

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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ORGANIZATION



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Agenda Items 4 and 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
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**WORKING GROUP'S PROPOSALS FOR FOOD ADDITIVES IN THE PROPOSED
DRAFT REVISED STANDARD FOR INFANT FORMULA**

AND

**PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS
FOR INFANTS AND YOUNG CHILDREN**

I BACKGROUND INFORMATION

Introduction

1. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) decided at its 23rd session held in Berlin, Germany, from 26th to 30th November 2001, to set up an *Ad Hoc* Working Group¹ (CCNFSDU-*Ad Hoc* WG Food Additives) whose mandate would be to prepare Proposed Draft Lists of Food Additives for the Proposed Draft Revised Standards for Infant Formula and for Processed Cereal-Based Foods for Infants and Young Children, based on comments submitted by the *Ad Hoc* Working Group Members. The Proposed Draft Lists of Food Additives will be considered by the 24th session of the CCNFSDU (Berlin, Germany, November 2002).

Membership of the *Ad Hoc* WG on Food Additives

2. Members of the *Ad Hoc* Working Group were²: Switzerland (Chair), Canada, China, Denmark, France, Germany, India, Indonesia, Japan, Netherlands, Nigeria, Poland, Romania, Slovak Republic, Sweden, Tanzania, Thailand, Turkey, United Kingdom, United States of America, The European Commission (EC), Asociacion Latinoamericana de C&T de Alimentos (ALACCTA), Council for Responsible Nutrition (CRN), European Network of Childbirth Associations (ENCA), International Baby Food Action Network (IBFAN), International Special Dietary Foods Industries (ISDI) and Marinalg/Biopolymer.
3. Comments were requested by the Codex Circular Letter 2001/45-NFSDU.

1 ALINORM 03/26, Paras 68 and 113

2 ALINORM 03/26, Para 68, Footnote 10

4. Additionally, Switzerland, in her capacity as Chair of the CCNFSDU-*Ad Hoc* Working Group on Food Additives, sent an Information Letter and Request for Comments (February 2002) to Members of the *Ad Hoc* Working Group.
5. The Proposed Draft Lists of Food Additives were elaborated based on the comments received from the following Member States and International Organizations:
 - Germany
 - Poland
 - Switzerland
 - Tanzania
 - Turkey
 - United Kingdom
 - United States of America
 - European Commission
 - European Network of Childbirth Associations
 - International Baby Food Action Network
 - International Special Dietary Foods Industries
 - Marinalg/Biopolymer
6. Comments submitted in response to the CL 2001/45-NFSDU which were not considered by the *Ad Hoc* Working Group will be issued separately.
7. The following *Ad Hoc* Working Group's proposals for food additives in the Proposed Draft Revised Standards for Infant Formula and for Processed Cereal-Based Foods have been prepared based on the mandate given to the *Ad Hoc* Working Group by the 23rd session of the CCNFSDU and taking into account the comments received in reply to the Information Letter (February 2002) sent by Switzerland to all members of the *Ad Hoc* Working Group.
8. Whereas Infant Formula is included in the CODEX GENERAL STANDARD FOR FOOD ADDITIVES (GSFA) – Food Category No. 13.1 and in a separate Food Category no. 13.1.1, Processed Cereal-Based Foods fall under Food Category no. 13.2: “Weaning foods for infants and young children”. However, this Food Category covers two Codex Standards. These are :
 - CODEX STAN 73-1981, Canned Baby Food and the
 - CODEX STAN 74-1981, Processed Cereal-Based Foods for Infants and Young Children.
9. One of the principles underlying the Food Category System of the GSFA is as follows:

“The Food Category System is hierarchical, meaning that when the use of an additive is permitted in a general category, it is automatically permitted in all its sub-categories, unless otherwise stated. Similarly, when an additive is permitted in a sub-category, its use is also allowed in any further sub-categories and in descriptors or individual foodstuffs mentioned in a sub-category.”³
10. This leads to the fact that there are more food additives foreseen in the GSFA for Food Category no. 13.2 than in the Proposed Revised Standard for Processed Cereal-Based Foods itself since the GSFA Food

³ Codex Alimentarius, Volume 1A-1999, Codex General Standard for Food Additives (CODEX STAN 192-1995 (Rev. 2-1999), Paragraph 5, letter (a))

Category no. 13.2 caters for more additive needs and usage in the various foods put together as a group. This inconsistency between the GSFA and the Proposed Revised Codex Standard for Processed Cereal-Based Foods as regards food additives was identified by several members of the *Ad Hoc* Working Group.

