



**REP12/FA**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX ALIMENTARIUS COMMISSION**

*Thirty fifth Session  
Rome, Italy, 2-7 July 2012*

## **REPORT OF THE FORTY-FOURTH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES**

*Hangzhou, China  
12 – 16 March 2012*

NOTE: This report contains Codex Circular Letter CL 2012/5-FA



**Food and Agriculture  
Organization of  
the United Nations**



**World Health  
Organization**

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**CL 2012/5-FA  
March 2011**

**To:** Codex Contact Points  
Interested International Organizations

**From:** Secretariat,  
Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme  
Viale delle Terme di Caracalla  
00153 Rome, Italy

**Subject:** **Distribution of the Report of the Forty-fourth Session of the Codex Committee on Food Additives (REP12/FA)**

The report of the Forty-fourth Session of the Codex Committee on Food Additives will be considered by the 35<sup>th</sup> Session of the Codex Alimentarius Commission (Rome, Italy, 2-7 July 2012).

## **PART A – MATTERS FOR ADOPTION BY THE 35<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION**

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

- 1. Food additive provisions of the *General Standard for Food Additives (GSFA)*, at Steps 8 and 5/8, respectively (para. 131 and Appendix VI);**
- 2. Draft revision of the *Standard for Food Grade Salt (CODEX STAN 150-1985) (N08-2010)*, at Step 5 (para. 136 and Appendix XI);**
- 3. Proposed draft amendments to the *International Numbering System for Food Additives*, at Step 5/8 (para. 152 and Appendix XII);**
- 4. Proposed draft *Specifications for the Identity and Purity of Food Additives*, at Step 5/8 (para. 156 and Appendix XIII).**

### **Other matters for adoption**

- 5. Risk Analysis Principles Applied by the Codex Committee on Food Additives (para. 21 and Appendix II);**
- 6. Revision of the names and descriptors of food category 16.0 and 12.6.1 of the GSFA (para. 114 and Appendix X).**

Governments and international organizations wishing to submit comments on the above texts should do so in writing, *preferably by e-mail*, to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: [codex@fao.org](mailto:codex@fao.org), fax : +39 06 57054593) **before 15 May 2012**.

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

- 7. Comments at Step 3 on the provisions for aspartame-acesulfame salt (INS 962) of the GSFA (para. 22 and Appendix IX, Part 1);**
- 8. Proposals for new provisions for nisin (INS 234) in 08.0 “Meat and meat products, including poultry and game” sub-categories of the GSFA (para. 80);**
- 9. Proposals for new food additive provisions in food category 16.0 “Prepared foods” of the GSFA (para. 115);**
- 10. Proposals for new additive provisions and/or revision of food additive provisions of the GSFA (para. 87);**

Governments and international organizations wishing to submit comments and information on the above matters should do so in writing according to the *Procedure for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additive* (Procedural Manual of the Codex Alimentarius Commission), *preferably by e-mail*, to the Secretariat of the Codex Committee on Food Additives, China National Center for Food Safety Risk Assessment (CFSA), 7 Panjiayuan Nanli, Chaoyang District, Beijing 100021, China (e-mail: [secretariat@ccfa.cc](mailto:secretariat@ccfa.cc), Telefax: + 86 10 67711813;), with a copy to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: [codex@fao.org](mailto:codex@fao.org), *preferably*; fax : +39 06 57054593) **before 15 October 2012**.

## TABLE OF CONTENTS

SUMMARY AND CONCLUSIONS .....	page v
LIST OF ABBREVIATIONS .....	page vii
REPORT OF THE 44 <sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES .....	page 1
SUMMARY STATUS OF WORK .....	page 23
	<b>Paragraph</b>
Introduction .....	1
Opening of the Session .....	2 - 4
Adoption of the agenda (Agenda Item 1) .....	5 - 7
Matters referred by the Codex Alimentarius Commission and other Codex Committees and Task forces (Agenda Item 2) .....	8 - 13
Draft Risk analysis principles applied by the CCFA (Agenda Item 2a) .....	14 - 21
Matters of Interest arising from FAO/WHO and from the 74 <sup>th</sup> Meeting of the Joint FAO/WHO expert committee on food additives (JECFA) (Agenda Item 3) .....	22 - 38
Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards (Agenda Item 4a) .....	39 - 46
Discussion paper on the alignment of the food additive provisions of the standards for meat products and relevant provisions of the GSFA (Agenda Item 4b) .....	47 - 59
Pending draft and proposed draft food additive provisions of the GSFA; Comments and information on several food additives; Draft and proposed draft food additive provisions (Provisions in Tables 1 and 2 of Table 3 food additives with “acidity regulator” and “emulsifier, stabilizer and thickener” function; Provisions for aluminium containing food additives (Agenda Items 5a, 5b, 5c and 5d) ...	60 - 104
Revision of the name and descriptors of food category 16.0 (Agenda Item 5e) .....	105 - 115
Discussion paper on use of note 161 (Agenda Item 5f) .....	116 - 130
General conclusion for Agenda Item 5 .....	131 - 135
Draft revision of the <i>Codex Standard for Food Grade Salt</i> (CODEX STAN 150-1985)(N08-2010) (Agenda Item 6) .....	136 - 141
Proposals for addition and/or amendments to the <i>International Numbering System for Food Additives</i> (Agenda Item 7) .....	142 - 152
Specifications for the identity and purity of food additives arising from the 74 <sup>th</sup> JECFA Meeting (Agenda Item 8) .....	153 - 156
Proposals for additions and changes to the priority list of compounds proposed for evaluation by JECFA (Agenda Item 9a) .....	157 - 163
Discussion paper on mechanisms for re-evaluation of substances by JECFA (Agenda Item 9b) .....	164 - 172
Prototype of a database for processing aids (Agenda Item 10) .....	173 - 184
Other business and future work (Agenda Item 11) .....	185
Date and place of the next session (Agenda Item 12) .....	186

## LIST OF APPENDICES

<b>Appendix I:</b>	List of Participants .....	24
<b>Appendix II:</b>	Risk Analysis Principles Applied by the Codex Committee on Food Additives .....	42
<b>Appendix III:</b>	Action Required as a Result of Changes in the Acceptable Daily Intake (ADI) Status and other Toxicological Recommendations arising from the 74 <sup>th</sup> JECFA .....	45
<b>Appendix IV:</b>	Status of Endorsement and/or Revision of Maximum Levels of Food Additives and Processing Aids in Commodity Standards .....	46
<b>Appendix V:</b>	Decision-Tree for the Recommended Approach to Alignment of the GSFA and Commodity Standards Food Additive Provisions .....	48
<b>Appendix VI:</b>	Codex <i>General Standard for Food Additives</i> - Draft and proposed draft food additive provisions (for adoption at Step 8 and Step 5/8 of the Procedure) .....	49
<b>Appendix VII:</b>	Codex <i>General Standard for Food Additives</i> – Revocation of food additive provisions (for approval) .....	59
<b>Appendix VIII:</b>	Codex <i>General Standard for Food Additives</i> – Discontinuation of work on draft and proposed draft food additive provisions (for information) .....	61
<b>Appendix IX:</b>	Codex <i>General Standard for Food Additives</i> – New provisions (Step 3 and Step 4) .....	73
<b>Appendix X:</b>	Codex <i>General Standard for Food Additives</i> – Revised Titles and Descriptors of Food categories 16.0 and 12.6.1 (for adoption) .....	75
<b>Appendix XI:</b>	Draft revision of the Codex <i>Standard for Food Grade Salt</i> (CODEX STAN 150-1985) (for adoption at Step 8 of the Procedure) .....	76
<b>Appendix XII:</b>	Proposed draft Amendments to the <i>International numbering system of food additives</i> (for adoption at Step 5/8 of the Procedure) .....	82
<b>Appendix XIII:</b>	Proposed draft <i>Specifications for the identity and purity of food additives</i> (for adoption at Step 5/8 of the Procedure).....	85
<b>Appendix XIV:</b>	Priority list of compounds proposed for evaluation by JECFA .....	86

## SUMMARY AND CONCLUSIONS

The Forty-fourth Session of the Codex Committee on Food Additives reached the following conclusions:

### Matters for Adoption/Consideration by the 35<sup>th</sup> Session of the Codex Alimentarius Commission

#### **Draft and proposed draft Standards and Related Texts for adoption at Steps 8 or 5/8**

The Committee forwarded:

- Draft and proposed draft food additive provisions of the *General Standard for Food Additives* (GSFA), for adoption at Steps 8 and 5/8 respectively (para. 131 and Appendix VI);
- Draft revision of the *Standard for Food Grade Salt* (CODEX STAN 150-1985), for adoption at Step 8 (para. 141 and Appendix XI);
- Proposed draft amendments to the *International Numbering System for Food Additives*, for adoption at Step 5/8 (para. 152 and Appendix XII); and
- Proposed draft *Specifications for the Identity and Purity of Food Additives*, for adoption at Step 5/8 (para. 156 and Appendix XIII).

#### **Other Matters for adoption**

The Committee forwarded:

- Risk Analysis Principles Applied by the Codex Committee on Food Additives (para. 21 and Appendix II); and
- Revision of the names and descriptors of food category 16.0 and 12.6.1 of the GSFA, for adoption (para. 114 and Appendix X).

#### **Codex Standard and Related Texts for revocation**

The Committee agreed to request the 35<sup>th</sup> Session of the Commission to revoke:

- *Information on the Use of Food Additives in Foods* (CAC/MISC 1-1989) (para. 13);
- Food additive provisions of the GSFA (paras 75, 83 and 88 and Appendix IV); and
- Specifications for Potassium bromate (INS 924a) (para. 156 and Appendix XIII).

#### **Other Matters for information by the 35<sup>th</sup> Session of the Codex Alimentarius Commission**

The Committee agreed:

- To discontinue work on a number of draft and proposed draft food additive provisions of the GSFA (para. 131 and Appendix VIII);
- To continue testing the decision-tree approach for the alignment of the food additives provisions in commodity standards and the GSFA and prepare a proposal for the revision of the food additive provisions of the five standards for processed meat and the relevant food categories of the GSFA (para. 59).

### Matters Referred to Codex Committees and Task Forces

All active commodity committees

- The Committee encourage commodity committees to accompany their proposals for endorsement with technological justification to facilitate the endorsement and reduce inconsistencies (para. 43).

Committee on Methods of Analysis and Sampling (CCMAS)

- The CCFA agreed to forward to the CCMAS the clarification regarding the need for methods for halogens in the *Standard for Food Grade Salt* (CODEX STAN 150-1985) (para. 139).

**LIST OF ABBREVIATIONS USED IN THIS REPORT**

ADI	Acceptable Daily Intake
bw	body weight
CAC	Codex Alimentarius Commission
CAC/GL	Codex Alimentarius Commission / Guidelines
CAC/MISC	Codex Alimentarius Commission / Miscellaneous
CCCF	Codex Committee on Contaminants in Foods
CCNEA	FAO/WHO Coordinating Committee for the Near East
CCFA	Codex Committee on Food Additives
CCFFP	Codex Committees on Fish and Fishery Products
CCGP	Codex Committee on General Principles
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committees on Nutrition and Food for Special Dietary Uses
CFSA	China National Center for Food safety Risk Assessment
CL	Circular Letter
CRD	Conference Room Document
EHC	Environmental Health Criteria
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GEGR	Glycerol esters of gum rosin
GETOR	Glycerol esters of tall oil rosin
GEWR	Glycerol esters of wood rosin
GIFSA	Global Initiative for Food-related Scientific Advice
GSFA	General Standard for Food Additives
GMP	Good Manufacturing Practice
INS	International Numbering System
IPA	Inventory of Substances Used as Processing Aids
JECFA	Joint FAO/WHO Expert Committee on Food Additives
ML	Maximum Level
PTWI	Provisional Tolerable Weekly Intake
WHO	World Health Organization
WTO	World Trade Organization

## INTRODUCTION

1. The Codex Committee on Food Additives (CCFA) held its Forty-fourth Session in Hangzhou (China) from 12 to 16 March 2012, at the kind invitation of the Government of the People's Republic of China. Dr Junshi Chen, Professor of the China National Center for Food Safety Risk Assessment (CFSA), Ministry of Health, chaired the Session. The Session was attended by: 211 delegates from 51 Member countries; one Member organization; Observers from 29 international organizations; FAO and WHO. The list of participants, including the Secretariat, is given in Appendix I to this report.

## OPENING OF THE SESSION

2. Dr Xiaohong Chen, Vice-Minister of Health, welcomed the participants on behalf of the Minister of Health of the People's Republic of China.

3. The Vice-Minister informed the Committee that the Chinese Government had given a high priority to food safety and had taken a series of measures to enhance food safety since the entry in force of the "Food Safety Law". The measures included improving the legal framework for food safety, performing comprehensive food safety controls, accelerating the development and implementation of national food safety standards, and further increasing active participation in Codex activities. The Vice-Minister emphasised that China, as host country of the CCFA and elected member of the Executive Committee of the Codex Alimentarius Commission, would continue to take an active part in promoting food safety, trade and technical cooperation at the international level.

## Division of Competence

4. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

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

5. The Committee agreed to consider a proposal of the Delegation of Brazil to include a new provision for ascorbyl palmitate (INS 304) in the *General Standard for Food Additives* (GSFA) (CRD 18) under Agenda Item 5. With this modification, the Committee adopted the Provisional Agenda as its Agenda for the Session.

6. The Committee agreed to establish in-session Working Groups, open to all interested members and observers and working in English only, on:

- Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards (Agenda Item 4a), chaired by Australia;
- The International Numbering System (INS) for food additives (Agenda Item 7), chaired by Iran; and
- The priority list of substances proposed for evaluation by JECFA (Agenda Item 9a), chaired by the Canada.

7. The Committee agreed to discuss the Agenda Items in the following order: 1, 2, 2a, 3, 8, 4b, 10, 5e, 5f, 5a, 5b, 5c, 5d, 4a, 6, 7, 9a, 9b and 11.

## MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES (Agenda Item 2)<sup>2</sup>

8. The Committee noted the information presented in CX/FA 12/44/2 concerning the decisions and discussions of the Commission, the Executive Committee and other Codex committees related to its work.

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<sup>1</sup> CX/FA 12/44/1

<sup>2</sup> CX/FA 12/44/2; CRD 6 (Unsolicited comments of Brazil, India, Indonesia, Japan, Kenya and Philippines)

9. In particular the Committee commented and/or made decisions as follows:

**Revocation / revision of: *Information on the Use of Food Additives in Foods* (CAC/MISC 1-1989) and the *Guidelines for the Evaluation of Food Additive Intakes* (CAC/GL 3-1989)**

10. The Secretariat recalled that the 34<sup>th</sup> Session of the Commission had requested the Committee to consider the need to revoke or revise these 1989 texts.

11. The Committee agreed to revoke the *Information on the Use of Food Additives in Foods* (CAC/MISC 1-1989), as its content was already included in the Preamble of the *General Standard for Food Additives* (GSFA).

12. The Committee was of the view that the *Guidelines for the Evaluation of Food Additive Intakes* (CAC/GL 3-1989) contained useful guidance for countries to assess food additive intakes and that it should be revised taking into account the FAO/WHO *Principles and Methods for the Risk Assessment of Chemicals in Foods* (EHC 240).

**Conclusion**

13. The Committee recommended to the 35<sup>th</sup> Session of the Commission to revoke the *Information on the Use of Food Additives in Foods* (CAC/MISC 1-1989). It further agreed to establish an electronic Working Group, led by Brazil and open to all interested Members and Observers and working in English only, to prepare a project document for new work in the revision of the *Guidelines for the Evaluation of Food Additive Intakes* (CAC/GL 3-1989) and possibly including an outline of the revised Guidelines, for consideration at its next Session.

**DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CCFA (Agenda Item 2a)<sup>3</sup>**

14. The Committee recalled that it had agreed at its 43<sup>rd</sup> Session that separate risk analysis principles for the CCFA and the Codex Committee on Contaminants in Foods (CCCF) would be useful to allow the texts to develop independently in accordance with the needs of each Committee. Therefore, the Committee had requested that the Codex Secretariat prepare draft Risk analysis principles applied by the CCFA, by deleting any reference to the CCCF in the current risk analysis principles document, for consideration at this session.

15. The Committee noted that the document, prepared with the assistance of the JECFA Secretariat, did not intend to change the risk assessment principles of the CCFA and included three types of amendments: (i) deletion of references to the CCCF and of paragraphs that were specific to the CCCF; (ii) editorial amendments to improve the readability of the text; and (iii) editorial amendments to ensure consistency with other Codex texts on risk analysis and with JECFA current procedures. The Committee noted that any further revision of the text were outside the scope of this work.

16. The Committee agreed with all amendments concerning deletion of the references to the CCCF and improving the readability of the text; and noted that inconsistencies between the Spanish and English version would be removed.

17. The Committee considered the other amendments in detail as follows:

**Section 1 – Scope**

18. The Committee did not support the proposal of one delegation to delete the last sentence of paragraph 1 because it would preclude the CCFA seeking advice from other internationally recognised expert bodies or FAO/WHO *ad hoc* consultations for matters that did not fall within the JECFA's terms of reference.

**Section 3 – CCFA**

19. The Committee agreed to replace the “temporary” definition of safety assessment in the footnote with the one included in the glossary of FAO/WHO *Principles and Methods for the Risk Assessment of Chemicals in Foods* (EHC 240); and to retain paragraph 22<sup>4</sup>, as it reflected CCFA's requests to JECFA to consider different scenarios and for consistency with other Codex texts on risk analysis.

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<sup>3</sup> CX/FA 12/44/3 Rev; CRD 6 (Unsolicited comments of Brazil, India, Indonesia, Japan, Kenya and Philippines)

<sup>4</sup> Paragraph 19 in Appendix II to this report



20. Noting that risk assessment could encompass safety assessment, the Committee agreed to the proposal to refer throughout the text to “risk assessment”.

### **Conclusion**

21. The Committee agreed to forward the *Risk Analysis Principles applied by the Committee on Food Additives* (see Appendix II) to the 35<sup>th</sup> Session of the Commission for adoption and inclusion in the Procedural Manual, through the Committee on General Principles (CCGP).

### **MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE 74<sup>th</sup> MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 3)<sup>5</sup>**

22. The Representatives of FAO and WHO, while referring to CX/FA 12/44/4 and CX/FA 12/44/4 Add.1, informed the Committee on the activities in scientific advice to Codex and to Member countries, including the results and recommendations of the 74<sup>th</sup> meeting of JECFA (Rome, Italy, 14-23 June 2011).

#### **FAO and WHO activities**

23. The Representatives of FAO and WHO informed the Committee on the recent accomplishments in the area of scientific advice, in particular of the Joint FAO/WHO *ad hoc* Expert Meeting on Dietary Exposure Assessment for Veterinary Drugs Residues in food, held in conjunction with the 75<sup>th</sup> JECFA meeting for residues of veterinary drugs in food (Rome, 8-17 November 2011). The Committee also noted that the guidance for addressing emergency risk assessment activities, developed by a joint FAO/WHO Workshop (Rome, March 2011) was now available at: <http://www.fao.org/docrep/014/ba0092e/ba0092e00.pdf>

24. The Representatives stressed the importance to ensure adequate financial resources for the FAO and WHO work on scientific advice and drew attention to the Global Initiative for Food Related Scientific Advice (GIFSA)<sup>6</sup> to facilitate provision of extra-budgetary resources for scientific advice activities to FAO and WHO members. The Committee noted that FAO and WHO were developing guidance to ensure that no undue influence would be made regarding specific risk assessment activities.

#### **74<sup>th</sup> meeting of JECFA**

25. The Joint Secretariat of JECFA presented the results of the 74<sup>th</sup> Meeting of JECFA and indicated that in addition to safety assessments of 12 food additives and specifications for 32 food additives the Meeting had also evaluated two contaminants.

#### **Actions required as a result of changes to Acceptable Daily Intake (ADI) status and other toxicological recommendations**

26. The Joint Secretariat of JECFA presented the recommendations in Table 1 of CX/FA 12/44/4 Add.1 for the food additives evaluated by the 74<sup>th</sup> Meeting of JECFA.

*Aluminium-containing food additives (including new food additives potassium aluminium silicate and potassium aluminium silicate-based pearlescent pigments)*

27. The Committee noted that JECFA had established a provisional tolerable weekly intake (PTWI) of 2 mg/kg for all aluminium containing food additives. The estimated mean dietary exposure to aluminium-containing food additives for adults are up to the PTWI and for children could exceed the PTWI by up to 2-fold.

28. The Committee noted that the 74<sup>th</sup> JECFA had prepared new tentative specifications for nine aluminium-containing food additives and agreed to request the in-session Working Group on INS to allocate an INS number for potassium aluminium silicate-based pearlescent pigments.

*Benzoe tonkinensis*

29. The Committee was informed that the available data were inadequate to establish an Acceptable Daily Intake (ADI) because of the variability in composition and the inadequate characterization of the material

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<sup>5</sup> CX/FA 12/44/4; CX/FA 12/44/4 Add.1

<sup>6</sup> Contact points FAO: Dominique Di Biase, [Dominique.DiBiase@fao.org](mailto:Dominique.DiBiase@fao.org); WHO: Angelika Tritscher, [tritschera@who.int](mailto:tritschera@who.int)

tested. The Committee encouraged the submission of requested data to finalize specifications to characterize the material tested.

*Glycerol ester of gum rosin (GEGR) (INS 445(i)); Glycerol ester of tall oil rosin (GETOR) (INS 445(ii)); and Glycerol ester of wood rosin (GEWR) (INS 445(iii))*

30. The Committee was informed that JECFA had withdrawn the group ADI for GEGR and GEWR and established a temporary group ADI of 0-12.5 mg/kg body weight, pending the submission of toxicity studies on GEGR, as well as additional compositional information on the GEWR from *Pinus elliottii*. The temporary group ADI would be withdrawn, if the requested information is not submitted by the end of 2012. JECFA was unable to complete the evaluation of GETOR because additional data were required to characterize the GETOR in commerce. JECFA noted that the information should be submitted by the end of 2012. The Committee encouraged submission of requested data to establish an ADI (or group ADI) for the three substances and information to characterize the material tested and data for specifications.

