codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/NFSDU 06/28/4-Add.2**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Sheraton Chiangmai Hotel, Chiang Mai, Thailand

PROPOSALS OF THE WORKING GROUP FOR SECTIONS ON FOOD ADDITIVES

Prepared by Switzerland

SECTIONS A & B

4. FOOD ADDITIVES

Background

1. The current Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (ALINORM 06/29/06, Appendix IVA) is at Step 6 of the Codex step procedure.

2. At its 27th session held in November 2005, "The Committee recognized that it was not possible to consider the Section on food additives at the current session due to lack of time, therefore the Committee accepted the kind offer of the Delegation of Switzerland to prepare a revised list of additives taking into account proposals made by the Codex Committee on Food Additives and Contaminants (CCFAC) on this Section for the Draft Revised Standard for Cereal-Based Foods for Infants and Young Children and comments submitted in view of the 27th session. The revised list would then be circulated in view of its consideration by the 28th session of the Committee" (ALINORM 06/29/06, paragraph 109).

Switzerland has prepared this document based on the comments received in view of and at the 27th session (CX/NFSDU 05/27/6; CX/NFSDU 05/27/6-Add.2; Conference Room Documents issued during the 27th session) as well as written comments which have been issued in view of the forthcoming 28th session (CX/NFSDU 06/28/4).

The following Codex members and observers submitted comments on food additives:

27th Session:	Brazil	ENCA
	China	IBFAN
	European Union (EU)	ISDI
	India	

	Iran	
	Kuwait	
	Turkey	
	Venezuela	
	United States of America (USA)	
28th Session:	India	AIDGUM
	USA	

3. The views expressed in the comments received differ considerably in their approach and can be roughly grouped as follows:

- No additives or very few additives should be permitted in infant formula: reduce current list
- Maintain the status quo of the standard since this was approved already by CCNFSDU, CCFAC and CAC; expand only when justified
- Additions of specific additives requested (mainly by observers)

In view of these strongly conflicting opinions about the use of additives in infant formula, it did not seem possible to propose a revised list that would allow the Committee to easily reach consensus.

4. The conflicting opinions and their justifications which are partly health considerations rather refer to the application of different principles or concepts applied when discussing food additives for infant formula. Due note was taken of the proposal made by the USA that CCNFSDU should elaborate its own working principles before making decisions on specific food additive provisions in standards for foods for infants and children. Switzerland therefore undertook a close review of the reports of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in order to find out whether the use of additives in baby food had been considered by this Expert committee.

JECFA

5. At its 15th meeting held in 1971, (WHO TRS 488, page 6), JECFA considered the Draft Report prepared by an FAO/WHO Meeting on Additives in Baby Foods (FAO/WHO Meeting on Additives), which had been held from 14th to 16th June 1971 (WHO TRS 488, pages 29-37). This Meeting had been convened with the following Terms of reference:

(a) to set forth the principles to be considered in accepting the use of additives in baby foods ;

(b) to draw attention to the need for specific toxicological approaches to the evaluation of the safety of food additives in infant formulas and baby food ;

(c) to discuss a number of additives in respect to which specific queries had been raised.

6. The FAO/WHO Meeting on Additives made a distinction between baby foods suitable for infants up to the age of 12 weeks and those designed to be given to the older infant. This distinction was based on the argument that for a variety of physiological reasons, the very young infant is relatively more vulnerable. The Meeting also set forth certain more stringent testing procedures that, it was suggested, should be employed when considering the acceptability of food additives in baby foods. Finally, the Meeting considered briefly the general principles to be borne in mind when considering the technological aspects of food additives in baby foods.

7. The FAO/WHO Meeting on Additives concluded in its report about the use of food additives in infant food (below 12 weeks of age) that "It is likely that the detoxicating mechanisms, the permeability

of certain tissues, and other protective mechanisms of the infant aged up to 12 weeks may not have developed to a point where they are able to cope with substances that present no problem to the adult. There is little evidence regarding the age of maturation of detoxicating mechanisms, particularly as regards individual variability. However, it may be assumed that by the end of the twelfth week most of the necessary protective mechanisms have developed. Few additives have been investigated in relation to their effects on very young children. It is therefore prudent that foods intended for infants under 12 weeks should contain no additives at all." (Principles for the safety assessment of food additives and contaminants in food, WHO, Geneva 1987).

