codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3 **CX/FA 07/39/2**
February 2007

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Thirty-ninth Session

Beijing, China, 24 – 28 April 2007

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES[1]

PART 1. MATTERS ARISING FROM THE 29TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Geneva, Switzerland, 3-7 July 2006)

1.1 Terms of Reference of the Committee on Food Additives [2]

1. The Commission adopted the terms of reference proposed for both committees with the amendments proposed by the Delegation of Brazil in its written comments, thereby deciding to replace the Committee on Food Additives and Contaminants with the two new Committees. The Commission agreed that each Committee should review its terms of reference at its first session.

2. The Commission agreed that the responsibility for considering food irradiation should be transferred to the Committee on Food Hygiene and adopted the amendment to point g) of its terms of reference as proposed.

3. The Commission adopted the consequential amendments to several sections of the Procedural Manual as proposed in ALINORM 06/29/4-Add.1, with the understanding that they can be reviewed by the Commission in the light of future developments.

4. The Committee **is invited** to review its terms of reference (see Annex I), as agreed by the Commission.

1.2 Draft and proposed draft standards and related texts adopted at Step 8 and Step 5/8[3]

5. The Commission adopted at Step 8 and Steps 5/8 the following draft standards and related texts as proposed by the Codex Committee on Food Additives and Contaminants at its 38th session:

- Revision of the Preamble of the Codex General Standard for Food Additives;
- Food Additives Provisions of the General Standard for Food Additives (GSFA);
- Amendments to the International Numbering System for Food Additives;
- Specifications for the Identity and Purity of Food Additives arising from the 65th JECFA meeting.

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1 This document only contains information on matters arising from or referred by the 29th Session of the Codex Alimentarius Commission (Part 1) and from other Codex Committees (Part 2) that are specific to the activities of the Codex Committee on Food Additives. Other decisions and guidance of the 29th Session of the Commission are found in ALINORM 06/29/41. The Codex Secretariat will report verbally on matters of horizontal nature as appropriate to the discussion of the Committee.

2 ALINORM 06/29/41, paras 26-29 and Appendix III.

3 ALINORM 06/29/41, paras 39-51 and Appendix IV.

6. In addition, the Commission adopted the following texts:

- Amendments of the Annex to Table 3 of the GSFA;
- Revision of the Descriptor of Food Category 13.6 "Food Supplement" of the GSFA.

1.3 Draft and proposed draft food additive provisions of the General Standard for Food Additives (GSFA)[4]

7. The following paragraphs provide information concerning the additional decisions taken by the Commission in regard to the adoption of the draft and proposed draft Food Additives Provisions of the General Standard for Food Additives (GSFA):

8. After some discussion, the Commission adopted the draft and proposed draft food additive provisions of the GSFA (ALINORM 06/29/12, Appendices VII and IX) at Step 8 or Step 5/8 with the exception of Food Categories No. 02.2.1.2 (Margarine and similar products), No. 13.1.1 (Infant formulae) and No. 13.1.2 (Follow-up formulae) in those two Appendices and decided to defer the consideration of food additive provisions of those food categories, pending finalization of the draft Standard for Fat Spreads and Blended Spreads, and the draft Standard for Infant Formula and submission of the food additive sections of these standards for endorsement by CCFAC.

9. As recommended by the Executive Committee, the Commission invited CCFAC to review Food Category 02.2.1.2 in order to ensure one-to-one correspondence with the relevant commodity standards.

10. The Commission endorsed the following recommendations of the Executive Committee:

(i) The Codex Committee on Food Additives and Contaminants (CCFAC) should, in its future report, clearly establish a distinction between:

a) additive provisions included in adopted standards and proposed for incorporation into the GSFA;

b) revocation of existing relevant provisions in the GSFA in order to ensure consistency with existing standards; and

c) proposed amendments to current additives provisions in Codex standards for inclusion in the GSFA. These amendments may be referred to the relevant Committee (when active committees exist and relevant standards are under consideration). The Committee may develop them as new provisions or amendments to the GSFA, in which case they should follow the Step Procedure in order to allow for comments.