*Octenyl succinic acid (OSA) modified gum arabic (INS 423)*

31. The Joint Secretariat of JECFA informed the Committee that JECFA had deferred further evaluation of OSA modified gum arabic pending the submission of data, to be provided by the end of 2013; the existing temporary ADI “not specified” was retained. The Committee encouraged submission of requested information to complete evaluation and characterize the identity of the material tested.

*Polydimethylsiloxane (INS 900a)*

32. The Committee was informed that JECFA had withdrawn the temporary ADI of 0-0.8 mg/kg body weight per day and re-established the ADI of 0-1.5 mg/kg body weight established at its eighteenth meeting.

*Ponceau 4R (INS 124)*

33. The Committee noted that JECFA had concluded that the new data regarding ponceau 4R did not indicate a need to revise the existing ADI of 0-4 mg/kg body weight and that dietary exposure did not present a health concern. No action was required by CCFA.

*Pullulan (INS 1204)*

34. The Committee was advised that the dietary exposure to pullulan as a dietary fibre could reach 1g/kg body weight per day for children and 0.4 g/kg body weight per day for adults and gastrointestinal effects observed in humans should be taken into account when considering appropriate use levels. The Joint Secretariat of JECFA stressed that JECFA had assessed the safety and not the efficacy of pullulan used as a dietary fibre; and had maintained the previously established ADI “not specified” for food additive uses. No action is required by CCFA.

*Pullulanase from Bacillus deramificans expressed in Bacillus licheniformis*

35. The Committee was informed that JECFA had established an ADI “not specified” for pullulanase from *B. deramificans* expressed in *B. licheniformis* when used in the applications specified and in accordance with good manufacturing practice. The Committee recommended adding pullulanase from *B. deramificans* expressed in *B. licheniformis* to the database for processing aids when it would become available (see Agenda Item 10).

*Quinoline yellow (INS 104)*

36. The Committee was informed that JECFA had established a temporary ADI of 0-5 mg/kg body weight, pending submission of requested toxicological studies by the end of 2013, and had withdrawn the previously established ADI of 0-10 mg/kg body weight. Additional information on the composition of the product in commerce was required, in particular relating to the identity and purity of the unmethylated form of quinoline yellow. The Committee encouraged submission of requested information and information to characterize the product in commerce.

*Sunset Yellow FCF (INS 110)*

37. The Committee was informed that JECFA had established an ADI of 0-4 mg/kg body weight and had withdrawn the previous ADI of 0-2.5 mg/kg body weight. It was further noted that JECFA had concluded that dietary exposure to sunset yellow FCF did not present a health concern.

## Conclusion

38. The final recommendations regarding action required as a result of changes to the status of acceptable daily intake (ADI) and other toxicological recommendations are summarised in Appendix III.

## ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES AND PROCESSING AIDS IN CODEX STANDARDS (Agenda Item 4a)<sup>7</sup>

39. The Delegation of Australia, as Chair introduced the report of the in-session Working Group on Endorsement (CRD 3).

40. The Committee considered the recommendations of the Working Group as follows.

### 31<sup>st</sup> Session of the Committee on Fish and Fish Products (CCFFP)

*Standard for Fish Sauces* (CODEX STAN 302-2011)

41. The Committee endorsed the food additive provisions of the Standard, as amended by the Working Group, with the exception of the provision for tartrates, which should have a numeric Maximum Level, since these additives have a numerical ADI. The Committee recommended that the CCFFP consider a ML of 200 mg/kg (as tartaric acid), which was under consideration for food category 12.6.4 “Clear sauce (e.g. fish sauce)” of the *General Standard for Food Additives* (GSFA).

42. The Delegations of the European Union and Norway expressed a reservation concerning the provisions for caramel III – ammonia caramel (INS 150c) and caramel IV – sulfite ammonia caramel (INS 150d) because they had safety concerns.

43. The Committee encouraged the CCFFP and other commodity committees to cross-reference the GSFA in their standards, wherever possible, and to accompany their proposals for endorsement with technological justifications to facilitate the endorsement and reduce inconsistencies with the GSFA. The Committee encouraged all delegations to take an active role in promoting a better understanding of the GSFA and a better communication between commodity committees and the CCFA.

### 6<sup>th</sup> Session of the FAO/WHO Coordinating Committee for the Near East (CCNEA)

*Regional Standard for Halwa Tehenia (Near East)* (CODEX STAN 390-2011)

44. The Committee endorsed the food additive provisions of the Regional Standard, as proposed by the CCNEA.

### 33<sup>rd</sup> Session of the Committee on Nutrition and Food for Special Dietary Uses (CCNFSDU)

*Standard for Infant Formulas and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)

45. The Committee endorsed the provisions for sodium and potassium phosphates in the Standard, as amended by the in-session Working Group. The Committee noted that the endorsed provision for sodium and potassium phosphates was 45 mg/100 ml, as phosphorus.

## Conclusion

46. The status of the endorsement of food additive provisions is presented in Appendix IV.

## DISCUSSION PAPER ON THE ALIGNMENT OF THE FOOD ADDITIVE PROVISIONS OF THE STANDARDS FOR MEAT PRODUCTS AND RELEVANT PROVISIONS OF THE GSFA (Agenda Item 4b)<sup>8</sup>

47. The Committee recalled that the issue of the alignment of the food additive provisions of the standards for meat products with the relevant food categories of the GSFA had been discussed at its 42<sup>nd</sup> Session following a request from the Commission to revise the list of food additive provisions of these standards.

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<sup>7</sup> CX/FA 12/44/4; CRD 3 (Report of the in-session Working Group on Endorsement); CRD 7 (Unsolicited comments of Brazil; China, Egypt, European Union; India; Indonesia, Kenya and Thailand); CRD 22 (Comments of Ghana)

<sup>8</sup> CX/FA 12/44/6; CRD 8 (Unsolicited comments of European Union, India, Mali and Thailand); CRD 22 (Comments of Ghana)

Based on the outcome of an electronic Working Group, the 43<sup>rd</sup> Session had generally supported a decision-tree approach as a way to progressively achieve the goal to make the GSFA the single Codex reference for food additives, while ensuring that food additives were technologically justified and safe for use. The 43<sup>rd</sup> Session had established a new electronic Working Group to continue work on the decision-tree approach including a proposal for the revision of the food additive provisions of the five standards for processed meat.

48. The Delegation of Australia, as Chair of the Working Group, introduced the report in CX/FA 12/44/6 and said that the compromise approach proposed by the Working Group recognised that commodity standards had legitimate technical reasons for a reduced set of additive provisions but recognized also that, where possible, the relevant provisions of the GSFA should be used as default.

49. The Working Group proposed to include specific food additive provisions for commodities covered by Codex standards through footnotes in the GSFA. The notes would be added at the appropriate places to either allow or not allow certain food additives for the specific commodity. The specific food additive provisions in the commodity standards could then be deleted and replaced with the general reference to the GSFA, as described in the Codex Procedural Manual.

50. There was general consensus in the Working Group that it was not appropriate to automatically allow the addition of all Table 3 food additives to commodity standards. Two options were proposed: (i) To allow all Table 3 food additives currently listed in the commodity standard to be added at GMP (unless it has been established that it is technologically justified to restrict their use for the commodity) through the GSFA; and (ii) Allow all Table 3 food additives in the functional classes defined in the commodity standard to be used.

51. The Working Group had applied the revised decision-tree approach to the five meat standards and made proposals for the changes necessary in the GSFA.

## **Discussion**

### *Decision tree*

52. There was some concern that the approach proposed might lead to a proliferation of notes, however, the Delegation of Australia explained that this approach might also lead to the deletion of a number of notes aimed at preserving the identity of certain commodity standards and to the reduction of use of Note 161 (*see* Agenda Item 5f).

53. The Delegation of India, proposed to include a new box in the decision-tree (between boxes B and C) to address the case where a GSFA food category contains food additives, which are not permitted in the relevant commodity standard (*see* CRD 8). The purpose of the new box was to consider the inclusion of the relevant footnote (excluding the food additive for this commodity) only after checking if the use of the food additive in that commodity was justified. The Committee generally supported the proposal; however, it was of the opinion that this could be included when refining the decision-tree based on more experience with its application.

54. The Delegation of the European Union, proposed the inclusion of a statement allowing for flexibility in the use of the decision-tree, in particular to consider entries on a case-by-case basis when it was clear that adherence to the general approach would lead to a result, which was either not consistent with the intentions of a commodity committee or not consistent with the general principles for entry in the GSFA (*see* CRD 8). They also proposed some changes to language used in the boxes of the decision-tree to adapt it the terminology used in the GSFA and proposed a correction to the directions of the arrows from Box H to Boxes I and J. They also proposed that in case a food additive provision was contained in the commodity standard but not in the relevant food category of the GSFA, the process for inclusion of the food additive provision in the GSFA should be started. The Committee agreed to these changes.

55. The Committee concurred with the opinion of the Working Group that it was not appropriate to automatically allow the addition of all Table 3 food additives to commodity standards and supported option 1, which allows for all Table 3 food additives currently listed in a commodity standard to be added at GMP through the GSFA unless it was technologically justified to restrict their use for the commodity (Box I).

### *Alignment of the food additive provision of the five standards for meat with the GSFA*

56. The Committee considered the proposal of the electronic Working Group, as presented in the Annex to CX/FA 12/44/6.

57. The Committee overall agreed to the amendments to relevant provisions of the GSFA food categories but realized that more work was necessary, in particular on Table 3 food additives, and that the food additive sections of the five meat standards needed to be revised to make a general reference to the GSFA and provisions for flavourings, as recommended in the Procedural Manual.

### Conclusion

58. The Committee agreed that the decision-tree, as presented in Appendix V, should be used as tool by the CCFA for working on the alignment of commodity standards and the GSFA.

59. The Committee agreed to continue testing the decision-tree on the alignment of the food additive provisions of other commodity standards and established an electronic Working Group led by Australia, open to all members and observers and working in English only, to: (i) Finalise application of the decision tree approach to the five standards for meat and make relevant proposals for amendments to the GSFA and the commodity standards; (ii) Apply the decision-tree approach to the Codex *Standard for bouillons and consommés* (CODEX STAN 117-1981), as well as to the standards related to chocolate and cocoa products: *Standard for cocoa butters* (CODEX STAN 86-1981), *Standard for chocolate and chocolate products* (CODEX STAN 87-1981), *Standard for cocoa powders (cocoa) and dry mixtures of cocoa and sugars* (CODEX STAN 105-1981) and *Standard for cocoa (cacao) mass (cocoa/chocolate liquor) and cocoa cake* (CODEX STAN 141-1983) and prepare the relevant proposals for amending the GSFA and the commodity standards; and (iii) Further improve the decision-tree to taking into account the experience gained by applying it and the proposal of India.

**PENDING DRAFT AND PROPOSED DRAFT FOOD ADDITIVE PROVISIONS AND RELATED MATTERS OF THE GSFA (Agenda Item 5a)<sup>9</sup>; COMMENTS AND INFORMATION ON SEVERAL FOOD ADDITIVES (Agenda Item 5b)<sup>10</sup>; DRAFT AND PROPOSED DRAFT FOOD ADDITIVE PROVISIONS (PROVISIONS IN TABLES 1 AND 2 OF TABLE 3 FOOD ADDITIVES WITH “ACIDITY REGULATOR” AND “EMULSIFIER, STABILIZER AND THICKENER” FUNCTION (Agenda Item 5c)<sup>11</sup>; PROVISIONS FOR ALUMINIUM CONTAINING FOOD ADDITIVES OF THE GSFA (Agenda Item 5d)<sup>12</sup>**

60. The Delegation of the United States of America, as Chair introduced the report of the pre-session Working Group on the GSFA, as presented in CRD 2.

61. The Working Group had made recommendations on:

- Pending draft and proposed draft food additive provisions and related matters that had not been considered by the 43<sup>rd</sup> Session of the Committee due to time constraints, which were compiled in CX/FA 12/44/7 (Agenda Item 5a);
- Replies to CL 2011/4-FA, part B (points 9-11) and to CL 2011/17-FA concerning the provisions for carotenoids in food category 02.1.2 “vegetable oils and fats”, which were compiled in CX/FA12/44/8 (Agenda Item 5b); and
- Proposed horizontal approach for the consideration of the “acidity regulators” listed in Table 3 of the GSFA, which was presented in CX/FA 12/44/9 Add.1 (Agenda Item 5c);

62. Due to time constraints the Working Group could not complete its agenda, which also included: (i) the proposed horizontal approach for “emulsifiers, stabilizers and thickeners” listed in Table 3 (CX/FA 12/44/9 Add.1) (Agenda Item 5c); (ii) the draft and proposed draft provisions in Table 1 and Table 2 of the GSFA for “acidity regulators” and for “emulsifiers, stabilizers and thickeners”, listed in Table 3 of the GSFA (CX/FA

<sup>9</sup> CX/FA 12/44/7; CRD 2 (Report of physical Working Group on the GSFA); CRD 9 (Comments of Brazil, China, Costa Rica, European Union, India, Kenya, Philippines, Republic of Korea, FIVS, IADSA; IFU, NATCOL and OIV); CRD 20 (Comments of Indonesia); CRD 21 (Comments of Japan); CRD 23 (Comments of Malaysia); CRD 24 (Comments of Paraguay)

<sup>10</sup> REP11/FA App. IV and VII; CX/FA 12/44/8; CRD 10 (Comments of China and European Union); CRD 20 (Comments of Indonesia); CRD 23 (Comments of Malaysia)

<sup>11</sup> CX/FA 12/44/9; CX/FA 12/44/9 Add.1; CX/FA 12/44/9/Add.2 ; CRD 11 (Comments of China, European Union, India, Japan, FIVS, ICGMA, IFAC and SSMO)

<sup>12</sup> CX/FA 12/44/10; CX/FA 12/44/10 Add.1; CRD 12 (Comments of China, Colombia, India, Kenya and Thailand)

12/44/9), and comments submitted at Step 3 and Step 6, compiled in CX/FA 12/44/9 Add.2 and relevant CRDs (Agenda Item 5c); and (iii) the provisions for aluminium-containing food additives (CX/FA11/43/10; CX/FA12/44/10 Add.1) and relevant comments (Agenda Item 5d).

63. The Committee considered the recommendations and of the Working Group and took decisions and commented as follows:

### **Matters related to Agenda Item 5a**

#### **Recommendation 1 - Adoption: Tables 1 and 2**

64. The delegations of the European Union and Norway expressed their general reservation concerning the provisions for caramel III – ammonia caramel (INS 150c) and caramel IV – sulphite ammonia caramel (INS 150d) because they had safety concerns. The Delegation of the European Union also expressed general reservation for the use of colours in food categories related to cocoa based confectionary products, as they were concerned that this could mislead consumers.

(i) *Ammonium salts of phosphatidic acid* (INS 442)

65. The Committee amended Note P to replace “formulation” with “fermentation”.

(ii) *Caramel III – ammonia caramel* (INS 150c)

66. The Committee noted that the proposed provisions for caramel III were revisions of adopted provisions, to replace current GMP levels with numerical levels.

(iii) *Para-hydroxybenzoates* (INS 214, 218)

67. Several delegations were concerned that the provision for para-hydroxybenzoates in food category 04.1.2.5 “Jams, jellies, marmalades” could create an inconsistency with the *Standard for jams, jellies and marmalades* (CODEX STAN 296-2009). It was noted that food category 04.1.2.5 did not have a one-to-one correspondence with CODEX STAN 296-2009 and also included non-standardised food, such as reduced-sugar products. The Committee further noted that the alignment of the food additive provisions of commodity standards and the GSFA would be addressed separately.

68. The Delegation of the European Union expressed a reservation to the adoption this provision due to the fact that, in their view, it was not technologically justified other than in low-sugar versions of this food category

(iv) *Phosphates*

69. The Committee deleted Note K “Excluding cows milk” associated to in food category 01.1.1 “Milk and buttermilk (plain)” noting that phosphates were also used in UHT and sterilised cows’ milk. One delegation noted that the inclusion of food additives in food category 01.1.1 did not comply with the definition of milk in the *General Standard for the use of dairy terms* (CODEX STAN 206-1999), which does not allow any “addition to it”. The Codex Secretariat clarified that this definition did not include any reference to treatment of milk.

(iv) *Sorbates* (INS 200-204)

70. The Delegation of the European Union expressed a reservation to the use of sorbates in food category 04.1.2.5 “Jams, jellies, marmalades”, due to the fact that, in their view, it was not technologically justified other than in low-sugar version of this food category.

#### **Recommendations 2 and 3 - Discontinuation of work and revocation**

71. The Committee endorsed the recommendations of the Working Group regarding discontinuation and revocation.

#### **Recommendation 4 - Circulation for comments**

72. The Committee did not endorse this recommendation related to two provisions for phosphates but agreed:

- to revise the provision in food category 01.3.2 “Beverage whiteners” to a maximum level of 13,000 mg/kg and to forward it for adoption at Step 8; and

- to discontinue work on the provision in food category 09.2.5 “Smoked dried, fermented, and/or salted fish and fish products, including mollusc, crustaceans and echinoderms”.

### **Recommendation 5 - New provisions for circulation for comments at Step 3**

73. The Committee endorsed this recommendation and recalled that the two new provisions for aspartame-acesulfame salt (INS 962) were the result of a specific request for new uses of intensive sweeteners.

### **Recommendation 6 - Adoption: Table 3**

74. The Committee endorsed the recommendation regarding the adoption of the proposed draft Table 3 provisions for lycopenes (INS 160d (i)(ii)(iii)) and sodium hydrogen sulfate (INS 514 (ii)).

### **Recommendations 7, 8 and 9 - Nisin (INS 234)**

75. The Committee noted the concern of the Working Group as to whether the JECFA Acceptable Daily Intake (ADI) for nisin (33,000 units/kg body weight) was calculated correctly. The Working Group questioned the calculation provided in the current Note 28 “ADI conversion: if a typical preparation contains 0.025 µg/U, then the ADI of 33 000 units/kg body weight becomes: [(33 000 units/kg body weight) x (0.025 µg/unit) x (1 mg/1 000 µg)] = 0.825 mg/kg body weight” and noted that the conversion was necessary to correlate the ADI to exposure resulting from maximum use levels, expressed in mg nisin/ kg food. The Working Group had deferred the discussion on the revision of Note 28 pending clarification from JECFA.

76. The Joint JECFA Secretariat informed the Committee that the ADI for nisin was derived in units/kg body weight based on a publication of 1949, in which the unit of antibiotic activity was defined as the amount that would “just inhibit the growth of the test organism, *Streptococcus agalactae*, in 1 ml of broth (test Ai)”. The specific activity being 1300 units/mg of nisin preparation. This is not identical with, though similar to, the currently used IUs, defined as the amount of nisin required to inhibit one cell of *Streptococcus agalactae* in 1 ml of broth (with pure nisin having an activity of about 40000 IU/mg. The Committee further noted that the risk assessment conducted by JECFA was based on studies conducted using nisin preparations and the ADI derived was based on the activity of the preparation, and using a study by Tramer and Fowler, 1964, as the pivotal study. To what extent the preparation used had the same purity level as preparations used today was unclear. Hence, the specific activity might have been lower, should the preparation used in the earlier studies have been of a lower purity. It was also noted that the specifications prepared by the 71<sup>st</sup> JECFA considered nisin and nisin preparation as synonyms.

77. With regard to recommendation 7, which requested the JECFA Secretariat to verify the calculation of the ADI for nisin; to clarify the basis of the ADI for nisin; and provide the calculation to convert the ADI to mg nisin/kg body weight, the joint JECFA Secretariat replied that it was not sure at this stage of the feasibility to provide these replies to the Committee and if the answer could not be provided, it might be necessary for JECFA to re-evaluate the substance.

78. Noting the possibility to provide JECFA with a data package for the re-evaluation of nisin, the Committee agreed to endorse recommendation 7 and to consider the inclusion on nisin in the priority list (*see* Agenda Item 9a).

79. Due to the unresolved issue regarding the conversion of the ADI to mg nisin/kg body weight, the Committee did not agree to associate a new Note “as nisin” to all adopted provisions for nisin in Tables 1 and 2 of the GSFA (Recommendation 8).

80. Whilst the Committee discontinue work on nisin in food category 08.0 “Meat and meat products, including poultry and game, it agreed to request specific proposals for the use of nisin in 08.0 sub-categories that should be provided according to the *Procedure for consideration of the entry and review of food additives provisions in the General Standard for Food Additives* (Codex Procedural Manual) for consideration at its next Session (Recommendation 9).

### **Recommendation 10 - Provisions for aspartame-acesulfame salt (INS 962)**

81. The Committee noted that the Working Group had deferred discussion on food additive provisions associated with Note 161, pending the outcome of the discussion under Agenda Item 5f. The relevant provisions, which were the result of four years of work of the Committee, had been compiled in Appendix 1 (Part IV) of CRD 2.

82. The Committee did not support Recommendation 10.

**Recommendation 11 - Provisions for acesulfame potassium (INS 950) and aspartame (INS 951)**

83. The Committee agreed that the United States of America would address the issue of the application of Note 188 “Not to exceed the maximum use level for acesulfame potassium (INS 950) singly or in combination with aspartame-acesulfame salt (INS 962)” to provisions for acesulfame potassium and Note 191 “Not to exceed the maximum use level for aspartame (INS 951) singly or in combination with aspartame-acesulfame salt (INS 962)” to provisions for aspartame (*see* para. 134).

