

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Items 6 and 7

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CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES Twenty-fifth Session

**“Brückenforum Bonn”, Friedrich-Breuer-Strasse 17,
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WORKING GROUP'S PROPOSALS FOR FOOD ADDITIVES IN THE PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA AND IN THE PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

(Prepared by Switzerland based on the comments submitted by Members of the Working Group)

I. BACKGROUND INFORMATION

INTRODUCTION

1. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) decided at its 24th session held in Berlin, Germany, from 4th to 8th November 2002, to set up a Working Group¹ whose mandate would be to prepare Proposed Draft Lists of Food Additives for the Proposed Draft Revised Standard for Infant Formula and for the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children, based on comments submitted by the Working Group Members. The Proposed Draft Lists of Food Additives will be considered by the 25th session of the CCNFSDU (Bonn, Germany, 3rd – 7th November 2003) under Agenda items 6 and 7 according to the Provisional Agenda (CX/NFSDU 03/1, July 2003) as CRDs 3 and 4 respectively.

MEMBERSHIP OF THE CCNFSDU-WG FOOD ADDITIVES

2. Members of the Working Group are²: 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.

¹ ALINORM 03/26A, Paras 52 and 71

² ALINORM 03/26, Para 68, Footnote 10

REQUEST FOR COMMENTS

3. Switzerland, in her capacity as Chair of the CCNFSDU-Working Group on Food Additives, sent an Information Letter and Request for Comments (March 2003) to Members of the Working Group.

COMMENTS RECEIVED

4. The following Members of the Working Group submitted comments in reply to the Request for Comments sent out by Switzerland:
 - Germany
 - India
 - Nigeria
 - Poland
 - United Kingdom
 - United States of America
 - European Commission
 - European Network of Childbirth Associations
 - International Special Dietary Foods Industries

II. INTRODUCTION TO THE WORKING GROUP'S PROPOSALS FOR FOOD ADDITIVES IN THE PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA AND IN THE PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

5. These Working Group's proposals for food additives in the Proposed Draft Revised Standard for Infant Formula and in the Proposed Draft Revised Standard for Processed Cereal-Based Foods have been prepared based on the mandate given to the Working Group by the 24th session of the CCNFSDU and taking into account the comments received in reply to the Information Letter (March 2003) sent by Switzerland to all members of the Working Group.

THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (GSFA) – FOOD CATEGORY No. 13.2

6. Processed Cereal-Based Foods fall under Food category 13.2 of the GSFA: "Weaning foods for infants and young children". This food category covers two Codex Standards. These are :
 - CODEX STAN 73-1981, Canned Baby Food
 - CODEX STAN 74-1981, Processed Cereal-Based Foods for Infants and Young Children
7. Another relevant document is
 - CAC/GL 08/1991, Guideline on Formulated Supplementary Foods for Older Infants and Young Children.
8. One of the principles underlying the Food Category System of the GSFA is recalled here:
9. "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 13.2 than in the Proposed Draft Revised Standard for Processed Cereal-Based Foods itself since the GSFA food category 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 Draft Revised Codex Standard for Processed Cereal-Based Foods as regards food additives was identified by several Working Group Members in their comments.

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

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. Many food additives are multifunctional, meaning that they can have several technological functions. In these cases, the primary and most appropriate function has been identified and is listed under that technological function in the following proposals. Although at times, this may seem as though a particular food additive has been « misplaced ».

CARRY-OVER

13. The carry-over of food additives from raw materials and other ingredients is regulated differently in 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

14. “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.”: “Advisory List(s) of Mineral Salts and Vitamin compounds for the Use in Foods for Infants and Children”

15. The GSFA has a general Carry-Over Principle under Section 4.1 which is entitled “Compliance with the Carry-Over Principle” which 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.”

16. Therefore, 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.

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

17. L(+)-Lactic Acid producing cultures are not included in the list of additives, since these are not 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 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.

