codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
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PROPOSED LIST OF FOOD ADDITIVES FOR THE CODEX DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

Prepared by the Electronic Working Group

INTRODUCTION

This document is laid out as follows:

PART 1: Background Information

PART 2: Section A which contains the Electronic Working Group's proposed list of food additives for **Section A: Draft Revised Standard for Infant Formula** (Step 6) of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants.

PART 3: Section B which contains the proposal made by Switzerland of food additives for **Section B: Formulas for Special Medical Purposes Intended for Infants** (Step 3) of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants.

PART 1: BACKGROUND INFORMATION

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) decided at its 26th session (Bonn, Germany, 1st - 5th November 2004) to set up an Electronic Working Group (EWG), open to all interested delegations, which would be chaired by Switzerland. The mandate of this EWG was to "prepare a revised list of additives taking into account all written comments received and the discussion at the present (2004) session, for consideration by the next (2005) session of the Committee[1]. On 15th February 2005, the Codex secretariat sent out a letter, on behalf of the Swiss Chair, to all Codex Members and Observers requesting participation in the EWG. The following Members and Observers replied to the Swiss call to join the EWG: Australia, Belgium, Canada, the European Commission, Japan, Poland and the United States of America.

[1] Report of the 26th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, ALINORM 05/28/26, paragraph 69.

Switzerland prepared a first proposal based on the comments submitted in response to various CCNFSDU documents regarding the revision of the list of food additives in the Draft Revised Standard for Infant Formula (Section A), and in particular, the written comments sent in response to the various documents issued in view of the CCNFSDU 2004 session, including the relevant parts of the 2004 session report, ALINORM 05/28/26, paragraphs 66-69 as well as the recent discussions held at the 37th session of the Codex Committee on Food Additives and Contaminants (CCFAC), ALINORM 05/28/12, especially regarding the recommendation to all Codex Committees as to the fact that INS no. 322 refers to both Lecithin and Partially hydrolysed lecithin.

During the elaboration of the proposed lists of food additives for Section A, the EWG took good note of the opinion expressed by JECFA regarding the use of food additives in foods for infants. Infant formulae may be the only food for infants during their first months of life. For this reason it is imperative that this food only contains additives that are technologically justified or even indispensable. Indeed, JECFA expressed the opinion that children should not be exposed to food additives before the age of 12 weeks, and that the ADI does not apply to children below the age of 12 weeks[2]. Furthermore, the opinion expressed by the EC Scientific Committee on Food (SCF) was also taken into account. The SCF has endorsed the principle that additives should not be used in foods for infants and young children[3], although exceptional technological circumstances may justify the use of an additive. Therefore, the SCF has always performed a new risk assessment on evaluated food additives when the proposed use is for foods intended for infants and young children.

1.1 Working principles for the inclusion of food additives on the list of permitted food additives in Infant formula

The EWG recalled the basic principles for the use of food additives (also see the Codex General Standard for Food Additives Codex STAN 192-1995, Rev. 5-2004) and the Codex Procedural Manual (14th Edition).

As a rule, only food additives which have been evaluated by JECFA and found acceptable for use in foods should be included in the Draft revised Standard for Infant formula and formula for special medical purposes intended for infants. Furthermore, food additives which have been allocated a numerical ADI should have a numerical maximum level of use. However, while CCFAC has stated that this is the generally accepted procedure, exceptions to use GMP are allowed when agreed on a case-by-case basis (ALINORM 03/12A, Para. 44).

Consistent with the Codex General Principles for the Use of Food Additives and the Preamble to the Codex General Standard for Food Additives (CX-STAN 192-1995, Rev. 5-2004), justifications for a food additive functional class, or supporting information about any additional food additive and its use level should address the following questions:

1. Will the functional class or additive preserve the nutritional quality of the food?

2. Will the functional class or additive provide necessary ingredients or constituents for the food?

3. Will the functional class or additive enhance the keeping quality or stability of a food or improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer; or

4. Will the functional class or additive aid in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities?

[2] WHO (1978). Evaluation of certain food additives. Twenty-first report of the Joint FAO/WHO Expert Committee on food additives. World Health Organisation, Geneva, Technical Report series no 617.