**Others**

84. The Committee noted that no proposals had been put forward in response to request for information for new uses for cyclotetraglucose (INS 1504(i)) and cyclotetraglucose syrup (1504(ii)). The Committee also noted that the Working Group had not discussed other proposals for new uses submitted in response to specific requests for: lauric arginate ethyl esters (INS 243), lycopenes (INS 160d(i,ii,iii)); sucrose oligoesters type I and type II (INS 473a) and steviol glycosides (INS 960), which had been compiled in Appendix 7 of CRD 2.

85. The Committee agreed to enter into the GSFA all the provisions at Step 4; these provisions would be circulated for comments at Step 3 and considered by the Committee at a later stage (*see* Appendix IX, part B).

86. The Committee discussed the need to establish a process for consideration of a number of unsolicited proposals for “new entries” in the GSFA and recalled that the *Procedure for consideration of the entry and review of food additives provisions in the General Standard for Food Additives*, detailed the information that should support specific requests for new and revised provisions of the GSFA.

87. The Committee agreed to issue a Circular Letter, attached to the report of this Session, requesting proposals for “new entries” or revisions to the GSFA to be submitted according the above *Procedure*. To facilitate their consideration by Committee the proposals would be considered by an electronic Working Group (*see* para. 134), which would compile them in a document including a summary of the information supporting the proposal. The Committee noted that the Delegation of Brazil would submit the request in CRD 18 (*see* para. 5) in reply to this Circular Letter.

88. To facilitate the task of the electronic Working Group, the Committee agreed to consider only proposals submitted by the set deadline (approximately five months before the Committee’s Session). The Committee also noted that this process would only allow entering provisions, as proposed drafts, into the GSFA but that, due to the present backlog, it would be difficult to predict when these proposed draft provisions could be considered for adoption.

**Matters related to Agenda Item 5b**

89. The Committee recalled that the Working Group had considered the information submitted in response to a numbers of requests for comments from its 43<sup>rd</sup> Session regarding: (i) provisions for erythrosine (INS 127), lauric arginate ethyl esters (INS 243), steviol glycosides (INS 960) and sulfites (INS 220-228, 539) in Tables 1 and 2 of the GSFA; (ii) specific provisions for steviol glycoside in Tables 1 and 2 of the GSFA; (iii) proposed draft provision for cassia gum (INS 427) in Table 3 of the GSFA; (iv) proposals on uses and use levels for cassia gum (INS 427) in food categories listed in the Annex to Table 3; and (v) information submitted in response to a request for further consideration on the draft provision for the use of carotenoids (INS 160a(i, iii), 160e, 160f) in food category 02.1.2 “Vegetable oils and fats”.

90. The Committee endorsed the recommendations:

- to adopt the provisions for erythrosine (INS 127) in food category 08.3 “Processed comminuted meat, poultry and game products”; steviol glycosides (INS 960) in food category 05.2 “Confectionery including hard and soft candy, nougats, etc other than food categories 05.1, 05.3 and 05.4”; and sulfites (INS 220-228, 539) in food category 04.1.2.8 “Fruit preparations, including pulp, purees, fruit topping and coconut milk”; and
- to discontinue a number of provisions for lauric arginate ethyl esters (INS 243).



### **Recommendation 12 - Adoption: Table 3**

91. The Committee endorsed the recommendation to adopt the proposed draft Table 3 provisions for cassia gum (INS 427).

92. The Committee noted that the Working Group had deferred discussion on: (i) food additive provisions associated with Note 161, pending the outcome of the discussion under Agenda Item 5f (compiled in Appendix 1 Part IV of CRD 2); (ii) food additive provisions related to the food categories 08.0 “Meat and meat products, including poultry and game”, pending the outcome of the discussion under Agenda Item 4b (compiled in Appendix 1 Part II of CRD 2); and food additive provisions related to food category 16.0 “Composite foods – foods that could not be placed in categories 01-15”, pending the outcome of the discussion under Agenda Item 5e (compiled in Appendix 1 Part I of CRD 2).

### **Others**

93. The Committee recalled that the 34<sup>th</sup> Session of the Commission had returned the provision for carotenoids in food category 02.1.2 “Vegetable oils and fats” to the Committee for further consideration and that the Working Group could not find a suitable note to align the provision with the *Standard for Edible fats and oils not covered by individual standards* (CODEX STAN 19-1981). The Committee agreed to a proposal of the Delegation of Malaysia, in CRD 23, to revise the maximum level of the draft provision to: 25 mg/kg, singly or in combination with a new Note “Only for use in vegetable fats conforming to the *Standard for Edible Fats and Oils Not Covered by Individual Standards* (CODEX STAN 19-1981), singly or in combination” and to forward the revised provision to the Commission for adoption.

### **Matters related to Agenda Item 5c**

94. The Delegation of the United States of America introduced the Working Group discussion on the proposed horizontal approach for consideration of provisions in Tables 1 and 2 of the food additives listed in Table 3 with “acidity regulators” function. The Working Group had tried to classify the food categories in the Annex to Table 3, into three groups: where acidity regulators were: (i) acceptable and technologically justified; (ii) not justified; and (iii) should be considered on a case-by-case basis. The outcome of the discussion was presented in Appendix 8 of CRD 2.

95. The Delegation further noted that the horizontal approach was complex because the food category system was hierarchical and many “acidity regulators” food additives had other technological functions. However, to start applying the horizontal approach, they proposed to adopt work on Tables 1 and 2 provisions of those food categories “acidity regulators” that were acceptable and technologically justified and to discontinue work where “acidity regulators” were not justified.

96. Delegations mentioned possible difficulties with the application of the horizontal approach as follows: for food categories containing products where food additives had different functions, or when the use of food additives was limited to some of the products in the same food category, such as reconstituted and recombined milks.

97. The Committee generally agreed to the horizontal approach as a tool to make progress with the GSFA; however, many delegations considered that the tool still needed more reflection and refinement before being used. The Committee, therefore, agreed:

- to discontinue work on the provisions in Tables 1 and 2 of food additives listed in Table 3 with “acidity regulators” function in those food categories where their uses were “not justified”, namely food categories 01.1.1.1 “Milk (plain)”; 01.2.1 “Fermented milks (plain)”; 04.1.1 “Fresh fruit”; 04.1.1.2 “Surface-treated fresh fruit”; 04.2.1.3 “Peeled, cut or shredded fresh vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds”; 9.1.1 “Fresh fish”; and 10.1 “Fresh eggs”<sup>13</sup>; and
- not to take any action on the other provisions in Tables 1 and 2 of food additives listed in Table 3 with “acidity regulators” function at the present Session.

98. The Committee agreed that the electronic Working Group (*see* para. 133) would continue working on the application of the horizontal approach to the provisions in Tables 1 and 2 of food additives listed

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<sup>13</sup> These provisions are included in Appendix VIII

in Table 3 with “acidity regulators” function and to further refine the horizontal approach for consideration of the food additives with “emulsifier, stabilizer and thickener” function, for consideration at the next Session.

#### **Matters related to Agenda Item 5d**

99. The Delegation of Brazil, as Chair, introduced the report of the electronic Working Group on the provisions for aluminium-containing food additives (CX/FA 12/44/10 and CX/FA 12/44/10 Add.1), which had not been considered by the physical Working Group due to time constraints. They explained that the work aimed at reducing the levels of use and uses of aluminium-containing food additives because of the JECFA recommendations and the revised PTWI.

100. The Delegation illustrated the approach taken to elaborate the Working Group’s recommendations, which did not in all cases represent a consensus in the Working Group and were presented to the Committee for further discussion. The Delegation noted that more work was necessary to find suitable alternatives to encourage the food industry to replace aluminium-containing food additives. It was noted that the food industry uses food additives on the basis of national legislation and that alternatives to aluminium-containing food additives also required changes in national legislations.

101. The Committee considered the recommendations of the Working Group as follows:

#### **Recommendations 1-3**

102. The Committee agreed:

- that only numerical MLs should be set for aluminium-containing food additives; MLs should be reported on “as aluminium basis” and include Note 6 “As aluminium” accordingly;
- that the conversion should take the average percentage of aluminium among the molecular formulas, when more than one molecular formula was identified for an aluminium-containing food additive; and
- to revise in Note 174 of the GSFA the name of “sodium aluminium silicate” (INS 554) to “sodium aluminosilicate” for consistency with the *Class Names and the International Numbering System of Food Additives* (CAC/GL 36-1989) and the JECFA specifications.

#### **Recommendations 4-7**

103. The Committee noted that these recommendations were for: adoption (Recommendation 4); further discussion (Recommendation 5); circulation for comments (Recommendation 6); and revocation/discontinuation (Recommendation 7). Because of time constraints and the need for further work on Recommendations 4, 5 and 6, the Committee agreed to consider only Recommendation 7 and to request the electronic Working Group (*see* para. 133) to further work on recommendations 4, 5 and 6 to further reduce uses and use levels of aluminium-containing food additives and to seek alternatives to these food additives.

104. The Committee agreed to discontinue/revoke work on all provisions with the exception of the following provisions, which were included, at the levels indicated below, with the ones for further discussion for consideration by the electronic Working Group (*see* para. 133):

- aluminium ammonium sulfate (INS 523) in food categories 06.2 “Flours and starches (including soybean powder)”; 7.1.4 “Bread-type products, Bread-type products, including bread stuffing and bread crumbs”; 07.2 “Fine bakery wares (sweet, salty, savoury) and mixes”; 09.2 “Processed fish and fish products, including mollusks, crustaceans, and echinoderms”; and 09.3 “Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms” which were reported to be used at a lower level of 100 mg/kg; and
- sodium aluminosilicate (INS 554) in food category 01.8.2 “Dried whey and whey products, excluding whey cheese”, which was reported to be used at a maximum level of 570 mg/kg as anticaking agent.

**REVISION OF THE NAME AND DESCRIPTOR OF FOOD CATEGORY 16.0 (Agenda Item 5e)<sup>14</sup>**

105. The Committee recalled that the issue of how to deal with food category 16.0 “Composite foods – foods that could not be placed in categories 01-15” had been on its agenda since its 40<sup>th</sup> Session because of the uncertainty of the scope of products included in this category.

106. At its 43<sup>rd</sup> Session the Committee had established an electronic Working Group to develop a discussion paper, which would give a detailed description of the products to be included in this category and make proposals for revision of the name and descriptors of food category 16.0, as necessary.

107. The Delegation of the United States of America, as Chair, presented the report of the Working Group (in CX/FA 12/44/11) that proposed to amend the title of food category 16.0 to read “Prepared foods” and to include a descriptor and examples for this category, which would cover frozen, ready-to-heat and dehydrated foods. As a consequential change to limit the scope of the food category 16.0, the Working Group proposed to include snack dips in food category 12.6.1 and to amend its name to read “Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dip)”. The Working Group also proposed to amend Section 5, paragraph (c) of the Preamble of the GSFA to clarify that: (i) the carry-over principle applied to these composite foods; and (ii) food additives might also be used to provide a technological function at a level that was specifically needed for the composite food.

**Discussion**

108. Several delegations were of the opinion that there was no common basis for the foods to be included in the revised food category 16.0. They also considered that the descriptor of the food category was not flexible enough to allow future inclusion of other foods. They were of the opinion that food category 16.0 should be used only if food additive provisions could not be addressed by the appropriate GSFA food category 1 to 15 and, in such a case, the inclusion of food category 16.0 should be limited to this specific type of product. They proposed to name the category “Foods not covered by categories 1–15” and to include provisions in this category on a case-by-case basis. They also proposed to delete the descriptor and the examples of the category, recognising that these could be developed successively depending on the provisions included.

109. These delegations did, in particular, not support bullet (ii) as, in their view, the application of the carry-over principle was adequately covered in section 5 (c) of the Preamble and for the same reasons strongly opposed the proposal to amend section 5(c).

110. Several other delegations fully supported the proposals of the Working Group. They were of the opinion that the revised name, descriptor and examples provided useful information of the scope of food category 16.0.

111. Some delegations also supported the proposed amendments to section 5(c) of the Preamble to clarify how the carry-over principle relates to the products in food category 16.0. These delegations also saw value in maintaining bullet (ii) in the descriptor.

112. As a compromise, it was proposed: to keep the name of the food category as proposed by the Working Group; to delete all examples; and to include the following sentence “These foods are not included in the other food categories (01–15) and should be considered on a case-by-case basis” at the beginning of the descriptor. It was also proposed to discontinue and revoke all provisions presently related to food category 16.0 and to repopulate it on a case-by-case basis. It was noted that the name and descriptor of food category 16.0 could be revised, when necessary.

113. After some discussion the Committee agreed to the above compromise and agreed to keep section 5(c) of the Preamble unchanged.

**Conclusion**

114. The Committee agreed to forward to the 35<sup>th</sup> Session of the Commission: the revised titles and descriptors of food category 16.0 and 12.6.1 for adoption (*see* Appendix X); and food additive provisions of

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<sup>14</sup> CX/FA 12/44/11; CRD 13 (Unsolicited comments of Brazil, Egypt, European Union, India, Indonesia, Kenya, Paraguay, Philippines, Thailand and ICGMA); CRD 24 (Comments of Paraguay)

food category 16.0 (adopted and in the step process), for revocation and discontinuation (*see* Appendices VII and VIII).

115. The Committee also agreed that the Codex Secretariat would issue a Circular Letter requesting proposals for inclusion of provisions in the revised food category 16.0. The proposals should be submitted according to the *Procedures for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives* (Codex Procedural Manual). In particular, the proposals should clarify why the provisions could not be covered by food categories 1-15.

#### **DISCUSSION PAPER ON USE OF NOTE 161 (Agenda Item 5f)<sup>15</sup>**

116. The Committee recalled it had discussed the issue since its 41<sup>st</sup> Session and that it had not been possible to reach consensus on the use of Note 161 “Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble”. At its 43<sup>rd</sup> Session the Committee had been divided between delegations concerned over the implications of the use of Note 161 on trade which, in their view, undermined the international standard-setting efforts of Codex and the value of Codex’s science-based decisions and other delegations that felt that the use of Note 161 was important in particular because, in their view, the procedures established in Section 3.2 of the Preamble of the GSFA and in the Procedural Manual had not been rigorously followed.<sup>16</sup>

117. At its 43<sup>rd</sup> Session the Committee had agreed to establish an electronic Working Group, led by South Africa, to continue working on a discussion paper on the application of Note 161, and in particular to formulate recommendations to facilitate a uniform implementation of Section 3.2 of the Preamble of the GSFA to address the use of Note 161.

#### **Findings and proposals of the Working Group**

118. The Delegation of South Africa introduced the report of the electronic Working Group (CX/FA 12/44/12) and reported that the Analysis of the Use of Note 161 had shown that up to 2010, Note 161 had been assigned to provisions for sweeteners and colours only and in 2011, no provisions with Note 161 were forwarded to, nor adopted by, the 34<sup>th</sup> Session of the Commission<sup>17</sup>. Looking at the occurrence of Note 161 in the adopted provisions for sweeteners and colours, the Working Group had found that the use of Note 161 had decreased over time and that it was associated with a variety of food categories for both sweeteners and colours coinciding with the Committee’s working lists of food categories in which the use of sweeteners and colours are technologically justified.<sup>18</sup>

119. The Working Group had analysed the relation of Note 161 and the implementation of Section 3.2 of the Preamble to the GSFA and had found that the Preamble provided general guidance to national authorities when interpreting the acceptable maximum use levels in the GSFA to account for differences in national practices relating to food additive uses, while neither imposing national practices on the global community nor preventing progress on the GSFA. The *Procedures for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives* (Codex Procedural Manual) explicitly considered the criteria in Section 3.2 of the Preamble by asking the question “Does the food additive use meet the criteria of Section 3.2 of the Preamble of the General Standard for Food Additives?”

120. The Working Group proposed two basic options for discussion in the Committee: (i) to delete Note 161 from all provisions in the GSFA; or (ii) to retain Note 161, either with the current text or revised text, and develop procedures and data/information requirements for the inclusion of Note 161 in the GSFA and to agree that these procedures and requirements should limit the use of Note 161 as much as possible.

#### **Discussion**

121. The Chairperson said that the Committee had not used Note 161 at the last Session and had held the relevant provisions. He proposed, as a first step, to agree not to use Note 161 anymore in provisions to be

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<sup>15</sup> CX/FA 12/44/12; CRD 14 (Comments of Brazil, China, Costa Rica, Dominican Republic, India, Kenya, Mali, Paraguay and FIVS); CRD 22 (Comments of Ghana); CRD 24 (Comments of Paraguay)

<sup>16</sup> REP 11/FA, paras. 107 – 114.

<sup>17</sup> REP 11/FA, Appendix III, REP 11/CAC, Appendix III

<sup>18</sup> CX/FA 08/40/5, Part 2, Appendix I and CX/FA 11/43/7 Appendix, respectively.

adopted and maintain the existing instances of Note 161 until an agreement could be found on how to deal with them.

122. There was no objection in the Committee that the use of Note 161 should be reduced; however, there was no consensus that the Note should not be used anymore or that it should be deleted.

123. Different proposals were made how to reduce or clarify the use of Note 161.

124. Other interventions reiterated the opinion that Note 161 should be discontinued and/or deleted as it did not deal with safety concerns and was jeopardizing the objective of Codex to harmonize standards and could cause barriers to trade.

125. Other interventions recalled that Note 161 had been introduced to allow making progress in the GSFA, but its use should be consistent and on a case-by-case basis.

126. The Chairperson proposed to set up an electronic Working Group to initially address the use of Note 161 in the provisions for sweeteners, both adopted and in the Step process, and to find a consistent alternative approach. In his opinion trying to find criteria for the use of Note 161 was not a solution.

127. The Committee agreed in principle to the proposal of the Chair.

128. The Delegation of the European Union proposed the terms of reference for such an electronic Working Group, using language from the report of the physical Working Group (CRD 2), as follows: “To consider the applicability of replacing Note 161 in provisions for sweeteners where Note 161 is currently listed, with notes which further define the scope of the use of the food additive, or alternative approaches.”

129. Different proposals were made how to indicate the goal of the exercise in the terms of reference:

- “The goal is to avoid making reference to national legislation.”
- “The goal is to reduce and, if possible, avoid making reference to national legislation”.

## **Conclusion**

130. As there was no consensus in the Committee on either of these proposals, the Chair concluded that the discussion on the Agenda Item be suspended.

## **GENERAL CONCLUSIONS FOR AGENDA ITEM 5**

131. The Committee agreed to forward to the 35<sup>th</sup> Session of the Commission:

- Draft and proposed draft food additive provisions for adoption at Step 8 and Step 5/8 (Appendix VI)<sup>19</sup>;
- Food additive provisions recommended for revocation (Appendix VII)<sup>20</sup>; and
- Draft and proposed draft food additive provisions recommended for discontinuation (Appendix VIII)<sup>21</sup>.

132. The Committee agreed to include in the GSFA new food additives provisions listed in Appendix IX<sup>22</sup> and to circulate the two provisions for aspartame-acesulfame salt (INS 962) for comments at Step 3 (*see* para. 73) for consideration at its next Session.

## **Work for the 45<sup>th</sup> Session of the CCFA**

### **Electronic Working Group on the GSFA**

133. The Committee established an electronic Working Group led by the United States of America, open to all members and observers and working in English only, to:

- prepare recommendations for the implementation of the horizontal approach to the provisions in Tables 1 and 2 of food additives listed in Table 3 with “acidity regulators” function (*see* para. 97);

<sup>19</sup> Appendix VII includes recommendations for adoption from Agenda Item 5a

<sup>20</sup> Appendix VII includes recommendations for revocation arising from Agenda Items 5a, 5b, 5d and 5e

<sup>21</sup> Appendix VIII also includes recommendations for discontinuation arising from Agenda Items 5a, 5b, 5d and 5e

<sup>22</sup> Appendix XI includes recommendations from Agenda Item 5a

- further elaborate the horizontal approach to consider the provisions with “emulsifier, stabilizer and thickener” function (*see* para. 98); and
- prepare proposals for consideration of recommendations 4, 5 and 6 in CX/FA 12/44/10, related to aluminium-containing food additives (*see* paras 103-104).

#### Other requests

134. The Committee agreed to request the Delegation of the United States of America to:

- prepare proposals to address the issue of the application of note 188 to provisions for acesulfame potassium and Note 191 to provisions for aspartame (*see* para. 83);
- compile in a structured form the information submitted on: (i) proposals for provisions for nisin in 08.0 sub-categories (*see* para. 80); (ii) proposals for new / revised food additive provisions of the GSFA (*see* para. 87); (iii) proposals for food additive provisions in food category 16.0 (*see* para. 115); and (iv) comments on two provisions for aspartame-acesulfame salt (*see* para. 132)

#### Physical Working Group on the GSFA

135. The Committee agreed to establish a physical Working Group, which would meet immediately prior to its 45<sup>th</sup> Session and be chaired by the United States of America, and work in English only, to consider and prepare recommendations for the Plenary on the work assigned to the electronic Working Group and to the United States of America.

#### **DRAFT REVISION OF THE CODEX STANDARD FOR FOOD GRADE SALT (CODEX STAN 150-1985) (N05-2010) (Agenda Item 6)<sup>23</sup>**

136. The Committee recalled that it had agreed at its 42<sup>nd</sup> Session that the revision of the *Standard for Food Grade Salt* (CODEX STAN 150-1985) should focus on the revision of the sections on food additives, contaminants, hygiene and methods of analysis and sampling, without reopening the discussion on other sections. The 43<sup>rd</sup> Session of the Committee had revised these sections and forwarded the revised proposed Standard to the Commission for adoption at Step 5 and the section on method of analysis and sampling to the Committee on Methods of Analysis and Sampling (CCMAS) for endorsement and advice on the possibility of converting the methods for heavy metals and copper to criteria.

137. The Committee noted that CRD 19 contained the relevant discussion and decisions of the 33<sup>rd</sup> Session of the CCMAS (Budapest, Hungary, 5-9 March 2012).

#### **Specific comments**

138. The Committee agreed to remove all methods, which had not been endorsed by the CCMAS from Section 9 “Methods of Analysis and Sampling”.