8. However, the experts accepted "that in practice there may be certain exceptions on technological grounds to the exclusion of food additives from food for infants under 12 weeks. The use of food additives may be justified, for example, to increase shelf life, to ensure adequate sterilization by promoting homogenization, or to maintain consistency and texture in order to ensure safe and acceptable use. However, appeal to the eye or organoleptic acceptability to the mother, as opposed to the infant, does not constitute justification" (Principles for the safety assessment of food additives and contaminants in food, WHO, Geneva 1987).

9. The FAO/WHO Meeting on Additives also discussed some additives to be used in infant formula and accepted the following: lecithin, monoglycerides and diglycerides, naturally occurring antioxidants such as tocopherols and ascorbic acid, or their appropriate esters, nitrogen and carbon dioxide for packaging, a variety of suitable and available compounds as buffers and pH regulators. Furthermore, only L-lactic acid should be used in infant foods and in case of phosphate and calcium the ratio of both elements should be taken into account. Similarly, addition of sodium compounds should consider total sodium intake. (Principles for the safety assessment of food additives and contaminants in food, WHO, Geneva 1987).

10. The FAO/WHO Meeting on Additives also discussed the toxicological requirements and agreed that "Before a food additive is regarded as safe for use in food intended for infants up to 12 weeks of age, the toxicological studies should be extended to include animals in the corresponding period of life." (Principles for the safety assessment of food additives and contaminants in food, WHO, Geneva 1987).

11. JECFA endorsed all the recommendations made by the FAO/WHO Meeting on Additives at its 15th Meeting held in 1971, and has applied these principles whenever infant/baby food was discussed (29th Meeting: WHO TRS 733. p 11ff; 31st Meeting: WHO TRS 759, p 10). The Guidance document adopted by JECFA in 1987 (Principles for the Safety Assessment of Food Additives and Contaminants in Food (WHO Environmental Health Criteria 70, EHC 70) confirmed these principles again.

12. Since JECFA "considers it to be prudent that food intended for infants younger than 12 weeks of age should not contain any additives" (EHC 70), it is our understanding that the adoption of an ADI by JECFA does not mean that this ADI automatically applies to infants younger than 12 weeks. If a food additive is also intended to be used in infant formula, the safety assessment of that particular food additive should include safety studies involving exposure of that additive to very young animals.

13. With respect to infant formula, one might question the appropriateness of the principles used in the food additive risk management by the CCFAC for food additive entries in the Codex General Standard for Food Additives (GSFA) for foods for children and adults. It may rather be concluded that the establishment of an ADI in itself is not sufficient and that additional issues need to be considered.

Status of the additives listed in the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

14. Taking into account the aforementioned considerations made by JECFA, Switzerland decided to check the status of the additives proposed for infant formula by JECFA using the on-line database and reports available from the Joint Secretariats' homepage (http://www.fao.org/ag/agn/jecfa/archive_en.stm). The information given in this Discussion document is

not a comprehensive summary of JECFA's opinion. An attempt has been made to distil the most relevant information on this subject. The column "JECFA status" in the Appendix to this document shall therefore be used with caution as it was completed merely in order to allow the CCNFSDU to carry out a fruitful discussion and to develop principles on how to proceed further on the issue of food additives in infant formula and formulas for special medical purposes intended for infants.

15. As can be seen from the Appendix, some additives have been evaluated by JECFA specifically for use in infant food (< 12 weeks), whilst for others the evaluation does not specifically refer to young infants although the toxicological database possibly contains data that are relevant to this segment of the population; and then there are some recent entries and proposals that have no safety clearance by JECFA at all (specifically the proposal for INS no. 308 Delta-tocopherol and INS no. 309 Gamma-tocopherol are unclear since JECFA has not evaluated these additives specifically and it is unknown whether the pure substances are commercially available).

Possible actions by CCNFSDU

16. Considering the fact that JECFA fundamentally discussed additives in baby food and foods for young infants more than thirty five years ago, the CCNFSDU may wish to consider sending the issue to JECFA for further consideration and advice to Codex. Specific attention should be given by JECFA to the question of whether an ADI (not specified or numerical) established by JECFA applies to young infants below 12 weeks of age and what scientific principles should apply to the use of additives in the food intended for them. A further question to ask would be whether an ADI "not specified" justifies a GMP use level in infant formula. JECFA should, if feasible (considering the work load and available resources), also comment on the specific additives listed in the current draft standard.