(ii) When provision for additives for inclusion into the GSFA result in amendments to additive provisions in Codex standards, consequential amendments should be made to the relevant standards, and that the report of CCFAC should include a table showing the existing additive provisions in Codex standards.

11. The Committee **is invited** to: i) review Food Category 02.2.1.2 in order to ensure one-to-one correspondence with the relevant commodity standards; and ii) take into account the above recommendations when considering the incorporation into the GSFA of food additives provisions included in commodity standards.

1.4 Proposed draft standards and related texts adopted at Step 5[5]

12. The Commission adopted at Step 5 and advanced to Step 6 the proposed draft Revision of the Codex Class Names and the International Numbering System for Food Additives – CAC/GL 36-1989 (N07-2005).

1.5 Revocation of existing Codex standards and related texts[6]

13. The Commission agreed to revoke the food additive provisions in Appendices VII and XII of ALINORM 06/29/12 as proposed by the Committee, with the exception of Food Categories No. 02.2.1.2 (Margarine and similar products), No. 13.1.1 (Infant formulae) and No. 13.1.2 (Follow-up formulae), and agreed to revoke the food additives provisions in Annex II of ALINORM 06/29/7.

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4 ALINORM 06/29/41, paras 42, 49 and 51.
5 ALINORM 06/29/41, paras 99-102 and Appendix V.
6 ALINORM 06/29/41, paras 121-123 and Appendix VII.

1.6 Proposals for the elaboration of new standards and related texts and for the discontinuation of work[7]

14. The Commission approved the elaboration of Guidelines for the Use of Flavourings (N03-2006), as proposed by the Codex Committee on Food Additives and Contaminants at its 38th session.

15. The Commission agreed that, following its earlier decision on the additive provisions in food categories No. 02.2.1.2 (Margarine and similar products), No. 13.1.1 (Infant formulae) and No. 13.1.2 (Follow-up formulae), the additives corresponding to these categories should be deleted from the list of additives in Appendix XIII of ALINORM 06/29/12. The Commission agreed to discontinue work on all other additive provisions as proposed.

1.7 Others

1.7.1 General Standard for Food Additives (GSFA)[8]

16. The Commission agreed to reassign the food additive provisions as illustrated in the Annex of ALINORM 06/29/9C-Add.2.

17. The Commission agreed with the approach proposed by the CCFAC to replace food additive provisions of those Codex commodity standards that have one-to-one correspondence with the GSFA food categories, with a text referring to the provisions of the relevant GSFA category.

18. The Commission agreed to request Codex commodity committees, when they consider new entities or revision of food additive provisions in these commodity standards, to provide to the CCFAC justification of technological need for the food additives, based upon section 3.2 of the Preamble of the GSFA.

1.7.2 Critical Review of Proposals for New Work and Monitoring Progress of Standards Development[9]

19. The 29th Session of the Commission endorsed the proposal of the 57th Session of the Executive Committee to recommend to Codex Committees and Task Forces:

- To prioritize work when the agenda of the Committee includes many items of work;
- To invite all Chairpersons, or host countries for adjourned committees, to provide their comments on the items of work that have been under consideration for more than five years; and
- To inform the Executive Committee and the Commission of the proposed timeframe for completion of all items that have been approved as new work prior to 2004.

20. The Committee **is invited** to consider the above recommendations.

PART 2. MATTERS ARISING FROM OTHER CODEX COMMITTEES AND TASK FORCES

2.1 Codex Committee on Food Labelling (34th Session, Ottawa, Canada, 1-5 May 2006)[10]

Provisions for labelling of carriers and packaging gases (Codex *Class Names and International Numbering System for Food Additives* – CAC-GL 36-1989)

21. The Committee noted that the revised list of functional classes included some other amendments as compared with the current list in the *General Standard* and that the Committee would need to consider the inclusion of these revisions in the *General Standard* after they had been finalized. In particular, it was noted that the class of “acids” had been deleted and integrated into “acidity regulators”.

22. Several delegations pointed out that they had been informed of the request from CCFAC during the present session, since CCFAC had been held immediately prior to the CCFL, and therefore they could not express a position on this question at this stage but needed more time to consider the implications of the revision of the functional classes more carefully, especially as regards carriers and packaging gases.