[3] Opinion of the Scientific Committee on Food on the applicability of the ADI (Acceptable Daily Intake) for food additives to infants (expressed on 17/09/1998)

A member of the EWG proposed that the food additives that are currently listed in the existing standard (Codex Stan 72-1981) should be reconsidered and that if considered necessary, the permitted level of use should be the minimal level necessary to obtain the desired effect. The EWG notes the importance of this proposal and therefore brings it forward for consideration by the Committee. Therefore, the EWG requests the CCNFSDU to examine this proposal and to take the necessary decisions.

1.2 Functional classes for food additives in Sections A and B

The following functional classes were recognised by all members of the EWG as being necessary for the manufacture of Infant formula (Section A):

4.1 Thickeners

4.2 Emulsifiers

4.3 Acidity Regulators

4.4 Antioxidants

One of the members of the EWG, however, was opposed to the inclusion of several food additives listed under three of the functional classes: 4.1 Thickeners (410 Carob bean gum, 1412 Distarch phosphate, 1414 Acetylated distarch phosphate, 1413 phosphated distarch phosphate, 1440 Hydroxypropyl starch, 407 Carrageenan, 415 Xanthan gum); 4.2 Emulsifiers: 472e Diacetyltartaric and fatty acid of esters of glycerol and 4.3 Acidity Regulators: 524 Sodium hydroxide, 500ii Sodium hydrogen carbonate, 500i Sodium carbonate, 525 Potassium hydroxide, 501ii Potassium hydrogen carbonate, 501i Potassium carbonate, 526 Calcium hydroxide). The EWG considers that if there is a safety concern regarding the use of specific food additives listed under a recognised functional class, then this safety concern as well as the scientific data on which it is based should be brought to the attention of the CCNFSDU which will take the most appropriate decision after serious deliberation. Therefore, the current proposal of the EWG includes all the food additives whose use has been considered technologically justified by the majority of the members of the EWG.

The EWG requests the CCNFSDU to closely examine the proposed food additives taking into account all the above-given comments and subsequently decide on the final list of food additives which will be included in Section A of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants.

1.3 Carry-over of food additives

Several proposals were made to delete Section 4.6 Carry-over of food additives and to replace it by a reference to Section 3 of the Principles relating to carry-over of food additives. There were comments that the exception of the carry-over principle for infant formula was not consistent with the General Standard for Food Additives. Furthermore, it was argued that the restriction on carry-over made it difficult to develop new formula with certain desired beneficial qualities. The EWG would like to draw the attention of the CCNFSDU to the recent decision taken by the CCFAC at it 37th session during the endorsement of the food additives in the Draft revised Standard on Processed Cereal-based Foods for Infants and Young Children (ALINORM 05/28/12, paragraph 46). Indeed, the CCFAC did not delete the principle of the carry-over of food additives, but rather decided to include "some text to clarify the conditions on the carry-over of food additives applied to the Processed cereal-based foods Standard". Therefore, the EWG did not amend section 4.6 and requests the CCNFSDU to examine this issue carefully at its November 2005 session.

1.4 Nutrient Carriers

There was a proposal to include Nutrient Carriers as a new functional class in the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants especially as it would be necessary to consider the substances used to disperse different oil and fat soluble nutrients into infant formula and formula for special medical purposes intended for infants. However, considering the fact that the CCFAC has not yet resolved the issue of carriers, it would seem premature to include a new functional class on Nutrient carriers in the section on food additives at this stage. Therefore, the proposed class of

nutrient carriers has neither been introduced in Section A nor in Section B. The EWG proposes that the matter of nutrient carriers be examined in the context of Section 3 by the EWG led by Germany.

1.5 Revisions made to the list of food additives in Section A as compared to the list included in ALINORM 05/28/26

1.5.1 Functional Class names edited

The functional class names have been edited in order to make them consistent with the terms used in the Codex General Standard for Food Additives (4.1 Thickening Agents →Thickeners and 4.3 pH -Adjusting Agents →Acidity Regulators).

1.5.2 Maximum levels of permitted food additives

The Maximum levels of the food additives are set for 100 ml of the ready-to-drink product with the exception of the ML for antioxidants as these are expressed in mg/kg fat.

1.5.3 Specific amendments to the list of food additives reviewed by the EWG

Section 4.1 Thickeners

INS 415 Xanthan Gum has been included in the list of thickeners with a ML consistent with Good Manufacturing Practice (GMP). Xanthan Gum has been evaluated by JECFA and assigned an ADI of "Not Specified". Xanthan Gum protects from physical separation. It is an emulsion stabiliser and contributes to the adjustment of viscosity.