17. CCNFSDU may, possibly in collaboration with CCFA, elaborate separate principles for additives to be used in infant formula. These principles should follow existing and future advice from JECFA and should take into account the principles used for the elaboration of the GSFA where applicable; where such principles are not suitable, deviating principles should be developed.

18. The discussion on principles should also address the issue of whether the use of additives in *Formulas for Special Medical Purposes Intended for Infants* requires the development of specific principles; in this respect, it should be noted that this question was not addressed by JECFA.

19. Based on the preceding review, the following options are presented to the CCNFSDU for consideration and possible future action:

Option 1: Proceed with all food additives already listed in the current standard; discuss other additives after JECFA has delivered its opinion

Option 2: Proceed with non-controversial food additives cleared by JECFA for infants

Option 3: Put section 4 on food additives on hold until JECFA has delivered its opinion

4. FOOD ADDITIVES (INFANT FORMULA)

APPENDIX

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
4.1	Thickeners						
4.1.1	412	Guar gum	0.1 g in liquid formulas containing hydrolysed protein	Retains homogeneity	JECFA (19th): ADI NS; infants <12 weeks not mentioned Tox database: teratogenicity ok in two species	With restrictions: EU Against: Argentina, Brazil, India, ENCA, IBFAN In favour: China	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	Retains homogeneity	JECFA (25th): ADI NS; infants <12 weeks not mentioned Tox database: not teratogenic in several mammalian species; did not cause any significant compound-related effects in a three-generation reproduction study	In favour (0.1): Iran, Turkey, Venezuela Higher level (0.5): Kuwait. ISDI Against: Argentina, Brazil, India, ENCA, IBFAN	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	Retains homogeneity	JECFA (15th) Modified starches only for infants >12 weeks JECFA (25th): ADI NS; infants <12 weeks not mentioned Tox database: study in pigs weaned at day 3	Against: Argentina,India, ENCA, IBFAN	0.5 g singly or in combination in soy-based infant formula only

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
4.1.4	1414	Acetylated distarch phosphate	0.5 g singly or in combination in soy-based infant only	Retains homogeneity	JECFA (15th) Modified starches only for infant >12 weeks JECFA (26th): ADI NS; infants <12 weeks not mentioned Tox database: three generation study available	Against: Argentina, India, ENCA, IBFAN	0.5 g singly or in combination in soy-based infant formula only
4.1.5	1413	Phosphated distarch phosphate	2.5 g singly or in combination in soy-based infant only	Retains homogeneity	JECFA (15th) Modified starches only for infant >12 weeks JECFA (25th): ADI NS; infants <12 weeks not mentioned Tox database: three generation study available; study in pigs weaned at day 3	Against: Argentina, India, ENCA, IBFAN	2.5 g singly or in combination in soy-based infant formula only
4.1.6	1440	Hydroxy-propyl starch	2.5 g singly or in combination in soy-based infant only	Retains homogeneity	JECFA (15th) Modified starches only for infant >12 weeks JECFA (25th): ADI NS; infants <12 weeks not mentioned Tox database: sub-chronic study in five-week-old rats	Against: Argentina,India, ENCA, IBFAN	2.5 g singly or in combination in soy-based infant formula only
4.1.7	407	Carrageenan	0.03 g in regular milk- and soy-based infant formula only 0.1 g in hydrolysed protein and/or amino-acid liquid infant formula only	Retains homogeneity	JECFA (57th): ADI NS; infants <12 weeks not mentioned Tox database: Reproductive and developmental studies	Against: Argentina, EU, Brazil; India, ENCA, IBFAN, ESPGHAN	0.03 g in regular milk- and soy-based infant formula only 0.1 g in hydrolysed protein and/or amino-acid liquid infant formula only