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7 ALINORM 06/29/41, paras 124, 136 and Appendix VIII.
8 ALINORM 06/29/41, paras 188-193.
9 ALINORM 06/29/41, para. 8 and ALINORM 06/29/3, paras 64-65.
10 ALINORM 06/29/22, paras 7-13.

23. The Committee agreed that before it could consider the labelling provisions applying to new and amended functional classes of additives, these classes had to be clearly defined and asked the CCFAC to clarify the conditions under which carriers and packing gases were considered as additives or as processing aids, possibly with some specific examples. The Committee noted that the next session of the CCFAC was expected to finalise the revision of the Class Names and agreed to consider this question further at its next session in the light of the conclusions of the CCFAC.

24. The Committee **is invited** to clarify the conditions under which carries and packing gases are considered as additives or as processing aids, possibly with some specific examples, for replying to the Codex Committee on Food Labelling.

2.2 Codex Committee on Fish and Fishery Products (28th Session, Beijing, China, 18-22 September 2006)[11]

Draft Standard for Sturgeon Caviar

25. The Delegation of Japan pointed out that JECFA had not been able to allocate an ADI for boric acid (INS 284) and sodium tetraborate (INS 285) due to lack of long term studies and therefore this additive could not be included in the standard in the absence of a risk assessment The Committee recalled that only food additives that had been assigned an ADI by JECFA could be allowed at a specific level of use and therefore agreed to ask the Committee on Food Additives to place these two additives on the priority list of additives for evaluation by JECFA.

26. The Committee **is invited** to consider the above request.

2.3 Codex Committee on Nutrition and Food for Special Dietary Uses (28th Session, Chiang Mai, Thailand, 30 October – 3 November 2006)[12]

Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infant: Section A – Draft Revised Section for Infant Formula

27. The Committee noted that the basis of the advice provided by JECFA on additives in foods for young infants had been established in 1971 and agreed that further advice on the inclusion of additives in infant formula was necessary. The Committee agreed to ask the CCFA to put forward the following question to JECFA: to what extent an ADI established by JECFA, whether numerical or not specified, applied to young infants below 12 weeks; what scientific principles should apply to the evaluation of additives intended for this group of population; and whether the establishment of an ADI in itself was sufficient or whether other issues had to be addressed.

28. The Committee agreed to forward the additives in Table 2 (including additives for which suitability for use in sections A and B should be determined) to the CCFA for advice on their suitability in the products covered by sections A and B and evaluation by JECFA if required, in the light of the advice that would be provided on the general questions mentioned above. The Committee agreed to forward the additives in Table 3 (including additives intended only for FSMP) to CCFA for advice on their suitability in the products covered by section B and evaluation by JECFA if required.

29. The Committee **is invited** to consider the requests of the Codex Committee on Nutrition and Food for Special Dietary Uses. To facilitate the consideration of these requests the entire discussion of the Committee, including Tables 2 and 3, are reproduced in Annex II of this document.

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[11] ALINORM 07/30/18, paras 20-22.

[12] ALINORM 07/30/26, paras 56-68 and Appendix III.

Annex I

TERMS OF REFERENCE OF THE COMMITTEE ON FOOD ADDITIVES

Terms of reference:

(a) to establish or endorse permitted maximum levels for individual food additives;

(b) to prepare priority lists of food additives for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives;

(c) to assign functional classes to individual food additives;

(d) to recommend specifications of identity and purity for food additives for adoption by the Commission;

(e) to consider methods of analysis for the determination of additives in food; and

(f) to consider and elaborate standards or codes for related subjects such as the labelling of food additives when sold as such.

Annex II

Extract from the report of the 28th Session of the Codex Committee on Nutrition and Food for Special Dietary Uses (ALINORM 07/29/26, paras 56-68 and Appendix III)

DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS: SECTION A DRAFT REVISED STANDARD FOR INFANT FORMULA (Agenda Item 4a)

Section 4. Food Additives

56. The Delegation of Switzerland presented the report of the electronic working group that had worked between the sessions in order to redraft the Section on additives at the request of the last session of the Committee and pointed out that the approaches to the use of additives in infant formula varied widely between delegations.