139. In reply to the request from the CCMAS, the Committee agreed to forward the following reply provided by the Observer of EuSALT to the CCMAS to clarify the need for the methods for halogens,:

“Both EuSalt standards are titrimetric methods for assay determinations of chloride. Statistics as r and R are known it provides a method to measure the chloride. An alternative is to calculate the assay of NaCl via 100 % minus impurities, but the methods of EuSalt should remain as a analytical method that provides through the halogens measurement a measurement an accurate method to measure chloride.”

140. The Committee did not have any specific comments on other sections of the Standard.

#### **Status of the draft revision of the *Standard for Food Grade Salt* (CODEX STAN 150-1985) (N08-2010)**

141. The Committee agreed to forward the revised draft Standard to the 35<sup>th</sup> Session of the Commission for adoption at Step 8 (*see* Appendix XI).

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<sup>23</sup> REP11/FA App. IX; CX/FA 12/44/13; CRD 15 (Comments of St Lucia and Thailand); CRD 19 (Matters referred from the 13<sup>th</sup> Session of the CCMAS)

**INTERNATIONAL NUMBERING SYSTEM (INS) FOR FOOD ADDITIVES (Agenda Item 7)<sup>24</sup>**

142. The Delegation of Iran, as Chair introduced the report of the in-session Working Group on the International Numbering System (INS) (CRD 4).

143. The Committee considered the recommendations of the Working Group as follows and, in addition to minor editorial changes to correct typing error concluded/commented as follows:

**Recommendations 1 and 2**

144. The Committee endorsed the recommendations for addition and modification of existing INS names and technological purposes to Section 3 as follows:

- three new substances and associated technological purposes: paprika extract (INS 160c(ii)), sodium potassium hexametaphosphate (INS 452vi) and potassium aluminium silicate (INS 561);
- one new INS number and associated technological purpose: paprika oleoresin (INS 160c(i));
- three names were amended and a new technological purpose added: ponceau 4R (cochineal red A) (INS 124), aluminium powder (INS 173) and lithol rubine BK (INS 180);
- one name and its associated INS was changed: sodium potassium triphosphate (INS 451(vii)).

145. The numerical subscript “(vii)” of sodium potassium hexametaphosphate (INS 452) proposed by the Working Group was changed with “(vi)” not to create a gap in the numbering of the subscripts of INS 452 “polyphosphates”.

**Recommendations 3 and 4**

146. The Committee endorsed the recommendations to add new technological purposes associated with 23 substances; and to delete two technological purposes that were not listed in Section 2 (i.e. conditioning agent and flavouring adjuvant).

147. The Committee noted that the recommendations, as in CRD 4, included some information/justification left from CX/FA 12/44/14, which were not relevant to the recommendation.

**Recommendation 5**

148. The Committee endorsed the recommendation to remove potassium bromate (INS 924a) and calcium bromate (INS 924b) from Section 3.

**Recommendation 6**

149. The Committee agreed to establish an electronic Working Group, led by Iran, open to all members and observers and working in English only, to: (i) consider the replies to the CL requesting proposals for changes and/or additions to the INS list; and (ii) prepare a proposal for circulation for comments at Step 3.

**Other**

150. The Committee agreed to request the Codex Secretariat to add a column to list the functional class that corresponds to the listed technological purposes in Sections 3 and 4 of the INS.

151. The Committee noted that it was not appropriate assigning an INS number to potassium aluminium silicate-based pearlescent pigments (*see* para. 28).

**Status of the amendment to the International Numbering System (INS) for food additives**

152. The Committee agreed to forward the proposed draft amendments to the INS to the 35<sup>th</sup> Session of the Commission for adoption at Step 5/8, with the recommendation to omit Steps 6 and 7 (*see* Appendix XII).

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<sup>24</sup> CX/FA 12/44/14; CX/FA 12/44/14 Add.1 ); CRD 4 (Report of the in-session working group on INS); CRD 16 (Comments of China, India, Malaysia and Mali)

### **SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 74<sup>th</sup> JECFA (Agenda Item 8)<sup>25</sup>**

153. The FAO JECFA Secretary presented the results of the 74<sup>th</sup> Meeting of JECFA regarding the specifications for identity and purity of food additives, as outlined in the Annex of CX/FA 12/44/15. The Secretary informed the Committee that a total of 25 specifications had been prepared as full specifications, seven as tentative. Nine revised specifications for aluminium-containing food additives were not republished, two were maintained and one was withdrawn.

154. The JECFA Secretary informed the Committee of an inconsistency that had been noted in the full specifications for Modified starches (INS 1400, 1401, 1402, 1403, 1404, 1405, 1410, 1412, 1413, 1414, 1420, 1422, 1440, 1442, 1450, 1451) and Octenyl succinic acid modified gum arabic (INS 423), where a specific step in the analytical procedure for product purity tests for degree of esterification was different than the same method published in the specifications prepared at the 72<sup>nd</sup> JECFA. The JECFA Secretariat recommended that these two full specifications be held until the inconsistency would be resolved.

155. The Committee also noted that a corrigendum had been introduced in the specifications for Sucrose esters of fatty acids (INS 473) in FAO JECFA Monographs 10, 2010 to amend the last line in the method of assay to read: "T is the sum of all peak areas eluting within 43 min".

#### **Status of the specifications for the identity and purity of food additives**

156. The Committee agreed to forward the specifications for 22 food additives (new and revised) to the 35<sup>th</sup> Session of the Commission for adoption at Steps 5/8, with the recommendation to omit Steps 6 and 7 (*see* Appendix XIII). The Committee further agreed to request the Commission to revoke the specifications for potassium bromate (INS 924a).

### **PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF FOOD ADDITIVES PROPOSED FOR EVALUATION BY JECFA (REPLIES TO CL 2010/10-FA) (Agenda Item 9a)<sup>26</sup>**

157. The Delegation of Canada, as Chair introduced the report of the in-session Working Group on Priority (CRD 5).

158. The Committee noted that the Working Group had updated information on the status of the requests from the 2011 Priority list, which were not scheduled for evaluation at the 76<sup>th</sup> meeting of JECFA (Geneva, Switzerland, June 2012). In particular, it was noted:

- xanthan gum (INS 415), pectin (INS 440) and OSA-modified starch (starch sodium octenil succinate) (INS 1450) – data for xanthan gum and pectin would be available in December 2013 and for OSA-modified starch in December 2012. The safety evaluations required specialised expertise since they related to the safety assessment in infant formula;
- data for monk fruit extract/Lo han guo (LHG); *Siraitia grosvenorii* Swingle – data would be available in December 2013;
- *Acacia polyacantha* var. *Campylacantha*, kakamut gum, arabino-galactan protein complex – data for specifications were now available and data for safety assessment in December 2013; and
- 72 flavourings – data were already available.

#### **New requests for evaluation**

159. The Committee did not add polyglycerol esters of interesterified ricinoleic acid (INS 476) to the priority list because it was clarified that the request related to the GSFA and not to the Priority list. The Chair of the Working Group encouraged delegations to clearly indicate the name of the compound and question to JECFA in the box at the top of the form.

160. The Committee agreed with the other requests, which included: advantame and glucoamylase from *Trichoderma reesei* expressed in *Trichoderma reesei* (safety assessment and establishment of specifications)

<sup>25</sup> CX/FA 12/44/15; CX/FA 12/44/15 Add. 1 (Comments of European Union)

<sup>26</sup> CX/FA 12/44/16; CRD 5 (Report of the in-session Working Group on Priorities for Evaluation by JECFA); CRD 17 (Comments of Brazil, Egypt, India, Mali, Paraguay, Sudan and Thailand)



and annatto extracts, bixin-based (INS 160b(i)) and annatto extracts, norbixin-based (INS 160b(ii)) (revision of specifications).

161. The Committee included in the Priority list re-evaluation of nisin (INS 234), subject to confirmation on the feasibility of the JECFA Secretariat to provide the replies requested by the Committee (*see* Agenda Item 5a). The Delegation of Japan confirmed that data for nisin would be available in December 2012.

#### **Others**

162. The Observer from IFAC confirmed that the additional information requested by the 74<sup>th</sup> JECFA for glycerol ester of gum rosin (GEGR) (INS 445(i)) and glycerol ester of wood rosin (GEWR) (INS 445(iii)) would be available in December 2012.

#### **Conclusion**

163. The Committee agreed to forward the Priority list of substances proposed for evaluation by JECFA to the 35<sup>th</sup> Session of the Commission for approval (*see* Appendix XIV).

#### **DISCUSSION PAPER ON MECHANISM FOR RE-EVALUATION OF SUBSTANCES BY JECFA (Agenda Item 9b)<sup>27</sup>**

164. At its 43<sup>rd</sup> Session the Committee had agreed to establish an electronic Working Group to develop prioritization criteria in accordance with a framework for a re-evaluation scheme, proposed by the JECFA Secretariat, through and to test the criteria focusing initially on food colours.

#### **Outcome of the Working Group**

165. The Delegation of Canada, as Chair, introduced the report of the electronic Working Group (CX/FA 12/44/17) and said that the proposed Prioritization Criteria for the Re-evaluation of Food Additives by JECFA were set out in a simple form of questions with two or three possible answers. The first question was to determine if provisions for the food additive existed in Codex or were considered in the Codex step process (pre-screening) and, if not, the food additive would be re-evaluated.

166. The remainder of the Prioritization Criteria form consisted of seven questions in three sections:

- section A (two questions) on the food additive's status with JECFA;
- section B (three questions) on safety issues; and
- section C (two questions) on intake.

167. Each question had either three possible answers (Low, Medium, or High) or two possible answers (Low or Medium). A maximum possible score of medium reflected a reduced importance of the question. The score assigned to each Section was the highest score of any question in that Section. Each Section, therefore, had a score of Low, Medium or High; and all section had equal weight in the final score. When applied the scheme would result in prioritized groups of additives with no priority ranking of additives within a group and it would be at JECFA's discretion to prioritize additives within a group.

168. The Delegation drew the Committee's attention to the points for which there was not unanimous agreement in the Working Group (CX/FA 12/44/17, para 8 (i)-(vi)). The Delegation also pointed out that the last two items of the terms of reference had not been completed and proposed to consider the Prioritization Criteria form and, if the criteria were accepted, whether to continue work on the third and fourth terms of reference.

#### **Discussion**

169. The following comments were made in the discussion:

- the elaboration of a list for prioritization should be done by JECFA to prioritize additives within functional classes;
- the re-evaluation would require resources – what would be the benefit of this work?;

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<sup>27</sup> CX/FA 12/44/17; CRD 17 (Comments of Brazil, Egypt, India, Mali, Paraguay, Sudan and Thailand); CRD 24 (Comments of Paraguay)

- when going to the next step of the 107 colours, many would be in the same group and would then have to be prioritized by JECFA;
- pre-screening question: seems too restrictive; additives with JECFA specifications but no ADI, which aren't included in the GSFA should not be excluded from the start;
- A1: The time since the last evaluation is not important.
- B1: Should include a NOEL "no observed effect level" used in toxicological studies.
- B1: The "genotoxicity" note that was part of the answer for the "Medium" response should be moved to the "High" response.
- B1: The word "reviews" should be replaced with "risk assessments".
- B1: Increased concern could be specified with words such as "that suggest greater toxicity" as newer studies might also show that a food additive is safer (lower toxicity), which would reduce its priority for re-evaluation.
- B1: It was suggested to include "by an internationally recognized body" after "conducted" in question B1 but it was questioned what would constitute an internationally recognized body, just organizations like JECFA or others like Health Canada, the US Food and Drug Administration (FDA), and European Food Safety Authority (EFSA). If unclear the text should better remain unchanged.
- B2: A high score i.e. serious health effects should become an immediate priority and outside of the prioritization process.
- B3: Should contain the wording "Is there a body of medically confirmed case reports" to indicate that there were not just one or two unconfirmed reports.
- B3: How could JECFA objectively evaluate non-toxicological studies?
- C2: Section C should be more specific with regard to intake.

170. The above concerns were addressed by the Joint JECFA Secretariat and Delegation of Canada as follows:

- assigning the task of prioritization to JECFA as suggested would not work because of the limited resources;
- JECFA would have to balance the need for new evaluations against re-evaluating additives as resources for evaluation were not likely to increase;
- pre-screening question: It would be best to submit food additives that are not in the GSFA, as new data;
- B3: The objectivity of information (on non-toxicological studies), would be incumbent on the data provided;
- although there were 107 colours on the list, the majority of them would not make it past the pre-screening question as many of the colours had an unacceptable toxicological profile or did not have enough data to support their safety and would not be in the GSFA;
- A1/B3: Concerns regarding the time of the last JECFA evaluation and the objectivity of non-toxicological studies by assigning lower maximum scores to questions A1 and B3;
- B1: The "High" reply in question B1 could read, "Yes, there are new genotoxicity, chronic, reproductive.....or special studies ...".

171. The Chair summarized that there seemed to be general agreement with the Criteria, which should now be tested since most of the concerns could easily be addressed. Therefore, he suggested continuing work on the third and fourth terms of reference in an electronic Working Group. Based on the outcome of the exercise the scheme could be reviewed and improved if necessary.

## Conclusion

172. The Committee agreed to establish an electronic Working Group, led by Canada, open to all interested members and observers and working in English only, with the following terms of reference:

- i. to compile information from members and other organizations, including from the industry producing food additives, on the detailed list of the 107 food colours evaluated by JECFA since 1956;
- ii. to establish a prioritized list of food colours based on the prioritization tool as discussed at the present Session for action by CCFA, including for consideration for re-evaluation by JECFA.

## PROTOTYPE OF A DATABASE ON PROCESSING AIDS (Agenda Item 10)<sup>28</sup>

173. The Committee recalled that at its 43<sup>rd</sup> Session it had discussed a draft structure and content of the database, and criteria for the entry and update of the database based on the outcome of an electronic Working Group, led by New Zealand, and had agreed to the proposal of the Chairperson to follow a stepwise approach. In the first step, China would develop a prototype of the database showing the main layout and present it at the next Session of the Committee. The criteria for the entry of substances and the management of the database would be considered at a subsequent step.

## Discussion

174. The Delegation of China introduced the prototype that was developed in cooperation with New Zealand, taking into account the discussions at the 43<sup>rd</sup> Session of the Committee. They explained that while the definition of processing aids was contained in the Procedural Manual, the *Guidelines on Substances Used as Processing Aids* (CAC/GL 75-2010) had served as the background for the development of the database, providing the principles for the safe use of processing aids.

175. The Delegation noted that, when considering the entries in the database it should not be assumed that all entries of the Inventory of the Substances Used as Processing Aids (IPA) are correct, but the criteria on safety and technological use established in CAC/GL 75-2010 should always be met. The database had a search function and a draft form for the request of entry for new substances.

176. The prototype of the database was available online at <http://www.ccfa.cc/IPA/>. (“IPA” should be capitalized) and at any time delegations could send proposals for improving the database to China to the following address: [ipa\\_db@ccfa.cc](mailto:ipa_db@ccfa.cc).

177. The following comments were made on the function and structure of the database:

178. It was noted that it was not possible to include examples of food uses and level of residues in the database at this time; however, CAC/GL 75-2010 mentioned in 3.3 that “*The safety of a substance used as a processing aid should be demonstrated by the supplier or the user of the substance. The demonstration of safety should include appropriate assessment of any unintended or unavoidable residues resulting from its use as a processing aid under conditions of GMP*”. For the future development of the database for each food category, any potential residues should be indicated to permit assessment of the safety. In the “area of utilization” sub-categories with different entries could be foreseen to facilitate this.

179. It was noted that the field “adoption” should be deleted and also noted that the present format of the database did not seem to be suitable for enzymes.

180. Concerning the relation of the database with Codex, the Secretariat clarified that the work on the processing aids database was outside the responsibility of the Codex Secretariat, but that a link from the Codex website could be established.

181. Concerning the future of the current IPA, the Codex Secretariat clarified that this was an initiative undertaken by New Zealand since the Codex inventory had been revoked. The Delegation of New Zealand confirmed that the IPA would be maintained for some more years until the work on the database was finalised.

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<sup>28</sup> CX/FA 12/44/18

182. The Chair noted that the database would also be useful to see what processing aids were used in different countries. To continue work, he proposed to follow the stepwise approach agreed at the last Session and to develop criteria for entry of processing aids into the database in an electronic Working Group, to discuss this at the next Session. Following this China would complete the database.

### **Conclusion**

183. The Committee welcomed the prototype of the database and thanked China for preparing it. The Committee noted that any comments on the structure of the database should be sent directly to China.

184. The Committee agreed to establish an electronic Working Group, led by New Zealand and co-chaired by China, open to all members and observers and working in English only to develop criteria for the entry of substances in the database for processing aids.

### **OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)**

185. The Committee noted that there was no other business.

### **DATE AND PLACE OF THE NEXT SESSION (Agenda Item 12)**

186. The Committee was informed that its Forty-fifth Session was tentatively scheduled to be held in Beijing, China, from 18 to 22 March 2013. The exact venue and date would be determined by the host Government in consultation with the Codex Secretariat.

## SUMMARY STATUS OF WORK

SUBJECT	STEP	FOR ACTION BY:	DOCUMENT REFERENCE (REP12/FA)
Draft and proposed draft food additive provisions of the <i>General standard for food additives</i> (GSFA)	8 and 5/8	35 <sup>th</sup> CAC	Para. 131 and App. VI
Proposed draft revision of the <i>Standard for Food Grade Salt</i> (CODEX STAN 150-1985) (N08-2010)	8	35 <sup>th</sup> CAC	Para. 141 and App. VIII
Proposed draft amendments to the <i>International numbering system</i> (INS) for food additives	5/8	35 <sup>th</sup> CAC	Para.152 and App. XII
<i>Specifications for the identity and purity of food additives</i> arising from the 74 <sup>th</sup> JECFA meeting	5/8	35 <sup>th</sup> CAC	Para. 156 and App. XIII
Principles for Risk Analysis applied by the Codex Committee on Food Additives	Adoption	35 <sup>th</sup> CAC	Para. 21 and App. II
Title and descriptor of food category 16.0 of the GSFA and 12.6.1	Adoption	35 <sup>th</sup> CAC	Para. 106
Draft and proposed draft food additives provisions of the GSFA	3	45 <sup>th</sup> CCFA	Para. 132 and App. IX
Amendments to the <i>International numbering system</i> (INS) for food additives	1,2,3	eWG (Iran)	Para. 149
<i>Specifications for the identity and purity of food additives</i> arising from the 76 <sup>th</sup> JECFA meeting	1,2,3	45 <sup>th</sup> CCFA	---
Food additive provisions of the GSFA	Revocation	35 <sup>th</sup> CAC	Para. 131 and App. VIII
Draft and proposed draft food additive provisions of the GSFA	Discontinuation	35 <sup>th</sup> CAC	Para. 131 and App. V
Discussion paper on the revision of the <i>Guidelines for the Evaluation of Food Additive Intakes</i> (CAC/GL 3-1989)	---	Brazil	Para. 13
Application of the decision-tree on the alignment of the food additive provisions of commodity standards and relevant provisions of the GSFA	---	eWG (Australia)	Para. 59 and App. V
Discussion paper on use of Note 161 in the GSFA	---	---	Para. 114
Provisions for aluminium-containing food additives (recommendations for adoption, discontinuation and revocation)	---	eWG (United States of America)	Para. 133
Recommendations for provisions in Tables 1 and 2 food additive listed in Table 3 with “acidity regulator” function and horizontal approach for provisions in Tables 1 and 2 food additive listed in Table 3 with “emulsifier, stabilizer and thickener” function	---	eWG (United States of America)	Para. 133
Proposals for application of Note 188 to provisions for acesulfame potassium and Note 191 to provisions for aspartame	---	United States of America	Para. 134
Compilation of information submitted on: proposals for provisions for nisin in 08.0 sub-categories; proposals for new / revised food additive provisions of the GSFA; proposals for food additive provisions in food category 16.0; and comments on two provisions for aspartame-acesulfame salt	---	United States of America	Para. 134
Proposed prioritized list of colours for re-evaluation by JECFA	---	eWG (Canada)	Para. 172
Database on processing aids - Criteria for entry of substances in the database	---	eWG (New Zealand and China)	Para. 184
Information document on the GSFA	---	Codex Secretariat	---
Information document on food additive provisions in commodity standards	---	Codex Secretariat	---
Information document on Inventory of Substances used as Processing Aids (IPA), (updated list)	---	New Zealand	---

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Appendix II**RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES**

(for adoption)

**Section 1. Scope**

1. This document addresses the application of risk analysis principles by the Codex Committee on Food Additives (CCFA) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters that are not within the terms of reference of JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies or FAO/WHO *ad hoc* consultations, as approved by the Commission.
2. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

**Section 2. CCFA and JECFA**

3. CCFA and JECFA recognize that continuous interaction between risk assessors and risk managers is critical to the success of their risk analysis activities.
4. CCFA and JECFA should continue to develop procedures to enhance communication between the two committees.
5. CCFA and JECFA should ensure that their contributions to the risk analysis process involve all interested parties and are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.
6. JECFA, in consultation with CCFA, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria are used by CCFA in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum criteria for data have been met when preparing the draft agendas for meetings of JECFA.

**Section 3. CCFA**

7. CCFA is primarily responsible for recommending risk management proposals for adoption by the CAC.
8. CCFA shall base its risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments<sup>1</sup>, of food additives.
9. In cases where JECFA has performed a risk assessment and CCFA or the CAC determines that additional scientific guidance is necessary, CCFA or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.
10. CCFA's risk management recommendations to the CAC with respect to food additives shall be guided by the principles described in the Preamble and relevant annexes of the *Codex General Standard for Food Additives*.
11. CCFA's risk management recommendations to the CAC that involve health and safety aspects of food standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*.
12. CCFA's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors described in the risk assessments and the recommendations by JECFA.