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
4.1.8	415	Xanthan gum	GMP	Retains homogeneity	JECFA (30th): ADI NS; infants <12 weeks not mentioned Tox database: three-generation reproduction study adverse effects attributable to xanthan gum were not found	Against: Argentina,EU; India, ENCA, IBFAN	-
4.2	**Emulsifiers** ***If more than one of the substances INS 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**						
4.2.1	322	Lecithins[6*]	0.5 g in all types of infant formula	Retains homogeneity	JECFA (17th): ADI NS JECFA (15th): suitable for infant formula	Against, India, IBFAN Only certain cases: ENCA	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	Retains homogeneity	JECFA (17th): ADI NS (not limited) JECFA (15th): suitable for infant formula	Against, India, IBFAN Only certain cases: ENCA	0.4 g in all types of infant formula
4.2.3	472c	Citric and fatty acid esters of glycerol*	0.75 g in powder formula 0.9 g in liquid formula containing hydrolysed protein or amino acids	Retains homogeneity	JECFA (17th): ADI NS (not limited); infants <12 weeks not mentioned	Against, India, IBFAN Only certain cases: ENCA	-
4.2.4	473	Sucrose esters of fatty acids*	12 mg in formula containing hydrolysed protein or amino acids	Retains homogeneity	JECFA (49th) :ADI specified at 0-30 mg/kg bw; infants <12 weeks not mentioned Tox database does not address youg animals	Against, India, IBFAN Only certain cases: ENCA	-

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
4.2.5	472e	Tartaric and fatty acid esters of glycerol	GMP (China) 0.5 mg (USA)	Retains homogeneity	JECFA (61st) ADI specified at 0-50 mg/kg bw (2003); infants <12 weeks not mentioned Tox database	In favour: China, Turkey, Venezuela, ISDI Against, India, IBFAN Only certain cases: ENCA	-
4.2.6	472a	Acetic and fatty acid esters of glycerol	GMP (USA)		JECFA (17th): ADI NS (not limited); infants <12 weeks not mentioned	Against: India, IBFAN Only certain cases: ENCA	-
4.3	**Acidity Regulators**						
4.3.1	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	pH- adjustment	JECFA (9th): not limited JECFA (15th): suitable chemical compound for baby food (not specifically mentioned); attention to total sodium /content intake		Limited by good manufacturing practice 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		pH- adjustment	JECFA (29th): NS; anion not mentioned for use in infant foods		Limited by good manufacturing practice and within the limits for sodium and potassium in Section 3.1.2.(c) in all types of infant formula

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
4.3.3	500i	Sodium carbonate		pH- adjustment	JECFA (29th): NS; anion not mentioned for use in infant foods		Limited by good manufacturing practice and within the limits for sodium and potassium in Section 3.1.2.(c) in all types of infant formula
4.3.4	525	Potassium hydroxide		pH- adjustment	JECFA (29th): NS; not mentioned for use in infant foods		Limited by good manufacturing practice and within the limits for sodium and potassium in Section 3.1.2.(c) in all types of infant formula
4.3.5	501ii	Potassium hydrogen carbonate		pH- adjustment	JECFA (29th): NS; not mentioned for use in infant foods		Limited by good manufacturing practice and within the limits for sodium and potassium in Section 3.1.2.(c) in all types of infant formula
4.3.6	501i	Potassium carbonate		pH- adjustment	JECFA (29th): NS; not mentioned for use in infant foods		Limited by good manufacturing practice and within the limits for sodium and potassium in Section 3.1.2.(c) in all types of infant formula

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
4.3.7	526	Calcium hydroxide		pH- adjustment	JECFA (29th): NS; anion not mentioned for use in infant foods JECFA (15th): suitable chemical compound for baby food (not specifically mentioned); attention to Ca:P ratio		Limited by good manufacturing practice and within the limits for sodium and potassium in Section 3.1.2.(c) in all types of infant formula
4.3.8	331i	Sodium dihydrogen citrate		pH- adjustment	JECFA (23rd): not limited; infants <12 weeks not mentioned		-
4.3.9	331iii	Trisodium citrate		pH- adjustment	JECFA (23rd): not limited; infants <12 weeks not mentioned		-
4.3.10	332i	Potassium dihydrogen citrate		pH- adjustment	JECFA (23rd): not limited; infants <12 weeks not mentioned		-
4.3.11	332ii	Tripotassium citrate		pH- adjustment	JECFA (23rd): not limited; infants <12 weeks not mentioned		-
4.3.12	270	L(+) lactic acid	Limited by GMP in all types of infant formula	pH- adjustment	JECFA (17th): not limited; only L-lactic in infant food.		Limited by good manufacturing practice in all types of infant formula
4.3.13	330	Citric acid	Limited by GMP in all types of infant formula	pH- adjustment	JECFA (17th): not limited; infants <12 weeks not mentioned		Limited by good manufacturing practice in all types of infant formula

