

Governments wishing to submit comments on all aspects of the Amendments, including possible implications for their economic interests should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 30 May 1999**

Endorsement of Maximum Levels for Additives and Contaminants

- 6. Section on Health Related Substances in the Codex Standard for Natural Mineral Waters** (para. 91, Appendix VI).

Proposed Draft Standards and Related Texts at Step 5

7. **Proposed Draft Annex A to the General Standard for Food Additives (Guidelines for the Estimation of Appropriate Levels of Use of Food Additives)** (para. 58, Appendix IV)
8. **Proposed Draft Maximum Levels for Tin** (para. 131, Appendix IX)
9. **Proposed Draft Maximum Level for Patulin** (para.117 , Appendix IX)

Governments wishing to submit comments regarding the implications which the proposed draft standards 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) to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 30 May 1999**.

B. REQUEST FOR COMMENTS AND INFORMATION

Governments and interested international organizations wishing to submit comments on the following matters are invited to do so **before 1 October 1999** as follows: Mr. E.F.F. Hecker, Chairman of the Committee, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 EK The Hague, The Netherlands (telefax No. 31.70.378.6141), with a copy to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy.

1. **Proposed Draft Amendments to the General Standard for Food Additives at Step 3 of the Accelerated Procedure: Preamble** (paras. 33, 39, 56, Appendix V)
2. **Proposed Draft Amendment to the General Standard for Food Additives at Step 3: Table 3** (paras. 12 and 56, Appendix XI)

The Committee agreed to ask for comments on the inclusion of the additives with an ADI "not specified" in Table 3 of the Standard (use according to GMP).

3. **Proposed Draft Amendments to the Codex International Numbering System for Food Additives at Step 3 of the Accelerated Procedure** (para. 55, Appendix VIII)

The Committee agreed to circulate INS Number 586 4-Hexylresorcinol and an amendment to the functions of Pectins, at Step 3 of the Accelerated Procedure for comments, subject to confirmation by the Commission.

4. **Proposals for amendments to the Codex International Numbering System for Food Additives, including technological functions and functional classes/sub-classes** (para. 76)

Governments are invited to submit proposals for amendments to the INS and comments on the updating of technological functions and functional classes/sub-classes.

5. **Proposed Draft Maximum Levels for Ochratoxin A at Step 3** (para 109, Appendix IX)
6. **Draft Guideline Level / Proposed Draft Maximum Levels for Cadmium** (para. 136, Appendix X)
7. **Food Additives and Contaminants Proposed for Evaluation by JECFA** (para. 143, Appendix XII)
8. **Methods of analysis for the determination of food additives and contaminants in foods**

Governments are invited to present proposals for additional methods of analysis.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 31st Session of the Codex Committee on Food Additives and Contaminants are as follows:

MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- agreed to advance to Step 8 Table 1 (section including 23 additives) of the **Draft General Standard for Food Additives** (paras. 46 and 56, Appendix II);
- agreed to advance to Step 8 the revised Table 3 (and Annex to Table 3) of the **Draft General Standard for Food Additives** (paras. 52 and 56, Appendix III);
- forwarded draft specifications for the identity and purity of food additives to the Commission for adoption as **Codex Advisory Specifications** (paras. 65 and 68, Appendix VII);
- advanced the **INS numbers for argon, helium and oxygen** for adoption at Step 5 of the Accelerated Procedure (para. 74, Appendix VIII);
- agreed to align the **Health Related Limits for Certain Substances in the Codex Standard for Natural Mineral Waters** with the WHO *Guidelines for Drinking Water Quality* (para. 91, Appendix VI);
- agreed to advance to Step 5 the Proposed Draft **Annex A to the General Standard for Food Additives** (Guidelines for the Estimation of Appropriate Levels of Use of Food Additives) (para. 58, Appendix IV);
- agreed to advance to Step 5 the **Proposed Draft Maximum Levels for Tin** in canned foods (para. 131, Appendix IX) and the **Proposed Draft Maximum Level for Patulin** in apple juice and apple juice ingredients in other beverages (para. 117, Appendix IX);
- agreed to circulate circulate INS Number 586 for **4-Hexylresorcinol** and an amendment to the **functions of Pectins** at Step 3 of the Accelerated Procedure (para. 55, Appendix VIII);
- agreed to circulate the Proposed Draft Amendment to the **Preamble of the General Standard for Food Additives** at Step 3 of the Accelerated Procedure (para. 55, Appendix V);
- agreed to propose as new work : the **revision of the General Standard for Irradiated Foods** (para. 7) and the elaboration of two **Codes of Practice for the Prevention of Contamination by 1) Ochratoxin A and 2) Zearalenone** (paras. 106 and 112).

OTHER MATTERS OF INTEREST TO THE COMMISSION:

- agreed: to retain at Step 7 a number of additives which required reevaluation by JECFA (paras. 47 and 56); to return to Step 6 all other additives under consideration for inclusion in Table 1 of the **Draft General Standard for Food Additives** (paras. 48 and 56); to circulate at Step 3 several additives with an ADI "not specified" allocated by JECFA for inclusion in Table 3 (paras. 12 and 56, Appendix XI); and to consider further the use of colours in foods and processing aids (paras. 62 and 145);
- agreed to return to Step 6 for redrafting the draft maximum levels for **lead** (para. 126);
- agreed to return to Step 6 the Draft Guideline Level for Cadmium in Cereals Pulses and Legumes and to circulate at Step 3 the Proposed Draft Maximum Levels for **Cadmium** (para. 136, Appendix X) and the Proposed Draft Maximum Levels for **Ochratoxin A** (para. 109, Appendix IX);
- agreed to return to Step 3 for redrafting the **Proposed Draft Code of Practice for Source Directed Measures** (para. 120);
- decided that the document concerning **Methodology and Principles for Exposure Assessment** in the **General Standard for Contaminants and Toxins in Food** should be redrafted for consideration at the next session (paras. 61-63);
- agreed that the Proposed Draft Provisions to Maintain the Stability of Iodised Salt (Amendment to the **Standard for Food Grade Salt**) would be returned to Step 3 for redrafting (para. 150).

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OPENING OF THE SESSION

1) The 31st Session of the Codex Committee on Food Additives and Contaminants was held in The Hague, The Netherlands from 22-26 March 1999 at the kind invitation of the Government of the Netherlands. Mr. Edwin Hecker, Netherlands Ministry of Agriculture, Nature Management and Fisheries chaired the meeting. The meeting was attended by 280 delegates representing 55 Member countries and 46 international organisations.

2) Mrs. Faber, keynote speaker and State Secretary of the Netherlands Ministry of Agriculture, Nature Management and Fisheries, reflected on the interesting challenges for this Committee, in particular the General Standard for Food Additives, the integration of the risk analysis principles into the activities of the CCFAC and the progress achieved in the work on contaminants. Mrs. Faber also acknowledged the great importance of taking the consumer's perspective into account in the discussions of the CCFAC and expressed the hope that the Committee would make significant progress on the important issues under discussion.

3) The Committee heard a memorial tribute from the Delegations of the United States and Canada in remembrance of Dr. John Modderman and Mr. James Drum respectively. A moment of silence was observed by the Committee in recognition of their work for the CCFAC.

ADOPTION OF THE AGENDA (Agenda item 1)¹

4) The Committee adopted the Provisional Agenda as proposed. The Committee agreed to hold an informal *Ad Hoc* Working Group to discuss proposals for the priority evaluation of food additives and contaminants by JECFA (Agenda Item 16) under the chairmanship of Mr. J. Dornseiffen, The Netherlands.

APPOINTMENT OF THE RAPPORTEUR (Agenda item 2)

5) The Committee agreed with the suggestion of the Chairman to appoint Dr. Simon Brooke-Taylor (Australia) as Rapporteur.

MATTERS REFERRED FROM THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda item 3)²

6) The Committee noted that the Joint FAO/WHO/IAEA Study Group on Food Irradiation had considered the wholesomeness of food irradiated with doses above 10 kGy, the current limit in the Codex Standard, and had concluded that food irradiated to any dose appropriate to achieve the technological objective was both safe and nutritionally adequate. In view of this recommendation, the Committee considered the need for a revision of the current General Standard for Irradiated Foods.

7) The Delegations of the Philippines and India informed the Committee that the regulations on irradiated foods were being harmonized with the ASEAN countries and supported the revision of the standard. This view was supported by several delegations and the Committee agreed to propose the revision of the General Standard for Irradiated Foods as new work to the 23rd Session of the Commission. The Proposed Draft Revised Standard including the amendments proposed by the Study Group would be circulated after the Commission for comments at Step 3 and consideration by the next session. The Representative of WHO informed the Committee that the final report of the Study Group would be published in a few months, probably before the Commission.

8) The Committee was informed that the Third Joint FAO/WHO/UNEP Conference on Mycotoxins had been held in Tunis, Tunisia, from 3-6 March 1999 with the following objectives: (i) to increase the awareness of policy makers about mycotoxin contamination; (ii) to provide a forum for the exchange of current scientific information on mycotoxins, (iii) to promote the harmonization of mycotoxin regulations and control

¹ CX/FAC 99/1

² CX/FAC 99/2, CX/FAC 99/2-Addendum

procedures; and (iv) to provide recommendations for the assessment, prevention and control of mycotoxin contamination. The Committee noted that the report of the Conference would be made available on the Internet, and that its recommendations would be of use to its current work on contamination by mycotoxins.

SUMMARY REPORT OF THE FIFTY-FIRST MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (Agenda item 4a)³

9) A large number of food additives, including seven groups of flavouring agents containing approximately 170 substances, were evaluated at the fifty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In addition, national intake assessments of five food additives were evaluated. The summary report was published in July 1998.

10) Intake assessments of benzoates, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), sulfites, and *tert*-butylhydroquinone (TBHQ) were performed at the request of the Twenty-ninth Session of CCFAC. While mean intake estimates based on national food consumption data and national standards did not exceed the acceptable daily intakes (ADIs) for any of the food additives, all of them exceeded their respective ADIs when based on maximum limits in the General Standard on Food Additives (GSFA). Such intake estimates grossly overestimated actual intakes because the GSFA levels were compiled by adopting the highest level of use for any food category and the ranges of food uses specified in the GSFA were much wider than in national standards. The Committee noted that JECFA had identified food categories that contributed significantly to intake and recommended that CCFAC should review these.

11) The Committee noted that JECFA had adopted principles governing the toxicological evaluations and the development of specifications, which were included in the general consideration section of its reports, and that these principles would be used at subsequent meetings to promote consistency in its decision-making processes. For the first time, the general consideration items relating to specifications were published with the specifications⁴ with a request for review and comments by government delegations to CCFAC.

ACTION REQUIRED AS A RESULT OF CHANGES IN ADI STATUS AND OTHER TOXICOLOGICAL RECOMMENDATIONS (Agenda item 4b)⁵

12) New ADIs "not specified" were allocated at the fifty-first meeting of JECFA to *alpha*-acetolactate dehydrogenase, maltogenic amylase, processed *Eucheuma* seaweed (group temporary ADI "not specified" with carrageenan), sodium carboxymethyl cellulose, enzymatically hydrolyzed (group ADI with modified celluloses), *gamma*-cyclodextrin (temporary), and polyglycitol syrup (group ADI for materials conforming to the specifications for polyglycitol syrup and maltitol syrup). The Committee agreed to request comments for the inclusion of these additives in Table 3 of the GSFA at Step 3. No other action was required as a result of toxicological evaluations performed at the fifty-first meeting of JECFA.

13) The Table summarizing action required as a result of changes in ADI status or other toxicological recommendations is attached to this report as Appendix XI.

DISCUSSION PAPER ON THE APPLICATION OF RISK ANALYSIS PRINCIPLES FOR FOOD ADDITIVES AND CONTAMINANTS (Agenda Item 5)⁶

14) The Committee recalled that its last session had agreed that a discussion paper should be prepared by a Drafting Group⁷ to consider the integration of working principles for risk analysis into the work on additives and contaminants. The Delegation of the United States introduced the document, which considered the prioritization of work, the principles for risk assessment policy, and was intended to provide a framework for risk management decisions. Aspects relating to risk communication were emphasized, and specific questions concerning the working relationship between JECFA and CCFAC were put forward for consideration. The Delegation proposed that the paper should also be considered by JECFA in order to ensure a general policy for risk assessment and risk management could be applied to food additives and contaminants.

³ Summary and conclusions of the Fifty-first Meeting of JECFA, Geneva, 9-18 June 1998 (IPCS/98.14).

⁴ *Compendium of food additive specifications*. FAO Food and Nutrition Paper 52, Add. 6, 1998.

⁵ CX/FAC 99/3

⁶ CX/FAC 99/4, CRD 4 (comments of Thailand, European Community)

⁷ Australia, Netherlands, Sweden, Thailand, United Kingdom, United States

15) The Committee expressed its appreciation to the Delegation of the United States for this important paper. It was noted that further consideration should be given to its recommendations as it had not been circulated for comments prior to the meeting. Several delegations stressed the need to strengthen risk communication between JECFA, responsible for risk assessment and CCFAC, responsible to carry out risk management. The Committee agreed that input from JECFA would be necessary in the development of the paper and in order to define risk analysis principles.

16) In response to the remarks from the Delegation of Germany, speaking on behalf of the Member States of the European Union, concerning priorities for JECFA, the Committee recalled that JECFA was an independent FAO/WHO body setting its own priorities in accordance with its working procedures, while CCFAC made proposals concerning the establishment of priorities for JECFA, in the light of its own needs as related to risk management decisions. The Committee had an exchange of views on the issues which needed to be considered in the further development of working principles for risk analysis, and identified the following: the consideration of regional variations in intake; transparency in risk assessment decisions; the development of risk communication between risk assessors and risk managers and also between the CCFAC and other Codex Committees. The Committee noted that with input from the JECFA Secretariat consideration should be given to the development of a risk assessment policy statement.

17) The Committee agreed that the paper should be revised in the light of the comments received and the above discussions, in cooperation with the JECFA Secretariat, for consideration at the next session. The Committee agreed to inform the Commission about its continuing work on the integration of risk analysis principles.

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX STANDARDS (Agenda Item 6)⁸

18) In accordance with the Codex Alimentarius Commission Procedural Manual, the food additive provisions in several commodity standards were forwarded to the Committee for endorsement and incorporation into the General Standard for Food Additives. The Committee endorsed the provisions for food additives in the Draft Standards as proposed with the following exceptions, amendments and comments.

Draft Standard for Milk Powders and Cream Powders

19) The Committee decided that as polydimethylsiloxane (900) had a numerical ADI, a numerical maximum level was desirable for its use in milk powders and cream powders. The Committee agreed to refer back Polydimethylsiloxane (900) to the Committee for Milk and Milk Products for further consideration.

20) The Committee decided to withdraw the proposed level for Potassium Aluminium Silicate (555) as no ADI had been allocated to this additive.

Draft standard for Cheese

21) The Committee noted that no ADI was allocated and no specifications existed for Anthocyanines (163). The JECFA secretariat indicated that an ADI and specifications were allocated to (163) Grape Skin Extract. The Committee agreed to ask the CCMMP to clarify which substance should be used as a colour in red marbled cheese.

22) The Committee decided to withdraw the proposed levels for Vegetable Carbon (153) as no ADI had been allocated to this additive.

23) The Committee noted that Benzoylperoxide (928) was evaluated as flour treatment agent only and agreed that the proposed use as bleaching agent in milk and cream powders would have to be evaluated by JECFA and would therefore not be endorsed at this time.

⁸ CX/FAC 99/5 and comments from Thailand (CRD 5)

24) The Delegation of Switzerland objected to the inclusion of propionic acid (280) in the provisions for additives in cheese. However, the Committee agreed that propionic could be used according to GMP as its ADI was not limited.