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

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

18. These Working Group's proposals have taken due account of the « General Principles for the Use of Food Additives », which are laid down in the Preamble to the GSFA⁵ 3. General Principles for the Use of Food Additives:

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 of 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 : ».

19. So, 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 an ADI Not Specified, do not present a risk to the health of the consumer when consumed at the proposed level, their use is technologically justified).
20. The GSFA does not indicate specific criteria which apply to the use of food additives in Infant formula or in Processed cereal-based foods.

FOOD ADDITIVES FOR INFANT FORMULA AND FOR PROCESSED CEREAL-BASED FOODS INTENDED FOR HEALTHY INFANTS AND YOUNG CHILDREN

21. The following tables list food additives which are necessary for the production of infant formula and processed cereal-based foods intended for healthy infants and young children. Foods for special medical purposes (FSMP) intended for infants and young children with special physiological requirements may necessitate other food additives or different maximum levels of use; food additives for FSMP need a separate evaluation and listing in FSMPs.

DIFFERENCE IN TERMINOLOGY USED (FUNCTIONAL CLASSES / TECHNOLOGICAL FUNCTIONS / TECHNOLOGICAL USES)

22. There was a proposal to indicate the “functional classes” of the various food additives in order to be in line with the food labelling requirements as given in CODEX STAN 1-1985, and that the terms “technological functions” or “technological uses” should not be indicated. However, no revisions have been made in the present proposed lists of food additives in order to take into account this proposal since both Codex and JECFA have not entirely harmonised the use of this terminology.
23. Below is an example of the inconsistency in the use of the various terms:

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 ».

**TERMINOLOGY USED IN
CURRENT STANDARDS****FUNCTIONAL CLASS
TERMINOLOGY (for food****Labelling purposes)**

Thickening Agents
pH-Adjusting Agents

Thickener
Acidity Regulator

Leavening Agents

Raising Agent

MISSING FUNCTIONAL CLASSES (for food labelling purposes)

Enzymes
Flavours
Packaging Gas

*ENZYMES***24. Enzymes generally function as processing aids.***FLAVOURS***25. FLAVOURS ARE A DISTINCT CATEGORY. FLAVOURING SUBSTANCES ARE EVALUATED BY JECFA IN A CATEGORY WHICH IS DISTINCT FROM THE FOOD ADDITIVES CATEGORY AND ARE ASSIGNED JECFA NUMBERS THAT ARE SPECIFIC FOR FLAVOURINGS.***PACKAGING GAS*

26. There is no functional class of “packaging gases”. The gases included in the class “Propellants” are often used for technological purpose of packaging gas.

JECFA-EVALUATED FOOD ADDITIVES

27. Only those food additives which have been evaluated by JECFA and have been assigned an ADI (ADI “Not specified” or numerical) should be permitted for use in foods for infants and young children. Therefore the food additives which have not yet been evaluated by JECFA or have not been evaluated for a specific technological function (Hydrolysed lecithin, gamma- and delta-Tocopherols, Packaging gas, etc) should be referred by the CCNFSDU to the CCFAC with a request that they be included on the JECFA Priority List in view of their evaluation by JECFA.

MAXIMUM LEVEL OF USE TO BE INDICATED AS “PER LITER” OR “PER KILOGRAM”?

28. It was noted that the GSFA and the majority of Codex Commodity Standards that include provisions on food additives, indicate the maximum level of use as either per liter or per kilogram on an “as consumed basis”. It was therefore proposed that the maximum levels of use for the food additives given in the Proposed Draft Standard for Processed Cereal-Based foods for Infants and Young Children, be expressed as “Maximum level per kg of the product ready for consumption prepared following the manufacturers’ instructions”. This proposal seems to be justified; however, the text has not been amended due to the following reasons:

29. In the Infant formula Standard

- Section 3.1.1 on Essential Composition indicates the amounts as per 100 kilocalories or per 100 kilojoules
- Section 9.3 on the Declaration of the Nutritive Value indicates per 100g/food as sold as well as per 100 ml/ food ready for use.