Section 4.2 Emulsifiers

INS no. 322 Lecithins covers both Lecithin and Partially Hydrolysed Lecithin. Also refer to ALINORM 05/28/12, paragraph 67, fourth bullet point which gives the general recommendation made by the 37th session of the CCFAC in this regard.

Section 4.3 Acidity Regulators

Several phosphate salts are listed in the Table: phosphoric acid (ortho-) (INS 338), sodium orthophosphates (339 i, ii, iii), and potassium orthophosphates ((340 i, ii, iii). These food additives have been allocated a numerical ADI. Therefore, a numerical maximum level of use has been proposed. This is 0.1 g/l00ml expressed as P2O5, 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.

Section 4.4 Antioxidants

The Maximum level for the proposed food additives is in 100 ml of the ready-to-drink product except for the functional class 4.4 Antioxidants where the maximum level is expressed in mg/kg fat.

There were proposals made to include INS 308 Gamma-tocopherol and INS 309 Delta-tocopherol on the list of antioxidants. However, neither substance was included due to the fact that they have never been evaluated by JECFA.

1.6 New Table on Processing Aids

Packing Gas substances (INS 290 Carbon dioxide and INS 941 Nitrogen) have been included in a new section on Processing Aids in both Sections A and B. Packing gases are used under modified packaging atmosphere in order to guarantee the quality of the product by excluding oxygen from products and they are not incorporated into the products.

For infant formula, carbon dioxide, INS 290, and nitrogen, INS 941, have been proposed for use as packing gases. Carbon dioxide is already listed in Table 1 of the GSFA with a technical function of Packing gas whilst Nitrogen is listed in the JECFA summary page as Packaging gas. Thus, since this function is recognized and listed by both Codex and JECFA, the two gases have been included in this proposal.

PART 2

SECTION A: DRAFT REVISED STANDARD FOR INFANT FORMULA (At Step 6 of the Procedure)

4. FOOD ADDITIVES

The following food additives are permitted in the preparation of infant formula, as described in Section 1 of this Standard, and within the restrictions stated below:

INS No.	Substance	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification
4.1 Thickeners			
412	Guar gum	0.1 g in liquid formulas containing partially hydrolysed protein	Protects from physical separation.
410	Carob bean gum	0.1 g	Protects from physical separation. Emulsion stabiliser, adjustment of viscosity.
1412	Distarch phosphate	0.5 g singly or in combination in soy-based infant formula only	Protects from physical separation. Emulsion stabiliser, adjustment of viscosity.
1414	Acetylated distarch phosphate	0.5 g singly or in combination in soy-based infant formula only	Protects from physical separation. Emulsion stabiliser, adjustment of viscosity.
1413	Phosphated distarch phosphate	2.5 g singly or in combination in hydrolysed protein and/or amino acid-based infant formula only	Protects from physical separation. Emulsion stabiliser, adjustment of viscosity.
1440	Hydroxypropyl starch	2.5 g singly or in combination in hydrolysed protein and/or amino acid-based infant formula only	Protects from physical separation. Emulsion stabiliser, adjustment of viscosity.
407	Carrageenan	0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolysed protein and/or amino acid-based liquid infant formula only	Thickening agent also used as an emulsifier; higher emulsifying power than Lecithins and more hydrophilic capacities than Mono- and diglycerides.
415	Xanthan gum	GMP	Protects from physical separation. Emulsion stabiliser, adjustment of viscosity
4.2 Emulsifiers[5]			
322	Lecithins[6]	0.5 g in all types of infant formula	Natural stabiliser retains homogeneity.

[4] Except for the functional class 4.4 Antioxidants where the maximum level is expressed in mg/kg fat.
[5] 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.