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<sup>1</sup> Safety assessment - An approach that focuses on the scientific understanding and measurement of chemical hazards as well as chemical exposures, and ultimately the risks associated with them. Often used synonymously with risk assessment (EHC 240 – Glossary)



13. CCFA shall endorse maximum use levels only for those additives for which (i) JECFA has established specifications of identity and purity; and (ii) JECFA has completed a risk assessment and established a health-based guidance value.
14. CCFA shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives.
15. When establishing its standards, codes of practice, and guidelines, CCFA shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*, in addition to JECFA's risk assessment, and specify its reasons for doing so.
16. CCFA's risk communication with JECFA includes prioritising substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives.
17. CCFA shall consider the following when preparing its priority list of substances for JECFA review:
  - Consumer protection from the point of view of health and prevention of unfair trade practices;
  - CCFA's Terms of Reference;
  - JECFA's Terms of Reference;
  - The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
  - The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
  - The prospect of completing the work in a reasonable period of time;
  - The diversity of national legislation and any apparent impediments to international trade;
  - The impact on international trade (i.e., magnitude of the problem in international trade);
  - The needs and concerns of developing countries; and,
  - Work already undertaken by other international organizations.
18. When referring substances to JECFA, CCFA shall provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation.
19. CCFA may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.
20. CCFA requests JECFA to review any methods and guidelines being considered by CCFA for assessing maximum use levels for additives. CCFA makes any such request with a view toward obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a method or guideline for CCFA's work.

#### **Section 4. JECFA**

21. JECFA is primarily responsible for performing the risk assessments upon which CCFA and ultimately the CAC base their risk management decisions.
22. JECFA's scientific experts should be selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.
23. JECFA should strive to provide CCFA with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCFA's risk management discussions. For additives, JECFA should continue to use its safety assessment process for establishing ADIs.
24. JECFA should strive to provide CCFA with science-based quantitative risk assessments for food additives in a transparent manner.

25. JECFA should provide CCFA with information on the applicability and any constraints of the risk assessment to the general population to particular sub-populations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children, women of child-bearing age, the elderly).
26. JECFA should also strive to provide CCFA with specifications of identity and purity essential to assessing risk associated with the use of additives.
27. JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.
28. JECFA is responsible for evaluating exposure to additives.
29. When evaluating intake of additives during its risk assessment, JECFA should take into account regional differences in food consumption patterns.
30. JECFA should communicate to CCFA the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCFA with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.
31. JECFA should communicate to CCFA the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.
32. JECFA's risk assessment output in response to requests by CCFA is limited to presenting its deliberations and the conclusions of its risk assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include in the risk assessments alternative risk management options, JECFA should ensure that these are consistent with the *Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius* and *Risk Analysis Principles applied by the Codex Committee on Food Additives*.
33. When establishing the agenda for a JECFA meeting, the JECFA Secretariat works closely with CCFA to ensure that CCFA's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be given to food additives or groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority should normally be given to food additives that have not been previously evaluated.
34. When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

Appendix III

**ACTION REQUIRED AS A RESULT OF CHANGES IN THE ACCEPTABLE DAILY INTAKE  
(ADI) STATUS AND OTHER TOXICOLOGICAL  
RECOMMENDATIONS ARISING FROM THE 74<sup>TH</sup> MEETING OF JECFA**

<b>INS Number</b>	<b>Food additive</b>	<b>44<sup>th</sup> CCFA Recommendation</b>
	Aluminium-containing food additives (including new food additives potassium aluminium silicate and potassium aluminium silicate-based pearlescent pigments)	Encourage submission of the requested data for specifications.
	Benzoe Tonkinensis	Encourage submission of requested data to finalize specifications to characterize the material tested.
445(i)	Glycerol ester of gum rosin (GEGR)	Encourage submission of requested data to establish an ADI and information to characterize the material tested.
445(ii)	Glycerol ester of tall oil rosin (GETOR)	Encourage submission of requested information to establish an ADI (or include in the group-ADI for GEGR and GEWR) and to characterize the material tested and data for specifications.
445(iii)	Glycerol ester of wood rosin (GEWR)	Encourage submission of requested data to establish an ADI and information to characterize the identity of the material tested.
423	Octenyl succinic acid (OSA) modified gum arabic	Encourage submission of requested information to complete evaluation and characterize the identity of the material tested.
900a	Polydimethylsiloxane	Noted
124	Ponceau 4R	Noted
1204	Pullulan	Noted
	Pullulanase from <i>Bacillus deramificans</i> expressed in <i>Bacillus lichiformis</i>	Add to database for processing aids (when available).
104	Quinoline yellow	Encourage submission of requested information and information to characterize the product in commerce.
110	Sunset yellow FCF	Noted

Appendix IV**STATUS OF ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES AND PROCESSING AIDS IN CODEX STANDARDS****COMMITTEE ON FISH AND FISHERY PRODUCTS (CCFFP)*****Standard for Fish Sauce (CODEX STAN 302-2011)*****4. FOOD ADDITIVES**

Only those food additive classes listed below are technologically justified and may be used in products covered by this Standard. Within each additive class only those food additives listed below, or referred to, may be used and only for the functions, and within limits, specified.

<b>Functional Class</b>	<b>INS No.</b>	<b>Additive</b>	<b>Maximum level</b>	<b>Note</b>	<b>Endorsement status</b>
<b>Acidity regulators</b>	334; 335(i), (ii); 336(i), (ii); 337	Tartrates	GMP	Note 45 (as tartaric acid)	<b>Not Endorsed by 44<sup>th</sup> CCFA</b> (consider if 200 mg/kg is technologically justified)
	330, 331 (i), (iii); 332 (i), (ii)	Citrates	GMP		Endorsed by 44 <sup>th</sup> CCFA
	296, 350 (i), (ii); 351 (i), (ii); 352 (ii)	Malates	GMP		Endorsed by 44 <sup>th</sup> CCFA
	300	Ascorbic acid, L-	GMP		Endorsed by 44 <sup>th</sup> CCFA
	325	Sodium lactate	GMP		Endorsed by 44 <sup>th</sup> CCFA
	260	Acetic acid, glacial	GMP		Endorsed by 44 <sup>th</sup> CCFA
<b>Flavour enhancers</b>	621	Monosodium L-glutamate	GMP		Endorsed by 44 <sup>th</sup> CCFA
	630	Inosinic acid	GMP		Endorsed by 44 <sup>th</sup> CCFA
	631	Disodium 5'-inosinate	GMP		Endorsed by 44 <sup>th</sup> CCFA
	627	Disodium 5'-guanylate	GMP		Endorsed by 44 <sup>th</sup> CCFA
<b>Sweeteners</b>	950	Acesulfame potassium	1,000 mg/kg		Endorsed by 44 <sup>th</sup> CCFA
	955	Sucralose	450 mg/kg		Endorsed by 44 <sup>th</sup> CCFA
	951	Aspartame	350 mg/kg		Endorsed by 44 <sup>th</sup> CCFA
<b>Colours</b>	150c	Caramel III-Ammonia caramel	50,000 mg/kg		Endorsed by 44 <sup>th</sup> CCFA
<b>Emulsifiers and Stabilizers</b>	466, 468	Sodium carboxymethyl cellulose and crosslinked carboxymethyl cellulose	GMP		Endorsed by 44 <sup>th</sup> CCFA
<b>Preservatives</b>	210-213	Benzoates	1,000 mg/kg	Note 13 (as benzoic acid)	Endorsed by 44 <sup>th</sup> CCFA
	200-203	Sorbates	1,000 mg/kg	Note 13 (as sorbic acid)	Endorsed by 44 <sup>th</sup> CCFA

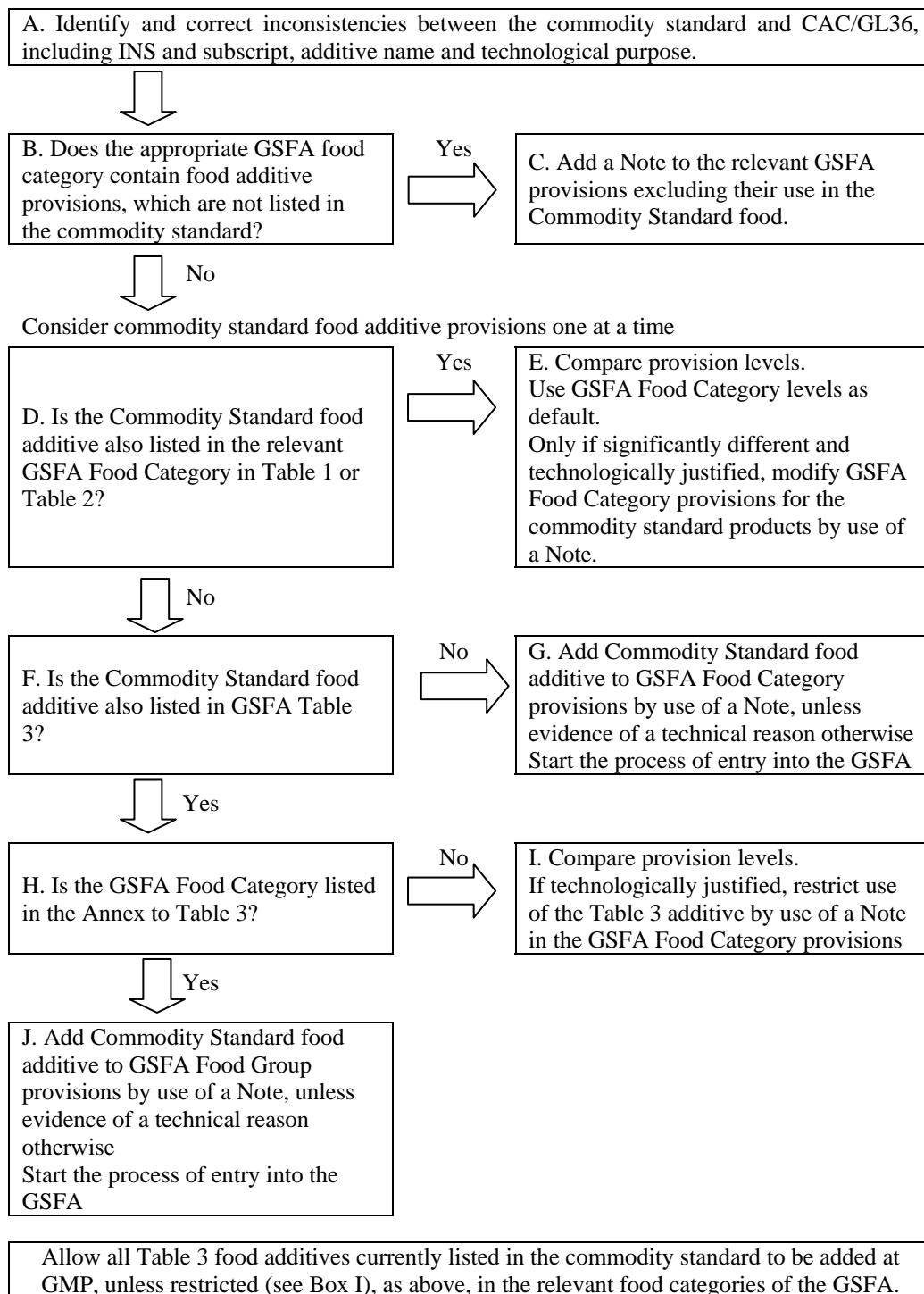
**REGIONAL COORDINATING COMMITTEE FOR NEAR EAST (CCNEA)*****Regional Standard for Halwa Tehenia (CODEX STAN 309-2011)*****4. FOOD ADDITIVES**

	<b>Endorsement status</b>
<b>4.1</b> Only acidity regulators and emulsifiers used in accordance with Table 3 of the <i>General Standard for Food Additives</i> (CODEX STAN 192-1995) are acceptable for use in foods conforming to this Standard.	Endorsed by 44 <sup>th</sup> CCFA
<b>4.2 Flavourings</b> Flavourings are acceptable for use in foods conforming to this Standard when used in accordance with good manufacturing practices and in compliance with the Codex <i>Guidelines for the Use of Flavourings</i> (CAC/GL 66-2008).	Endorsed by 44 <sup>th</sup> CCFA

**COMMITTEE ON NUTRITION AND SPECIAL DIETARY USES (CCNFSDU)*****Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)*****4. FOOD ADDITIVES**

<b>Additives considered as physiological body constituents</b>			
<b>INS</b>	<b>Additive</b>	<b>Maximum level in 100ml of the product ready for consumption</b>	<b>Endorsement status</b>
339i, ii and iii	Sodium dihydrogen phosphate, disodium hydrogen phosphate and trisodium phosphate	45 mg as phosphorus singly or in combination and within the limits for sodium, potassium and phosphorus in section 3.1.3 (e) in all types of infant formula	Endorsed by 44 <sup>th</sup> CCFA
340i, ii and iii	Potassium dihydrogen phosphate, dipotassium hydrogen phosphate and tripotassium phosphate		Endorsed by 44 <sup>th</sup> CCFA

**DECISION TREE FOR THE RECOMMENDED APPROACH TO ALIGNMENT OF THE GSFA AND COMMODITY STANDARDS FOOD ADDITIVE PROVISIONS<sup>1</sup>**



<sup>1</sup> The decision tree is a tool for CCFA to align commodity standards with the GSFA. However, it is recognised that there may be cases where the results of its application are not consistent with the intention of the commodity committee, or not consistent with the general principles for entry in the GSFA. In these cases entries should be considered on a case-by-case basis.

## CODEX GENERAL STANDARD FOR FOOD ADDITIVES

### DRAFT AND PROPOSED DRAFT FOOD ADDITIVE PROVISIONS

(for adoption at Step 8 and Step 5/8 of the Procedure)<sup>1</sup>

#### PART 1 – Provisions included in Table 1 and Table 2

#### AMMONIUM SALTS OF PHOSPHATIDIC ACID

INS 442 Ammonium salts of phosphatidic acid Functional Class: Emulsifier

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	5000 mg/kg	P	8	

#### ASCORBYL ESTERS

INS 304 Ascorbyl palmitate Functional Class: Antioxidant  
INS 305 Ascorbyl stearate Functional Class: Antioxidant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
06.4.3	Pre-cooked pastas and noodles and like products	500 mg/kg	10 & 211	8	2012r

#### ASPARTAME-ACESULFAME SALT

INS 962 Aspartame-acesulfame salt Functional Class: Sweetener

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
11.6	Table-top sweeteners, including those containing high-intensity sweeteners	GMP		5/8	
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	500 mg/kg	113	5/8	
13.6	Food supplements	2000 mg/kg	113	5/8	

#### CARAMEL III - AMMONIA CARAMEL

INS 150c Caramel III - ammonia caramel Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
01.6.1	Unripened cheese	15000 mg/kg	201	5/8	
05.1.3	Cocoa-based spreads, including fillings	50000 mg/kg		8	2012r
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	50000 mg/kg		8	2012r
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	50000 mg/kg		8	2012r
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	50000 mg/kg	89	8	2012r

<sup>1</sup> Provisions that are replacing or revising currently adopted provisions of the GSFA are grey highlighted

**CARAMEL IV - SULFITE AMMONIA CARAMEL**INS 150d Caramel IV - sulfite ammonia Functional Class: Colour  
caramel

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
05.1.2	Cocoa mixes (syrops)	50000 mg/kg		8	
05.1.3	Cocoa-based spreads, including fillings	50000 mg/kg		8	2012r
05.1.4	Cocoa and chocolate products	50000 mg/kg	183	8	
05.1.5	Imitation chocolate, chocolate substitute products	50000 mg/kg		8	
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	50000 mg/kg		8	2012r
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	50000 mg/kg		8	2012r

**CAROTENES, BETA-, VEGETABLE**

INS 160a(ii) beta-Carotenes, vegetable Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
05.1.3	Cocoa-based spreads, including fillings	100 mg/kg		5/8	
05.1.4	Cocoa and chocolate products	100 mg/kg	183	8	

**CAROTENOIDS**

INS 160a(i) beta-Carotenes, synthetic Functional Class: Colour

INS 160a(iii) beta-Carotenes, Blakeslea trispora Functional Class: Colour

INS 160e Carotenal, beta-apo-8'- Functional Class: Colour

INS 160f Carotenoic acid, ethyl ester, beta-apo-8'- Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
02.1.2	Vegetable oils and fats	25 mg/kg	Q	8	

**CYCLODEXTRIN, BETA-**

INS 459 Cyclodextrin, beta- Functional Class: Carrier, Stabilizer, Thickener

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
06.4.3	Pre-cooked pastas and noodles and like products	1000 mg/kg	153	5/8	

**ERYTHROSINE**

INS 127 Erythrosine Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
08.3	Processed comminuted meat, poultry, and game products	30 mg/kg	4	8	

**GRAPE SKIN EXTRACT**

INS 163(ii) Grape skin extract Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
05.1.3	Cocoa-based spreads, including fillings	200 mg/kg	181	5/8	
05.1.4	Cocoa and chocolate products	200 mg/kg	181 & 183	5/8	
05.2.2	Soft candy	1700 mg/kg	181	5/8	



**HYDROXYBENZOATES, PARA-**

INS 214	Ethyl para-hydroxybenzoate	Functional Class: Preservative
INS 218	Methyl para-hydroxybenzoate	Functional Class: Preservative

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
01.6.4	Processed cheese	300 mg/kg	27	8	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	120 mg/kg	27	8	
02.2.2	Fat spreads, dairy fat spreads and blended spreads	300 mg/kg	27	8	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	300 mg/kg	27	8	
04.1.2.3	Fruit in vinegar, oil, or brine	250 mg/kg	27	8	
04.1.2.5	Jams, jellies, marmelades	250 mg/kg	27	8	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	1000 mg/kg	27	8	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	800 mg/kg	27	8	
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	300 mg/kg	27	8	
05.1.3	Cocoa-based spreads, including fillings	300 mg/kg	27	8	
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	1000 mg/kg	27	8	
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	100 mg/kg	27	8	
12.3	Vinegars	100 mg/kg	27	8	
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	450 mg/kg	27 & 160	8	
14.2.4	Wines (other than grape)	200 mg/kg	27	8	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	1000 mg/kg	27 & F	8	

**PHOSPHATES**

INS 338	Phosphoric acid	Functional Class: Acidity regulator, Antioxidant, Sequestrant
INS 339(i)	Sodium dihydrogen phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 339(ii)	Disodium hydrogen phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 339(iii)	Trisodium phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Preservative, Sequestrant, Stabilizer, Thickener
INS 340(i)	Potassium dihydrogen phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 340(ii)	Dipotassium hydrogen phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 340(iii)	Tripotassium phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 341(i)	Monocalcium dihydrogen phosphate	Functional Class: Acidity regulator, Anticaking agent, Firming agent, Flour treatment agent, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 341(ii)	Calcium hydrogen phosphate	Functional Class: Acidity regulator, Anticaking agent, Firming agent, Flour treatment agent, Humectant, Raising agent, Stabilizer, Thickener
INS 341(iii)	Tricalcium phosphate	Functional Class: Acidity regulator, Anticaking agent, Emulsifier, Firming agent, Flour treatment agent, Humectant, Raising agent, Stabilizer, Thickener
INS 342(i)	Ammonium dihydrogen phosphate	Functional Class: Acidity regulator, Flour treatment agent
INS 342(ii)	Diammonium hydrogen phosphate	Functional Class: Acidity regulator, Flour treatment agent

## PHOSPHATES

INS 343(i)	Magnesium dihydrogen phosphate	Functional Class: Acidity regulator, Anticaking agent
INS 343(ii)	Magnesium hydrogen phosphate	Functional Class: Acidity regulator, Anticaking agent
INS 343(iii)	Trimagnesium phosphate	Functional Class: Acidity regulator, Anticaking agent
INS 450(i)	Disodium diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 450(ii)	Trisodium diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 450(iii)	Tetrasodium diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 450(v)	Tetrapotassium diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 450(vi)	Dicalcium diphosphate	Functional Class: Acidity regulator, Emulsifier, Firming agent, Raising agent, Sequestrant, Stabilizer, Thickener
INS 450(vii)	Calcium dihydrogen diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer
INS 451(i)	Pentasodium triphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 451(ii)	Pentapotassium triphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 452(i)	Sodium polyphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 452(ii)	Potassium polyphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 452(iii)	Sodium calcium polyphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer
INS 452(iv)	Calcium polyphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 452(v)	Ammonium polyphosphate	Functional Class: Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 542	Bone phosphate	Functional Class: Anticaking agent, Emulsifier, Humectant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
01.1.1	Milk and buttermilk (plain)	1500 mg/kg	33 & L	5/8	
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	1320 mg/kg	33	8	
01.3.1	Condensed milk (plain)	880 mg/kg	33	8	
01.3.2	Beverage whiteners	13000 mg/kg	33	8	
01.4	Cream (plain) and the like	2200 mg/kg	33	8	
01.5.1	Milk powder and cream powder (plain)	4400 mg/kg	33	8	
01.6.1	Unripened cheese	4400 mg/kg	33	8	
01.6.4	Processed cheese	9000 mg/kg	33	8	
01.6.5	Cheese analogues	9000 mg/kg	33	8	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	1500 mg/kg	33	5/8	
01.8.1	Liquid whey and whey products, excluding whey cheeses	880 mg/kg	33 & M	8	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	1500 mg/kg	33	8	
03.0	Edible ices, including sherbet and sorbet	7500 mg/kg	33	8	
04.1.2.3	Fruit in vinegar, oil, or brine	2200 mg/kg	33	5/8	
04.1.2.7	Candied fruit	10 mg/kg	33	8	
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	350 mg/kg	33	8	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	1500 mg/kg	33	8	
04.1.2.11	Fruit fillings for pastries	1500 mg/kg	33	8	
04.2.1.3	Peeled, cut or shredded fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	5600 mg/kg	33 & 76	5/8	
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	5000 mg/kg	33 & 76	8	