25) Regarding the use of Pimaricin (235) in sliced, cut, shredded or grated cheese the Committee noted that it was currently only permitted for use on the surface of cheese. Some delegations expressed concern with the extended use of pimaricin, as in their view it should only be used as surface treatment and was not intended to be consumed. The Committee decided that this provision would not be endorsed pending written technological justification of use from Canada.

Draft standard for Canned Applesauce

26) The Committee agreed to change the maximum levels for ascorbic acid to GMP as this additive had an ADI not specified.

Draft Standard for Canned Pears

27) The Committee decided that a numerical level was desirable for the use of L-Tartaric Acid (334) in canned pears due to its numerical ADI. The Committee decided to refer back this provision to the Committee on Processed Fruits and Vegetables.

Draft Standard for Pickles

28) The Committee decided that the proposed use of oleoresins in pickles should be referred back to the Committee on Processed Fruits and Vegetables for clarification.

Draft Standard for Kimchi

29) The Committee agreed that Carrageenan and Xanthan gum should be used according to GMP as their ADIs were "not specified".

Proposed Draft Revised Standard for Cocoa Powders

30) The Committee decided to withdraw the proposed level for Potassium Aluminium Silicate (555) as no ADI had been allocated to this additive.

Status of Endorsement of Maximum Levels for Food Additives in Codex Standards

31) The Committee endorsed the other food additive provisions, which are not specifically mentioned above, as proposed.

CONSIDERATION OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

DRAFT CODEX GENERAL STANDARD FOR FOOD ADDITIVES; REVISED TABLES 1, 2 AND 3, INCLUDING ANNEX TO TABLE 3 (Agenda Item 7a)⁹

Report of the Working Group on the Codex General Standard for Food Additives¹⁰

32) The *ad hoc* Working Group on the Codex General Standard for Food Additives and Contaminants was chaired by Dr. Rulis (USA) and co-chaired by Dr. Keefe (USA), with Mrs. Bente Fabech (Denmark) as Rapporteur. The Chairman of the Working Group briefly summarised its discussions and proposed several recommendations to the Committee.

⁹ CX/FAC 99/6 and CX/FAC 99/6- Add.1 (comments from United States, South Africa, Spain, Canada, Denmark, Japan, Norway, ESA, ELC, Biopolymer International, ISA/AIE, Marinalg International, CSPI, AMFEP, CEFIC, European Union, ISDC, UEITP, OIV, IPPA; CRD 5 (Sweden, EC, Thailand, IFU); CRD 7 (Korea, Italy, IFFJP)

¹⁰ Conference Room Document 1

33) As the GSFA was being developed on an additive-by-additive basis rather than by functional class, the Committee agreed to amend the footnote to Section 1.1 of the Preamble of the General Standard for clarification purposes. The Committee agreed to send the proposed amendment for comments at Step 3 of the Accelerated Procedure as it was non-controversial (see Appendix V).

34) The Committee generally agreed that the food additive provisions in Codex Commodity Standards needed to be included in the GSFA. The Delegation of the United States offered to assist the Codex Secretariat to incorporate them in the adopted sections of the General Standard to be included in the revised Codex Volume 1A.

Group I, Additives for which the Budget Method Screen does not present intake concern

35) The Committee discussed 26 additives which passed the Budget Method (Proposed Draft Annex A). It was pointed out that these additives did not present intake concerns. The Committee agreed to the changes in the entries for several additives as proposed by the Working Group

36) The Committee agreed to include Nitrous oxide in Table 3 as its uses as a propellant correspond to GMP. Its use as a packaging gas was referred back to JECFA for review.

37) The Committee agreed to move to Table 3 Alpha-Amylase (1100) and Protease (*Aspergillus oryzae* var.) (11011) on the basis of their evaluation by JECFA, and noted that provisions for their use in flours and starches would consequently be included in Tables 1 and 2.

38) As these enzymes could also be used as processing aids the Committee decided to add the following statement to the GSFA Preamble Section 6: "Tables 1, 2 and 3 do not include reference to uses of substances as processing aids".

39) The Committee agreed that in view of their non-controversial nature, this amendment and the amendment to the footnote should be sent for comments at Step 3 of the Accelerated Procedure (see Appendix V).

40) The Committee agreed that Azodicarbonamide (927a) should be listed only for use in flours and starches, as it had been evaluated only as flour treatment agent.

41) The Committee decided that Benzoyl Peroxide (928) needed to be evaluated by JECFA as new uses for this additive had been identified.

42) The Committee decided to maintain GMP provisions for Caramel Colour Class III and Class IV although these additives had numerical ADIs, as they were normally regulated by GMP provisions in member states. The Observer from IFU stated that the use of Caramel Colours was not necessary in concentrates (liquid or solid) for fruit juices although they may be used in finished products.

43) The Observer from the EC expressed concern that the Committee should forward to the Commission for adoption at Step 8 food additives for which JECFA had allocated a numerical ADI, without proposing numerical maximum use levels for all food categories in question. The Delegations of Switzerland and Norway supported this statement. Members were requested to provide information on suitable numerical values for consideration at the next session.

44) The Committee agreed to remove the reference to Glycerol Esters of Wood Rosin (445) in chewing gum as this substance was used as an ingredient in the gum base only.

45) As recommended by the Working Group, the Committee agreed that Stearyl Tartrate should be referred back to JECFA and retained at Step 7 pending reevaluation by JECFA as an emulsifier and flour treatment agent.

46) The Committee agreed to forward the revised Table 1 containing the remaining provisions for these additives (Group I) to the 23rd Session of the Commission for adoption at Step 8 (see Appendix II).

Group II - Additives to be forwarded to JECFA for clarification of their ADIs

47) The Committee decided to forward the following additives to JECFA for clarification of their ADI's: Sodium Ethyl p-Hydroxybenzoate (215), Sodium Propyl p-Hydroxybenzoate (217), Sodium Methyl p-Hydroxybenzoate (219), Calcium Sulfite (226), Sodium Formate (238), Calcium Formate (238), Synthetic gamma-Tocopherol (308), Synthetic delta-Tocopherol (309), Monomagnesium Orthophosphate (343i), Calcium Tartrate (354), Dipotassium Diphosphate (450iv), Calcium Dihydrogen Diphosphate (450vii), Dimagnesium Diphosphate (450viii), Sodium Calcium Polyphosphate (452iii), Trisodium Diphosphate (450ii), Sodium Trioleate (496).

Group III, Additives reviewed by the 51st JECFA meeting

48) The Committee, referring to the conclusions of the 51st JECFA (see para. 10), agreed to return the provisions for Benzoates, BHA, BHT, Sulfites and TBHQ to Step 6 for additional comments in accordance with the recommendations of JECFA that the levels in specific food categories be examined, because these provisions may contribute significantly to intake exceeding the ADI.

Annex to Table 3

49) The Committee agreed to amend the Title of the Annex to Table 3 to clarify its intention: "*Food categories or Individual Food Items Excluded from the General Conditions in Table 3*". The following statement was also added: "*The use of additives listed in Table 3 in the following foods is governed by the provisions in Tables 1 and 2*", for clarification purposes.

50) The Committee decided to include wine and fruit juices in the Annex to Table 3 and therefore agreed that any uses for Table 3 additives in these products would need to be specifically included in Tables 1 and 2. The Delegation of Thailand reserved its position on the inclusion of fruit juices in the Annex to Table 3.

51) Several delegations questioned whether wine should be covered by the General Standard. However, the Committee felt that wine was a foodstuff that should be represented in the Standard and that intake assessment of additives could not be done accurately if wine was excluded. The Committee also recalled that the Commission had previously accepted the food classification system used in the GSFA, including wine. The Committee noted the necessity for the GSFA to be consistent with the OIV standards for wine.

52) The Committee agreed to forward the amended Table 3 and the Annex to Step 8 for adoption by the 23rd Session of the Commission (see Appendix III).

53) The Committee agreed that all other additive provisions in the GSFA would be returned to Step 6 for redrafting on the basis of the comments received and the above discussion, circulation and consideration by the next session.

Other matters

54) The Committee noted the need for a small working group to consider Tables 1 and 2 of the GSFA between the sessions to identify errors and to confirm technological need and maximum use levels for remaining additives. The Delegations of South-Africa, Japan, United States, Brazil, Australia and the Observer from the EC agreed to participate to represent their respective continents. It was agreed that input from industry and consumer organizations would also be provided. The proposals of this working group would be submitted before the end of August 1999 to allow sufficient time for comments. The Committee also noted the offer of the Observer from Consumers International to prepare a paper on consumer deception but suggested that this information could be provided as a written comment.

55) The Committee decided to convene the *ad hoc* Working Group on the General Standard for Food Additives prior to its next session under the chairmanship of the United States and expressed its appreciation to the United States and the Working Group for their important work to address complex issues.

Status of the Draft General Standard for Food Additives

56) As indicated in the sections of the General Standard discussed above, the Committee agreed:

- to forward the revised Table 1 including Group I Additives and the revised Table 3 (and Annex) to Step 8 for adoption by the 23rd Session of the Commission (see Appendices II and III);
- to retain Stearyl Tartrate and the additives in Group II at Step 7 pending their reevaluation by JECFA;
- to return to Step 6 the additives in Group III reviewed by the 51st JECFA and all other additives under consideration for further comments and consideration by the next session;
- to circulate at Step 3 of the Accelerated Procedure the Proposed Draft Amendments to the Preamble subject to the approval of the Commission (see Appendix V),;
- to circulate for comments at Step 3 the additives which had been allocated an ADI "not specified" by the 51st JECFA (see Agenda Item 4b).

PROPOSED DRAFT GUIDELINES FOR THE DEVELOPMENT OF MAXIMUM LEVEL OF USE FOR FOOD ADDITIVES WITH NUMERICAL ACCEPTABLE DAILY INTAKES (Annex A) (Agenda Item 7b)¹¹

57) The Committee considered the paper prepared by the Delegation of Denmark, which set out the use of the Budget Method for screening use levels of food additives. The Committee agreed that the Budget Method as presented was a useful screening tool and that it should be incorporated into the General Standard.

Status of the Proposed Draft Guidelines for the Development of Maximum Level of Use for Food Additives with Numerical Acceptable Daily Intakes (Annex A to the GSFA)

58) The Committee decided that the proposed Draft Annex A (without the appendices included in the working paper) would be forwarded to the 23rd Session of the Commission for adoption at Step 5 (see Appendix IV).

DISCUSSION PAPER ON THE USE OF COLOURS IN FOODS (Agenda Item 8)¹²

59) The Delegation of Denmark introduced the paper briefly and drew particular attention to the proposed options for consideration.

60) Some delegations and the Observer of Consumers International expressed the view that particular attention should be given to colours in food in view of consumer concerns, the potential for hypersensitivity reactions and the questioning of technological justification for their use in certain cases. Some delegations further expressed their concern about the use of colours in infant formula. Other delegations pointed out that the principles included in the Preamble of the GSFA were applicable to colours as to all other additives and there was no justification to establish special or stricter criteria for colours. The Committee emphasised that in general, additives should not be used to mislead the consumers. Some delegations proposed to define basic foods as raw fresh foods.

61) After an extensive exchange of views on the recommendations, there was general support for the following options as a basis for further discussion:

- 1) CCFAC could develop a list of basic foods in which added colours will not be endorsed. The foods which should be regarded as basic foods should be listed with reference to the Food Categorisation System;
- 2) CCFAC could continue to apply the same criteria for endorsing maximum use levels for colours as for other food additives.

62) Many delegations expressed their appreciation for the work done by the Delegation of Denmark. All delegations and international organisations were invited to send their comments to Denmark, in order to revise the paper in view of the above recommendations for circulation and consideration by the next session.

63) The Committee noted that the Committee on Food Labelling was considering labelling related to hypersensitivity for all foods and additives, and that recommendations on this matter would be submitted to

¹¹ CX/FAC 99/7, CRD 5 (comments of Norway)

¹² CX/FAC 99/8, CRD 5 (comments of EC, Thailand and Japan)

the Commission for adoption at Step 8. The CCFL was also considering the “25% rule” for additives from a general point of view.

64) The JECFA Secretariat informed the Committee that the 53rd JECFA Meeting would consider the list of substances which can cause hypersensitivity and should be declared in the labelling, and the criteria for the inclusion of such substances in the list.

CONSIDERATION OF SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES (Agenda Item 9)¹³

65) The Committee noted that Specifications for the Identity and Purity of Food Additives arising from the 51st JECFA meeting (FAO FNP 52, Add. 6) had been circulated for comments under CL 1998/11-FAC. Based on recommendations made by the *Ad hoc* Working Group on Specifications, the Committee forwarded the substances in Category I to the Commission for adoption as Codex Advisory Specifications (see Appendix VII), and referred those in Category III (see CRD2) back to JECFA for further advice.

66) The Delegation of the Philippines expressed its objection to the review of synonyms for Processed *Eucheama* Seaweed and agreed to forward its objections to JECFA for further consideration.

67) The Committee noted that the *Ad hoc* Working Group had discussed the specification for Gum Arabic in detail but did not assign a category. The Delegation of Sudan proposed the establishment of distinct specifications for the gum obtained from *Acacia senegal* and the gum obtained from *Acacia seyal* to recognise significant differences in their characteristics. Several other delegations supported a specification for gum arabic obtained from *Acacia senegal*, *Acacia seyal* and other related species as this reflected current production and trade practices.

68) Following further discussion in plenary, the Committee agreed to forward the specification in FNP 52-Add.6 which cites only *Acacia senegal* and *Acacia seyal* as a source of Gum Arabic to the Commission for adoption as a Codex Advisory Specification. The Delegation of Sudan stated that more information was needed for the specification and offered to provide such information. The Committee recalled that all specifications adopted by the Commission were subject to possible future change if and when new data was developed warranting a re-evaluation by JECFA. The Committee placed the monograph in Category II so as to include the four amendments as discussed in the Working Group (see Appendix VII).

69) The Committee expressed its appreciation to the *Ad hoc* Working Group, chaired by Dr. P.M. Kuznesof (USA) with Mrs H. Wallin (Finland) and Mrs. I. Meyland (Denmark) as Rapporteur and Category Monitor, respectively. The Committee agreed that the Working Group was an important forum for member countries and international organisations to discuss technical issues regarding specifications, in a transparent manner. The Committee therefore re-established the *Ad hoc* Working Group on Specifications under the Chairmanship of the United States, with the task of reviewing specifications arising from the 53rd JECFA meeting prior to the 32nd Session of CCFA.

PROPOSED AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM, INCLUDING TECHNOLOGICAL FUNCTIONS AND FUNCTIONAL CLASSES/SUBCLASSES (Agenda Item 10)¹⁴

70) The Committee recalled that the last session had agreed to request information on functional classes assigned to individual additives and proposals for amendments to the INS, and considered the comments provided in reply to CL 1998/11-FAC.

71) The Delegation of Thailand expressed its objection to the attribution of an INS number to Konjac Flour, which was not classified as an additive in their country. The Committee however recalled that the last session had agreed to forward the Number for Konjac Flour to the Commission for adoption at Step 8, as it met the criteria established for inclusion of a compound in the INS.

72) The Delegation of Australia, referring to its written comments, proposed to attribute Number 586 to 4-

¹³ CX/FAC 99/9 (Request for comments and Provisional Agenda for the *ad hoc* Working Group on Specifications) CX/FAC 99/9-Add.1 (comments of Nigeria, AIPG, IFCGA, Marinalg International), CRD 2 (Report of the *ad hoc* Working Group on Specifications)

¹⁴ CX/FAC 99/10 (comments from Australia, Slovak Republic, South Africa, Canada, IPPA), CRD 5 (Thailand)

Hexylresorcinol, an inhibitor of polyphenol oxidase used to prevent the development of melanosis in prawns as an alternative to sulphites. The Delegation proposed to classify it as a colour retention agent and noted that other functions in the current classification might also be used. The Delegation of Finland recalled that the specification for that additive, which had been forwarded for adoption by the Commission, referred to its function as antioxidant and colour retention agent (see Appendix VII).