471	Mono- and diglycerides	0.4 g in all types of infant formula	Natural stabiliser, retains homogeneity of liquid products and reconstituted powders
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	Higher emulsifying power than Lecithins and more hydrophilic capacities than Mono- and diglycerides, especially in formulas not containing whole protein.
473	Sucrose esters of fatty acids	12 mg in formula containing hydrolysed protein, peptides or amino acids	Higher emulsifying power than Lecithins and more hydrophilic capacities than Mono- and diglycerides, especially in formulas not containing whole protein.
4.3 Acidity Regulators			
524	Sodium hydroxide	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	Buffering capacity. Improves in-processing handling, and also has a stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying. It is selected depending on the pH and composition of the infant formula.
500ii	Sodium hydrogen carbonate		
500i	Sodium carbonate		
525	Potassium hydroxide		
501ii	Potassium hydrogen carbonate		
501i	Potassium carbonate		
526	Calcium hydroxide		
331i	Sodium dehydrogenate citrate		
331ii	Trisodium citrate		
332i	Potassium dihydrogen citrate		
332ii	Tripotassium citrate		
270	L(+) Lactic acid	Limited by GMP in all types of infant formula	Natural acid for pH adjustment.
330	Citric acid	Limited by GMP in all types of infant formula	Buffering and chelating capacity.
338	Orthophosphoric acid	0.1 g expressed as P_2O_5, singly or in combination and within the limits for sodium, potassium and phosphorous in Section 3.1.3 (e) in all types of infant formula.	Stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying. Selected depending on pH and composition of formula.
339i	Monosodium orthophosphate		
339ii	Disodium orthophosphate		
339iii	Trisodium orthophosphate		

[6] INS no. 322 covers both Lecithin and Partially Hydrolysed Lecithin. Also refer to ALINORM 05/28/12, paragraph 67, forth bullet point which gives the general recommendation made by the 37th session of the CCFAC in this regard.

340i	Monopotossium orthophosphate		
340ii	Dipotassium orthophosphate		
340iii	Tripotassium orthophosphate		
4.4 Antioxidants			
306	Mixed tocopherols concentrate	300 mg/kg fat, singly or in combination in all types of infant formula	Protects from oxidation.
307	Alpha-tocopherol	300 mg/kg fat, singly or in combination in all types of infant formula	Protects from oxidation.
304	L-Ascorbyl palmitate	300 mg/kg fat, singly or in combination in all types of infant formula	Protects from oxidation.

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Function	**Substance**	**Maximum Level**	**Technological Justification**
Packing gas	Carbon dioxide	GMP	Neutral gas used to modify the packaging atmosphere by excluding oxygen
Packing gas	Nitrogen	GMP	Neutral gas used to modify the packaging atmosphere by excluding oxygen

PART 3

SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS
(At Step 3 of the Procedure)

Brief introduction

At the 26th session of the CCNFSDU (Bonn, Germany, 1st - 5th November 2004), "due to time constraints and similar issues pending resolution in section A, the Committee requested the Delegation of Switzerland to develop proposals for this section for consideration by the Committee at its next session.[7]" In the proposal made by Switzerland regarding Section B, the following functional classes have been considered necessary for the manufacture of formula for special medical purposes intended for infants:

4.1 Thickeners

4.2 Emulsifiers

4.3 Acidity Regulators

4.4 Antioxidants

4.5 Sweeteners

4.6 Colours

4. FOOD ADDITIVES

See Section A 4.

In addition to the additives allowed for use in Infant Formula (Section A), the following food additives are permitted in the preparation of Formula for Special Medical Purposes Intended for Infants.

[7] Report of the 26th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, ALINORM 05/28/26, paragraph 69.

INS No.	Substance	Maximum level in 100 ml of the ready-to-drink product[8]	Technological Justification
4.1 Thickeners			
401	Sodium alginate	100 mg	Used in some liquid formula containing fibre. When used in combination with additive 412, 401, 410, 415, the hydrocolloids in the mixture prevent the separation of fibre in the liquid feed. It is important during the sterilisation process that the room temperature viscosity of the product is reduced otherwise the sterilisation effect will be impaired. At the same time, the same viscosity and gelling effect must be thermo reversible in order to hold the fibres together during feeding. Single hydrocolloids do not have the necessary effect and there are no other protein-free additives available for this type of application.
405	Propane 1,2-diolalginate	20 mg	Retains its functionality over a wide pH range and is synergistic with other emulsifiers. This property has been beneficial in the development of acidic formulations which contain fat. The development of citric flavoured products is made possible; citric flavours are especially good at masking the bitter unpleasant taste of amino-acids.
410	Carob bean gum	0.5 g	Emulsion stabiliser, adjustment of viscosity. Used in some anti-regurgitating formulas. If a lower level is used, the solution separates very quickly in phases. Carob bean floats to the upper level of the solution very quickly, so a minimum viscosity is needed to prevent this phenomenon.
412	Guar gum	1 g	Minimises and delays physical separation of the product, fat separation and fat globule coalescence. Guar gum is an excellent water binder, it does not form gel, which is an advantage in liquid products, it is cold water soluble and will not modify the thickening effect obtained by carrageenan.
415	Xanthan gum	0.12 g	
440	Pectins	1 g	Used as a gelling agent instead of gelatine. Particularly efficient in presence of fruits and in acidic preparations. Thickening for semi-solid preparations. Optimum viscosity is achieved when used in conjunction with other thickening agents.
466	Sodium carboxymethyl cellulose	1 g	Better thickening, gel formation, solvation and less "sandy" product is obtained with additive 466 compared to pectin. It disperses easily in water forming colloidal solutions; it can therefore be used as a suspending agent, an emulsifying agent and in the preparation of gels. Furthermore, it improves dispersion of other agents. Its technological functions are hardly influenced by temperature and metal salts have little effect on its viscosity.
1450	Starch sodium octenyl succinate	2 g	Restores viscosity and stability properties that native starch tend to lose when processed.
4.2 Emulsifiers[9]			