General considerations

57. The Delegation of Switzerland, while presenting the report of the working group, recalled the background of consideration by JECFA of additives for use in infant foods, as follows. The Committee noted that the *Principles for the Safety Assessment of Food Additives and Contaminants* (WHO EHC 70, 1987) confirmed the principles that had been developed by the FAO/WHO Meeting on Additives in Baby Foods (1971), establishing a distinction between baby foods suitable for infants up to 12 weeks and older infants, due to physiological reasons, and concluded that "it is prudent that foods intended for infants under 12 weeks should contain no additives at all". However the *Principles* recognized "that in practice there may be certain exceptions on technological grounds", which were further specified. It was also noted that some additives had been evaluated by JECFA specifically for use in infant foods (for infants below 12 weeks) while others had been evaluated for the general population but not for this group of population.

58. The Committee noted that the basis of the advice provided by JECFA on additives in foods for young infants had been established in 1971 and agreed that further advice on the inclusion of additives in infant formula was necessary. The Committee agreed to ask the CCFA to put forward the following question to JECFA: to what extent an ADI established by JECFA, whether numerical or not specified, applied to young infants below 12 weeks; what scientific principles should apply to the evaluation of additives intended for this group of population; and whether the establishment of an ADI in itself was sufficient or whether other issues had to be addressed.

59. The Committee discussed whether the establishment of specific principles for use of additives in infant formula should be developed, as proposed by some delegations, and agreed that it would be preferable to defer consideration of this matter pending advice from JECFA.

60. Some delegations recalled that the revised Standard for Processed Cereal Based Foods for Infants and Young Children referred to the carry over of additives, and proposed to include a similar wording in the standard. The Chair recalled that the products were not the same and that carry over of additives was not allowed in the current Standard for Infant Formula. After some discussion, the Committee agreed to insert the text used for cereal based foods as an introduction to the list of additives and to ask the advice of the CCFA on the applicability of the language for carry over to infant formula.

Additives for inclusion in the Draft Standard

61. In view of the above considerations, the Committee considered the options put forward by the working group on how to proceed with the current section on additives:

1) Proceed with all food additives already listed in the current standard; defer discussion of other additives after JECFA has provided its opinion

2) Proceed with non controversial additives cleared by JECFA specifically for infants

3) Defer consideration of Section 4 until JECFA has provided its opinion

62. The EC explained that in their view the use of food additives in foods intended for infants and young children should be limited to those where there is a clear technological need and where that function can not be fulfilled by an additive on the list and expressed preference for option 2.

63. The Committee agreed to proceed with the first option and to establish a working group chaired by Switzerland during the session to identify the additives that could be included in the current Draft Standard and those that would require further consideration. The Committee considered three lists of additives that were proposed by the working group: Table 1: additives that are considered suitable for use in infant formula and formula for special medical purposes (FSMP) intended for infants use (sections A and B); Table 2 including additives for which suitability for use in sections A and B should be determined; and Table 3 including additives intended only for FSMP (section B).

64. As regards Table 1, the Delegation of the United States expressed the view that the list of additives in the current standard should be retained in view of their long history of use, with the understanding that it could be amended when new scientific advice became available.

65. The Delegation of the EC proposed to delete carrageenan from the current list in view of its adverse effects to health of young infants, until the JECFA reevaluation scheduled for 2007 became available. After some discussion, the Committee agreed to insert a footnote to the effect that national authorities may restrict the use of carrageenan until the evaluation by JECFA had been completed.

66. The Committee agreed that Table 1 would include all those additives and levels of use that were considered suitable for in infant formula and formula for special medical purposes and would be forwarded to the CCFA for endorsement and to the Commission as section 4 of the Draft Standard.

67. The Committee agreed to forward the additives in Table 2 to the CCFA for advice on their suitability in the products covered by sections A and B and evaluation by JECFA if required, in the light of the advice that would be provided on the general questions mentioned above. The Committee agreed to forward the additives in Table 3 to CCFA for advice on their suitability in the products covered by section B and evaluation by JECFA if required. Tables 2 and 3 are presented in Appendix III.

68. The Committee expressed its appreciation to the Delegation of Switzerland and to the working group for their comprehensive work in order to facilitate the update of the additives section.