73) In view of the non-controversial nature of this amendment, the Committee agreed to circulate INS Number 586 for 4-Hexylresorcinol as an antioxidant and colour retention agent at Step 3 of the Accelerated Procedure, subject to the approval of the Commission. The Committee also agreed to add “emulsifier” to the function of 440 Pectins, as proposed by IPPA in their written comments (see Appendix VIII).

74) The Committee recalled that INS Numbers 938 (Argon), 939 (Helium) and 948 (Oxygen) had been circulated at Step 3 of the Accelerated Procedure. As there was consensus on these proposals, the Committee agreed to advance them to Step 5 of the Accelerated Procedure for adoption by the Commission. The Proposed Draft Amendments to the INS are attached to this report as Appendix VIII.

75) The Observer from IPPA pointed out that sequestrants were identified as a sub-group of antioxidants, although they had other functions, such as controlling the availability of calcium to anionic gelling agents and the Committee agreed that “sequestrants” should be recognized as a separate functional class for clarification purposes. The Committee therefore recommended that the Committee on Food Labelling should consider the amendment of the General Standard for the Labelling of Prepackaged Foods, to include sequestrants in the list of additive classes (Section 4.2 List of Ingredients).

76) The Committee recalled its earlier discussions on the functions of additives, especially the need for clarification in the definition of functional classes, and recognized that the limited number of classes could create some confusion. Although it was not possible to come to a conclusion at this stage, the Committee agreed that further consideration should be given to the general questions of functional classes and subclasses in the framework of the development of the GSFA.

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX STANDARDS (Agenda Item 11a)¹⁵

77) The Committee noted that in accordance with the Codex Alimentarius Procedural Manual, all provisions in respect of food contaminants should be submitted for endorsement, and that the document did not include previously endorsed contaminant provisions.

78) The Committee was of the opinion that the proposed levels for Arsenic, Lead and Tin were high and that these levels were still under discussion by this Committee. It decided to inform the relevant Commodity Committees of its decision to withdraw Maximum Levels for Arsenic and return the standards for further consideration pending further developments concerning Maximum Levels for Lead and Tin in the General Standard for Contaminants and Toxins in Foods (GSCT).

Draft Revised Standard for Butter

79) The Committee endorsed the Maximum Level for Lead as proposed.

Draft Revised Standard for Sugars

80) The Delegation of the United States, supported by Denmark, expressed its concern that 1 mg/kg of Arsenic in sugar would be quite high regardless of other processing factors. The Committee decided not to endorse the Maximum Level for Arsenic in the Draft Revised Standard for Sugars taking into account the fact that Maximum Levels for Arsenic were still under discussion (see Agenda Item 15e).

Draft Revised Standard for Canned Applesauce

81) Several delegations expressed their opinions that the levels for both Lead and Tin were excessive for Canned Applesauce and suggested to lower the levels of Lead and Tin to 0.1mg/kg and 100 or 200 mg/kg

¹⁵ CX/FAC 99/11

respectively. The Delegation of Australia noted that the level of Tin proposed, 250 mg/kg, corresponded to the level considered at Step 3 for canned solid foods at the 30th Session.

82) The Committee decided to refer back the Draft Revised Standard for Canned Applesauce to the Committee on Processed Fruits and Vegetables for further consideration pending current development on Maximum Levels for Lead and Tin in the GSCT.

Draft Standard for Pickles

83) The Committee decided not to endorse the ML for Arsenic and to return the Draft Standard for Pickles to the Codex Committee on Processed Fruits and Vegetables for further consideration pending further developments on Maximum Levels for Lead and Tin in the GSCT.

Proposed Draft Revised Standard for Cocoa Butters, Proposed Draft Revised Standard for Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor) and Cocoa Cake, for use in the Manufacture of Cocoa and Chocolate Products and Proposed Draft Revised Standard for Cocoa Powders (Cocoas)

84) Several delegations felt that the proposed levels for lead in Cocoa Butter and Cocoa Powder were exceedingly high and no information was given to the Committee to justify currently proposed maximum levels for Lead.

85) The Committee recalled that the 17th Session of the Codex Committee on Cocoa Products and Chocolate (CCCPC) had discussed this matter recently and there was no need to refer it back to the CCCPC. The Committee also noted that the levels of lead proposed by the CCCPC reflected the levels which could be achieved by the industry.

86) The Delegation of Denmark stressed the need to go through all the Commodity Standards to consider the levels of Lead prior to the completion of the Draft Maximum Levels for Lead.

87) Several delegations also expressed the opinion that more information should be provided to the Committee to justify the levels of lead proposed in those commodities for endorsement; in addition the data should be based on sound science and reflect what was technologically feasible.

88) The Committee decided to send back to the CCCPC for further consideration the Proposed Draft Revised Standard for Cocoa Butters, Proposed Draft Revised Standard for Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor) and Cocoa Cake, for use in the Manufacture of Cocoa and Chocolate Products and Proposed Draft Revised Standard for Cocoa Powders (Cocoas).

COMMENTS ON SECTION 3.2 (Health Related Limits for Certain Substances) OF THE CODEX STANDARD FOR NATURAL MINERAL WATER (Agenda Item 11b)¹⁶

89) The Committee recalled that the last session had considered this issue, following the adoption of the Standard for Natural Mineral Waters by the 22nd Session of the Commission, and had circulated the Limits for Certain Substances for further comments. The Committee discussed the levels of several contaminants in natural mineral waters. Many delegations expressed the view that the proposed levels for contaminants in natural mineral water were too high and that natural mineral waters should comply with the WHO *Guidelines for Drinking Water Quality* (Volume 1, Recommendations, WHO, Geneva, 1993). Other delegations however considered that the composition of natural mineral waters was different according to the hydrology of the source and therefore different levels of contaminants may be justified.

90) The Delegation of Germany asked for the establishment of specific health related limits for certain substances in mineral water claimed to be suitable for infant food preparation.

91) The Committee agreed with the proposal of the Chairman to bring the levels of contaminants for natural mineral waters into line with the levels in the WHO *Guidelines for Drinking Water Quality*. The Health Related Limits for Certain Substances as amended are included in Appendix VI.

¹⁶ CX/FAC 99/12 (comments of Slovak Republic, Denmark, South Africa, United States, Canada), CRD 7 (Spain)

92) A number of delegations including Portugal, France, Italy, Germany, Tunisia and Switzerland did not agree with this decision for the reasons mentioned in para. 89 above.

CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS (Agenda Item 12)
REPORT OF THE *AD HOC* WORKING GROUP ON CONTAMINANTS AND TOXINS IN FOOD¹⁷

93) The report of the *Ad hoc* Working Group established by the last session with Denmark as Chair, Brazil as co-chair and Australia and the Netherlands as Rapporteurs was presented by its Chairman, Dr. Torsten Berg, who indicated that its essential objective was to achieve progress in developing the General Standard for Contaminants and Toxins in Foods, making recommendations to the Committee on Maximum Levels for individual contaminants in various foods.

94) The Committee agreed on the goals and terms of reference of the *ad hoc* Working Group as follows, noting that the responsibility for implementing the Standard belonged to member countries:

The goals:

- to achieve progress in the further developing of the General Standard for Contaminants and Toxins in Foods, and
- to bring forward information on contaminants for decision-making in the plenary Session of the CCFAC.

The terms of reference:

- to discuss and, if necessary, to put forward proposals concerning the refinement of the General Standard for Contaminants and Toxins in Foods,
- to discuss and make recommendations to the plenary Session of the CCFAC with relation to position and discussion papers, current maximum levels and Codes of Practice as well as draft standards for contaminants and toxins in foods,
- to review proposals for contaminants and toxins for the JECFA Priority List and make recommendations for prioritization to the plenary Session of the CCFAC, through the *ad hoc* Working Group on JECFA Priorities, and
- to discuss and make recommendations to the plenary Session of the CCFAC on other matters concerning contaminants and toxins in food as may be requested by the plenary.

95) The Committee agreed that the General Standard for Contaminants and Toxins in Food would be kept under review and included on the Agenda of the next session. The Committee noted that the Secretariat would publish the final sections of the GSCT in the revised Codex Volume 1A in the near future so there was no need to update the document prepared by the Delegation of the Netherlands and including these sections.

96) As proposed by the Working Group, the Committee recommended that relevant Commodity Committees take appropriate steps to remove the provisions concerning zinc, copper and iron from the Contaminants section from all commodity standards as these should rather be considered as quality parameters, and could be included as such in the standards if needed.

97) The Committee agreed to take up fumonisins as future work and accepted the offer of the Delegation of the United States to develop a position paper on fumonisins.

98) The Committee decided to re-install the *ad hoc* Working Group for the next session, expressing its appreciation for its work and that of its Chairman. Some delegations made remarks about the structure of the Working Group and proposed a more formal approach, similar to that taken in the Committee on Food Labelling. The Chairman of the Committee referred to the *ad hoc* nature of the Working Group but agreed to take these comments into account in the future.

99) The Representative of WHO informed the Committee that an International Total Diet Workshop co-sponsored by the US Food and Drugs Administration and WHO in cooperation with PAHO, would be held from July 26 to August 6, 1999 in Kansas City, USA. The Workshop would consider national experiences in conducting total diet studies with a view to developing harmonized approaches and to promote consistency and comparability in study results. The Representative indicated that the results of the Workshop would be useful as regards dietary intake of contaminants and pesticides, but also for nutrients and additives, and

¹⁷ CRD3 (Report of the Working Group on the GSCT)

invited interested countries to participate in this important event.

METHODOLOGY AND PRINCIPLES FOR EXPOSURE ASSESSMENT IN THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (Agenda item 13)¹⁸.

100) The Committee recalled that the 30th Session had accepted the offer of the United Kingdom to develop the document further, and noted that only a few comments had been received due to late circulation. The Delegation of the United Kingdom introduced the revised document, pointing out that its main purpose was to provide guidance in methodology and principles for exposure assessment as an annex to the General Standard.

101) Some delegations felt that the methodology used in the document should be simplified and more transparent. The delegation of France offered to prepare a discussion paper on the distribution-curve of contaminants in foods in collaboration with WHO. It was noted that as the Delegation of France was a member of the drafting group for this paper, their contribution could be provided to the United Kingdom for inclusion in the revised paper.

102) In response to the comments from several delegations on the use of food balance sheets based on regional diets as proposed by the United Kingdom, the Representative of WHO pointed out that the latest revision of these sheets would be presented to the Codex Committee on Pesticide Residues in April 1999 (CX/PR 99/3).

103) Some delegations and the Observer from Consumers International expressed their concern as to whether the food-intake data also represented infants and children. The WHO Representative pointed out that the food intake data were actually overestimating the real exposure and invited countries to provide relevant data for inclusion in the GEMS/Foods database.

104) The Committee decided that the Delegation of the United Kingdom, assisted by a Drafting Group¹⁹, would revise the document in the light of the comments received and the above discussion; the intent and objectives of the paper needed to be carefully considered by the Drafting Group. The Committee agreed that the redrafted document would be presented in the form of an annex to the General Standard for Contaminants and Toxins in Foods.

MYCOTOXINS IN FOOD AND FEED POSITION PAPER ON OCHRATOXIN A (Agenda item 14 a)²⁰

105) The Committee considered an updated version of the position paper CX/FAC 98/16, presented at the 30th session of the CCFAC, prepared by Sweden. The Committee considered the three recommendations of the Working Group on how to proceed with the work on Ochratoxin A.

106) Many countries supported the proposal to develop a code of practice for Ochratoxin A in cereals. The Committee agreed to the suggestion of the Secretariat for a working title "Code of practice for the prevention of contamination by Ochratoxin A in cereals". The Committee asked the Delegation of Sweden to develop this code, assisted by the United States, Canada, the United Kingdom, the Netherlands and Argentina. The Committee agreed to propose the elaboration of the code as new work to the Commission.

107) The Committee also discussed the proposal for a maximum level of 5 µg/kg for Ochratoxin A for cereals and cereal products, to be circulated at Step 3. Many delegations supported this proposal. The Observer from Consumers International supported the proposal, together with a sampling plan and stressed that consumers were exposed to Ochratoxin A and that immediate action was needed to protect them.

108) However, some delegations were in favour of obtaining more information about contamination levels and distribution, problems in trade and a risk assessment from JECFA, before circulating a maximum level in the Step Procedure. The Delegation of Brazil emphasized the importance of a sampling plan and an

¹⁸ CX/FAC 99/13, CRD 6 (comments of Thailand, Norway and France)

¹⁹ Australia, France, Denmark, India, Italy, Netherlands, United States of America, Thailand, Norway, WHO

²⁰ CX/FAC 99/14, CX/FAC/14-Add. 1 (comments of United Kingdom, Denmark, Poland, South Africa, Costa Rica, CECA/EUCA)

analytical method when proposing a maximum limit. The Delegation of the United States stated that the risk assessment by JECFA was needed to provide the scientific basis for an appropriate maximum level before circulation in the Step Procedure. The Delegation of the United Kingdom suggested the possibility of two levels: a level for trade and a lower level for direct consumption (comparable to the aflatoxin levels).

Status of the Proposed Draft Maximum Level for Ochratoxin A

109) The Committee agreed that the maximum level of 5 µg/kg for Ochratoxin A in cereals and cereal products would be circulated for comment at Step 3, including suggestions for sampling plans (see Appendix IX). The Committee also agreed to ask JECFA to perform a risk assessment on the levels of 5 and 20 µg/kg of Ochratoxin A in cereals and cereal products.

POSITION PAPER ON ZEARALENONE (Agenda Item 14b)²¹

110) The Committee recalled that the last session had asked the Delegation of Norway to prepare a position paper on zearalenone and considered the recommendations proposed in this paper, especially the need for a code of practice to reduce contamination rather than a maximum limit in the final product. The Committee noted that zearalenone was scheduled for evaluation by the 53rd Meeting of JECFA in 1999.

111) The Committee, recognizing that there were no identified trade problems with zearalenone, agreed that a maximum level was not necessary for the time being. The Committee, referring to its earlier decision to elaborate a code of practice for ochratoxin control, considered the opportunity of developing a single code addressing the contamination of cereals by mycotoxins in general, as proposed by the Delegation of France. The Delegation of Sweden, referring to its work on ochratoxin, pointed out that the measures to prevent contamination were different as compared to zearalenone. The Committee agreed to proceed with the development of separate codes at this stage, taking into account the framework which already existed in the *Code for the Reduction of Aflatoxin B₁ in Raw Materials and Supplemental Feedingstuffs*.

112) The Committee agreed that the Delegation of Norway would finalize the position paper for consideration by the next session and would prepare a Proposed Draft Code of Practice for the Prevention of Contamination of Cereals by Zearalenone. Subject to the approval of the Commission as new work, the Proposed Draft Code would be circulated at Step 3 for comments and consideration by the next session. The Committee expressed its appreciation to the Delegation of Norway for its work on zearalenone.

POSITION PAPER ON PATULIN (Agenda Item 14 c)²²

113) The Committee recalled that the 30th Session had accepted the offer of the Delegation of France to update the position paper in view of the comments received for further discussion. The Committee thanked the Delegation of France for its work and agreed that it would finalize the paper as a basis for future work.

PROPOSED DRAFT MAXIMUM LEVEL FOR PATULIN²³

114) The Committee discussed a proposal by the Observer from the International Soft Drinks Council (ISDC) to amend the scope so that it should not focus on ready made soft drinks. The Committee agreed that the proposed maximum levels for Patulin should apply to apple juice and apple juice ingredients in other beverages.