11. Furthermore, due consideration has been given to the Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children⁴.

MULTI-FUNCTIONALITY OF FOOD ADDITIVES

12. Most food additives are multifunctional, meaning that they can have several technological functions. In most cases, the primary and most appropriate function has been identified and the food additive has been listed in the most appropriate section. Although, this could seem as though that particular food additive could have been « misplaced ».

CARRY-OVER

13. The carry-over of food additives from raw materials and other ingredients is regulated differently in both the Processed Cereal-Based Foods and Infant Formula Proposed Draft Standards. Indeed, it is stated in the Proposed Draft Revised Standard for Infant Formula under Section 4.5 entitled “Carry-Over of food additives” that

“No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception :

- (a) of food additives listed under Sections 4.1 to 4.4 of this Standard within the limits of the maximum levels stipulated in this standard ; and
- (b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.”

14. The GSFA has a general Carry-Over Principle in Section 4 of that Standard. Section 4.1. which is entitled “Compliance with the Carry-Over Principle” states that:

Other than by direct addition, an additive may be present in a food as a result of carry-over from a food ingredient, subject to the following conditions:

- (a) the additive is permitted in the raw materials or other ingredients (including food additives) according to this General Standard;
- (b) the amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum amount so permitted; and
- (c) the food into which the additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the ingredients under proper technological conditions or manufacturing practice.”

15. Therefore, the *Ad Hoc* Working Group believes that the general Carry-Over Principle of the GSFA doesn't apply to Infant Formula. This isn't the case as regards Processed Cereal-Based Foods for which the carry-over of food additives from raw materials and other ingredients isn't excluded.

COLOURS AND SWEETENERS

16. Most of the comments were in favour of the exclusion of the Functional Classes of Colours and Sweeteners in both Standards. This is indeed reflected in the *Ad Hoc* Working Group's proposals.

L(+)-LACTIC ACID PRODUCING CULTURES AND ALPHA- AND BETA-AMYLASE

17. L(+)-Lactic Acid producing cultures are not included in the list of additives. Indeed, these are not considered to be food additives. Alpha- and beta-amylases (Malt carbohydrases) are included in the list of food additives for the Processed Cereal-Based Foods although they are considered as processing aids. The

⁴ Codex Alimentarius, Volume 4-1994, Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991)

decision as to whether they should definitely be included in the list of food additives should be taken by the Committee when it examines the Working Group's proposals.

CRITERIA FOR THE INCLUSION OF FOOD ADDITIVES IN THE PROPOSED REVISED STANDARDS AND THE GSFA

18. Several comments raised the question of the criteria for the inclusion of food additives in the two Codex Standards under revision and the GSFA. The United States of America submitted general comments on the GSFA in which the differences between Tables One and Two of the GSFA were explained.
19. There was a comment proposing the setting up of general principles or criteria which would guide the revisions of the food additives provisions so that the Codex objectives of facilitating international trade in foods whilst protecting consumers' health is achieved.
20. These *Ad Hoc* Working Group's proposals have taken due account of the « General Principles for the Use of Food Additives », which are laid down in the GSFA⁵:

« 3.1 (a) Only those food additives shall be endorsed and included in this Standard which, so far as can be judged on the evidence presently available from JECFA, present no risk to the health of the consumer at the levels of use proposed.

(b) The inclusion of a food additive in this Standard shall have taken into account any Acceptable Daily Intake, or equivalent assessment, established for the additive and its probable daily intake⁶ from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account shall be taken of the probable daily intake of the food additive by consumers of that group.

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

21. Therefore, the food additives in the proposals have been included in the lists once it has been established that they fulfil the above-given criteria (have been evaluated by JECFA and found acceptable for use, have been assigned a Numerical ADI or Not Specified, do not present a risk to the health of the consumer when consumed at the proposed level, their use is technologically justified).
22. There are no specific criteria which apply to the use of food additives in Infant Formula or in Processed Cereal-Based Foods.