30. In the Processed cereal-based foods Standard

- Section 4. Food Additives “The following additives are permitted in the preparation of processed cereal-based foods for infants and children, as described in Section 2.1 of this Standard (in 100 g of product, on a dry weight basis unless otherwise indicated)
- Section 8.4 a) on the Declaration of the nutritive value indicates per 100g or per 100 ml of the food as sold.

31. It is therefore proposed that the decision regarding any changes to be made in this regard be taken by the Committee at its 25th session.

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

4. Food Additives

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

WORKING GROUP’S PROPOSAL ALINORM 03/26A – Appendix II – as amended by the Working Group						
	INS NO.			Maximum level in 100 mL of the ready-to-drink product	Technological Justification	
4.1	Thickening Agents					
4.1.1	412	Guar gum		0.1 g in all types of infant formula	Protects from physical separation	
4.1.2	410	Carob bean gum (Locust bean gum)		0.1 g in all types of infant formula <i>REQUEST FOR 0.5 G</i>	Protects from physical separation Used in some anti-regurgitating formulas	
4.1.3	1412	Distarch phosphate	}	0.5 g singly or in combination in soy-based infant formula only	Physical properties that native starch tends to lose when processed	
4.1.4	1414	Acetylated distarch phosphate				
4.1.5	1413	Phosphated distarch phosphate		}		2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based infant formula only
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 liquid infant formula only	Thickening agent also used as an emulsifier; higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids	
4.2	Emulsifiers					
4.2.1	322 ¹	Lecithin ¹		0.5 g in all types of infant formula *	Natural stabiliser, retains homogeneity	
4.2.2	471	Mono- and diglycerides		0.4 g in all types of infant formula *	Natural stabiliser, retains homogeneity of liquid products and liquid reconstituted powders	

4.2.3	472c	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 *	Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids, especially in formulas not containing whole protein
4.2.4	473	Sucrose esters of fatty acids		12 mg in formula containing hydrolyzed protein, peptides or amino acids *	Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids, especially in formulas not containing whole protein
				* 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	

¹ INS no. 322 refers to both Lecithin and Partially hydrolyzed lecithin.

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	Buffering capacity Improve in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Selected depending on pH and composition of formula; also used as a buffering agent
4.3.2	500 ii	Sodium hydrogen carbonate	}		
4.3.3	500 i	Sodium carbonate	}		
4.3.4	525	Potassium hydroxide	}		
4.3.5	501 ii	Potassium hydrogen carbonate	}		
4.3.6	501 i	Potassium carbonate	}		
4.3.7	526	Calcium hydroxide	}		
4.3.8	331 i, iii	Sodium citrate(s)	}		
4.3.9	332 i, ii	Potassium citrate(s)	}		
4.3.10	270	L(+) Lactic acid ²	}	Limited by GMP in all types of infant formula	Natural acid found in fermented milk products
4.3.11	330	Citric acid	}		Buffering and chelating capacity
4.3.12	338	Phosphoric acid (Ortho-)	}	Limited by GMP and within the limits for sodium and potassium in Section 3.1.2(c) in all types of infant formula	Stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Selected depending on pH and composition of 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	}	<i>1 mg in all types of infant formula singly or in combination</i>	Protects from oxidation Synergistic effect with ascorbyl esters
4.4.2	307	<i>Alpha-Tocopherol</i>	}		
4.4.2	304	L-Ascorbyl palmitate		1 mg in all types of infant formula	Protects from oxidation Synergistic effect with tocopherols
4.5	Packaging Gas (Propellants)				
4.5.1	290	<i>Carbon dioxide</i>		<i>GMP</i>	Neutral gas used under modified packaging atmosphere in order to guarantee the quality of the product and to ensure shelf life; prevention of oxidation and rancidity
4.5.2	941	<i>Nitrogen</i>		<i>GMP</i>	
4.5.3	942	<i>Nitrous oxide</i>		<i>GMP</i>	
4.5.4	938	<i>Argon</i>		<i>GMP</i>	
4.5.5	939	<i>Helium</i>		<i>GMP</i>	
4.5.6	948	<i>Oxygen</i>		<i>GMP</i>	
4.5.7	949	<i>Hydrogen</i>		<i>GMP</i>	