115) Several delegations supported the proposed maximum level of 50 µg/kg as it was an appropriate level to ensure the protection of consumers, including children, and it was also technologically achievable. It was stated that 50 µg/kg was a feasible level but that the industry had difficulties to meet a level of 25 µg/kg due to the limits of methods of analysis; in addition minor blemishes and internal rot were not amenable to quality sorting.

²¹ CX/FAC 99/15, CX/FAC 99/15-Add.1 (comments of Denmark, Australia, United Kingdom, South Africa, Costa Rica), CRD 6 (United States)

²² CX/FAC 99/16

²³ CX/FAC 99/17; CRD 6 (Thailand); CRD 7 (Spain)

116) Other delegations, including France, were of the opinion that a level of 25 µg/kg was necessary to ensure adequate health protection, noting that special attention should be given to children who consume large amounts of apple juice. The Delegation of Thailand suggested that 25 µg/kg level would ensure proper health protection of consumers and that a Code of Practice could be developed if the level was not technologically feasible. The Delegation of the Netherlands, supported by a number of other delegations, suggested that the Committee seek further comments on the justification of the proposed maximum levels for patulin.

Status of the Proposed Draft Maximum Level for Patulin

117) The Committee agreed to forward the Proposed Draft Maximum Level of 50 µg/kg for Patulin in apple juice and apple juice ingredients in other beverages to the Commission for adoption at Step 5 (see Appendix IX) and to seek further comments at Step 6 for the justification of a maximum level of 25 µg/kg, as compared to 50 µg/kg.

INDUSTRIAL AND ENVIRONMENTAL CONTAMINANTS IN FOODS

COMMENTS ON THE PROPOSED DRAFT CODE OF PRACTICE FOR SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOOD WITH CHEMICALS (Agenda item 15a)²⁴

118) The Committee recalled that its last Session had agreed to circulate the Proposed Draft Code of Practice prepared by the Delegation of Sweden for comment and consideration at its next meeting. The Committee discussed whether the text should be advanced to Step 5 in its present state or returned to Step 3 for further development.

119) Some delegations stressed that source directed measures were the most important measures to reduce contaminants in foods. Other delegations felt that the objectives and the scope of this document should be clarified. In reply to these remarks, the Delegation of Sweden proposed that the document should focus on environmental contaminants and should include other amendments to address the comments received. Moreover, the Committee agreed that the reference to substances which were outside its terms of reference, e.g. pesticide residues, should be removed from the document.

Status of the Proposed Draft Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals

120) The Committee agreed to return the Proposed Draft Code to Step 3 for redrafting by the Delegation of Sweden, in order to incorporate the comments received, and consideration at the next session.

DRAFT MAXIMUM LEVELS FOR LEAD (Agenda item 15 b)²⁵

121) The Committee recalled that its last Session had accepted the offer of the Delegation of Denmark to review the draft maximum levels for lead in light of the appropriate risk assessment for children. The Delegation of Denmark highlighted the changes proposed to certain maximum levels in view of the data received. The Committee expressed its appreciation to the Delegation for its important work on lead.

122) Several delegations felt that the background of each level proposed should be made more transparent by the inclusion of appropriate references and that additional specific levels should be considered. In addition, some delegations pointed out that the data used should be quality assured and that intake figures should reflect regional diets as much as possible.

123) Some delegations expressed the view that in order to achieve progress, the draft maximum levels should be advanced further in the Procedure and the levels for which there was general agreement should be finalized. Other delegations felt that this document was not yet ready for advancement to Step 8 because JECFA would re-evaluate lead in June 1999 and additional quality assured data was necessary.

²⁴ CX/FAC 99/8 (comments of Slovak Republic, Denmark, United States, Canada, Netherlands) , CRD7 (Spain)

²⁵ CX/FAC 99/19, CX/FAC 99/19-Add 1 (comments of Germany, United Kingdom, UEITP, UFE), CRD 6 (France, United States)

124) The Delegation of Turkey pointed out that a single level for all fruit should be reconsidered in order to recognise the specific contribution of different types of fruit to total intake, and in particular the level proposed for raisins was too low. The Delegation of the United States expressed its concern about exposure for children and stressed the need for data of good quality on food produced according to GAP and GMP. This view was supported by the Delegation of the Philippines, who also stressed the need to consider levels of lead in fishery products from aquaculture and from other regions like Asia, and offered to provide data.

125) The Secretariat suggested to ask for comments on the appropriate methods of analysis as there was a reference to methods for certain levels, and to include the current lead levels in commodity standards in the revised document. The Delegation of Denmark indicated that this would be taken into account in the review. The Chairman urged Denmark, and all other countries responsible for redrafting documents, to finalize their revision before the October 1st 1999 in order to circulate the revised document well in advance of the next meeting to facilitate further progress.

Status of the Draft Maximum Levels for Lead

126) The Committee agreed to return the Draft Maximum Levels to Step 6 for redrafting by the Delegation of Denmark, with the assistance of the United States, on the basis of the above discussion and the comments received, with the understanding that the revised document would include appropriate references for the levels proposed.

COMMENTS ON THE PROPOSED DRAFT MAXIMUM LEVELS FOR TIN (Agenda Item 15 c)²⁶

127) The Committee recalled that the 30th Session had agreed to circulate at Step 3 the recommendations in a paper on tin prepared by Australia, Indonesia and Thailand, and revised by Australia, for maximum levels of 200 mg/kg in liquid canned foods and 250 mg/kg in solid canned foods.

128) Some delegations and the Observer from Consumer International argued that the proposed levels were too high, especially in view of the occurrence of acute toxicity (gastric irritation) at 150 mg/kg as reported by JECFA in its evaluation. Some delegations felt that if the proposed levels were adopted, this could be seen as allowing poor manufacturing practice. Some delegations proposed lower levels for all canned foods, with some exceptions for certain foods, including high acid foods if needed.

129) Other delegations pointed out that the acute toxicity mentioned was questionable and no long term effects had been reported. These delegations also explained that lower levels were not achievable for some high acid foods such as pineapple and that these proposed levels were based on technological need as well as safety. The Committee agreed to keep these issues under review and to ask JECFA to review acute toxicity of tin as a matter of priority.

130) The Delegation of Australia recalled that, as previously explained in the last session, "sacrificial" tin was necessary in these products to protect can integrity, an important food safety function, and pointed out that as tin was not necessary for low acid canned foods, the discussion of a limit for such products was not a relevant food safety matter.

Status of the Proposed Draft Maximum Levels for Tin

131) The Committee agreed to advance the proposed levels of 200 mg/kg in liquid canned foods and 250 mg/kg in solid canned foods to the Commission for adoption at Step 5 (see Appendix IX).

DISCUSSION PAPER ON CADMIUM (Agenda Item 15d)²⁷

132) The Committee recalled that the 30th Session had accepted the offer of Denmark to revise the discussion paper for circulation and further consideration. The Delegation of Denmark presented a list of

proposed maximum levels which had been revised in view of the comments received and the Committee

²⁶ CX/FAC 99/20 (comments of Slovak Republic, Denmark, United States, South Africa, Sweden, Canada, the Netherlands, Finland)

²⁷ CX/FAC 99/21, CX/FAC 99/21-Add.1 (comments of Sweden, Japan, United Kingdom, Poland, Germany, Spain, UEITP, UFE), CRD 6 (United States, Slovak Republic, France, Thailand)

discussed whether this list should be circulated at Step 3. The Committee recalled that the Draft Guideline Level for Cadmium in Cereals, Pulses and Legumes was at Step 7 as it had been initially considered by the Committee on Cereals Pulses and Legumes and forwarded to the CCFAC for finalization after the adjournment of the CCCPL. It was also noted that cadmium was scheduled for evaluation by the 55th JECFA Meeting in 2000.

133) Several delegations felt that it would be appropriate to forward the levels included in the discussion paper for comments at Step 3 in order to achieve progress on cadmium, in view of important public health concerns associated with this contaminant. Some delegations referred to their written comments on the specific levels proposed (such as potatoes, horse meat and soybean) and the Committee noted that further discussion would be required on the levels and the commodities concerned. The Delegation of France proposed to include mushrooms in the same category as leafy vegetables (instead of vegetables).

134) The Delegation of the United States stressed the importance of a thorough risk assessment in order to establish maximum levels; in particular, the bioavailability of cadmium and its accumulation in different types of vegetables due to the soil or other factors should be considered carefully, and quality assured data was necessary for that purpose. The Delegation therefore proposed to wait for the JECFA evaluation of cadmium before circulating the levels in the Step Procedure. The Delegation of Japan supported this view and pointed out that the changes to the levels and commodities proposed in the list had not been discussed in detail and further consideration should be given to the whole issue after the JECFA evaluation became available. The Delegation offered to provide to JECFA the results of several toxicity studies on cadmium contamination which were currently underway. Other delegations proposed to defer the decision pending evaluation of cadmium by JECFA.

135) Several delegations mentioned the possibility to proceed with the establishment of levels which were non controversial but to wait for further data when specific problems existed. A number of delegations observed that there would be enough time to take into account the JECFA evaluation in the elaboration procedure, but the circulation of specific levels at Step 3 would contribute to focus the discussion and comments and would facilitate further consideration of cadmium contamination. The Delegation of the United States pointed out that it should be clear that Maximum Levels for Cadmium would not be finalised until JECFA had examined data on the bioavailability of cadmium and provided a risk assessment for the Committee.

Status of the Draft Guideline Level and Proposed Draft Maximum Levels for Cadmium

136) The Committee agreed to return the *Draft Guideline Level for Cadmium in Cereals, Pulses and Legumes* to Step 6 and to circulate the other maximum levels at Step 3 for comments and consideration at the next session (see Appendix X). The Delegation of Japan reserved its position on this decision.

POSITION PAPER ON ARSENIC (Agenda Item 15e)²⁸

137) The Committee decided to ask the Delegation of Denmark to finalize the position paper in the light of comments received, and agreed that it would form the basis for future work until such time as routine methodology became available to determine toxic arsenic compounds in food.

DISCUSSION PAPER ON DIOXINS (Agenda item 15f)²⁹

138) The Committee recalled that the last session had accepted the offer of the Delegation of the Netherlands to prepare a discussion paper on dioxins for consideration at its next session. Some delegations pointed out that source directed measures were the most important solutions for this contamination problem, that there were analytical problems and that it would be premature to set maximum limits. The Committee asked delegations to gather information on this issue, especially on international trade in the most contaminated commodities, dairy products, fish, fish oil and meat (fat) and to send this information to the Delegation of the Netherlands.

²⁸ CX/FAC 99/22, CX/FAC 99/22 - Add. 1 (Comments of the United Kingdom, Sweden, Spain) CRD6 (USA, Thailand)

²⁹ CX/FAC 99/23, CX/FAC 99/23 (Comments of the United Kingdom, Sweden, Japan, Finland) CRD6 (Italy, France, Slovak Republic), CRD 7 (Germany, Belgium)

139) The Committee agreed that the Delegation of the Netherlands would revise the discussion paper for circulation and consideration at its next session.

PROPOSALS FOR THE PRIORITY EVALUATION OF FOOD ADDITIVES AND CONTAMINANTS BY JECFA (Agenda Item 16)³⁰

140) Mr. J. Dornseiffen (the Netherlands) introduced the report of the informal Working Group on Priorities for JECFA. The Committee agreed with the priorities proposed by the Working Group for both food additives and contaminants with the following amendments and comments.

141) As regards "nutritional consideration of calcium in food additives", the Delegation of Canada, which had proposed this entry, explained their concern that the calcium intake from calcium salts additives may result in the total calcium intake limit being exceeded. The Committee therefore agreed to delete the reference to "nutritional consideration".

142) The Committee agreed to add tin to the priority list of contaminants, for the assessment of its acute toxicity. At the request of the JECFA Secretariat, the Committee prioritized the first four contaminants for consideration by JECFA, in the following order: Ochratoxin A, cadmium, dioxins and dioxin-like PCBs, and fumonisins.

143) The Committee agreed on the priority list for food additives and contaminants presented in Appendix XII. The Committee agreed to request additional comments for additions or amendments to its Priority List, preferably well documented and in time, for consideration by the next session.

OTHER BUSINESS AND FUTURE WORK

COMMENTS ON METHODS OF ANALYSIS FOR THE DETERMINATION OF FOOD ADDITIVES AND CONTAMINANTS IN FOODS (Agenda Item 17a)³¹

144) Following the request for additional methods of analysis for the determination of food additives and contaminants in foods (CL 1997/6-FAC) on the basis of the criteria established earlier (ALINORM 97/12, para. 28), the Committee considered the comments from Sweden proposing methods for the determination of Lead, Cadmium, Zinc, Copper and Iron. The Committee agreed to forward these proposals to the Committee on Methods of Analysis and Sampling for consideration.

COMMENTS ON THE INVENTORY OF PROCESSING AIDS (Agenda Item 17b)³²

145) The Committee recalled that the 30th Session had agreed to ask for additional comments on the Inventory of Processing Aids as a follow-up to CL 1997/6-FAC. The Committee accepted the offer of the Delegation of New Zealand to develop a discussion paper on how Codex should deal with processing aids, with the support of Canada, The Netherlands, Australia and France.

146) The Delegation of the United States proposed to include Sodium Phosphate Tribasic as a microbial control agent in Appendix A of the *Codex Inventory of All Compounds Used As Processing Aids* in Codex Volume 1A. The Delegation of Turkey also proposed to include Potassium Carbonate Solution in the list.

147) Several delegations were of the opinion that further information about the use and function of these substances would be necessary before the Committee could address these requests. The Committee asked the Delegations of the United States and Turkey to provide the necessary information in order to consider these matters at the next session.

³⁰ CRD 8 (Report of the Working Group on Priorities), CX/FAC 99/24-Add 1 (comments of Canada, Slovak Republic, CRD 6 (Denmark) and CRD 7 (Netherlands).

³¹ CX/FAC 99/25 (Comments of Canada and Sweden)

³² CX/FAC 99/26 (Comments of Canada); CRD 4 (IDF)

COMMENTS ON PACKAGING PROVISIONS TO MAINTAIN THE STABILITY OF IODISED SALT IN THE CODEX STANDARD FOR FOOD GRADE SALT (Agenda Item 17 c)³³

148) The Committee recalled the decision of the 30th Session to circulate this proposal for comments and its approval by the 45th Session of the Executive Committee as new work, with the understanding that the proposed amendment referred to the packaging requirements to preserve the stability of iodised salt³⁴.

149) Several delegations expressed the view that the provisions concerning the packaging materials in Section 8.1 were too specific and stringent, and should be described in more general terms. The Delegation of Germany suggested to delete the last sentence of Section 8.1 (balancing the cost of different measures).

150) The Committee asked the Delegation of Malaysia to revise the document in the light of the comments received for circulation at Step 3 and further discussion at the next session, and noted that the recommendations of the International Council for Iodine Deficiency Disorders (ICIDD) and WHO concerning salt iodisation should be taken into account as appropriate.

FUTURE WORK

151) The Committee noted that, in addition to standing items on the Agenda, its future work would include the following matters:

Proposed Draft Revision of the General Standard for Irradiated Foods
Discussion paper on Risk Analysis Principles

General Standard for Food Additives

- Draft Tables 1,2 and 3
- Draft Annex A
- Discussion paper on colours in foods
- Discussion paper on processing aids

General Standard for Contaminants and Toxins in Food

- Methodology and Principles for Exposure Assessment
- Maximum levels for ochratoxin A, patulin, lead, tin, cadmium
- Code of Practice for Source Directed Measures
- Code of Practice for the prevention of contamination by ochratoxin
- Code of Practice for the prevention of contamination by zearalenone
- Discussion paper on fumonisins
- Discussion paper on dioxins

DATE AND PLACE OF NEXT SESSION (Agenda Item 18)

152) The Delegation of China invited the Committee to hold its 32nd Session in Beijing from 20 to 24 March 2000, pending a final approval from the State Council of China. This invitation arose from the close cooperation between the governments of China and The Netherlands, China's intention to become a member of WTO and the close relation between WTO and Codex. Several delegations welcomed this initiative as it supported the involvement of the Asian countries in Codex work.