II AD HOC WORKING GROUP'S PROPOSAL FOR FOOD ADDITIVES IN THE PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (CODEX STAN 72-1981)

⁵ Codex Alimentarius, Volume 1A-1999, Preamble to the General Standard for Food Additives (CODEX STAN 192-1995 (Rev. 2-1999), Paragraph 3

⁶ « Guidelines for Simple Evaluation of Food Additive Intake », CAC/VOL. XIV Ed. 1, Supplement 2 (1989), gives procedures for calculating the theoretical maximum daily intake (TMDI) and the estimated daily intake (EDI) of food additives ; other appropriate procedures may be used to calculate the TMDI and EDI ».

Food Additives

23. The following food additives are permitted in the preparation of Infant Formula, as described in Section 1 of this Standard, and with the restrictions stated below:

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			Maximum level in 100 ml of the ready-to-drink product
4.1	Thickening Agents		
	INS no.		
4.1.1	412	Guar gum	0.1 g in all types of infant formula
4.1.2	410	Carob bean gum (Locust bean gum)	0.1 g in all types of infant formula
4.1.3	1412	Distarch phosphate	} 0.5 g singly or in combination in soy-based infant formula only } 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based infant formula only
4.1.4	1414	Acetylated distarch phosphate	
4.1.5	1413	Phosphated distarch phosphate	
4.1.6	1440	Hydroxypropyl starch	
4.1.7	407	Carrageenan	0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolyzed protein and/or amino acid-based infant formula only
4.2 Emulsifiers			
4.2.1	322	Lecithin	0.5 g in all types of infant formula *
4.2.2	471	Mono- and diglycerides	0.4 g in all types of infant formula *
4.2.3	472 c	Citric and fatty acid esters of glycerol	0.75 g in powder formula * 0.9 g in liquid formula containing partially hydrolyzed protein, peptides or amino acids *
4.2.4	473	<i>Sucrose esters of fatty acids</i>	12 mg in formula containing hydrolyzed protein, peptides or amino acids *
			* If more than one of the substances INS Nos. 322, 471, 472c and 473 are added, the maximum level for each of those substances is lowered with the relative part as present of the other substances
4.3 pH-Adjusting Agents			
4.3.1	524	Sodium hydroxide	} Limited by GMP and within the limits for sodium and potassium in Section 3.1.2 (c) in all types of infant formula
4.3.2	500ii	Sodium hydrogen carbonate	
4.3.3	500i	Sodium carbonate	
4.3.4	525	Potassium hydroxide	
4.3.5	501ii	Potassium hydrogen carbonate	
4.3.6	501i	Potassium carbonate	
4.3.7	526	Calcium hydroxide	
4.3.8	331 (i, iii)	Sodium citrate	
4.3.9	332 (i, ii)	Potassium citrate	
4.3.10	270	L(+) Lactic acid	
4.3.11	330	Citric acid	
4.3.12	338	Orthophosphoric acid	} Limited by GMP and within the limits for sodium and potassium in Section 3.1.2 (c) in all types of infant formula
4.3.13	339 (i, ii, iii)	Sodium orthophosphates	

4.3.14	340 (i, ii, iii)	Potassium orthophosphates	
4.4 Antioxidants			
4.4.1	306	Mixed tocopherols concentrate	} 1 mg in all types of infant formula singly or in combination
4.4.2	307	Alpha-Tocopherol	
4.4.3	304	L-Ascorbyl palmitate	1 mg in all types of infant formula
4.5 Packaging Gas (Propellants)			
4.5.1	290	Carbon dioxide	GMP
4.5.2	941	Nitrogen	GMP
4.5.3	942	Nitrous oxide	GMP
4.5.4	938	Argon	GMP
4.5.5	939	Helium	GMP
4.5.6	948	Oxygen	GMP
4.5.7	949	Hydrogen	GMP

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Carry-over of Food Additives

24. No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:

- (a) of the food additives listed under Sections 4.1 to 4.5 of this Standard within the limits of the maximum levels stipulated in this Standard; and
- (b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.

III AD HOC WORKING GROUP'S PROPOSAL FOR FOOD ADDITIVES IN THE PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (CODEX STAN 74-1981)

Food Additives

25. The following food additives are permitted in the preparation of processed cereal-based foods for infants and young children, as described in Section 2.1 of this Standard (in 100 g of product, on a dry weight basis unless otherwise indicated).