[8] Except for the functional class 4.4 Antioxidants where the maximum level is expressed in mg/kg fat.

471	Mono- and diglycerides	0.5 g	Natural stabiliser that retains homogeneity of liquid products and liquid reconstituted powder. Because it has an intermediate hydrophilic/lipophilic balance (HLB) value, it is suitable for emulsifying products containing fats which require intermediate HLB emulsifiers. It is a robust substance in that it can withstand harsh processing conditions, such as spray drying and UHT processing. This property has been beneficial for the development of ready-to-feed UHT liquid products providing complete nutrition. It is also used extensively for emulsifying fat and carbohydrate components. Its resistance to ionic interactions makes it suitable for use in products containing mineral and trace element ions such as nutritionally complete products.
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	Higher emulsifying power than Lecithins and more hydrophilic capacities than Mono- and diglycerides, especially in formulas not containing whole protein.
472e	Diacetyltartaric and fatty acid esters of glycerol	0.5 g	Retains homogeneity of liquid products and liquid reconstituted powder especially in formulas where whole proteins are not used. Has a high HLB, works better in combination with additive 322 and 471.
473	Sucrose esters of fatty acids	12 mg in formula containing hydrolysed protein, peptides or amino acids	Higher emulsifying power than Lecithins and more hydrophilic capacities than Mono- and diglycerides, especially in formulas not containing whole protein.
4.3 Acidity Regulators			
4.4 Antioxidants			
4.5 Sweeteners			
950	Acesulfame potassium	45 mg for infants over one year of age	In order to improve dietary compliance, mask the unpleasant taste of certain FSMP mixtures in cases where additional sweetness from sugar is not appropriate because of : *Osmolality*: the addition of sugar increases the osmolality of the product which is not desirable in products for patients known to be at risk of diarrhoea. *Volume*: Sugar or other natural sweetening ingredients will greatly increase the bulk of a product and thus require much increased volumes of a product to be consumed to meet dietary
951	Aspartame	100 mg for infants over one year of age	
954	Saccharin	20 mg for infants over one year of age	

[9] 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.

955	Sucralose	40 mg for infants over one year of age	requirements. *Effect*: Natural sweeteners e.g. sugar, dried glucose syrup, maltodextrin on their own cannot mask the unpleasant and bitter taste of many synthetic ingredients such as amino acids. *Contraindications*: The inclusion of high levels of sugars in products for young children is discouraged to avoid dental caries and may be contraindicated for some special diets e.g. energy-restricted. Natural sweetening agents (e.g. sugar, glucose syrups) are used wherever possible, sweeteners are used only when absolutely necessary.
4.6 Colours			
160aii	Carotene, vegetable	3 mg for infants over one year of age	The mixture of amino acids, vitamin, mineral complex, unusual fats of fatty acids etc. gives a non-attractive colour to the FSMP product. The link between visual appearance and taste is well known: if a product looks better, the patient perceives that the product tastes better. Non compliance with the dietary regimen provided by these specialised foods may result in malnutrition, illness or rapid degeneration of the patient. Adding colours to these mixtures helps dietary compliance. Positive opinion on such usage has been expressed by the European Scientific Committee for Food in December 1996.

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