³³ CX/FAC 99/27 (Comments of Slovak Republic, South Africa, Italy, Canada and ESPA)

³⁴ ALINORM 99/3, para. 26 and Appendix 3

SUMMARY STATUS OF WORK

SUBJECT	STEP	For Action by	Document Reference in ALINORM 99/12A
Draft Specifications for the Identity and Purity of Food Additives	8	Governments 23 rd CAC	paras. 65-68 Appendix VII
Draft General Standard for Food Additives: Table 1 (provisions for 23 additives)	8	Governments 23 rd CAC	paras. 46, 56 Appendix II
Draft General Standard for Food Additives: Table 3 (and Annex)	8	Governments 23 rd CAC	paras. 52, 56 Appendix III
Draft Amendments to the INS	5A*	Governments 23 rd CAC	para. 74 Appendix VIII
Endorsement of Health Related Limits for Certain Substances in the Standard for Natural Mineral Waters		23 rd CAC	para. 91 Appendix VI
Draft General Standard for Food Additives: Table 1 (additives referred to JECFA)	7	JECFA CCFAC	paras. 47, 56
Draft General Standard for Food Additives: Table 1 (other additives)	6	Governments 32 nd CCFAC	paras. 48, 56
Draft Maximum Levels for Lead	6	Denmark Governments 32 nd CCFAC	para. 126
Proposed Draft Annex A to the General Standard for Food Additives (Guidelines for the Estimation of Appropriate Levels of Use of Food Additives)	5	Governments 23 rd CAC	para. 58 Appendix IV
Proposed Draft Maximum Level for Patulin	5	Governments 23 rd CAC	para. 131 Appendix IX
Proposed Draft Maximum Levels for Tin	5	Governments 23 rd CAC	para. 117 Appendix IX
Proposed Draft Amendment to the Preamble of the General Standard for Food Additives	3A*	CAC/Governments 32 nd CCFAC	paras. 33, 39, 56 Appendix V
Proposed Draft Amendments to the INS	3A*	CAC/Governments 32 nd CCFAC	para. 55 Appendix VIII
Proposed Draft Amendment to Table 3 of the General Standard for Food Additives	3	Governments 32 nd CCFAC	paras. 12, 56 Appendix XI
Proposed Draft Maximum Levels for Ochratoxin A	3	Governments 32 nd CCFAC	para. 109 Appendix IX
Draft Guideline Level and Proposed Draft Maximum Levels for Cadmium	6 and 3	Governments 32 nd CCFAC	para. 136 Appendix X
Proposed Draft Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals	3	Sweden/Governments 32 nd CCFAC	para. 120
Packaging Provisions for Maintaining the Stability of Iodised Salt in the Codex Standard for Food Grade Salt	3	Malaysia/Governments 32 nd CCFAC	para. 150

Proposed Draft Code of Practice for the Prevention of Contamination by Ochratoxin A in Cereals	1/2/3	Sweden/Governments 32nd CCFAC	para. 106
Proposed Draft Code of Practice for the Prevention of Contamination by Zearalenone in Cereals	1/2/3	Norway/Governments 32nd CCFAC	para. 112
Revision of the General Standard for Irradiated Foods	1/2/3	CAC/Governments 32nd CCFAC	para. 7
Methodology and Principles for Exposure Assessment in the Codex General Standard for Contaminants and Toxins in Foods (to develop a Proposed Draft Annex)		UK/Governments 32nd CCFAC	paras. 61-63
Food Additives and Contaminants Proposed for Evaluation by JECFA		Governments 32nd CCFAC	para. 143 Appendix XII
Methods of Analysis for the Determination of Food Additives and Contaminants in Foods		Governments 32nd CCFAC	para. 111
Discussion papers on: (prepared or coordinated by) 1) Risk Analysis Principles (United States) 2) Use of Processing Aids (New Zealand) 3) Use of Colours in Foods (Denmark) 4) Patulin (France) 5) Zearalenone (Norway) 6) Dioxins (Netherlands)		Governments 32nd CCFAC	1) para. 17 2) para. 145 3) para. 62 4) para. 113 5) para. 112 6) para. 139

* Accelerated Procedure.

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**DRAFT GENERAL STANDARD FOR FOOD ADDITIVES
(At Step 8 of the Procedure)**

TABLE 1 Additives Permitted for Use under Specified Conditions in Certain Food Categories or Individual Food Items

**DRAFT GENERAL STANDARD FOR FOOD ADDITIVES
(At Step 8 of the Procedure)**

TABLE 3 Additives Permitted for Use in Food in General unless Otherwise Specified, in Accordance with GMP

ANNEX Food Categories in Individual Food Items Excluded from the General Conditions of Table 3



Codex General Standard for Food Additives

TABLE ONE

Additives Permitted for Use Under Specified
Conditions in Certain Food Categories
or Individual Food Items

ALPHA-AMYLASE (ASPERGILLUS ORYZAE VAR.)

Alpha-Amylase (*Aspergillus oryzae* var.) INS: 1100

Function: Adjuvant, Enzyme, Flour Treatment Agent

Food Cat. No.	Food Category	Max Level	Comments
06.2	Flours and starches	GMP	
14.2.3	Wines	GMP	

AZODICARBONAMIDE

Azodicarbonamide INS: 927a

Function: Adjuvant, Flour Treatment Agent

Food Cat. No.	Food Category	Max Level	Comments
06.2	Flours and starches	45 mg/kg	

CARAMEL COLOUR, CLASS III

Caramel Colour, Class III - Ammonia Process INS: 150c

Function: Colour

Food Cat. No.	Food Category	Max Level	Comments
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog)	150 mg/kg	
01.2.1	Fermented milks (plain)	150 mg/kg	Note 12
01.2.2	Renneted milk	GMP	
01.3.2	Beverage whiteners	GMP	
01.4.3	Clotted cream	GMP	
01.4.4	Cream analogues	GMP	
01.5.2	Milk powder and cream powder analogues	GMP	
01.6.1	Unripened cheese	GMP	
01.6.2.2	Rind of ripened cheese	GMP	
01.6.3	Whey cheese	GMP	Note 3
01.6.4	Processed cheese	GMP	
01.6.5	Cheese analogues	GMP	
01.7	Dairy-based desserts (e.g., ice cream, ice milk, pudding, fruit or flavoured yoghurt)	2000 mg/kg	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	GMP	
03.0	Edible ices, including sherbert and sorbet	1000 mg/kg	
04.1.2.3	Fruit in vinegar, oil, or brine	GMP	
04.1.2.4	Canned or bottled (pasteurized) fruit	GMP	
04.1.2.5	Jams, jellies, marmelades	GMP	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	500 mg/kg	
04.1.2.7	Candied fruit	GMP	

Food Cat. No.	Food Category	Max Level	Comments
04.1.2.8	Fruit preparations, including pulp and fruit toppings	7500 mg/kg	
04.1.2.9	Fruit-based desserts, including fruit-flavored water-based	GMP	
04.1.2.11	Fruit fillings for pastries	7500 mg/kg	
04.2.2.3	Vegetables in vinegar, oil, or brine	500 mg/kg	
04.2.2.4	Canned or bottled (pasteurized) vegetables	GMP	
04.2.2.5	Vegetable, and nut & seed purees and spreads (e.g., peanut	GMP	
04.2.2.6	Vegetable, and nut & seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	GMP	
05.1.2	Cocoa-based spreads, including fillings	GMP	
05.2	Sugar-based confectionary, including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	GMP	
05.3	Chewing gum	20000 mg/kg	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	GMP	
06.3	Breakfast cereals, including rolled oats	6500 mg/kg	
06.5	Cereal and starch based desserts (e.g., rice puddings, tapioca pudding)	GMP	
07.2	Fine bakery wares	GMP	
08.0	Meat and meat products, including poultry and game	GMP	Note 3
09.1	Fresh fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	Notes 3 & 50
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	Note 50
09.3.3	Salmon substitutes, caviar, and other fish roe products	GMP	Note 50
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	500 mg/kg	Note 50
10.1	Fresh eggs	GMP	Notes 3 & 4
10.4	Egg-based desserts (e.g., custard)	GMP	
11.2	Other sugars and syrups (e.g., brown sugar, maple syrup)	GMP	
12.2	Herbs, spices, seasonings (including salt substitutes), and	GMP	
12.3	Vinegars	1000 mg/kg	
12.4	Mustards	GMP	
12.5	Soups and broths	GMP	
12.6	Sauces and like products	1500 mg/kg	
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 05.1.2	GMP	
12.9	Protein products	GMP	
13.3	Dietetic foods intended for special medical purposes	GMP	
13.4	Dietetic formulae for slimming purposes and weight reduction	GMP	
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4	GMP	
13.6	Food supplements	GMP	
14.1.2.3	Concentrates (liquid or solid) for fruit juice	GMP	
14.1.3.2	Canned or bottled (pasteurized) vegetable nectar	GMP	
14.1.3.4	Concentrates (liquid or solid) for vegetable nectar	GMP	
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	GMP	
14.2.1	Beer and malt beverages	GMP	
14.2.2	Cider and perry	GMP	
14.2.3.3	Fortified wine and liquor wine	GMP	
14.2.3.4	Aromatized wine	GMP	
14.2.4	Fruit wine	GMP	
14.2.6	Spiritous beverages	GMP	
15.0	Ready-to-eat savouries	GMP	
16.0	Composite foods (e.g., casseroles, meat pies, mincemeat) - foods that could not be place in food categories 01 - 15.	1000 mg/kg	

CARAMEL COLOUR, CLASS IV

Caramel Colour, Class IV - Ammonia Sulphite INS: 150d
Process

Food Cat. No.	Food Category	Max Level	Comments
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog)	150 mg/kg	
01.2.1	Fermented milks (plain)	150 mg/kg	Note 12
01.2.2	Renneted milk	GMP	
01.3.2	Beverage whiteners	GMP	
01.4.3	Clotted cream	GMP	
01.4.4	Cream analogues	GMP	
01.5.2	Milk powder and cream powder analogues	GMP	
01.6.1	Unripened cheese	GMP	
01.6.2.2	Rind of ripened cheese	GMP	
01.6.3	Whey cheese	GMP	Note 3
01.6.4	Processed cheese	100 mg/kg	
01.6.5	Cheese analogues	GMP	
01.7	Dairy-based desserts (e.g., ice cream, ice milk, pudding, fruit or flavoured yoghurt)	2000 mg/kg	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	GMP	
03.0	Edible ices, including sherbert and sorbet	1000 mg/kg	
04.1.2.3	Fruit in vinegar, oil, or brine	GMP	
04.1.2.4	Canned or bottled (pasteurized) fruit	GMP	
04.1.2.5	Jams, jellies, marmelades	1500 mg/kg	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	500 mg/kg	
04.1.2.7	Candied fruit	GMP	
04.1.2.8	Fruit preparations, including pulp and fruit toppings	7500 mg/kg	
04.1.2.9	Fruit-based desserts, including fruit-flavored water-based	GMP	
04.1.2.11	Fruit fillings for pastries	7500 mg/kg	
04.2.2.3	Vegetables in vinegar, oil, or brine	500 mg/kg	
04.2.2.4	Canned or bottled (pasteurized) vegetables	GMP	
04.2.2.5	Vegetable, and nut & seed purees and spreads (e.g., peanut	GMP	
04.2.2.6	Vegetable, and nut & seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	GMP	
05.1.2	Cocoa-based spreads, including fillings	GMP	
05.2	Sugar-based confectionary, including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	GMP	
05.3	Chewing gum	20000 mg/kg	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	GMP	
06.3	Breakfast cereals, including rolled oats	2500 mg/kg	
06.5	Cereal and starch based desserts (e.g., rice puddings, tapioca pudding)	GMP	
07.2.1	Cakes, cookies and pies (e.g., fruit-filled or custard types)	GMP	
07.2.2	Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins)	1200 mg/kg	
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	GMP	
08.0	Meat and meat products, including poultry and game	GMP	
09.1	Fresh fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	Note 50
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	Note 50
09.3.3	Salmon substitutes, caviar, and other fish roe products	GMP	Note 50
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	500 mg/kg	Note 50
10.1	Fresh eggs	GMP	Notes 3 & 4
10.4	Egg-based desserts (e.g., custard)	GMP	
11.2	Other sugars and syrups (e.g., brown sugar, maple syrup)	GMP	
12.2	Herbs, spices, seasonings (including salt substitutes), and	GMP	
12.3	Vinegars	GMP	
12.4	Mustards	GMP	
12.5.1	Ready-to-eat soups and broths, including canned, bottled, and	3000 mg/kg	

Food Cat. No.	Food Category	Max Level	Comments
12.5.2	Mixes for soups and broths	GMP	
12.6	Sauces and like products	1500 mg/kg	
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 05.1.2	GMP	
12.9	Protein products	GMP	
13.3	Dietetic foods intended for special medical purposes	GMP	
13.4	Dietetic formulae for slimming purposes and weight reduction	GMP	
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4	GMP	
13.6	Food supplements	GMP	
14.1.2.3	Concentrates (liquid or solid) for fruit juice	GMP	
14.1.3.2	Canned or bottled (pasteurized) vegetable nectar	GMP	
14.1.3.4	Concentrates (liquid or solid) for vegetable nectar	GMP	
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	GMP	
14.2.1	Beer and malt beverages	240 mg/kg	
14.2.2	Cider and perry	GMP	
14.2.3.3	Fortified wine and liquor wine	GMP	
14.2.3.4	Aromatized wine	GMP	
14.2.4	Fruit wine	GMP	
14.2.6.1	Spiritous beverages containing more than 15% alcohol	GMP	
14.2.6.2	Spiritous beverages containing less than 15% alcohol	240 mg/kg	
15.0	Ready-to-eat savouries	GMP	
16.0	Composite foods (e.g., casseroles, meat pies, mincemeat) - foods that could not be place in food categories 01 - 15.	1000 mg/kg	

DIMETHYL DICARBONATE

Dimethyl Dicarbonate

INS: 242

Function: Preservative

Food Cat. No.	Food Category	Max Level	Comments
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	250 mg/kg	Note 18
14.1.5	Coffee, coffee infusions (excluding flavoured coffees), and other hot cereal beverages, excluding cocoa	250 mg/kg	Notes 2 & 18
14.2.3	Wines	250 mg/kg	Note 18

FAST GREEN FCF

Fast Green FCF

INS: 143

Function: Colour

Food Cat. No.	Food Category	Max Level	Comments
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog)	100 mg/kg	
01.7	Dairy-based desserts (e.g., ice cream, ice milk, pudding, fruit or flavoured yoghurt)	100 mg/kg	Note 2
02.1.3	Lard, tallow, fish oil and other animal fats	GMP	
03.0	Edible ices, including sherbert and sorbet	100 mg/kg	
04.1.2.4	Canned or bottled (pasteurized) fruit	200 mg/kg	
04.1.2.5	Jams, jellies, marmelades	400 mg/kg	
04.2.2.3	Vegetables in vinegar, oil, or brine	300 mg/kg	
04.2.2.4	Canned or bottled (pasteurized) vegetables	200 mg/kg	
05.3	Chewing gum	300 mg/kg	
07.1.1	Breads and rolls	100 mg/kg	