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	5000 mg/kg	33 & 76	8	
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	2200 mg/kg	33	8	
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	2200 mg/kg	33	8	
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	2200 mg/kg	33 & 76	8	
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	2200 mg/kg	33	8	
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	2200 mg/kg	33 & 76	8	
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	1100 mg/kg	33	8	
05.1.3	Cocoa-based spreads, including fillings	880 mg/kg	33	8	
05.1.4	Cocoa and chocolate products	1100 mg/kg	33	8	
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	2200 mg/kg	33	8	
05.3	Chewing gum	44000 mg/kg	33	8	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	1500 mg/kg	33	8	
06.2.1	Flours	2500 mg/kg	33 & H	8	
06.4.1	Fresh pastas and noodles and like products	2500 mg/kg	33 & 211	5/8	
06.4.2	Dried pastas and noodles and like products	900 mg/kg	33 & 211	8	
06.4.3	Pre-cooked pastas and noodles and like products	2500 mg/kg	33 & 211	5/8	
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	7000 mg/kg	33	8	
06.6	Batters (e.g., for breading or batters for fish or poultry)	5600 mg/kg	33	5/8	
06.8.1	Soybean-based beverages	1300 mg/kg	33	5/8	
06.8.3	Soybean curd (tofu)	100 mg/kg	33	5/8	
07.1.1.2	Soda breads	9300 mg/kg	33 & N	8	
07.1.2	Crackers, excluding sweet crackers	9300 mg/kg	33 & N	8	
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	9300 mg/kg	33 & N	8	
07.1.4	Bread-type products, including bread stuffing and bread crumbs	9300 mg/kg	33 & N	8	
07.1.5	Steamed breads and buns	9300 mg/kg	33 & N	8	
07.1.6	Mixes for bread and ordinary bakery wares	9300 mg/kg	33 & N	8	
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	9300 mg/kg	33 & N	8	
08.2.1	Non-heat treated processed meat, poultry, and game products in whole pieces or cuts	2200 mg/kg	33	8	
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and	2200 mg/kg	33	8	
09.2.2	Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and	2200 mg/kg	33	8	
09.2.3	Frozen minced and creamed fish products, including mollusks, crustaceans, and	2200 mg/kg	33	8	
09.2.4.1	Cooked fish and fish products	2200 mg/kg	33	8	
09.2.4.2	Cooked mollusks, crustaceans, and echinoderms	2200 mg/kg	33	8	

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
09.3.1	Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	2200 mg/kg	33	5/8	
09.3.2	Fish and fish products, including mollusks, crustaceans, and echinoderms, pickled and/or in brine	2200 mg/kg	33	8	
09.3.3	Salmon substitutes, caviar, and other fish roe products	2200 mg/kg	33	5/8	
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	2200 mg/kg	33	8	
10.3	Preserved eggs, including alkaline, salted, and canned eggs	1000 mg/kg	33	8	
10.4	Egg-based desserts (e.g., custard)	1400 mg/kg	33	8	
12.1.2	Salt Substitutes	4400 mg/kg	33	8	
12.2.2	Seasonings and condiments	2200 mg/kg	33 & J	5/8	
12.5	Soups and broths	1500 mg/kg	33 & 127	8	
12.6	Sauces and like products	2200 mg/kg	33	8	
12.9	Soybean-based seasonings and condiments	1200 mg/kg	33	5/8	
13.2	Complementary foods for infants and young children	4400 mg/kg	33 & O	8	
14.1.2.2	Vegetable juice	1000 mg/kg	33	8	
14.1.2.4	Concentrates for vegetable juice	1000 mg/kg	33 & 127	8	
14.1.3.2	Vegetable nectar	1000 mg/kg	33	8	
14.1.3.4	Concentrates for vegetable nectar	1000 mg/kg	33 & 127	8	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	1000 mg/kg	33	8	
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	300 mg/kg	33 & 160	8	

**PROPYL GALLATE**

INS 310 Propyl gallate Functional Class: Antioxidant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
06.4.3	Pre-cooked pastas and noodles and like products	200 mg/kg	15, 130 & 211	8	2012r
12.5	Soups and broths	200 mg/kg	15, 127 & 130	5/8	

**SACCHARINS**

INS 954(i) Saccharin Functional Class: Sweetener  
 INS 954(ii) Calcium saccharin Functional Class: Sweetener  
 INS 954(iii) Potassium saccharin Functional Class: Sweetener  
 INS 954(iv) Sodium saccharin Functional Class: Sweetener

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
12.9.1	Fermented soybean paste (e.g., miso)	200 mg/kg		5/8	
12.9.2.1	Fermented soybean sauce	500 mg/kg		5/8	

**SORBATES**

INS 200	Sorbic acid	Functional Class: Preservative
INS 201	Sodium sorbate	Functional Class: Preservative
INS 202	Potassium sorbate	Functional Class: Preservative
INS 203	Calcium sorbate	Functional Class: Preservative

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	1000 mg/kg	42 & B	8	
01.2.2	Renneted milk (plain)	1000 mg/kg	42	8	
01.6.1	Unripened cheese	1000 mg/kg	42 & E	8	
01.6.2	Ripened cheese	3000 mg/kg	42	8	
01.6.4	Processed cheese	3000 mg/kg	42	8	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	1000 mg/kg	42	8	
04.1.2.2	Dried fruit	500 mg/kg	42	8	
04.1.2.5	Jams, jellies, marmelades	1000 mg/kg	42	8	
04.1.2.7	Candied fruit	500 mg/kg	42	8	
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	1000 mg/kg	42	8	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	1000 mg/kg	42	8	
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	1000 mg/kg	42	8	
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	1000 mg/kg	42	8	
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	1000 mg/kg	42	8	
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	1000 mg/kg	42	8	
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	1000 mg/kg	42 & C	8	
05.1.2	Cocoa mixes (syrups)	1000 mg/kg	42	8	
05.1.3	Cocoa-based spreads, including fillings	1000 mg/kg	42	8	
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	1500 mg/kg	42	8	
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	1000 mg/kg	42	8	
06.4.3	Pre-cooked pastas and noodles and like products	2000 mg/kg	42 & 211	8	
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	1000 mg/kg	42	8	
07.0	Bakery wares	1000 mg/kg	42	8	
08.4	Edible casings (e.g., sausage casings)	200 mg/kg	42 & D	8	
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	1000 mg/kg	42	8	
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	1000 mg/kg	42	8	
12.4	Mustards	1000 mg/kg	42	8	
12.5	Soups and broths	1000 mg/kg	42	8	
12.6	Sauces and like products	1000 mg/kg	42 & 127	8	

## SORBATES

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	1500 mg/kg	42	8	
13.6	Food supplements	2000 mg/kg	42	8	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	500 mg/kg	42 & 127	8	
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	500 mg/kg	42 & 160	8	
14.2.2	Cider and perry	500 mg/kg	42	8	
14.2.3	Grape wines	200 mg/kg	42	8	
14.2.4	Wines (other than grape)	500 mg/kg	42	8	
14.2.5	Mead	200 mg/kg	42	8	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	500 mg/kg	42 & F	8	

**STEARYL CITRATE**

INS 484

Stearyl citrate

Functional Class: Emulsifier, Sequestrant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
02.2.2	Fat spreads, dairy fat spreads and blended spreads	100 mg/kg	15	5/8	

**STEVIOLE GLYCOSIDES**

INS 960

Steviol glycosides

Functional Class: Sweetener

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	700 mg/kg	26 & 199	5/8	

**SUCRALOSE (TRICHLOROGALACTOSUCROSE)**

INS 955

Sucralose  
(Trichlorogalactosucrose)

Functional Class: Sweetener

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
06.8.1	Soybean-based beverages	400 mg/kg		5/8	

**SUCROGLYCERIDES**

INS 474

Sucroglycerides

Functional Class: Emulsifier

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
13.6	Food supplements	2500 mg/kg		8	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	200 mg/kg	A	8	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	5000 mg/kg		8	

**SULFITES**

INS 220	Sulfur dioxide	Functional Class: Antioxidant, Preservative
INS 221	Sodium sulfite	Functional Class: Antioxidant, Preservative
INS 222	Sodium hydrogen sulfite	Functional Class: Antioxidant, Preservative
INS 223	Sodium metabisulfite	Functional Class: Antioxidant, Bleaching agent, Flour treatment agent, Preservative
INS 224	Potassium metabisulfite	Functional Class: Antioxidant, Preservative
INS 225	Potassium sulfite	Functional Class: Antioxidant, Preservative
INS 227	Calcium hydrogen sulfite	Functional Class: Antioxidant, Preservative
INS 228	Potassium bisulfite	Functional Class: Antioxidant, Preservative
INS 539	Sodium thiosulfate	Functional Class: Antioxidant, Sequestrant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step	Year
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	100 mg/kg	44 & 206	8	2012r

**PART 2 - Provisions included in Table 3**

INS No	Food additive	Functional Class	Step
160d(i)	Lycopene (synthetic)	Colour	5/8
160d(iii)	Lycopene from <i>Blakeslea trispora</i>	Colour	5/8
160d(ii)	Lycopene extract from tomato	Colour	5/8
514(ii)	Sodium hydrogen sulfate	Acidity regulator	5/8
427	Cassia gum	Emulsifier Stabilizer Gelling agent Thickener	5/8

**Notes**

- Note 4 For decoration, stamping, marking or branding the product.
- Note 10 As ascorbyl stearate.
- Note 15 Fat or oil basis.
- Note 26 As steviol equivalents.
- Note 27 As para-hydroxybenzoic acid.
- Note 33 As phosphorus.
- Note 42 As sorbic acid.
- Note 44 As residual SO<sub>2</sub>.
- Note 76 Use in potatoes only.
- Note 89 For sandwich spreads only.
- Note 113 Use level reported as acesulfame potassium equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.44). Combined use of aspartame-acesulfame salt with individual acesulfame potassium or aspartame should not exceed the individual maximum levels for acesulfame potassium or aspartame (the reported maximum level can be converted to aspartame equivalents by dividing by 0.68).
- Note 127 As served to the consumer.
- Note 130 Singly or in combination: butylated hydroxyanisole (INS 320), butylated hydroxytoluene (INS 321), tertiary butylated hydroquinone (INS 319), and propyl gallate (INS 310).
- Note 153 For use in instant noodles only.
- Note 160 For use in ready-to-drink products and pre-mixes for ready-to-drink products only.
- Note 181 Expressed as anthocyanin.
- Note 183 Products conforming to the Standard for Chocolate and Chocolate Products (CODEX STAN 87-1981) may only use colours for surface decoration.
- Note 199 For use in microsweets and breath freshening mints at 6000 mg/kg as steviol equivalents.
- Note 201 For use in flavoured products only.
- Note 206 For use at 30 mg/kg as a bleaching agent only for products conforming to the Standard for Aqueous Coconut Products (CODEX STAN 240-2003).
- Note 211 For use in noodles only.
- Note A Except for use at 5,000 mg/kg in non-alcoholic aniseed-based, coconut-based, and almond-based drinks.
- Note B For use in flavoured products heat treated after fermentation only.
- Note C For use in potato dough and pre-fried potato slices only.
- Note D For use in collagen-based casings with a water activity greater than 0.6 only.
- Note E Except for use at 3,000 mg/kg in products containing added fruits, vegetables, or meats.
- Note F Excluding aromatized beer.
- Note H Except for use in self-raising flour at 12,000 mg/kg.
- Note J Except for use as a meat tenderizer at 35,000 mg/kg.
- Note L For use in sterilized and UHT treated milks only.

- Note M Except for use at 1,320 mg/kg to stabilize higher protein liquid whey used for further processing into whey protein concentrates.
- Note N For use as a flour treatment agent, raising agent or leavening agent.
- Note O For use as an acidity regulator only.
- Note P Only for use in flavoured fermented milks and flavoured fermented milks heat treated after fermentation.
- Note Q Only for use in vegetable fats conforming to the Standard for Edible Fats and Oils Not Covered by Individual Standards (CODEX STAN 19-1981), singly or in combination.



## CODEX GENERAL STANDARD FOR FOOD ADDITIVES

## REVOCATION OF FOOD ADDITIVE PROVISIONS

(for approval)

**ALUMINIUM AMMONIUM SULFATE**

INS 523 Aluminium ammonium sulfate Functional Class: Firming agent, Stabilizer

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.1.2.7	Candied fruit	200 mg/kg	6	8
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	35 mg/kg	6	8
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	200 mg/kg	6	8
10.2	Egg products	30 mg/kg	6	8
10.4	Egg-based desserts (e.g., custard)	380 mg/kg	6	8

**ALUMINIUM SILICATE**

INS 559 Aluminium silicate Functional Class: Anticaking agent

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.8.2	Dried whey and whey products, excluding whey cheeses	10000 mg/kg		8

**BENZOATES**

INS 210 Benzoic acid Functional Class: Preservative

INS 211 Sodium benzoate Functional Class: Preservative

INS 212 Potassium benzoate Functional Class: Preservative

INS 213 Calcium benzoate Functional Class: Preservative

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	1000 mg/kg	13	8

**CALCIUM ALUMINIUM SILICATE**

INS 556 Calcium aluminium silicate Functional Class: Anticaking agent

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.8.2	Dried whey and whey products, excluding whey cheeses	10000 mg/kg		8
11.1.2	Powdered sugar, powdered dextrose	15000 mg/kg	56	8

**CARAMEL III - AMMONIA CARAMEL**

INS 150c Caramel III - ammonia caramel Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	1000 mg/kg		8

**CARAMEL IV - SULFITE AMMONIA CARAMEL**

INS 150d Caramel IV - sulfite ammonia caramel Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	1000 mg/kg		8

**PROPYL GALLATE**

INS 310 Propyl gallate Functional Class: Antioxidant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
12.5.2	Mixes for soups and broths	200 mg/kg	15 & 130	8

**SODIUM ALUMINOSILICATE**

INS 554 Sodium aluminosilicate Functional Class: Anticaking agent

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
11.1.2	Powdered sugar, powdered dextrose	15000 mg/kg	56	8

**Notes**

Note 6 As aluminium.

Note 13 As benzoic acid.

Note 15 Fat or oil basis.

Note 56 Provided starch is not present.

Note 130 Singly or in combination: butylated hydroxyanisole (INS 320), butylated hydroxytoluene (INS 321), tertiary butylated hydroquinone (INS 319), and propyl gallate (INS 310).

## CODEX GENERAL STANDARD FOR FOOD ADDITIVES

DISCONTINUATION OF WORK ON DRAFT AND PROPOSED DRAFT  
FOOD ADDITIVE PROVISIONS

(for information)

**ACESULFAME POTASSIUM**

INS 950 Acesulfame potassium Functional Class: Flavour enhancer, Sweetener

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	350 mg/kg	188	3

**ACETIC ACID, GLACIAL**

INS 260 Acetic acid, glacial Functional Class: Acidity regulator, Preservative

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.2.1	Fermented milks (plain)	GMP		7

**ADIPATES**

INS 355 Adipic acid Functional Class: Acidity regulator  
 INS 356 Sodium adipates Functional Class: Acidity regulator  
 INS 357 Potassium adipates Functional Class: Acidity regulator  
 INS 359 Ammonium adipates Functional Class: Acidity regulator

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	1000 mg/kg	1 & 2	7

**ALLURA RED AC**

INS 129 Allura red AC Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	300 mg/kg	161	6

**ALUMINIUM AMMONIUM SULFATE**

INS 523 Aluminium ammonium sulfate Functional Class: Firming agent, Stabilizer

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	350 mg/kg	6	3
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	150 mg/kg	6	3
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	500 mg/kg	6	3
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	5 mg/kg	6	3
12.2	Herbs, spices, seasonings and condiments (e.g., seasoning for instant noodles)	500 mg/kg	6	3

**ALUMINIUM SILICATE**

INS 559

Aluminium silicate

Functional Class: Anticaking agent

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
07.1.6	Mixes for bread and ordinary bakery wares	10000 mg/kg	6 & 174	3
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	10000 mg/kg	6 & 174	3
12.1.1	Salt	10000 mg/kg	6	3
12.1.2	Salt Substitutes	10000 mg/kg		6
12.2.2	Seasonings and condiments	30000 mg/kg	6 & 174	3
12.5.2	Mixes for soups and broths	10000 mg/kg	6 & 174	3
12.6.3	Mixes for sauces and gravies	10000 mg/kg	6 & 174	3

**AMMONIUM SALTS OF PHOSPHATIDIC ACID**

INS 442

Ammonium salts of phosphatidic acid

Functional Class: Emulsifier

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
03.0	Edible ices, including sherbet and sorbet	7500 mg/kg		6

**ANNATTO EXTRACTS, NORBIXIN-BASED**

INS 160b(ii)

Annatto extracts, norbixin-based

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	200 mg/kg	185	4

**ASCORBIC ACID, L-**

INS 300

Ascorbic acid, L-

Functional Class: Acidity regulator, Antioxidant, Flour treatment agent

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.1.1	Fresh fruit	500 mg/kg		7

**ASCORBYL ESTERS**

INS 304

Ascorbyl palmitate

Functional Class: Antioxidant

INS 305

Ascorbyl stearate

Functional Class: Antioxidant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.6.1	Unripened cheese	500 mg/kg	10	3

**AZORUBINE (CARMOISINE)**

INS 122

Azorubine (Carmoisine)

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	500 mg/kg		7

**BRILLIANT BLACK (BLACK PN)**

INS 151

Brilliant black (Black PN)

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	500 mg/kg		7

**BRILLIANT BLUE FCF**

INS 133 Brilliant blue FCF Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	100 mg/kg	2	7

**BROWN HT**

INS 155 Brown HT Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	500 mg/kg		7

**CALCIUM ALUMINIUM SILICATE**

INS 556 Calcium aluminium silicate Functional Class: Anticaking agent

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10000 mg/kg	6 & 174	3
07.1.6	Mixes for bread and ordinary bakery wares	10000 mg/kg	6 & 174	3
07.2.3	Mixes for fine bakery wares (e.g., cakes, pancakes)	10000 mg/kg	6 & 174	3
12.1.2	Salt Substitutes	10000 mg/kg		6
12.2.2	Seasonings and condiments	30000 mg/kg	6 & 174	3
12.5.2	Mixes for soups and broths	10000 mg/kg	6 & 174	3
12.6.3	Mixes for sauces and gravies	10000 mg/kg	6 & 174	3

**CALCIUM CARBONATE**

INS 170(i) Calcium carbonate Functional Class: Acidity regulator, Anticaking agent, Colour, Stabilizer

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP	4 & 16	7
09.1.1	Fresh fish	GMP	4, 16 & 50	7
10.1	Fresh eggs	GMP	4	7

**CALCIUM GLUCONATE**

INS 578 Calcium gluconate Functional Class: Acidity regulator, Firming agent, Sequestrant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.2.1.3	Peeled, cut or shredded fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	800 mg/kg	58	7

**CALCIUM HYDROXIDE**

INS 526 Calcium hydroxide Functional Class: Acidity regulator, Firming agent

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.2.1.3	Peeled, cut or shredded fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	800 mg/kg	58	7

**CANTHAXANTHIN**

INS 161g Canthaxanthin

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	50 mg/kg		6
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	GMP		6
16.0	Prepared foods	80 mg/kg	2	6

**CARAMEL II - SULFITE CARAMEL**

INS 150b Caramel II - sulfite caramel

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	20000 mg/kg		4

**CARAMEL III - AMMONIA CARAMEL**

INS 150c Caramel III - ammonia caramel

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.6.2	Ripened cheese	50000 mg/kg		3
01.6.4	Processed cheese	50000 mg/kg		3
05.0	Confectionery	50000 mg/kg	183	3
06.4.2	Dried pastas and noodles and like products	50000 mg/kg		3
16.0	Prepared foods	20000 mg/kg		3

**CARAMEL IV - SULFITE AMMONIA CARAMEL**

INS 150d Caramel IV - sulfite ammonia caramel

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
05.0	Confectionery	50000 mg/kg	183	3
16.0	Prepared foods	20000 mg/kg	3	

**CAROTENES, BETA-, VEGETABLE**

INS 160a(ii) beta-Carotenes, vegetable

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
05.1.2	Cocoa mixes (syrups)	100 mg/kg		3
05.1.4	Cocoa and chocolate products	1000 mg/kg	183	3
16.0	Prepared foods	1000 mg/kg		3

**CAROTENOIDS**

INS 160a(i) beta-Carotenes, synthetic Functional Class: Colour

INS 160a(iii) beta-Carotenes, Blakeslea trispora Functional Class: Colour

INS 160e Carotenal, beta-apo-8'- Functional Class: Colour

INS 160f Carotenoid acid, ethyl ester, beta-apo-8'- Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
05.1.2	Cocoa mixes (syrups)	300 mg/kg		6
16.0	Prepared foods	500 mg/kg		6

**CITRIC ACID**

INS 330 Citric acid

Functional Class: Acidity regulator, Antioxidant, Sequestrant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.2.1	Fermented milks (plain)	1500 mg/kg	63	7

**CURCUMIN**

INS 100(i) Curcumin

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	500 mg/kg		7

**FUMARIC ACID**

INS 297 Fumaric acid

Functional Class: Acidity regulator

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.2.1	Fermented milks (plain)	GMP		7

**GLUCONO DELTA-LACTONE**

INS 575 Glucono delta-lactone

Functional Class: Acidity regulator, Raising agent, Sequestrant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.2.1	Fermented milks (plain)	GMP		7

**GRAPE SKIN EXTRACT**

INS 163(ii) Grape skin extract

Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
05.1.2	Cocoa mixes (syrops)	200 mg/kg	181	3
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	10000 mg/kg		3
16.0	Prepared foods	1500 mg/kg		3
16.0	Prepared foods	10 mg/kg		6

**HYDROCHLORIC ACID**

INS 507 Hydrochloric acid

Functional Class: Acidity regulator

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.2.1	Fermented milks (plain)	GMP		7

**HYDROXYBENZOATES, PARA-**

INS 214 Ethyl para-hydroxybenzoate

Functional Class: Preservative

INS 218 Methyl para-hydroxybenzoate

Functional Class: Preservative

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
03.0	Edible ices, including sherbet and sorbet	1000 mg/kg	27	6
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	12 mg/kg	27	6