² JECFA evaluated lactic acid for use as a food additive at its 9th and 17th Meetings. Lactic acid was assigned an ADI of “not specified” but it was determined that only the L+ form was safe for infants. An electronic search of the JECFA electronic data base for INS no 270 results in “No matches were found”; however, searching for Lactic Acid results in “Lactic acid No. 930 : Not Limited (No safety concern at current levels of intake when used as a flavouring substance); Functional class: Acid; Acidifier; Flavouring agent”.

IV. 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)

4. Food Additives

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

WORKING GROUP'S PROPOSAL ALINORM 03/26A – Appendix III – as amended by the Working Group					
	INS no.			Maximum level in 100 g of the product	Technological Justification
4.1	Emulsifiers				
4.1.1	322 ¹	Lecithin ¹		1.5 g	Natural stabiliser, retains homogeneity
4.1.2	471	Mono- and diglycerides		1.5 g	Retains homogeneity
4.1.3	472a	Acetic and fatty acid esters of glycerol	}	0.5 g singly or in combination	Retains homogeneity
4.1.4	472b	Lactic and fatty acid esters of glycerol	}		Retains homogeneity
4.1.5	472c	Citric and fatty acid esters of glycerol	}		Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids
			}		
4.2	pH-Adjusting Agents				
4.2.1	500 ii	Sodium hydrogen carbonate		GMP, within the limits for sodium	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering capacity
4.2.2	501 ii	Potassium hydrogen carbonate	}	GMP	pH-adjusting agent
			}		
4.2.3	170 i	Calcium carbonate	}		

4.2.4	270 ²	L(+) Lactic acid		1.5 g Request for L(+)-lactic acid producing cultures at GMP ³	Natural acid found in fermented milk Natural way to reduce pH Decreases risk of contamination from undesirable bacteria; adds taste; long use as an acidifier
4.2.5	330	Citric acid		2.5 g	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering and chelating capacity Citric acid and citrates are natural compounds

¹ INS no. 322 refers to both Lecithin and Partially hydrolyzed lecithin.

² JECFA evaluated lactic acid for use as a food additive at its 9th and 17th Meetings. Lactic acid was assigned an ADI of “not specified” but it was determined that only the L+ form was safe for infants. An electronic search of the JECFA electronic data base for INS no 270 results in “No matches were found”; however, searching for Lactic Acid results in “Lactic acid No. 930 : Not Limited (No safety concern at current levels of intake when used as a flavouring substance); Functional class: Acid; Acidifier; Flavouring agent”.

³ Cultures are not considered as food additives; CODEX STAN 72-1981 (Infant Formula) permits “4.3.11 L(+) Lactic acid producing cultures Limited by GMP in all types of infant formulae”

4.2.6	260	Acetic acid (Acetic, glacial)	}	Only for pH adjustment GMP	Improve in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Acetic acid and acetates are natural compounds Selected depending on the pH and composition of the formula
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	}		pH-adjustment to compensate for variable natural acidity of fruit
			}		
4.2.11	325	Sodium lactate (solution) – L(+)-form only	}		Improve in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Selected depending pH and composition of formula Lactic acid and lactates are natural compounds
4.2.12	326	Potassium lactate (solution) – L(+)-form only	}		
4.2.13	327	Calcium lactate – L(+)-form only	}		
			}		
4.2.14	331 i, iii	Sodium citrate	}		Improves in-processing handling, stabilising effect during industrial preparation such as
4.2.15	332 i, ii	Potassium citrate	}		