Food Cat. No.	Food Category	Max Level	Comments
07.2	Fine Bakery Wares	100 mg/kg	
08.1	Fresh meat, poultry and game	GMP	Note 4
08.2	Processed meat, poultry, and game products in whole pieces or	GMP	Notes 3 & 4
08.4	Edible casings (e.g., sausage casings)	GMP	Notes 3 & 4
09.2.4.1	Cooked fish	100 mg/kg	
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	100 mg/kg	
09.3.3	Salmon substitutes, caviar, and other fish roe products	100 mg/kg	
10.1	Fresh eggs	GMP	Notes 3 & 4
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	100 mg/kg	
14.2.6.1	Spirituous beverages containing more than 15% alcohol	100 mg/kg	
14.2.6.2	Spirituous beverages containing less than 15% alcohol	100 mg/kg	

FERRIC AMMONIUM CITRATE

Ferric Ammonium Citrate

INS: 381

Function: Anticaking Agent

Food Cat. No.	Food Category	Max Level	Comments
12.1	Salt	25 mg/kg	Note 23
14.1.4.3	Concentrates (liquid or solid) for drinks	10 mg/kg	Note 23

FERROCYANIDES

Sodium Ferrocyanide
Calcium Ferrocyanide

INS: 535
INS: 538

Potassium Ferrocyanide

INS: 536

Function: Anticaking Agent

Food Cat. No.	Food Category	Max Level	Comments
12.1	Salt	20 mg/kg	Note 24
12.2	Herbs, spices, seasonings (including salt substitutes), and	20 mg/kg	Note 24

FERROUS GLUCONATE

Ferrous Gluconate

INS: 579

Function: Acidity Regulator, Colour Retention Agent, Preservative

Food Cat. No.	Food Category	Max Level	Comments
04.2.2.3	Vegetables in vinegar, oil, or brine	150 mg/kg	Note 23 & 48

FERROUS LACTATE

Ferrous Lactate

INS: 585

Function: Acidity Regulator, Colour Retention Agent

Food Cat. No.	Food Category	Max Level	Comments
04.2.2.3	Vegetables in vinegar, oil, or brine	150 mg/kg	Note 23 & 48

GLYCEROL ESTER OF WOOD ROSIN

Glycerol Esters of Wood Rosin

INS: 445

Function: Adjuvant, Bulking Agent, Emulsifier, Stabilizer, Thickener

Food Cat. No.	Food Category	Max Level	Comments
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	150 mg/kg	
14.2.1	Beer and malt beverages	60 mg/kg	
14.2.6.2	Spirituous beverages containing less than 15% alcohol	60 mg/kg	

GUAIAIC RESIN

Guaiac Resin

INS: 314

Function: Antioxidant

Food Cat. No.	Food Category	Max Level	Comments
02.1	Fats and oils essentially free from water	1000 mg/kg	
02.2.1	Emulsions containing at least 80% fat	1000 mg/kg	
05.3	Chewing gum	1500 mg/kg	

LYSOZYME HYDROCHLORIDE

Lysozyme Hydrochloride

INS: 1105

Function: Preservative

Food Cat. No.	Food Category	Max Level	Comments
01.6.2	Ripened cheese	GMP	

ORTHO-PHENYLPHENOLS

Ortho-Phenylphenol

INS: 231

Sodium o-Phenylphenol

INS: 232

Function: Preservative

Food Cat. No.	Food Category	Max Level	Comments
04.1.1.2	Surface-treated fruit	12 mg/kg	Note 49

OXYTEARIN

Oxystearin

INS: 387

Function: Antifoaming Agent, Crystallization Inhibitor, Release Agent, Sequestrant

Food Cat. No.	Food Category	Max Level	Comments
02.1	Fats and oils essentially free from water	1250 mg/kg	
12.6.1	Emulsified or clear sauces (e.g., mayonnaise, salad dressing, soy sauce)	GMP	
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	250 mg/kg	

POLYDIMETHYLSILOXANE

Polydimethylsiloxane

INS: 900a

Function: Anticaking Agent, Antifoaming Agent

Food Cat. No.	Food Category	Max Level	Comments
01.5.1	Milk powder and cream powder	10 mg/kg	
02.1	Fats and oils essentially free from water	10 mg/kg	
02.2.1.2	Margarine and similar products (e.g., butter-margarine blends)	10 mg/kg	
04.1.2.3	Fruit in vinegar, oil, or brine	10 mg/kg	
04.1.2.4	Canned or bottled (pasteurized) fruit	10 mg/kg	
04.1.2.5	Jams, jellies, marmelades	30 mg/kg	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	10 mg/kg	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	110 mg/kg	
04.2.2.1	Frozen vegetables	10 mg/kg	Note 15
04.2.2.3	Vegetables in vinegar, oil, or brine	10 mg/kg	
04.2.2.4	Canned or bottled (pasteurized) vegetables	10 mg/kg	
04.2.2.5	Vegetable, and nut & seed purees and spreads (e.g., peanut	10 mg/kg	
05.1	Cocoa products and chocolate products including imitations and chocolate substitutes	10 mg/kg	
05.2	Sugar-based confectionary, including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	10 mg/kg	
05.3	Chewing gum	100 mg/kg	
06.6	Batters (e.g., for breading or batters for fish or poultry)	10 mg/kg	
12.1	Salt	10 mg/kg	
12.5	Soups and broths	10 mg/kg	
14.1.2	Fruit and vegetable juices	10 mg/kg	
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	20 mg/kg	
14.2.1	Beer and malt beverages	10 mg/kg	
14.2.2	Cider and perry	10 mg/kg	
14.2.3	Wines	10 mg/kg	
14.2.4	Fruit wine	10 mg/kg	

POLYVINYLPIRROLIDONE

Polyvinylpyrrolidone

INS: 1201

Function: Adjuvant, Emulsifier, Glazing Agent, Stabilizer, Thickener

Food Cat. No.	Food Category	Max Level	Comments
04.1.1.2	Surface-treated fruit	GMP	
05.3	Chewing gum	10000 mg/kg	
11.4	Table-top sweeteners, including those containing high-intensity sweeteners	3000 mg/kg	
12.3	Vinegars	40 mg/kg	
13.6	Food supplements	GMP	
14.1.4.3	Concentrates (liquid or solid) for drinks	500 mg/kg	
14.2.1	Beer and malt beverages	10 mg/kg	Note 36
14.2.2	Cider and perry	2 mg/kg	Note 36
14.2.3	Wines	60 mg/kg	Note 36

PROTEASE (A. ORYZAE VAR.)

Function: Enzyme, Flavour Enhancer, Flour Treatment Agent, Glazing Agent

Food Cat. No.	Food Category	Max Level	Comments
06.2	Flours and starches	GMP	

SUCROSE ACETATE ISOBUTYRATE

Sucrose Acetate Isobutyrate

INS: 444

Function: Acidity Regulator, Adjuvant, Emulsifier, Stabilizer

Food Cat. No.	Food Category	Max Level	Comments
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	500 mg/kg	

THIODIPROPIONATES

Thiodipropionic Acid

INS: 388

Dilauryl Thiodipropionate

INS: 389

Function: Antioxidant

Food Cat. No.	Food Category	Max Level	Comments
02.1	Fats and oils essentially free from water	200 mg/kg	Note 46
02.2.1.2	Margarine and similar products (e.g., butter-margarine blends)	200 mg/kg	Note 46
02.2.2	Emulsions containing less than 80% fat (e.g., minarine)	200 mg/kg	Note 46
09.2.2	Frozen battered fish, fish fillets and fish products, including mollusks, crustaceans, and echinoderms	200 mg/kg	Notes 15 & 46

Tocopherols (cont.)	
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"
15.0	Ready-to-eat savouries

DRAFT GSFA-TABLE ONE
1000 mg/kg Note 15
200 mg/kg

THERMALLY OXIDIZED SOYA BEAN OIL WITH MONO- AND DI-GLYCERIDES OF FATTY ACIDS

Thermally Oxidized Soya Bean Oil with Mono- and Di-Glycerides of Fatty Acids (TOSOM) INS: 479

Function: Emulsifier

Food Cat. No.	Food Category	Max Level	Comments
02.2.1.2	Margarine and similar products (e.g., butter-margarine blends)	5000 mg/kg	
02.2.2	Emulsions containing less than 80% fat (e.g., minarine)	5000 mg/kg	

TRIETHYL CITRATE

Triethyl Citrate INS: 1505

Function: Antifoaming Agent, Carrier Solvent, Sequestrant, Stabilizer

Food Cat. No.	Food Category	Max Level	Comments
10.2.1	Liquid egg products	2500 mg/kg	Note 47
10.2.3	Dried and/or heat coagulated egg products	2500 mg/kg	Note 47
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	200 mg/kg	

Notes¹ to Table One of the General Standard for Food Additives

Note 1: As adipic acid

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

Note 3: Surface treatment.

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

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

Note 6: As aluminium.

Note 7: Use level not in finished food.

Note 8: As bixin.

Note 9: As total bixin or norbixin.

Note 10: As ascorbyl stearate.

Note 11: Flour basis.

Note 12: Carryover from flavouring substances.

Note 13: As benzoic acid.

Note 14: On amount of milk used.

Note 15: Fat or oil basis.

Note 16: Use level in chicken feed to color chicken skins or eggs.

Note 17: As cyclamic acid.

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

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

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

Note 21: As calcium disodium EDTA.

Note 22: Used in heat-treated products only.

Note 23: As iron.

Note 24: As anhydrous sodium ferrocyanide.

Note 25: As formic acid.

Note 26: Gum base basis.

Note 27: As p-hydroxybenzoic acid.

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

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

Note 29: Reporting basis not specified.

Note 30: As residual NO₃ ion.

Note 31: Of the mash used.

Note 32: As residual NO₂ ion.

Note 33: As phosphorus.

Note 34: Anhydrous basis.

Note 35: Level in cocoa nibs.

Note 36: Residual level.

Note 37: As weight of nonfat milk solids.

Note 38: Level in creaming mixture.

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

Note 40: Use in packing medium only.

Note 41: Use in breading or batter coatings only.

Note 42: As sorbic acid

Note 43: As tin.

Note 44: As residual SO₂.

Note 45: As tartaric acid.

Note 46: As thiodipropionic acid.

Note 47: On egg yolk weight, dry basis.

Note 48: For olives only.

Note 49: For use on citrus fruits only.

Note 50: For use in fish roe only.

¹ Only the notes in bold above pertain to the additives forwarded by the CCFAC to the CAC with a recommendation for endorsement at Step 8.



Codex General Standard for Food Additives

TABLE THREE

ADDITIVES PERMITTED FOR USE IN FOOD IN GENERAL,
UNLESS OTHERWISE SPECIFIED, IN ACCORDANCE WITH GMP

INS No.	Additive
260	Acetic Acid
472a	Acetic and Fatty Acid Esters of Glycerol
1422	Acetylated Distarch Adipate
1414	Acetylated Distarch Phosphate
1401	Acid Treated Starch
406	Agar
400	Alginic Acid
1402	Alkaline Treated Starch
1100	Alpha-Amylase (<i>Aspergillus oryzae</i> var.)
1100	Alpha-Amylase (<i>Bacillus megaterium</i> expressed in <i>Bacillus subtilis</i>)
1100	Alpha-Amylase (<i>Bacillus stearothermophilus</i> expressed in <i>B. subtilis</i>)
1100	Alpha-Amylase (<i>Bacillus stearothermophilus</i>)
1100	Alpha-Amylase (<i>Bacillus subtilis</i>)
1100	Alpha-Amylase (Carbohydrase) (<i>Bacillus licheniformis</i>)
559	Aluminium Silicate
264	Ammonium Acetate
403	Ammonium Alginate
503(i)	Ammonium Carbonate
510	Ammonium Chloride
380	Ammonium Citrate
503(ii)	Ammonium Hydrogen Carbonate
527	Ammonium Hydroxide
328	Ammonium Lactate
300	Ascorbic Acid
162	Beet Red
1403	Bleached Starch
1101(iii)	Bromelain
263	Calcium Acetate
404	Calcium Alginate
556	Calcium Aluminium Silicate
302	Calcium Ascorbate
170(i)	Calcium Carbonate
509	Calcium Chloride
333	Calcium Citrate
578	Calcium Gluconate
623	Calcium Glutamate, DI-L-
629	Calcium Guanylate, 5'-
526	Calcium Hydroxide
633	Calcium Inosinate, 5'-
327	Calcium Lactate
352(ii)	Calcium Malate, D,L-
529	Calcium Oxide
282	Calcium Propionate
634	Calcium Ribonucleotides, 5'-
552	Calcium Silicate

INS No.	Additive
516	Calcium Sulphate
150a	Caramel Colour, Class I
290	Carbon Dioxide
410	Carob Bean Gum
407	Carrageenan
140	Chlorophylls
1001	Choline Salts
330	Citric Acid
472c	Citric and Fatty Acid Esters of Glycerol
1400	Dextrins, white and yellow, Roasted Starch
628	Dipotassium Guanylate, 5'-
632	Dipotassium Inosinate, 5'-
627	Disodium Guanylate, 5'-
631	Disodium Inosinate, 5'-
635	Disodium Ribonucleotides, 5'-
1412	Distarch Phosphate
1405	Enzyme Treated Starch
315	Erythorbic Acid
462	Ethyl Cellulose
467	Ethyl Hydroxyethyl Cellulose
297	Fumaric Acid
418	Gellan Gum
575	Glucono Delta-Lactone
1102	Glucose Oxidase (<i>Aspergillus niger, var.</i>)
620	Glutamic Acid, L-
422	Glycerol
626	Guanylic Acid, 5'-
412	Guar Gum
414	Gum Arabic
507	Hydrochloric Acid
463	Hydroxypropyl Cellulose
1442	Hydroxypropyl Distarch Phosphate
464	Hydroxypropyl Methyl Cellulose
1440	Hydroxypropyl Starch
630	Inosinic Acid, 5'-
1202	Insoluble Polyvinylpyrrolidone
953	Isomalt
416	Karaya Gum
[425]	Konjac Flour
270	Lactic Acid
472b	Lactic and Fatty Acid Esters of Glycerol
966	Lactitol
322	Lecithin
1104	Lipase (Animal Sources)
1104	Lipase (<i>Aspergillus oryzae, var.</i>)
504(i)	Magnesium Carbonate
511	Magnesium Chloride
580	Magnesium Gluconate
625	Magnesium Glutamate, DI-L-
504(ii)	Magnesium Hydrogen Carbonate
528	Magnesium Hydroxide
329	Magnesium Lactate, D,L-
530	Magnesium Oxide
553(i)	Magnesium Silicate (Synthetic)
296	Malic Acid, D,L-
965	Maltitol (including Maltitol Syrup)
421	Mannitol

INS No.	Additive
461	Methyl Cellulose
465	Methyl Ethyl Cellulose
460(i)	Microcrystalline Cellulose
471	Mono- and Diglycerides
624	Monoammonium Glutamate, L-
622	Monopotassium Glutamate, L-
621	Monosodium Glutamate, L-
1410	Monostarch Phosphate
941	Nitrogen
942	Nitrous Oxide
1404	Oxidized Starch
1101(ii)	Papain
440	Pectins (Amidated and Non-amidated)
1413	Phosphated Distarch Phosphate
1200	Polydextroses
261	Potassium Acetate
402	Potassium Alginate
303	Potassium Ascorbate
501(i)	Potassium Carbonate
508	Potassium Chloride
332i	Potassium Dihydrogen Citrate
577	Potassium Gluconate
501(ii)	Potassium Hydrogen Carbonate
351(i)	Potassium Hydrogen Malate, D,L-
525	Potassium Hydroxide
326	Potassium Lactate (Solution)
351(ii)	Potassium Malate, D, L-
283	Potassium Propionate
515	Potassium Sulphate
460(ii)	Powdered Cellulose
944	Propane
280	Propionic Acid
1100I	Protease (<i>Aspergillus oryzae</i> var.)
470	Salts of Myristic, Palmitic and Stearic Acids (Ammonium, Calcium, Potassium, Sodium)
470	Salts of Oleic Acid (Calcium, Potassium, Sodium)
551	Silicon Dioxide (Amorphous)
262(i)	Sodium Acetate
401	Sodium Alginate
554	Sodium Aluminosilicate
301	Sodium Ascorbate
500(i)	Sodium Carbonate
466	Sodium Carboxymethyl Cellulose
331(i)	Sodium Dihydrogen Citrate
316	Sodium Erythorbate
365	Sodium Fumarate
576	Sodium Gluconate
500(ii)	Sodium Hydrogen Carbonate
350(i)	Sodium Hydrogen Malate, D, L-
524	Sodium Hydroxide
325	Sodium Lactate (Solution)
350(ii)	Sodium Malate, D,L-
281	Sodium Propionate
500(iii)	Sodium Sesquicarbonate
420	Sorbitol (including Sorbitol Syrup)
1420	Starch Acetate
1450	Starch Sodium Octenylsuccinate