## HYDROXYBENZOATES, PARA-

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.2.1.3	Peeled, cut or shredded fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	12 mg/kg	27	6
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	700 mg/kg	27	6
14.2.1	Beer and malt beverages	200 mg/kg	27	6
14.2.3	Grape wines	50 mg/kg	27	6

**IRON OXIDES**

INS 172(i)	Iron oxide, black	Functional Class: Colour
INS 172(ii)	Iron oxide, red	Functional Class: Colour
INS 172(iii)	Iron oxide, yellow	Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
05.1.3	Cocoa-based spreads, including fillings	GMP		6

**LACTIC ACID, L-, D- and DL-**

INS 270	Lactic acid, L-, D- and DL-	Functional Class: Acidity regulator
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FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.2.1	Fermented milks (plain)	GMP		7

**LAURIC ARGINATE ETHYL ESTER**

INS 243	Lauric arginate ethyl ester	Functional Class: Preservative
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FoodCatNo	FoodCategory	MaxLevel	Comments	Step
08.1	Fresh meat, poultry, and game	200 mg/kg		3
09.1	Fresh fish and fish products, including mollusks, crustaceans, and echinoderms	200 mg/kg		3
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and	200 mg/kg		3
09.2.2	Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and	200 mg/kg		3
09.2.3	Frozen minced and creamed fish products, including mollusks, crustaceans, and	200 mg/kg		3

**MAGNESIUM CARBONATE**

INS 504(i)	Magnesium carbonate	Functional Class: Acidity regulator, Anticaking agent, Colour retention agent
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FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP	16	7

**MAGNESIUM HYDROXIDE**

INS 528	Magnesium hydroxide	Functional Class: Acidity regulator, Colour retention agent
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FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP	16	7



**MAGNESIUM HYDROXIDE CARBONATE**

INS 504(ii) Magnesium hydroxide carbonate Functional Class: Acidity regulator, Anticaking agent, Carrier, Colour retention agent

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP	16	7

**MALIC ACID, DL-**

INS 296 Malic acid, DL- Functional Class: Acidity regulator

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.2.1	Fermented milks (plain)	GMP		7

**NISIN**

INS 234 Nisin Functional Class: Preservative

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.1	Milk and dairy-based drinks	500 mg/kg	28	3
01.6.1	Unripened cheese	500 mg/kg	28	3
01.6.2	Ripened cheese	500 mg/kg	28	3
01.6.4	Processed cheese	500 mg/kg	28	3
08.0	Meat and meat products, including poultry and game	500 mg/kg	28	3

**PHOSPHATES**

INS 338	Phosphoric acid	Functional Class: Acidity regulator, Antioxidant, Sequestrant
INS 339(i)	Sodium dihydrogen phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 339(ii)	Disodium hydrogen phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 339(iii)	Trisodium phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Preservative, Sequestrant, Stabilizer, Thickener
INS 340(i)	Potassium dihydrogen phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 340(ii)	Dipotassium hydrogen phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 340(iii)	Tripotassium phosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 341(i)	Monocalcium dihydrogen phosphate	Functional Class: Acidity regulator, Anticaking agent, Firming agent, Flour treatment agent, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 341(ii)	Calcium hydrogen phosphate	Functional Class: Acidity regulator, Anticaking agent, Firming agent, Flour treatment agent, Humectant, Raising agent, Stabilizer, Thickener
INS 341(iii)	Tricalcium phosphate	Functional Class: Acidity regulator, Anticaking agent, Emulsifier, Firming agent, Flour treatment agent, Humectant, Raising agent, Stabilizer, Thickener
INS 342(i)	Ammonium dihydrogen phosphate	Functional Class: Acidity regulator, Flour treatment agent
INS 342(ii)	Diammonium hydrogen phosphate	Functional Class: Acidity regulator, Flour treatment agent
INS 343(i)	Magnesium dihydrogen phosphate	Functional Class: Acidity regulator, Anticaking agent
INS 343(ii)	Magnesium hydrogen phosphate	Functional Class: Acidity regulator, Anticaking agent
INS 343(iii)	Trimagnesium phosphate	Functional Class: Acidity regulator, Anticaking agent
INS 450(i)	Disodium diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 450(ii)	Trisodium diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 450(iii)	Tetrasodium diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 450(v)	Tetrapotassium diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 450(vi)	Dicalcium diphosphate	Functional Class: Acidity regulator, Emulsifier, Firming agent, Raising agent, Sequestrant, Stabilizer, Thickener

PHOSPHATES

INS 450(vii)	Calcium dihydrogen diphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer
INS 451(i)	Pentasodium triphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 451(ii)	Pentapotassium triphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 452(i)	Sodium polyphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 452(ii)	Potassium polyphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 452(iii)	Sodium calcium polyphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer

PHOSPHATES

INS 452(iv)	Calcium polyphosphate	Functional Class: Acidity regulator, Emulsifier, Humectant, Raising agent, Sequestrant, Stabilizer, Thickener
INS 452(v)	Ammonium polyphosphate	Functional Class: Emulsifier, Humectant, Sequestrant, Stabilizer, Thickener
INS 542	Bone phosphate	Functional Class: Anticaking agent, Emulsifier, Humectant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
02.1.2	Vegetable oils and fats	220 mg/kg	33	6
02.1.3	Lard, tallow, fish oil, and other animal fats	220 mg/kg	33	6
04.1.2.1	Frozen fruit	200 mg/kg	33	6
04.1.2.2	Dried fruit	10 mg/kg	33	6
04.1.2.4	Canned or bottled (pasteurized) fruit	200 mg/kg	33	6
04.1.2.5	Jams, jellies, marmelades	530 mg/kg	33	6
06.1	Whole, broken, or flaked grain, including rice	440 mg/kg	33	6
06.2.2	Starches	6200 mg/kg	33	3
06.8.2	Soybean-based beverage film	35000 mg/kg	33	3
06.8.4	Semi-dehydrated soybean curd	35000 mg/kg	33	3
06.8.5	Dehydrated soybean curd (kori tofu)	35000 mg/kg	33	3
06.8.6	Fermented soybeans (e.g., natto, tempe)	35000 mg/kg	33	3
06.8.7	Fermented soybean curd	35000 mg/kg	33	3
07.0	Bakery wares	9300 mg/kg	33	6
08.1.2	Fresh meat, poultry, and game, comminuted	2200 mg/kg	33	6
09.1.1	Fresh fish	GMP 33	6	
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	2200 mg/kg	33	3
12.2.1	Herbs and spices	GMP	33	6
12.4	Mustards	1320 mg/kg	33	6
12.5.1	Ready-to-eat soups and broths, including canned, bottled, and frozen	1320 mg/kg	33	6
12.5.2	Mixes for soups and broths	6600 mg/kg	33	6
12.10	Protein products other than from soybeans	35000 mg/kg	33	3
14.2.1	Beer and malt beverages	440 mg/kg	33	6
14.2.3	Grape wines	440 mg/kg	33	6
14.2.4	Wines (other than grape)	440 mg/kg	33	6
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	12000 mg/kg	33	6
16.0	Prepared foods	2000 mg/kg	33	6

**POLYGLYCEROL ESTERS OF FATTY ACIDS**

INS 475 Polyglycerol esters of fatty acids Functional Class: Emulsifier

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	10000 mg/kg		4

**POLYSORBATES**

INS 432	Polyoxyethylene (20) sorbitan monolaurate	Functional Class: Emulsifier
INS 433	Polyoxyethylene (20) sorbitan monooleate	Functional Class: Emulsifier
INS 434	Polyoxyethylene (20) sorbitan monopalmitate	Functional Class: Emulsifier
INS 435	Polyoxyethylene (20) sorbitan monostearate	Functional Class: Emulsifier
INS 436	Polyoxyethylene (20) sorbitan tristearate	Functional Class: Emulsifier

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	1000 mg/kg		6

**POTASSIUM DIHYDROGEN CITRATE**

INS 332(i)	Potassium dihydrogen citrate	Functional Class: Acidity regulator, Sequestrant, Stabilizer
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FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP	16	7

**QUINOLINE YELLOW**

INS 104	Quinoline yellow	Functional Class: Colour
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FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	500 mg/kg		7

**SODIUM ALUMINIUM PHOSPHATES**

INS 541(i)	Sodium aluminium phosphate, acidic	Functional Class: Acidity regulator, Emulsifier, Raising agent, Stabilizer, Thickener
INS 541(ii)	Sodium aluminium phosphate, basic	Functional Class: Acidity regulator, Emulsifier, Stabilizer, Thickener

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	2000 mg/kg	6	6
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	2000 mg/kg	6	6
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	2000 mg/kg	6	6
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	2000 mg/kg	6 & 72	6
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	350 mg/kg	29	3
06.2	Flours and starches (including soybean powder)	3600 mg/kg	6	3
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	2000 mg/kg	6	6
10.4	Egg-based desserts (e.g., custard)	2000 mg/kg	6	6
12.5.2	Mixes for soups and broths	2000 mg/kg	6 & 127	6
16.0	Prepared foods	190 mg/kg	6	6

**SODIUM ALUMINOSILICATE**

INS 554	Sodium aluminosilicate	Functional Class: Anticaking agent
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FoodCatNo	FoodCategory	MaxLevel	Comments	Step
06.3	Breakfast cereals, including rolled oats	20000 mg/kg	6	3
06.4.3	Pre-cooked pastas and noodles and like products	20000 mg/kg	6	3

## SODIUM ALUMNSILICATE

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	20000 mg/kg	6	3
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	10000 mg/kg	6 & 174	3

**SODIUM DIACETATE**

INS 262(ii) Sodium diacetate Functional Class: Acidity regulator, Preservative, Sequestrant

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	3000 mg/kg		7

**SODIUM DIHYDROGEN CITRATE**

INS 331(i) Sodium dihydrogen citrate Functional Class: Acidity regulator, Emulsifier, Sequestrant, Stabilizer

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP	16	7

**SORBATES**

INS 200 Sorbic acid Functional Class: Preservative  
 INS 201 Sodium sorbate Functional Class: Preservative  
 INS 202 Potassium sorbate Functional Class: Preservative  
 INS 203 Calcium sorbate Functional Class: Preservative

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
03.0	Edible ices, including sherbet and sorbet	1000 mg/kg	42	6
04.1.2.1	Frozen fruit	1000 mg/kg	42	6
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	1500 mg/kg	42	6
05.1.4	Cocoa and chocolate products	1000 mg/kg	42	6
06.2	Flours and starches (including soybean powder)	1000 mg/kg	42	6
06.4.2	Dried pastas and noodles and like products	2000 mg/kg	42	6
12.6.1	Emulsified sauces and dips (e.g., mayonnaise, salad dressing, onion dip)	3350 mg/kg	42	6
12.6.2	Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy)	2000 mg/kg	42	6
12.6.3	Mixes for sauces and gravies	2000 mg/kg	42	6
12.6.4	Clear sauces (e.g., fish sauce)	2000 mg/kg	42	6
14.1.2.2	Vegetable juice	1000 mg/kg	42	6
14.1.2.4	Concentrates for vegetable juice	1000 mg/kg	42	6
14.1.3.2	Vegetable nectar	1000 mg/kg	42	6
14.1.3.4	Concentrates for vegetable nectar	1000 mg/kg	42	6
14.1.4.1	Carbonated water-based flavoured drinks	1000 mg/kg	42	6
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades	1000 mg/kg	42	6
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	1500 mg/kg	42	6
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	600 mg/kg	42	6

**STEAROYL LACTYLATES**

INS 481(i) Sodium stearoyl lactylate Functional Class: Emulsifier, Stabilizer  
 INS 482(i) Calcium stearoyl lactylate Functional Class: Emulsifier

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	5000 mg/kg		7

**SUCROSE ESTERS OF FATTY ACIDS**

INS 473 Sucrose esters of fatty acids Functional Class: Emulsifier, Stabilizer

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	10000 mg/kg		7

**TARTRATES**

INS 334 L(+)-Tartaric acid Functional Class: Acidity regulator, Antioxidant, Sequestrant  
 INS 335(i) Monosodium tartrate Functional Class: Acidity regulator, Sequestrant, Stabilizer  
 INS 335(ii) Sodium L(+)-tartrate Functional Class: Acidity regulator, Sequestrant, Stabilizer  
 INS 336(i) Monopotassium tartrate Functional Class: Acidity regulator, Sequestrant, Stabilizer  
 INS 336(ii) Dipotassium tartrate Functional Class: Acidity regulator, Sequestrant, Stabilizer  
 INS 337 Potassium sodium L(+)-tartrate Functional Class: Acidity regulator, Sequestrant, Stabilizer

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	600 mg/kg	2 & 45	7

**TARTRAZINE**

INS 102 Tartrazine Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	500 mg/kg		7

**TRIPOTASSIUM CITRATE**

INS 332(ii) Tripotassium citrate Functional Class: Acidity regulator, Sequestrant, Stabilizer

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
04.1.1.2	Surface-treated fresh fruit	GMP	16	7

**TRISODIUM CITRATE**

INS 331(iii) Trisodium citrate Functional Class: Acidity regulator, Emulsifier, Sequestrant, Stabilizer

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
01.2.1	Fermented milks (plain)	1500 mg/kg	63	7
04.1.1	Fresh fruit	2000 mg/kg		7

**ZEAXANTHIN, SYNTHETIC**

INS 161h(i) Zeaxanthin, synthetic Functional Class: Colour

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
16.0	Prepared foods	100 mg/kg		4

**Notes**

Note 1 As adipic acid.

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

Note 6 As aluminium.

Note 10 As ascorbyl stearate.

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

Note 27 As para-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: [(33 000 U/kg bw) x (0.025 µg/U) x (1 mg/1 000 µg)] = 0.825 mg/kg bw

- Note 33 As phosphorus.
- Note 42 As sorbic acid.
- Note 45 As tartaric acid.
- Note 50 For use in fish roe only.
- Note 58 As calcium.
- Note 63 On amount of dairy ingredients.
- Note 72 Ready-to-eat basis.
- Note 127 As served to the consumer.
- Note 129 For use as an acidity regulator in grape juice.
- Note 161 Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.
- Note 174 Singly or in combination: sodium aluminosilicate (INS 554), calcium aluminium silicate (INS 556), and aluminium silicate (INS 559).
- Note 181 Expressed as anthocyanin.
- Note 183 Products conforming to the Standard for Chocolate and Chocolate Products (CODEX STAN 87-1981) may only use colours for surface decoration.
- Note 185 As norbixin.
- Note 188 Not to exceed the maximum use level for acesulfame potassium (INS 950) singly or in combination with aspartame-acesulfame salt (INS 962).

## CODEX GENERAL STANDARD FOR FOOD ADDITIVES

## NEW PROVISIONS – STEP 3 AND STEP 4

**PART 1 – for comments at Step 3****ASPARTAME-ACESULFAME SALT**

INS 962 Aspartame-acesulfame salt Functional Class: Sweetener

FoodCatNo	FoodCategory	MaxLevel	Comments	Step
14.1.3.1	Fruit nectar	350 mg/kg	113	3
14.1.3.3	Concentrates for fruit nectar	350 mg/kg	113 & 127	3

**Notes**

Note 113 Use level reported as acesulfame potassium equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.44). Combined use of aspartame-acesulfame salt with individual acesulfame potassium or aspartame should not exceed the individual maximum levels for acesulfame potassium or aspartame (the reported maximum level can be converted to aspartame equivalents by dividing by 0.68).

Note 127 As served to the consumer.

**Part B – include in the GSFA at Step 4**

LAURIC ARGINATE ETHYL ESTER (INS 243)					
Functional Class: Preservative					
Food Cat No.	Food Category	Max Level		Notes	Step
09.2.4	Cooked and/or fried fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg		4
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	200	mg/kg		4
09.3.1	Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	200	mg/kg		4
09.3.2	Fish and fish products, including mollusks, crustaceans and echinoderms, pickled and/or in brine	200	mg/kg		4
09.3.3	Salmon substitutes, caviar and other fish roe products	200	mg/kg		4
09.3.4	Semi-preserved fish and fish products, including mollusks, crustaceans and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	200	mg/kg		4

LYCOPENES					
INS 160d(i) Lycopene, synthetic		Functional Class: Colour			
INS 160d(ii) Lycopene, tomato		Functional Class: Colour			
INS 160d(iii) Lycopene, <i>Blakeslea trispora</i>		Functional Class: Colour			
Food Cat No.	Food Category	Max Level		Notes	Step
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)	100	mg/kg		4
02.1	Fats and oils essentially free from water	25	mg/kg		4
02.2.1	Butter	25	mg/kg		4
06.4.2	Dried pastas and noodles and like products	100	mg/kg	Note 211	4
09.2	Processed fish and fish products, including mollusks, crustaceans and echinoderms	100	mg/kg	Note 95	4
10.1	Fresh Eggs	1000	mg/kg	Note 4	4
10.2.1	Liquid Egg Products	100	mg/kg		4
10.2.2	Frozen Egg Products	100	mg/kg		4

<b>LYCOPENES</b>					
<b>INS 160d(i) Lycopene, synthetic</b>		<b>Functional Class: Colour</b>			
<b>INS 160d(ii) Lycopene, tomato</b>		<b>Functional Class: Colour</b>			
<b>INS 160d(iii) Lycopene, <i>Blakeslea trispora</i></b>		<b>Functional Class: Colour</b>			
<b>Food Cat No.</b>	<b>Food Category</b>	<b>Max Level</b>		<b>Notes</b>	<b>Step</b>
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	50	mg/kg		4

<b>SUCROSE OLIGOESTERS TYPE I AND TYPE II (INS 473a)</b>					
<b>Functional Class: Emulsifier, Stabilizer</b>					
<b>Food Cat No.</b>	<b>Food Category</b>	<b>Max Level</b>		<b>Notes</b>	<b>Step</b>
01.3.2	Beverage whiteners	5,000	mg/kg		4
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	5,000	mg/kg		4
01.4.4	Cream analogues	5,000	mg/kg		4
01.6.4	Processed cheese	1,500	mg/kg		4
01.7	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)	5,000	mg/kg		4
02.1.2	Vegetable oils and fats	50,000	mg/kg		4
02.1.3	Lard, tallow, fish oil, and other animal fats	5,000	mg/kg		4
02.2.2	Fat spreads, dairy fat spreads and blended spreads	10,000	mg/kg		4
02.3	Fat emulsions mainly of type oil in- water, including mixed and/or flavoured products based on fat emulsions	5,000	mg/kg		4
05.1.4	Cocoa and chocolate products	6,000	mg/kg		
05.1.5	Imitation chocolate, chocolate substitute products	6,000	mg/kg		4
05.2.1	Hard candy	50,000	mg/kg		4
05.2.2	Soft candy	5,000	mg/kg		4
05.3	Chewing gum	50,000	mg/kg		4
06.8.8	Other soybean protein products	10,000	mg/kg		4
12.2.1	Herbs and spices	2,000	mg/kg		4
12.2.2	Seasonings and condiments	20,000	mg/kg		4
12.6.3	Mixes for sauces and gravies	5,000	mg/kg		4
13.6	Food supplements (Hard capsule)	50,000	mg/kg		4
	Food supplements (Tablet)	50,000	mg/kg		4

<b>STEVIOLE GLYCOSIDES (INS 960)</b>					
<b>Functional Class: Sweetener</b>					
<b>Food Cat No.</b>	<b>Food Category</b>	<b>Max Level</b>		<b>Notes</b>	<b>Step</b>
9.2.4.3	Fried fish and fish products, including mollusks, crustaceans, and echinoderms	250	mg/kg		4
09.3.2	Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	120	mg/kg		4
09.3.3	Salmon substitutes, caviar, and other fish roe products	120	mg/kg		4

## NOTES

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

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

Note 211: For use in noodles only.



**CODEX GENERAL STANDARD FOR FOOD ADDITIVES****REVISED TITLES AND DESCRIPTORS OF FOOD CATEGORIES 16.0 AND 12.6.1****(for adoption)****FOOD CATEGORY 16.0****16.0 Prepared foods**

These foods are not included in the other food categories (01-15) and should be considered on a case-by-case basis. Prepared foods are mixtures of multiple components (e.g., meat, sauce, grain, cheese, vegetables); the components are included in other food categories. Prepared foods require minimal preparation by the consumer (e.g., heating, thawing, rehydrating). Provisions for additives will be listed in this food category in the GSFA only if the additive is needed: (i) solely to have a technological function in the prepared food as sold to the consumer; or (ii) at a use level that has an intentional technological function in the prepared food that exceeds the use level that can be accounted for by carry-over from the individual components.

**FOOD CATEGORY 12.6.1****12.6.1 Emulsified sauces and dips (e.g., mayonnaise, salad dressing, onion dip)**

Sauces, gravies, dressings, **and dips** based, at least in part, on a fat- or oil-in water emulsion. Examples include: salad dressing (e.g., French, Italian, Greek, ranch style), fat-based sandwich spreads (e.g., mayonnaise with mustard), salad cream, fatty sauces **and snack dips (e.g., bacon and cheddar dip, onion dip)**.

Appendix XI**REVISION OF THE CODEX STANDARD FOR FOOD GRADE SALT  
(CODEX STAN 150-1985)<sup>1</sup>**

(N08-2010)

**(for adoption at Step 8 of the Procedure)****1. SCOPE**

This standard applies to salt used as an ingredient of food, both for direct sale to the consumer and for food manufacture. It applies also to salt used as a carrier of food additives and/or nutrients. Subject to the provisions of this standard more specific requirements for special needs may be applied. It does not apply to salt from origins other than those mentioned in Section 2, notably the salt which is a by-product of chemical industries.

**2. DESCRIPTION**

Food grade salt is a crystalline product consisting predominantly of sodium chloride. It is obtained from the sea, from underground rock salt deposits or from natural brine.