4.2.16	333	Calcium citrate	}		pasteurisation, sterilisation, drying; Buffering and chelating capacity Citrates are natural compounds
4.2.17	507	Hydrochloric acid	}		Acidifier, pH-adjustment
4.2.18	524	Sodium hydroxide	}		Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying
4.2.19	525	Potassium hydroxide	}		
4.2.20	526	Calcium hydroxide	}		
4.2.21	575	Glucono delta-lactone	}		Slow release acidifier Secondary leavening agent
4.2.22	334	L(+)-Tartaric acid - L(+)form only	}	0.5 g singly or in combination	
4.2.23	335 i, ii	Sodium L(+)-Tartrates - L(+)forms only	}	Tartrates as residue in biscuits and rusks	In conjunction with 500 ii leavening/raising agent in biscuits and rusks
4.2.24	336	Potassium L(+)-Tartrate - L(+)form only	}		
4.2.25	337	Potassium Sodium L(+)-Tartrate - L(+)form only	}		
4.2.26	338	Orthophosphoric acid	}		Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering and chelating capacity
4.2.27	339 i, ii, iii	Sodium orthophosphates	}	Only for pH adjustment	
4.2.28	340 i, ii, iii	Potassium orthophosphates	}	0.1 g as P ₂ O ₅	
4.2.29	341 i, ii, iii	Calcium orthophosphates	}		
4.3	Antioxidants				
4.3.1	306	Mixed tocopherols concentrate	}	300 mg/kg fat, singly or in combination	Protect from oxidation Synergistic effect with ascorbyl esters
4.3.2	307	Alpha-tocopherol	}		
4.3.3	304	L-Ascorbyl palmitate		200 mg/kg fat	Protects from oxidation Synergistic affect with tocopherols
4.3.4	300, 301, 303 ⁴	L-Ascorbic acid and its sodium and potassium salts	}	50 mg, expressed as ascorbic acid and within the limits for sodium	Antioxidant in cereal bars Reduce discoloration in fruit preparations
4.3.5	302	Calcium ascorbate		20 mg, expressed as ascorbic acid	
4.4	Flavours				
4.4.1		Vanilla extract		GMP	Component of chocolate and part of the characterising flavour
4.4.2		Ethyl vanillin	}	7 mg on an "as consumed basis"	

4.4.3		Vanillin	}		Other flavours may be needed, further discussion is necessary
4.5	Enzymes				
4.5.1		Malt carbohydrases		GMP	Should be listed separately in a separate list of processing aids and therefore should not be listed as food additives.
4.6	Leavening Agents				
4.6.1	503 i	Ammonium carbonate	}	Limited by GMP	Raising agent in rusks and biscuits Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying
4.6.2	503 ii	Ammonium hydrogen carbonate	}		
4.6.3	500 i, ii	Sodium carbonates		Limited by GMP	Raising agent in rusks and biscuits Sometimes used in combination with 503 i or 503 ii Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying
4.6.4	501 i, ii	Potassium carbonates		Limited by GMP	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying

⁴ INS no. 303 Potassium ascorbate: Specifications not indicated by JECFA.

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	Thickening agent and emulsion stabiliser
4.7.2	412	Guar gum	}		
4.7.3	414	Gum arabic	}		For fruit coating to prevent fruit from sticking together Also used as an ingredient of nutrient forms
4.7.4	415	Xanthan gum	}	Singly or in combination: 1 g in weaning food 2 g in gluten-free cereal-based foods	Thickener for semi-solid preparation Optimum viscosity achieved in combination with other thickeners

4.7.5	440	Pectins (<i>Amidated and Non-Amidated</i>)	} }		Gelling agent in place of gelatine Particularly efficient in presence of fruits and acidic preparations Optimum viscosity achieved in combination with other thickeners Used as binder in extruded cereals increasing cohesiveness of the cereal pieces after rehydration
4.7.6	1404	Oxidized starch	}	5 g singly or in combination	<i>Physical properties that native starch tend to lose when processed</i>
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 (<i>amorphous</i>)		0.2 g for dry cereals only	Most neutral Anticaking agent, prevents clumping Ensures even distribution of nutrients
4.9	Packaging Gas (<i>Propellants</i>)				
4.9.1	290	Carbon dioxide		GMP	Neutral gas used under modified packaging atmosphere to protect quality and guarantee shelf life
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	