INS No.	Additive
553(iii)	Talc
417	Tara Gum
472f	Tartaric, Acetic and Fatty Acid Esters of Glycerol (mixed)
957	Thaumatococcus
171	Titanium Dioxide
413	Tragacanth Gum
1518	Triacetin
380	Triammonium Citrate
332(ii)	Tripotassium Citrate
331(iii)	Trisodium Citrate
415	Xanthan Gum
967	Xylitol

**FOOD CATEGORIES OR INDIVIDUAL FOOD ITEMS EXCLUDED FROM
THE GENERAL CONDITIONS OF TABLE THREE**

THE USE OF 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
01.2	Fermented and Renneted Milk Products (plain) Excluding excluding food category 01.1.2 (dairy based drinks)
01.4.1	Pasteurized Cream
01.4.2	Sterilized, UHT, whipping or whipped, and reduced fat creams
02.1	Fats and oils, essentially free from water
02.2.1.1	Butter and concentrated butter (<u>Only</u> Butter)
04.1.1	Fresh Fruit
04.1.1.2	Surface treated fruit
04.1.1.3	Peeled or cut fruit
04.2.1	Fresh Vegetables
04.2.1.2	Surface-treated vegetables
04.2.1.3	Peeled or cut vegetables
04.2.2.1	Frozen vegetables
06.1	Whole, broken or flaked grains, including rice
06.2	Flours and starches
06.4	Pastas and Noodles (<u>Only</u> Dried Products)
08.1.1	Fresh meat, poultry and game, whole pieces or cuts
08.1.2	Fresh meat, poultry and game, comminuted
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	White and semi-white sugar (sucrose or saccharose), fructose, glucose (dextrose), xylose; sugar solutions and syrups, also (partially) inverted sugars, including molasses, treacle and sugar toppings
11.2	Other sugars and syrups (e.g., brown sugar and maple syrup)
11.3	Honey
12.1	Salt
12.2	Herbs, Spices, seasoning (including salt substitutes) and condiments (<u>Only</u> herbs and salt substitutes)
12.8	Yeast
13.1	Infant formulae and follow-on formulae
13.2	Foods for young children (weaning foods)
14.1.1.1	Natural Mineral Waters and Source Waters (Only Natural Mineral Waters)
14.12.1	Canned or bottled (pasteurized) fruit juice
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal beverages, excluding cocoa
14.2.3	Wines

**PROPOSED DRAFT ANNEX A TO THE GENERAL STANDARD FOR FOOD ADDITIVES
(At Step 5 of the Procedure)**

GUIDELINES FOR THE ESTIMATION OF APPROPRIATE LEVELS OF USE OF FOOD ADDITIVES

This annex is intended as a guidance to screen proposals for use of additives based on consideration of their maximum use level and the physiological upper limit to the amount of food and drink that can be consumed each day. The Annex is not intended for allocating provisions for the use of an additive and cannot be used for calculating accurate additive intakes.

I. FOOD ADDITIVE, BASIC PRINCIPLES FOR CALCULATION ON USE LEVELS.

Guideline 1

The levels and quantities of food additives used in the Budget Method calculations should be expressed on the same basis as the substances on which the ADI was allocated (e.g., an acid or its salts). For foods sold as concentrates or powders intended for reconstitution before consumption, the Budget calculation on the food additive use levels should be performed on the ready-to-eat product.

II. ESTIMATION OF THE SAFETY ASPECTS ON USE LEVELS - FOOD ADDITIVES WITH NO NUMERICAL ADI.

Guideline 2

FOOD ADDITIVES WITH ADI "NOT SPECIFIED"

When an additive has been allocated an ADI "not specified"¹ it could in principle, be allowed for use in foods in general with no limitation other than in accordance with Good Manufacturing Practices (GMP). It should, however, be born in mind that ADI not specified does not mean that unlimited intake is acceptable. The term is used by JECFA in case where "on the basis of the available data (chemical, biochemical, toxicological, and other) the total daily intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food does not, in the opinion of the Committee, represent a hazard to health"¹. If, therefore, a substance is used in larger amounts and/or in a wider range of foods than originally envisaged by JECFA it may be necessary to consult JECFA to ensure that the new uses fall within the evaluation. For example a substance may have been evaluated as a humectant without including a later use as a bulk sweetener, which could give considerable higher intake.

Guideline 3

FOOD ADDITIVES EVALUATED AS "ACCEPTABLE" FOR CERTAIN PURPOSES

In some cases, JECFA has been unable to allocate an ADI but nevertheless found a specific use of a substance acceptable. In such cases, the additive in question should only be authorized in accordance with the conditions specified. In case of any other reported uses CCFAC should request JECFA to re-evaluate the additive in question in light of the new information on uses.

III. ESTIMATION OF THE SAFETY ASPECTS ON USE LEVELS - FOOD ADDITIVES WITH NUMERICAL ADI.

Guideline 4

FRACTIONS OF THE ADI TO BE USED FOR SOLID FOOD AND BEVERAGES RESPECTIVELY

If an additive is proposed for use in both solid food and in beverages the full ADI cannot be used for both for uses in solid food and uses in beverages. It is therefore necessary to allocate a fraction of the ADI to each of the applications. As a first approach, it may be appropriate to assume that one-half of the ADI is allocated to

¹ *Principles for the safety assessment of food additives and contaminants in food.* Geneva, World Health Organization, 1987 (Environmental Health Criteria, No. 70), p. 83.

each solid and liquid foods. However, in special cases other fractions may be more appropriate as long as the sum of the fractions does not exceed the figure for the ADI (e.g. $F_S = 1/4$ and $F_B = 3/4$; $F_S = 1/6$ and $F_B = 5/6$), where F_S is the fraction for use in solid food and F_B is the fraction for use in beverages). If the additive is used only in solid food, then $F_S = 1$ and $F_B = 0$ and if the additive is used only in beverages, then $F_S = 0$ and $F_B = 1$.

IIIA FOOD ADDITIVE USES IN SOLID FOOD

GUIDELINE 5

USE LEVELS BELOW $F_S \times ADI \times 40$

If the proposed use levels are below $F_S \times ADI \times 40$, these food additive provisions could be suitable in food in general.

GUIDELINE 6

USE LEVELS BELOW $F_S \times ADI \times 80$

If the proposed use levels are below $F_S \times ADI \times 80$ they are acceptable provided the daily consumption of the foods containing the additive will usually not exceed half of the assumed maximum total solid food intake (i.e. 12.5 g/kg bw/day).

Guideline 7

USE LEVELS BELOW $F_S \times ADI \times 160$

If the proposed use levels are below $F_S \times ADI \times 160$ they are acceptable provided the daily consumption of the foods containing the additive will usually not exceed one fourth of the assumed maximum total solid food intake (i.e., 6.25 g/kg bw/day).

GUIDELINE 8

USE LEVELS BELOW $F_S \times ADI \times 320$

If the proposed use levels are below $F_S \times ADI \times 320$ they could be accepted provided the daily consumption of the foods containing the additive will usually not exceed one eighth of the assumed maximum total food intake (i.e., 3.13 g/kg bw/day).

GUIDELINE 9

USE LEVELS ABOVE $F_S \times ADI \times 320$

If the proposed levels are higher than $F_S \times ADI \times 320$ they should only be accepted for products where calculation of potential intake from all proposed uses will show that exceeding the ADI is unlikely, or if estimation of the intake of the additive based on more exact intake estimates methods show that the use levels are acceptable (e.g., food consumption surveys)

IIIB FOOD ADDITIVE USES IN BEVERAGES

Guideline 10

USE LEVELS BELOW $F_L \times ADI \times 10$

If the proposed levels are below $F_L \times ADI \times 10$, the additive could be accepted for use in all beverages in general.

Guideline 11

USE LEVELS BELOW $F_L \times ADI \times 20$

If the proposed use levels are below $F_L \times ADI \times 20$ they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed half of the assumed maximum total intake of beverage (i.e., 50 ml/kg bw/day).

Guideline 12

USE LEVELS BELOW $F_L \times ADI \times 40$

If the proposed use levels are below $F_L \times ADI \times 40$ they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed a fourth of the assumed maximum total intake of beverage (i.e., 25 ml/kg bw/day).

Guideline 13**USE LEVELS BELOW $F_L \times ADI \times 80$**

If the proposed use levels are below $F_L \times ADI \times 80$ they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed an eighth of the assumed maximum total intake of beverage (i.e., 12.5 ml/kg bw/day).

Guideline 14**USE LEVELS ABOVE $F_L \times ADI \times 80$**

Levels above $F_L \times ADI \times 80$ should only be accepted for products where calculation of potential intake will show that exceeding the ADI is unlikely (e.g., strong alcoholic beverages).

**PROPOSED DRAFT AMENDMENT TO THE PREAMBLE OF THE
GENERAL STANDARD FOR FOOD ADDITIVES
(At Step 3 of the Accelerated Procedure)**

Section 1.1 Permitted Food Additives

The following statement is added to the Footnote:

“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.”

Section 6. Format of the Standard

The following sentence is added:

“Tables 1, 2 and 3 do not include reference to the uses of substances as processing aids.”

CODEX STANDARD FOR NATURAL MINERAL WATERS

Endorsement of Health-Related Limits for Certain Substances (endorsed with amendments)

Section 3.2 Health-Related Limits for Certain Substances

Antimony	0.005 mg/l
Arsenic	0.01 mg/l, calculated as total As
Barium	0.7 mg/l
Borate	5 mg/l, calculated as B
Cadmium	0.003 mg/l
Chromium	0.05 mg/l, calculated as total Cr
Copper	1 mg/l
Cyanide	0.07 mg/l
Fluoride	See section 6.3.2 (Additional Labelling Requirements)
Lead	0.01 mg/l
Manganese	0.5 mg/l
Mercury	0.001 mg/l
Nickel	0.02 mg/l
Nitrate	50 mg/l, calculated as nitrate
Nitrite	0.02 mg/l (set as a quality limit, except for infants)
Selenium	0.01 mg/l

DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES²**CATEGORY I (RECOMMENDED TO THE COMMISSION FOR ADOPTION)****Food additives**

Acetone	Isobutanol
Aluminium powder	Methyl <i>p</i> -hydroxybenzoate
Calcium gluconate	Mineral oil (medium and low viscosity)
Calcium propionate	Petroleum jelly
Calcium sorbate	Polydextroses
Canthaxanthin	Polyglycitol syrup
Carnauba wax	Potassium gluconate
Carthamus red	Potassium sorbate
Carthamus yellow	Propane-2-ol
Diacetyltartaric and fatty acid esters of glycerol (DATEM)	Propionic acid
Dichloromethane	Propyl <i>p</i> -hydroxybenzoate
Ethyl <i>p</i> -hydroxybenzoate	Sodium carboxymethyl cellulose, enzymatically hydrolysed
Glucono <i>delta</i> -lactone	Sodium gluconate
Hexanes	Sulfur dioxide
Hexylresorcinol, 4-	

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

Flavouring agents

The substances under the following JECFA numbers:

No.	Name	No.	Name
139	Acetone	282	Hexanol, 3-
219	Hydroxybutyric acid lactone, 4-	283	Heptanone, 2-
220	Valerolactone, <i>gamma</i> -	284	Heptanol, 2-
221	Hydroxy-3-pentenoic acid lactone, 4-	285	Heptanone, 3-
222	ETHYL-3-HYDROXY-4-METHYL-2(5H)- FURANONE, 5-	291	Octanol, 3-
223	Hexalactone, <i>gamma</i> -	292	Nonanone, 2-
224	Hexalactone, <i>delta</i> -	293	Nonanol, 2-
225	Heptalactone, <i>gamma</i> -	294	Nonanone, 3-
226	Octalactone, <i>gamma</i> -	295	Decanol, 3-
227	Dibutyl- <i>gamma</i> -butyrolactone, 4,4-	296	UNDECANONE, 2-
228	Octalactone, <i>delta</i> -	297	Undecanol, 2-
229	Nonalactone, <i>gamma</i> -	298	Tridecanone, 2-
230	Hydroxynonanoic acid <i>delta</i> -lactone	301	Methyl-2-pentanone, 4-
231	Decalactone, <i>gamma</i> -	302	Dimethyl-4-heptanone, 2,6-
232	Decalactone, <i>delta</i> -	303	Dimethyl-4-heptanol, 2,6-
233	Undecalactone, <i>gamma</i> -	305	Isopropyl acetate
234	Hydroxyundecanoic acid lactone, 5-	307	Isopropyl butyrate
235	Dodecalactone, <i>gamma</i> -	309	Isopropyl isobutyrate
236	Dodecalactone, <i>delta</i> -	310	Isopropyl isovalerate
237	Hydroxy-3,7-dimethyloctanoic acid lactone, 6-	311	Isopropyl myristate
238	Tetradecalactone, <i>delta</i> -	312	Isopropyl tiglate
240	Hexadecenlactone, <i>omega</i> -6-	313	Octyl acetate, 3-
242	Dodecalactone, <i>epsilon</i> -	314	Pentenoic acid, 4-
243	Dimethyl-3-hydroxy-2,5-dihydrofuran-2- one, 4,5-	315	Hexen-1-ol, <i>cis</i> -3-
245	Hydroxy-2,4-decadienoic acid <i>delta</i> - lactone, 5-	318	Hexen-1-ol, 4-
246	Hydroxy-2-decenoic acid <i>delta</i> -lactone	320	Heptenal, <i>cis</i> -4-
250	Methyldecylaldehyde, <i>gamma</i> -	321	Octen-1-ol, <i>cis</i> -3-
251	Isobutyl alcohol	322	Octen-1-ol, <i>cis</i> -5-
252	Isobutyraldehyde	323	Octenal, <i>cis</i> -5-
253	Isobutyric acid	324	Nonen-1-ol, <i>cis</i> -6-
254	Methylbutyraldehyde, 2-	325	Nonenal, <i>cis</i> -6-
255	Methylbutyric acid, 2-	326	Decenal, 4-
256	Ethylbutyraldehyde, 2-	328	DECENOIC ACID, 9-
257	Ethylbutyric acid, 2-	330	Undecenal, 10-
258	Methylbutyraldehyde, 3-	331	Undecenoic acid, 10-
259	Isovaleric acid	332	Linoleic acid
261	Methylvaleric acid, 2-	335	Ethyl 3-hexenoate
262	Methylpentanoic acid, 3-	336	Hexenyl <i>cis</i> -3-hexenoate, <i>cis</i> -3-
263	Methyl-1-pentanol, 3-	343	Ethyl 10-undecenoate
264	Methylpentanoic acid, 4-	345	Ethyl oleate
265	Methylhexanoic acid, 2-	346	Methyl linoleate & methyl linolenate, mixture
266	Methylhexanoic acid, 5-	349	DIMETHYL-5-HEPTENAL, 2,6-
267	ETHYL-1-HEXANOL, 2-	351	Ethyl 2-methyl-4-pentenoate
268	Trimethyl-1-hexanol, 3,5,5-	354	Methyl 3,7-dimethyl-6-octenoate
269	Trimethylhexanal, 3,5,5-	355	Methyl-4-pentenoic acid, 2-
272	Dimethyl-1-octanol, 3,7-	356	Linalool
274	Methylnonanoic acid, 4-	357	Tetrahydrolinalool
275	Methylundecanal, 2-	358	Linalyl formate
277	Isopropyl alcohol	359	Linalyl acetate
278	Butanone, 2-	360	Linalyl propionate
279	Pentanone, 2-	361	Linalyl butyrate
280	Pentanol, 2-	362	Linalyl isobutyrate
363	Linalyl isovalerate	415	Heptanedione, 2,3-
364	Linalyl hexanoate	419	Ethylcyclopentenolone
366	Terpineol, <i>alpha</i> -	420	Dimethyl-1,2-cyclopentanedione, 3,4-