**3. ESSENTIAL COMPOSITION AND QUALITY FACTORS****3.1 Minimum NaCl content**

The content of NaCl shall not be less than 97% on a dry matter basis, exclusive of additives.

**3.2 Naturally present secondary products and contaminants**

The remainder comprises natural secondary products, which are present in varying amounts depending on the origin and the method of production of the salt, and which are composed mainly of calcium, potassium, magnesium and sodium sulphates, carbonates, bromides, and of calcium, potassium, magnesium chlorides as well. Natural contaminants may also be present in amounts varying with the origin and the method of production of the salt. Copper shall not exceed 2 mg/kg (expressed as Cu).

**3.3 Use as a carrier**

Food grade salt shall be used when salt is used as a carrier for food additives or nutrients for technological or public health reasons. Examples of such preparations are mixtures of salt with nitrate and/or nitrite (curing salt) and salt mixed with small amounts of fluoride, iodide or iodate, iron, vitamins, etc., and additives used to carry or stabilize such additions.

**3.4 Iodisation of food grade salt**

In iodine-deficient areas, food grade salt shall be iodised to prevent iodine-deficiency disorders (IDD) for public health reasons.

**3.4.1 Iodine compounds**

For the fortification of food grade salt with iodine, use can be made of sodium and potassium iodides or iodates.

**3.4.2 Maximum and minimum levels**

The maximum and minimum levels used for the iodisation of food grade salt are to be calculated as iodine (expressed as mg/kg) and shall be established by the national health authorities in the light of the local iodine deficiency situation.

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<sup>1</sup> The *Codex Standard for Food Grade Salt* was adopted by the Codex Alimentarius Commission at its 16<sup>th</sup> session in 1985. A revised Standard was adopted by the 22<sup>nd</sup> session in 1997 and amended by the 23<sup>rd</sup> session in 1999, the 24<sup>th</sup> session in 2001 and the 29<sup>th</sup> session in 2006.

### 3.4.3 Quality assurance

The production of iodised food grade salt shall only be performed by reliable manufacturers having the knowledge and the equipment requisite for the adequate production of iodised food grade salt, and specifically, for the correct dosage and even intermixing.

## 4. FOOD ADDITIVES

Food additives listed in Tables 1 and 2 of the *Codex General Standard for Food Additives* (CODEX STAN 192-1995) in Food Category 12.1.1 (Salt) may be used in foods subject to this standard.

## 5. CONTAMINANTS

The products covered by this Standard shall comply with the Maximum Levels of the *Codex General Standard for Contaminants and Toxins in Foods and Feeds* (CODEX/STAN 193-1995).

## 6. FOOD HYGIENE

It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

## 7. LABELLING

In addition to the requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985) the following specific provisions apply:

### 7.1 The name of the product

7.1.1 The name of the product, as declared on the label shall be "salt".

7.1.2 The name "salt" shall have in its close proximity a declaration of either "Food Grade" or "Cooking Salt" or "Table Salt".

7.1.3 Only when salt contains one or more ferrocyanide salts, added to the brine during the crystallization step, the term "dendritic" could be included accompanying the name.

7.1.4 Where salt is used as a carrier for one or more nutrients, and sold as such for public health reasons, the name of the product shall be declared properly on the label, for example "salt fluoridated", "salt iodated", "salt iodized", "salt fortified with iron", "salt fortified with vitamins" and so on, as appropriate.

7.1.5 An indication of either the origin, according to the description on Section 2, or the method of production may be declared on the label, provided such indication does not mislead or deceive the consumer.

### 7.2 Labelling of non-retail containers

Information for non-retail containers shall either be given on the container or in accompanying documents, except that the name of the product, lot identification and name and address of the manufacturer or packer shall appear on the container. However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such mark is clearly identifiable with the accompanying documents.

## 8. PACKAGING, TRANSPORTATION AND STORAGE

In any salt iodisation program, it is important to ensure that salt contains the recommended amount of iodine at the time of consumption. The retention of iodine in salt depends on the iodine compound used, the type of packaging, the exposure of the package to prevailing climatic conditions and the period of time between iodisation and consumption. To ensure that iodized salt ultimately reaches the consumer with the specified level of iodine, the following precautions may be taken into consideration by countries where climatic and storage conditions could result in a large amount of iodine loss:

8.1 If necessary in order to avoid the loss of iodine, iodised salt should be packed in air tight bags of either high density polyethylene (HDPE) or polypropylene (PP) (laminated or non-laminated) or LDPE-lined jute bags (Grade 1803 DW jute bags lined with 150 gauge polyethylene sheet). In many countries, this may

require a major switch from conventional packaging materials made of straw or jute. The cost of adding extra iodine to compensate for its loss from cheaper packaging (i.e., straw or jute) must be weighed against the cost of switching to the above expensive packing material.

8.2 Bulk packing units should not exceed 50 kg (in accordance with International Labour Organization (ILO) Conventions) to avoid the use of hooks for lifting the bags.

8.3 Bags that have already been used for packing other articles such as fertilizers, cement, chemicals, etc. should not be reused for packing iodised salt.

8.4 The distribution network should be streamlined so as to reduce the interval between iodisation and consumption of salt.

8.5 Iodised salt should not be exposed to rain, excessive humidity or direct sunlight at any stage of storage, transportation or sale.

8.6 Bags of iodised salt shall be stored only in covered rooms or “godowns” that have adequate ventilation.

8.7 The consumer should be similarly advised to store iodised salt in such a manner as to protect it from direct exposure to moisture, heat and sunlight.

## **9. METHODS OF ANALYSIS AND SAMPLING**

### **9.1 Sampling (see Appendix)**

### **9.2 Determination of sodium chloride content**

This method allows the calculation of sodium chloride content, as provided for in Section 3.1, on the basis of the results of the determinations of sulphate (Method 9.4), calcium and magnesium (Method 9.5), potassium (Method 9.6) and loss on drying (Method 9.7). Convert sulphate to  $\text{CaSO}_4$  and unused calcium to  $\text{CaCl}_2$ , unless sulphate in sample exceeds the amount necessary to combine with calcium, in which case convert calcium to  $\text{CaSO}_4$  and unused sulphate first to  $\text{MgSO}_4$  and any remaining sulphate to  $\text{Na}_2\text{SO}_4$ . Convert unused magnesium to  $\text{MgCl}_2$ . Convert potassium to  $\text{KCl}$ . Convert unused halogens to  $\text{NaCl}$ . Report the  $\text{NaCl}$  content on a dry matter basis, multiplying the percentage  $\text{NaCl}$  by  $100/100\text{-P}$ , where P is the percentage loss on drying.

### **9.3 Determination of insoluble matter**

According to ISO 2479-1972 "Determination of matter insoluble in water or in acid and preparation of principal solutions for other determinations".

### **9.4 Determination of sulphate content**

According to ISO 2480-1972 "Determination of sulphate content - barium sulphate gravimetric method". Alternatively, EuSalt/AS 015-2007 "Determination of Elements Emission Spectrometric Method (ICP-OES)" or EuSalt/ AS 018-2005 "Determination of Anions High Performance Ion Chromatography (HPIC) may be used."

### **9.5 Determination of calcium and magnesium contents**

According to ISO 2482-1973 "Determination of calcium and magnesium contents - EDTA complexometric methods". Alternatively, EuSalt/AS 009-2005 "Determination of Calcium and Magnesium Flame Atomic Absorption Spectrometric Method" or EuSalt/ AS 015-2007 "Determination of Elements Emission Spectrometric Method (ICP-OES) may be used.

### **9.6 Determination of potassium content**

According to EuSalt/AS 008-2005 "Determination of potassium by flame atomic absorption spectrophotometric method". Alternatively EuSalt/ AS 015-2007 "Determination of Elements Emission Spectrometric Method (ICP-OES) may be used.

### **9.7 Determination of the loss on drying (conventional moisture)**

According to ISO 2483-1973 "Determination of the loss of mass at  $110^\circ\text{C}$ ".

### **9.8 Determination of copper content**

According to EuSalt/AS 015-2007 "Determination of Elements Emission Spectrometric Method" (ICP-OES).

### **9.9 Determination of arsenic content**

According to EuSalt/AS 015-2007 "Determination of Elements Emission Spectrometric Method" (ICP-OES) may be used.

### **9.10 Determination of mercury content**

According to method EuSalt/AS 012-2005 "Determination of total mercury content - cold vapour atomic absorption spectrometric method" or EuSalt/AS 015-2007 "Determination of Elements Emission Spectrometric Method (ICP-OES).

### **9.11 Determination of lead content**

According to method EuSalt/AS 013-2005 "Determination of total lead content - flame atomic absorption spectrometric method". Alternatively, EuSalt/AS 015-2007 "Determination of Elements Emission Spectrometric Method (ICP-OES) may be used.

### **9.12 Determination of cadmium content**

According to method EuSalt/AS 014-2005 "Determination of total cadmium content - flame atomic absorption spectrometric method". Alternatively, EuSalt/AS 015-2007 "Determination of Elements Emission Spectrometric Method (ICP-OES) may be used.

### **9.13 Determination of iodine content**

According to method EuSalt/AS 002-2005 "Determination of total iodine content - titrimetric method using sodium thiosulfate". Alternatively the method from WHO/UNICEF/ICCIDD "Assessment of iodine deficiency disorders and monitoring their elimination. A guide for programme managers. Third edition, Annex 1: Titration method for determining salt iodate and salt iodine content. World Health Organization, Geneva, 2007" or EuSalt/AS 019-2009 "Determination of Total Bromine and Iodine Emission Spectrometric Method (ICP-OES)" may be used.

## **APPENDIX**

### **METHOD FOR THE SAMPLING OF FOOD GRADE SALT FOR THE DETERMINATION OF SODIUM CHLORIDE**

#### **1. SCOPE**

This method specifies the sampling procedure to be applied when determining the main component in order to assess the food grade quality of sodium chloride (salt) as provided for in the Codex Standard for Food Grade Salt, Section 3: "Essential Composition and Quality Factors".

The criterion to be used for acceptance or rejection of a lot or consignment on the basis of this sample is also provided.

#### **2. FIELD OF APPLICATION**

This method is applicable to the sampling of any type of salt intended for use as food, either prepacked or in bulk.

#### **3. PRINCIPLE**

This method represents a variables sampling procedure for mean quality: blended bulk sample analysis.

A blended bulk sample is produced in such a way that it is representative of the lot or consignment. It is composed of a proportion of items drawn from the lot or consignment to be analyzed.

Acceptance criterion is on the basis that the mean value obtained from analyses of those blended bulk samples must comply with the provision in the Standard.

#### **4. DEFINITIONS**

The terms used in this sampling method refer to those in the "*General Guidelines on Sampling*" (CAC/GL 50-2004) unless stated otherwise.

#### **5. EQUIPMENT**

The sampling equipment used should be adapted to the nature of the tests to be carried out (for example: sampling by borer, sampling equipment made of chemically inert material, etc.). The containers used for collecting the samples should be made of a chemically inert material and should be air-tight.

#### **6. PROCEDURE**

##### **6.1 Prepacked Salt**

Sampling may be carried out by "random sampling" or by "systematic sampling". The choice of the method to be used depends on the nature of the lot (for example: if the packages are marked with successive numbers, systematic sampling may be suitable).

##### **6.1.1 Random sampling**

Draw the n items from the lot in such a way that each item in the lot has the same chance of being selected.

##### **6.1.2 Systematic sampling**

If the N units in the lot have been classified and can be numbered from 1 to N, the 1-in-k systematic sampling of n items can be obtained as follows:

- a) Determine the k value as  $k = N/n$ . (If k is not an integer, then round to the nearest integer).
- b) From the first k items in the lot take one at random and then take every  $k^{\text{th}}$  item thereafter.

## 6.2 Salt in Bulk

Here, the lot is fictitiously divided into items (strata); a lot with a total mass of  $m$  kg is considered to be composed of  $m/100$  items. In this case, it is necessary to draw up a "stratified sampling" plan appropriate to the lot dimension. The samples are selected from all the strata in proportion to the stratum sizes.

Note: Stratified sampling of a population which can be divided into different subpopulations (called strata) is carried out in such a way that specified proportions of the sample are drawn from the different strata.

## 6.3 Constitution of the Sample

6.3.1 The size and the number of the items forming the sample depend on the type of salt and the lot magnitude. The minimum size to be taken into account should be in accordance with one of the following specifications according to the circumstances:

- 250 g of salt in bulk or prepacked in more than 1 kg packages;
- one package for prepacked salt in 500 g or 1 kg packages.

The appropriate number of samples to be drawn from the lot, shall be determined in accordance with "*General Guidelines on Sampling*" (CAC/GL 50-2004).

6.3.2 Combine and mix well the different items drawn from the lot. This blended bulk sample constitutes the laboratory sample. More than one laboratory sample may be composed in such a manner.

## 7. ACCEPTANCE CRITERION

7.1 Determine the NaCl content (%) of at least two test portions of the laboratory sample.

7.2 Calculate the average of the results obtained for the  $n$  test portions of the laboratory sample using:

$$\bar{x} = \frac{\sum x}{n} \quad (n \geq 2)$$

7.3 In accordance with the provision for the relevant NaCl content (%), a lot or a consignment shall be considered acceptable if the following condition is verified:

$$\bar{x} \geq \text{minimum level specified.}$$

## 8. SAMPLING REPORT

The sampling report should contain the following information:

- a) type and origin of the salt;
- b) alterations of state of the salt (e.g. presence of foreign matter);
- c) date of sampling;
- d) lot or consignment number;
- e) method of packing;
- f) total mass of lot or consignment
- g) number, unit mass of packages and whether the mass is given net or gross;
- h) number of items sampled;
- i) number, nature and initial position of sampled items;
- j) number, composition and mass of the bulk sample(s) and the method used to obtain and conserve it (them);
- k) names and signatures of the people who carried out the sampling.

Appendix XII**PROPOSED DRAFT AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM FOR  
FOOD ADDITIVES****(for adoption at Step 5/8 of the Procedure)****Section 3 and 4 – International numbering system for food additives****Part 1** – Amendments to the names of food additives and technological purposes (changes are indicated in **bold**; deletions ~~strikethrough~~)

<b>INS No.</b>	<b>Name of Food Additive</b>	<b>Technological Purpose</b>
124	Ponceau 4R ( <b>Cochineal red A</b> )	colour
<b>160 c(i)</b>	Paprika oleoresin	colour
<b>160 c(ii)</b>	<b>Paprika extract</b>	<b>colour</b>
173	Aluminium <b>powder</b>	<b>surface colourant</b>
180	Lithol <b>rubine</b> BK	colour
<del>452(vi)</del> <b>451(iii)</b>	<del>Sodium potassium tripolyphosphate</del> <b>Sodium potassium triphosphate</b>	acidity regulator emulsifier moisture-retention agent raising agent sequestrant stabilizer
<b>452(i)</b>	<b>Sodium potassium hexametaphosphate</b>	<b>acidity regulator</b> <b>emulsifier</b> <b>moisture-retention agent</b> <b>raising agent</b> <b>sequestrant</b> <b>stabilizer</b> <b>texturizing agent</b>
<b>561</b>	<b>Potassium aluminium silicate</b>	<b>carrier</b>

**Part 2** – additional technological purposes and deletions (changes are indicated in **bold**; deletions ~~strikethrough~~)

<b>INS No.</b>	<b>Name of Food Additive</b>	<b>Technological Purpose</b>
170(i)	Calcium carbonate	acidity regulator anticaking agent <b>dough conditioner</b> <b>firming agent</b> surface colourant stabilizer
220	Sulfur dioxide	antioxidant <b>bleaching agent</b> <b>flour treatment agent</b> preservative



INS No.	Name of Food Additive	Technological Purpose
221	Sodium sulfite	antioxidant <b>bleaching agent</b> <b>flour treatment agent</b> preservative
224	Potassium metabisulfite	antioxidant <b>bleaching agent</b> <b>flour treatment agent</b> preservative
334	L(+)- Tartaric Acid	acidity regulator antioxidant <b>flavour synergist</b> sequestrant
386	Disodium ethylenediaminetetraacetate	antioxidant <b>colour stabilizer</b> preservative sequestrant <b>stabilizer</b>
481(i)	Sodium stearoyl lactylate	<b>dough conditioner</b> emulsifier stabilizer <b>whipping agent</b>
482(i)	Calcium stearoyl lactylate	<b>dough conditioner</b> emulsifier <b>stabilizer</b> <b>whipping agent</b>
484	Stearyl citrate	<b>antioxidant</b> emulsifier sequestrant
501(ii)	Potassium hydrogen carbonate	acidity regulator <b>raising agent</b> stabilizer
523	Aluminium ammonium sulfate	<b>acidity regulator</b> <b>buffer</b> <b>colour fixative</b> firming agent <b>raising agent</b> stabilizer
551	Silicon dioxide, amorphous	anticaking agent <b>carrier</b> <del>conditioning agent</del> <b>defoaming agent</b>
579	Ferrous gluconate	colour retention agent <b>colour stabilizer</b>

<b>INS No.</b>	<b>Name of Food Additive</b>	<b>Technological Purpose</b>
901	Beeswax	<b>carrier</b> clouding agent <b>coating agent</b> glazing agent <b>stabilizer</b> <b>texturizing agent</b> <b>thickener</b>
902	Candelilla wax	<b>carrier</b> clouding agent glazing agent <b>surface-finishing agent</b> <b>texturizing agent</b>
903	Carnauba wax	acidity regulator <b>anticaking agent</b> bulking agent carrier glazing agent
905c(i)	Microcrystalline wax	glazing agent <b>defoaming agent</b>
905d	Mineral oil, high viscosity	<b>defoaming agent</b> glazing agent sealing agent
925	Chlorine	flour bleaching agent
928	Benzoyl peroxide	<b>bleaching agent</b> flour treatment agent preservative
1201	Polyvinylpyrrolidone	bodying agent <b>coating agent</b> dispersing agent stabilizer
1204	Pullulan	film-forming agent glazing agent <b>thickener</b>
1521	Polyethylene glycol	antifoaming agent <b>binder</b> carrier emulsifier <del>flavouring adjuvant</del> glazing agent plasticizer

### **Part 3 – Withdrawal from the INS**

Potassium bromate (INS 924a) and calcium bromate (INS 924b).

**PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES****(for adoption at Step 5/8 of the Procedure)****Part 1 – for adoption****SPECIFICATIONS DESIGNATED AS FULL (FAO JECFA Monographs 11, Rome, 2011):**

Caramel colours (R) (INS 150a, 150b, 150c, 150d)  
β-apo-8'-Carotenal (R) (INS 160e)  
β-apo-8'-Carotenoic acid ethyl ester (R) (INS 160f)  
β-Carotene, synthetic (R) (INS 160a (i))  
Hydroxypropylmethyl cellulose (R) (INS 464)  
Magnesium silicate, synthetic (R) (INS 553(i))  
Nitrous oxide (R) (INS 942)  
Ponceau 4R (R) (INS 124)  
Pullulan (R) (INS 1204)  
Pullulanase from *Bacillus deramificans* expressed in *Bacillus licheniformis* (N)  
Sodium carboxymethyl cellulose (R) (INS 466)  
Sucrose monoesters of lauric, palmitic or stearic acid (R)

**SPECIFICATIONS REVISED (FULL) WITHOUT BEING REPUBLISHED (available in the electronic version of the specifications at the FAO JECFA website):**

Aluminium ammonium sulfate (INS 523)  
Aluminium lakes of colouring matters  
Aluminium potassium sulfate (INS 522)  
Aluminium powder (INS 173)  
Aluminium silicate (INS 559)  
Aluminium sulfate, anhydrous (INS 520)  
Calcium aluminium silicate (INS 556)  
Sodium aluminium phosphate, acidic (INS 541(i))  
Sodium aluminium phosphate, basic (INS 541(ii))

**SPECIFICATIONS CORRECTED (FULL) WITHOUT BEING REPUBLISHED (available in the electronic version of the specifications at the FAO JECFA website):**

Sucrose esters of fatty acids (INS 473)

**Part 2 – for revocation****SPECIFICATIONS WITHDRAWN:**

Potassium bromate (INS 924a)

Appendix XIV**PRIORITY LIST OF COMPOUNDS PROPOSED FOR EVALUATION BY JECFA**

<i>Compound</i>	<i>Question(s) to be answered</i>	<i>Data availability (when, what)</i>	<i>Proposed by</i>
Xanthan gum (INS 415)	Safety assessment for use in infant formula and formulae for special medical purposes intended for infants	December 2013	United States of America
Pectin (INS 440)	Safety assessment for use in infant formula and formulae for special medical purposes intended for infants	December 2013	United States of America and Iran
OSA-modified starch (starch sodium octenyl succinate) (INS 1450)	Safety assessment for use in infant formula and formulae for special medical purposes intended for infants	December 2012	United States of America
Monk fruit extract/Lo han guo (LHG); <i>Siraitia grosvenorii</i> Swingle	Safety assessment and establishment of specifications	December 2013	United States of America
<i>Acacia polyacantha</i> var. <i>Campylacantha</i> , kakamut gum, arabino- galactan protein complex	(1) Establishment of specifications; and (2) Safety assessment (pending further data)	(1) December 2012 (2) December 2013	Sudan
72 Flavourings	Safety assessment and establishment of specifications	Immediately	United States of America
Advantame	Safety assessment and establishment of specifications	Immediately	Australia
Glucoamylase from <i>Trichoderma reesei</i> expressed in <i>Trichoderma reesei</i>	Safety assessment and establishment of specifications	November 2012	European Union

<i>Compound</i>	<i>Question(s) to be answered</i>	<i>Data availability (when, what)</i>	<i>Proposed by</i>
Annatto extracts, bixin-based (INS 160b(i)) and annatto extracts, norbixin-based (INS 160b(ii))	Revision of specifications (change of purity test and revision of specific limits for residual solvents)	December 2012	Japan
Nisin (INS 234)	Re-evaluation (subject to confirmation)	December 2012	44 <sup>th</sup> CCFA Japan