Maximum level in 100 g of the product			
4.1	Emulsifiers		
4.1.1	322	Lecithin	1.5 g
4.1.2	471	Mono- and diglycerides	1.5 g
4.1.3	472a	Acetic and fatty acid esters of glycerol	} 0.5 g singly or in combination

4.1.4	472b	Lactic and fatty acid esters of glycerol	
4.1.5	472c	Citric and fatty acid esters of glycerol	
4.2 pH-Adjusting Agents			
4.2.1	500ii	Sodium hydrogen carbonate	GMP, within the limits for sodium
4.2.2	501ii	Potassium hydrogen carbonate	} GMP
4.2.3	170i	Calcium carbonate	
4.2.4	270	L(+) Lactic acid	1.5 g
4.2.5	330	Citric acid	2.5 g
4.2.6	260	Acetic acid (Acetic acid, glacial)	} Only for pH adjustment GMP
4.2.7	261	Potassium acetates	
4.2.8	262 (i, ii)	Sodium acetates	
4.2.9	263	Calcium acetate	
4.2.10	296	Malic acid (DL) - L(+)-form only	
4.2.11	325	Sodium lactate (solution) - L(+)-form only	
4.2.12	326	Potassium lactate (solution) - L(+)-form only	
4.2.13	327	Calcium lactate - L(+)-form only	
4.2.14	331 (i, ii)	Sodium citrate	
4.2.15	332 (i, ii)	Potassium citrate	
4.2.16	333	Calcium citrate	
4.2.17	507	Hydrochloric acid	
4.2.18	524	Sodium hydroxide	
4.2.19	525	Potassium hydroxide	
4.2.20	526	Calcium hydroxide	
4.2.21	575	Glucono delta-lactone	0.5 g singly or in combination
4.2.22	334; 335 i, ii; 336 i, ii; 337	Tartrates - L(+)-forms only	} Tartrates as residue in biscuits and rusks
4.2.23	338	Orthophosphoric acid	} Only for pH adjustment 0.1 g as P ₂ O ₅
4.2.24	339i-iii	Sodium orthophosphates	
4.2.25	340i-iii	Potassium orthophosphates	
4.2.26	341i-iii	Calcium orthophosphates	
4.3 Antioxidants			
4.3.1	306	Mixed tocopherols concentrate	} 300 mg/kg fat, singly or in combination
4.3.2	307	Alpha-tocopherol	
4.3.3	304	L-Ascorbyl palmitate	200 mg/kg fat
4.3.4	300, 301, 303	L-Ascorbic acid and its sodium and potassium salts	50 mg, expressed as ascorbic acid and within the limits for sodium
4.3.5	302	Calcium ascorbate	20 mg, expressed as ascorbic acid
4.4 Flavours			
4.4.1		Vanilla extract	GMP
4.4.2		Ethyl vanillin	} 7 mg on an as consumed basis
4.4.3		Vanillin	

4.5	Enzymes		
4.5.1		Malt carbohydrases	GMP
4.6 Leavening Agents			
4.6.1	503i	Ammonium carbonate	} Limited by GMP
4.6.2	503ii	Ammonium hydrogen carbonate	
4.6.3	500 (i, ii)	Sodium carbonates	Limited by GMP
4.6.4	501 (i, ii)	Potassium carbonates	Limited by GMP
4.7 Thickening Agents			
4.7.1	410	Carob bean gum	} Singly or in combination: 1 g in weaning food 2 g in gluten-free cereal based foods
4.7.2	412	Guar gum	
4.7.3	414	Gum arabic	
4.7.4	425	Xanthan gum	
4.7.5	440	Pectins (Amidated and Non-Amidated)	
4.7.6	1404	Oxidized starch	} 5 g singly or in combination
4.7.7	1410	Monostarch phosphate	
4.7.8	1412, 1413, 1414, 1422	Modified starches	
4.7.9	1420	Starch acetate esterified with acetic anhydride	
4.7.10	1450	Starch sodium octenyl succinate	
4.7.11	1451	Acetylated oxidized starch	
4.8 Anti-caking Agent			
4.8.1	551	Silicon dioxide (amorphous)	0.2 g, for dry cereals only
4.9 Packaging Gas (Propellants)			
4.9.1	290	Carbon dioxide	GMP
4.9.2	941	Nitrogen	GMP
4.9.3	942	Nitrous oxide	GMP
4.9.4	938	Argon	GMP
4.9.5	939	Helium	GMP
4.9.6	948	Oxygen	GMP
4.9.7	949	Hydrogen	GMP

26. The Committee is invited to consider the lists of additives proposed for inclusion in the Proposed Draft Revised Standard for Infant Formula and the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children (subject to endorsement by the Codex Committee on Food Additives and Contaminants).