CODEX DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS – SECTION 4. FOOD ADDITIVES

TABLE 1

see Section 4. Food ADDITIVES in Appendix II

TABLE 2

SECTION a of the Draft revised standard - request for ADDITIONAL Food Additives

	INS no.	**Additive**	**Maximum level in 100 ml of the product ready for consumption**	**Technological Justification**
4.1 Thickeners				
4.1.8	415	Xanthan gum	GMP	Retains homogeneity
4.7.3	414	Gum arabic (acacia)	GMP	Retains homogeneity
4.2 Emulsifiers				
4.2.3	472c	Citric and fatty acid esters of glycerol	0.75 g in powder formula[1)] 0.9 g in liquid formula containing hydrolysed protein or amino acids[1)]	Retains homogeneity
4.2.4	473	Sucrose esters of fatty acids	12 mg in formula containing hydrolysed protein or amino acids[1)]	Retains homogeneity
4.2.5	472e	Tartaric and fatty acid esters of glycerol	0.5 mg	Retains homogeneity
4.2.6	472a	Acetic and fatty acid esters of glycerols	GMP	Retains homogeneity
4.3 Acidity Regulators				
4.3.8	331i	Sodium dihydrogen citrate	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in section 3.1.3 (e) in all types of infant formula	pH adjustment
4.3.9	331iii	Trisodium citrate		pH adjustment
4.3.10	332i	Potassium dihydrogen citrate		pH adjustment
4.3.11	332ii	Tripotassium citrate		pH adjustment
4.3.14	338	Phosphoric acid	0.1 g expressed as P_20_5 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	pH adjustment
4.3.15	339i	Monosodium dihydrogen monophosphate		pH adjustment
4.3.16	339ii	Disodium hydrogen monophosphate		pH adjustment
4.3.17	339iii	Trisodium monophosphate		pH adjustment
4.3.18	340i	Monopotassium dihydrogen monophosphate		pH adjustment
4.3.19	340ii	Dipotassium hydrogen monophosphate		pH adjustment
4.3.20	340iii	Tripotassium monophosphate		pH adjustment
4.4 Antioxidants				
4.4.1	306	Vitamin E concentrate	1 mg in all types of infant formula singly or in combination	Protects from oxidation
4.4.4	309	Gamma-tocopherol		Protects from oxidation
4.4.5	308	Delta-tocopherol		Protects from oxidation

[1)] If more than one of the substances INS 472c, 473 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances

TABLE 3

Section b of the Draft revised standard REQUEST FOR ADDITIONAL FOOD ADDITIVES

	INS no.	Additive	Maximum level in 100 ml of the product ready for consumption	Technological Justification
4.1 Thickeners				
	401	Sodium alginate	100 mg	Retains homogeneity
	405	Propane 1,2-diolalginate	20 mg	Retains homogeneity
	410	Carob bean gum (Locust bean gum) [1)]	0.5 g	Retains homogeneity
	412	Guar gum[1)]	1 g	Retains homogeneity
	415	Xanthan gum	0.12 g	Retains homogeneity
	440	Pectins	1 g	Retains homogeneity
	466	Sodium carboxymethyl cellulose	1 g	Retains homogeneity
	1450	Starch sodium octenyl succinate	2 g	Retains homogeneity
	414	Gum arabic (acacia)	GMP	Retains homogeneity
4.2 Emulsifiers[2)]				
	471	Mono- and diglycerides[1)]	0.5 g	Retains homogeneity
	472c	Citric and fatty acid esters of glycerol	0.75 g in powder formula 0.9 g in liquid formula containing partially hydrolysed protein, peptides or amino acids	Retains homogeneity
	472e	Diacetyltartaric and fatty acid esters of glycerol	0.5 g	Retains homogeneity
	473	Sucrose esters of fatty acids	12 mg in formula containing hydrolysed protein, peptides or amino acids	Retains homogeneity

[1)] These additives are in the present Codex standard 72-1981 for Infant Formula at different levels.
[2)] If emulsifiers are used in combination, the combined levels should be within the levels listed and be proportionately reduced, and with the minimum amount necessary to achieve the intended technical effect.