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
4.3.14	338	Phosphoric acid	0.1 g expressed as P_2O_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	JECFA (15th): suitable chemical compound for baby food (not specifically mentioned); attention to Ca:P ratio MTDI: 70 mg/kg bw as P (combined for all P sources)	Against: India	-
4.3.15	339i	Monosodium dihydrogen monophosphate		pH- adjustment	JECFA (15th): suitable chemical compound for baby food (not specifically mentioned); attention to Ca:P ratio JECFA (29th): NS; mentioned for use in infant foods MTDI: 70 mg/kg bw as P (combined for all P sources)	Against: India	-
4.3.16	339ii	Disodium hydrogen monophosphate		pH- adjustment	JECFA (15th): suitable chemical compound for baby food (not specifically mentioned); attention to Ca:P ratio JECFA (29th): NS; mentioned for use in infant foods MTDI: 70 mg/kg bw as P (combined for all P sources)	Against: India	-

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
4.3.17	339iii	Trisodium monophosphate		pH- adjustment	JECFA (15th): suitable chemical compound for baby food (not specifically mentioned); attention to Ca:P ratio JECFA (29th): NS; mentioned for use in infant foods MTDI: 70 mg/kg bw as P (combined for all P sources)	Against: India	-
4.3.18	340i	Monopotassium dihydrogen monophosphate		pH- adjustment	JECFA (29th): NS; not mentioned for use in infant foods MTDI: 70 mg/kg bw as P (combined for all P sources)	Against: India	-
4.3.19	340ii	Dipotassium hydrogen monophosphate		pH- adjustment	JECFA (29th): NS; not mentioned for use in infant foods MTDI: 70 mg/kg bw as P (combined for all P sources)	Against: India	-
4.3.20	340iii	Tripotassium monophosphate		pH- adjustment	JECFA (29th): NS; not mentioned for use in infant foods JECFA: Buffer/Sequestrant/Emulsion stabiliser MTDI: 70 mg/kg bw as P (combined for all P sources)	Against: India	-

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
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	JECFA (15th): suitable naturally occurring antioxidant for infant food	Only certain cases: ENCA Against: IBFAN	
4.4.2	307b	Mixed tocopherol concentrate		Protects from oxidation	JECFA (15th): suitable naturally occurring antioxidant for infant food	Only certain cases: ENCA Against: IBFAN	1 mg in all types of infant formula
4.4.3	304i	L-Ascorbyl palmitate	1 mg in all types of infant formula singly or in combination	Protects from oxidation	JECFA (15th): suitable naturally occurring antioxidant for infant food	Only certain cases: ENCA Against: IBFAN	1 mg in all types of infant formula
4.4.4	309	Gamma-tocopherol	1 mg in all types of infant formula singly or in combination	Protects from oxidation	JECFA (15th): suitable naturally occurring antioxidant (?); however, historically the INS referred to the synthetic product, we wonder whether really a commercial product exists; no ADI from JECFA	In favour: China, Kuwait, Turkey, Venezuela, ISDI Only certain cases: ENCA Against: IBFAN	-
4.4.5	308	Delta-tocopherol	1 mg in all types of infant formula singly or in combination	Protects from oxidation	JECFA (15th): suitable naturally occurring antioxidant, however, historically the INS referred to the synthetic product, we wonder whether really a commercial product exists; no ADI from JECFA	In favour: China, Kuwait, Turkey, Venezuela, ISDI Only certain cases: ENCA Against: IBFAN	-
4.9	**Packing Gases**						
4.9.1	290	Carbon dioxide	GMP	Used to pack under inert atmosphere	JECFA (15th): may be required in certain cases		

	INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product[4]	Technological Justification	JECFA status	Comments from members, observers	In current standard
4.9.2	941	Nitrogen		Protect nutrient quality and guarantee product shelf life		Preferable to use food grade: India	

The following **additional** food additives are permitted in the preparation of Formula for Special Medical Purposes Intended for Infants

INS No.	Substance	Maximum level in 100 ml of the ready-to-drink product[1]	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)	0.5 g	Retains homogeneity
412	Guar gum	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.
4.2 Emulsifiers[2]			
471	Mono- and diglycerides	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
4.5 Sweeteners			

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

[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.

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 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.
951	Aspartame	100 mg for infants over one year of age	
954	Saccharin	20 mg for infants over one year of age	
955	Sucralose	40 mg for infants over one year of age	
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.