367	Terpinyl formate	422	Ethyl-2-hydroxy-4-methylcyclopent-2-en-1-one, 3-
368	Terpinyl acetate	423	Ethyl-2-hydroxy-3-methylcyclopent-2-en-1-one, 5-
369	Terpinyl propionate	425	Methyl-2,3-cyclohexadione, 1-
375	Menthan-2-one, <i>p</i> -		
378	Dihydrocarveol	426	Hydroxy-3,5,5-trimethyl-2-cyclohexen-1-one, 2-
379	DIHYDROCARVYL ACETATE	427	Menthol
380a	Carvone, (+)-	429	Menthone
380b	Carvone, (-)-	430	Isomenthone, (±)-
381	Carveol	431	Menthyl acetate
382	Carvyl acetate	432	Menthyl isovalerate
384	Damascone, <i>beta</i>	433	Menthyl lactate, (-)-
385	Damascone, <i>alpha</i> -	435	Piperitone
386	Damascone, <i>delta</i> -	437	Hydroxy-3-methyloctanoic acid <i>gamma</i> -lactone, 4-
387	Damascenone	439	Carvonementhenol, 4-
388	Ionone, <i>alpha</i> -	443	Menthol ethylene glycol carbonate, (-)-
389	Ionone, <i>beta</i> -	444	Menthol 1- & 2-propylene glycol carbonate, (-)-
391	Ionol, <i>alpha</i> -	445	Menthone 1,2-glycerol ketal, (-)-
393	Dihydro- <i>alpha</i> -ionone	446	Menthone 1,2-glycerol ketal, (±)-
395	Dihydro- <i>beta</i> -ionol	447	Menthyl succinate, mono-
399	Methyl- <i>beta</i> -ionone	448	Ethylhexyl tiglate, 1-
401	Allyl- <i>alpha</i> -ionone	450	Furfural
403	Irone, <i>alpha</i> -		
404	Methylionone, <i>alpha</i> - <i>iso</i> -		
405	Acetoin		
408	Diacetyl		
410	Pentadione, 2,3-		
412	HEXANEDIONE, 2,3-		
413	Hexanedione, 3,4-		
415	Heptanedione, 2,3-		

CATEGORY II

(RECOMMENDED FOR ADOPTION AFTER EDITORIAL CHANGES, INCLUDING TECHNICAL REVISIONS)

Food Additives

Gum arabic

Editorial changes:

1. Under "Synonyms" delete Gum hashab, kordofan gum and Gum talha
2. Under "Definition" delete last sentence (Gums from other *Acacia* species are not included in these specifications)
- 3-4. Under "Description" delete fourth and fifth indent, i.e. sentences referring to immunological differentiation and technological interchangeability, respectively

Flavouring agents

None

**PROPOSED AMENDMENTS TO THE INTERNATIONAL NUMBERING
SYSTEM FOR FOOD ADDITIVES**

(At Step 5 of the Accelerated Procedure)

INS NUMBER	COMPOUND	TECHNOLOGICAL FUNCTION
938	Argon	Packing Gas
939	Helium	Packing Gas
948	Oxygen	Packing Gas

**PROPOSED DRAFT AMENDMENT TO THE INTERNATIONAL NUMBERING
SYSTEM FOR FOOD ADDITIVES**

(At Step 3 of the Accelerated Procedure³)

INS NUMBER	COMPOUND	TECHNOLOGICAL FUNCTION
586	4-Hexylresorcinol	Colour Retention Agent, Antioxidant
440	Pectins	Thickener, Stabilizer, Gelling Agent, <u>Emulsifier</u>

³ Subject to approval by the Commission

**PROPOSED DRAFT MAXIMUM LEVEL FOR PATULIN
(At Step 5 of the Procedure)**

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

**PROPOSED DRAFT MAXIMUM LEVEL FOR TIN
(At Step 5 of the Procedure)**

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

**PROPOSED DRAFT MAXIMUM LEVEL FOR OCHRATOXIN A
(At Step 3 of the Procedure)**

Ochratoxin A 5 µg/kg in cereals and cereal products

**DRAFT GUIDELINE LEVEL FOR CADMIUM IN FOOD
(At Step 6 of the Procedure)**

Food	ML (mg/kg)
CEREALS, PULSES and LEGUMES	0.1

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

Food	ML (mg/kg)
Fruit	0.05
Vegetables, including potatoes (edible part)	0.05
Leafy Vegetables	0.2
Wheat Grain and Rice	0.2
Soybeans and Peanuts	0.2
Meat of Cattle, Poultry, Pig and Sheep	0.05
Meat of Horse	0.2
Liver of Cattle, Poultry, Pig and Sheep	0.5
Kidney of Cattle, Poultry, Pig and Sheep	1.0
Crustaceae	0.5
Molluscs	1.0

ACTION REQUIRED AS A RESULT OF CHANGES IN ADI STATUS OR OTHER TOXICOLOGICAL RECOMMENDATIONS

Substance	Previous ADI and other toxicological recommendations	Present ADI and other toxicological recommendations	Current Codex Uses ¹	Notes
Enzyme preparations <i>alpha</i> -Acetolactate decarboxylase Maltogenic amylase	Not specified (temporary) Not specified (temporary)	Not specified Not specified	None None	Full ADI established Full ADI established
Flavouring agent <i>trans</i> -Anethole Furfural Menthol	0 - 0.6 mg/kg bw (Temporary) No ADI allocated 0 – 0.2 mg/kg bw	0 - 2 mg/kg bw No ADI allocated ² 0 – 4 mg/kg bw	None None None	ADI increased No action required ADI increased
Food colours Curcumin Riboflavin from genetically modified <i>Bacillus subtilis</i>	0 – 0.1 mg/kg bw (temporary) -	0 – 1 mg/kg bw (temporary) ³ 0 – 0.5 mg/kg bw (group ADI with synthetic riboflavin and riboflavin-5'-phosphate)	Edible fats and oils; Margarine; Minarine; Mayonnaise; Bouillons and consomes; Butter and whey butter; Processed cheeses; Processed cheese preparations <i>Riboflavin</i> : Bouillons and consomes; Pickle cucumbers; Processed cheese preparations; Processed cheeses; Tilsiter; Limburger; Butterkäse; Romadur; Edelpilzkäse	Temporary ADI increased No action required
Glazing agent Mineral oil (medium- and low-viscosity) Class I ⁴ Class II ⁶ and Class III ⁷	0 – 1 mg/kg bw (temporary) 0 – 0.01 mg/kg bw (temporary group ADI)	0 – 1 mg/kg bw (temporary) ⁵ 0 – 0.01 mg/kg bw (temporary group ADI) ⁵	raisins	No action required No action required

¹ Only in those adopted standards.

² Data were insufficient for establishing an ADI.

³ Results of a study of reproductive toxicity on a substance complying with the specifications for curcumin and information on the need and technological justification for alternative solvents for use in the current manufacturing processes of curcumin are required for evaluation in 2001.

⁴ Including P70(H) oil.

⁵ Information requested at the 44th meeting of the Committee is required for evaluation in 2002. This includes information about the compositional factors in mineral oils that influence their absorption and toxicity and a study in F344 rats of at least one year duration with a reversal period of one year. In addition, research on the pharmacokinetics of mineral oils and their potential effects on immune function know to be in progress should be submitted for review at that time.

⁶ Including N70(H) and N70(A) oils.

⁷ Including P15(H), N15(H) and N10(A) oils.

Substance	Previous ADI and other toxicological recommendations	Present ADI and other toxicological recommendations	Current Codex Uses ¹	Notes
Preservatives Calcium hydrogen sulphite Calcium metabisulphite Calcium sulphite Potassium hydrogen sulphite Potassium metabisulphite Potassium sulphite Sodium hydrogen sulphite Sodium metabisulphite Sodium sulphite Sodium thiosulphite	0 – 0.7 mg/kg bw (group ADI)	0 – 0.7 mg/kg bw (group ADI) ⁸	Jams and jellies - - Quick frozen French-fried potatoes; Concentrated pineapple juice with preservatives; Quick frozen lobsters Quick frozen French-fried potatoes; Mango chutney; Quick frozen lobsters; Quick frozen shrimps and prawns Quick frozen French-fried potatoes; Concentrated pineapple juice with preservatives; Quick frozen lobsters; Quick frozen shrimps and prawns Quick frozen French-fried potatoes; Concentrated pineapple juice with preservatives Quick frozen French-fried potatoes; Mango chutney; Quick frozen lobsters; Quick frozen shrimps and prawns Quick frozen French-fried potatoes; Concentrated pineapple juice with preservatives; Quick frozen lobsters; Quick frozen shrimps and prawns -	Group ADI maintained.

⁸ The Committee reiterated its recommendation made at the 30th meeting that, when a suitable alternative method of preservation exists, its use should be encouraged, particularly in those applications (e.g. control of enzymic browning in fresh salad vegetables) in which the use of sulphites may lead to high levels of acute exposure and which have most commonly been associated with life-threatening adverse reactions. Appropriate labelling would help to alert individuals who cannot tolerate sulphites.

Substance	Previous ADI and other toxicological recommendations	Present ADI and other toxicological recommendations	Current Codex Uses ¹	Notes
Sulphur dioxide			White sugar; Powdered sugar; Fructose; Powdered dextrose; Dextrose anhydrous; Dextrose monohydrate; Soft sugars; Glucose syrup; Dried glucose syrup; Canned chestnuts; Pickled cucumbers; Raisins; Dried apricots; Jams and jellies; Citrus marmalade; Vinegar; Wheat flour; Concentrated pineapple juice with preservatives	
Sweetening agent Stevioside	-	No ADI allocated ⁹	None	No action required
Thickening agents Carrageenan	Not specified	Not specified (group ADI; temporary) ¹⁰	GSFA Table 3 ¹¹ ; Canned green and wax beans; Canned sweet corn, Canned mushrooms, Canned asparagus, Canned green peas; Canned palmito; Pickled cucumbers; Canned carrots; Processed cheese preparations; Cottage cheese; Cream cheese; Flavoured yoghurt and products heat-treated after fermentation; Cream; Evaporated milks; Minarine; Mayonnaise; Infant formula, Follow up formula; Bouillons and consommés; Quick frozen blocks of fish fillet, minced fish flesh and mixture of fillets and minced fish flesh; Quick frozen fish sticks, fish portions and fish fillets-breaded or in batter; Canned finfish; Canned sardines and sardine-type products; Canned tuna and canned bonito	New temporary group ADI

⁹ An ADI could not be established because the data were insufficient and because specifications were not prepared.

¹⁰ Clarification of the significance of the promotion of colon cancer observed in experiments in rats is required for evaluation in 2001.

¹¹ Additives Permitted for Use In Food In General, Unless Otherwise Specified, In Accordance with GMP

Substance	Previous ADI and other toxicological recommendations	Present ADI and other toxicological recommendations	Current Codex Uses ¹	Notes
Processed <i>Eucheuma</i> seaweed	0 – 20 mg/kg bw (temporary)		None	
Sodium carboxymethyl cellulose, enzymatically hydrolyzed	-	Not specified (group ADI) ¹²	Na CMC: GSFA Table 3 ¹³ ; Mayonnaise; Minarine; Bouillons and consommés; Cottage cheese, Flavoured yoghurt and products heat-treated after fermentation; Cream; Processed cheese preparations; Quick frozen blocks of fish fillet, minced fish flesh and mixture of fillets and minced fish flesh; Quick frozen fish sticks, fish portions and fish fillets-breaded or in batter; Canned finfish; Canned sardines and sardine-type products; Canned tuna and canned bonito	
Miscellaneous substances gamma-cyclodextrin	-	Not specified (temporary)	None	
Glucono delta-lactone	Not specified		GSFA Table 3 ¹⁷ ; Luncheon meat, Cooked cured chopped meat	New group ADI (no change for glucono delta-lactone)
Calcium gluconate	0 – 50 mg/kg bw ¹⁴	Not specified (group ADI)		
Magnesium gluconate	0 – 50 mg/kg bw ^{14,15}			
Potassium gluconate	0 – 50 mg/kg bw ^{14,16}			
Sodium gluconate	0 – 50 mg/kg bw ^{14,16}			
Polyglycitol syrup	-	Not specified ¹⁸	None	

¹² Included in the group ADI for modified celluloses: ethyl cellulose, ethylhydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, methyl cellulose, methyl ethyl cellulose and sodium carboxymethyl cellulose.

¹³ Additives Permitted for Use In Food In General, Unless Otherwise Specified, In Accordance with GMP

¹⁴ Also includes the free acid

¹⁵ Intake limited by laxative action.

¹⁶ No restriction provided that the contribution made to food is assessed and considered acceptable.

¹⁷ Additives Permitted for Use In Food In General, Unless Otherwise Specified, In Accordance with GMP

¹⁸ Group ADI for materials conforming to the specifications for polyglycitol syrup and maltitol syrup.

**FOOD ADDITIVES AND CONTAMINANTS PROPOSED
FOR EVALUATION BY JECFA**

***Food additives for toxicological evaluation
and development of specifications***

Proposed by

aspartame-acesulfame salt	Netherlands
benzoyl peroxide	CCFAC
cochineal extract, carmine, and carminic acid (potential allergenicity)	Canada
cross-linked sodium carboxymethyl cellulose	Netherlands
flavouring agents	United States
lycopene	Netherlands
nitrous oxide	CCFAC
calcium in food additives	Canada
stearyl tartrate	CCFAC
d-tagatose	Denmark
trehalose	United Kingdom
food additives removed earlier from the GSFA	CCFAC

Contaminants and naturally occurring toxins

ochratoxin A	United States
cadmium	Japan, United States
dioxins and dioxin-like PCBs	CCFAC
fumonisin	United States, IPCS
chloropropanols	United States
ethyl carbamate	CCFAC
glycyrrhizic acid	Denmark
nitrate	Netherlands
phenylhydrazines (including agaritine)	Denmark
polycyclic aromatic hydrocarbons	Denmark, Netherlands, Canada
tin (acute reference dose)	CCFAC
trichothecenes (including T2 and DON)	Netherlands, China

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel.: 57051 Telex: 625825-625853 FAO Email: codex@fao.org Facsimile: 3906.5705.4593

ALINORM 99/12A
Corrigendum

Report of the 31st Session of the Codex Committee on Food Additives and Contaminants

Appendix II - Draft General Standard for Food Additives

Additives Permitted for use under Specified Conditions in Certain Food Categories or Individual Food Items

The following section was omitted and should be included in the Appendix:

STEARYL CITRATE

Stearyl Citrate

INS: 484

Function: Antifoaming Agent, Emulsifier, Sequestrant

Food Cat. No.	Food Category	Max Level	Comments
02.1	Fats and oils essentially free from water	GMP	
02.2.1.2	Margarine and similar products (e.g., butter-margarine blends)	100 mg/kg	Note 15
05.3	Chewing gum	15000 mg/kg	
14.1.4	Water-based flavoured drinks, including "sport" or "electrolyte"	500 mg/kg	