

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
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World Health
Organization

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Agenda Item 9

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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 DRAFT REVISION OF THE LIST OF FOOD ADDITIVES

REVISED LIST OF FOOD ADDITIVES IN INFANT FORMULA

Prepared by Switzerland

FOOD ADDITIVES (INFANT FORMULA (IF))

Request for additional food additives for use in infant formula (Section A) and formula for specific medical purposes (Section B)

Some explanations from Switzerland

Switzerland asked the industry (International Special Dietary Food Industries (ISDI)) to clarify which of the additional food additives were really needed (technologically justified) and were used in the production of infant formulas. Switzerland then revised the list of food additives in infant formulas based on the comments submitted by ISDI. The table below presents the revised list of food additives including the comments submitted by ISDI. In light of the submitted information, Switzerland would like to recommend to the Committee to proceed in two steps:

- 1. To delete the following food additives from the list: INS numbers 306, 308, 309, 414, 472a, 338, 401, 405, 412, 466 and 471.*
- 2. To request JECFA to evaluate the following food additives: INS numbers 472c, 473, 472e, 410, 415, 440 and 1450.*

Section A

INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product ⁴	Technological Justification	JECFA status	Comments	Approved in
Thickeners						
415	Xanthan gum	GMP	Retains homogeneity	30 th JECFA (1986): ADI NS; infants <12 weeks not mentioned Tox database: three-generation reproduction study adverse effects attributable to Xanthan gum were not found	Pending a re-evaluation by JECFA Date of placing on the market: before 1998	EU (27 countries 1.2 g/L in FSMP) USA (GRAS* for food in general)
414	Gum Arabic (acacia)	GMP	Retains homogeneity	-	ISDI: can be deleted Deletion does not apply to the use of INS 414 as a carrier of nutrient preparations as authorized in CAC/GL 10-1979	
Emulsifiers						
472c	Citric and fatty acid esters of glycerol*	0.75 g in powder formula ¹ 0.9 g in liquid formula ² containing hydrolysed protein or amino acids	Retains homogeneity	17 th JECFA (1973): ADI NS (not limited); infants <12 weeks not mentioned	Pending a re-evaluation by JECFA Date of placing on the market: before 1995	Australia, Canada, China, EU (27 countries), Malaysia, New Zealand, USA (GRAS for food in general)
473	Sucrose esters of fatty acids*	12 mg in formula ³ containing hydrolysed protein or amino acids	Retains homogeneity	49 th JECFA (1997): ADI specified at 0-30 mg/kg bw; infants <12 weeks not mentioned	Pending a re-evaluation by JECFA Date of placing on the market: before 1995	Japan, EU (27 countries)

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

² If more than one of the substances INS 472c, 473 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances.

INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product ⁴	Technological Justification	JECFA status	Comments	Approved in
472e	Tartaric and fatty acid esters of glycerol	GMP (China) 0.5 g	Retains homogeneity	61 st JECFA (2003) ADI specified at 0-50 mg/kg bw (2003); infants <12 weeks not mentioned	Pending a re-evaluation by JECFA Date of placing on the market: 1998	Australia, New Zealand, USA (GRAS for food in general)
472a	Acetic and fatty acid esters of glycerol	GMP (USA)		17 th JECFA (1973): ADI NS (not limited); infants <12 weeks not mentioned	Not supported by ISDI: can be deleted	-
Acidity Regulators						
338	Phosphoric acid	0.1 g expressed as P ₂ O 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		15 th JECFA (1971): 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)	Not supported by ISDI: can be deleted	-
Antioxidants						
306	Vitamin E concentrate	1 mg in all types of infant formula singly or in combination	Protect from oxidation		Is equivalent to JECFA specification INS 307b, therefore INS 306 can be deleted	
309	Gamma tocopherol	1 mg in all types of infant formula singly or in combination	Protect from oxidation		It is not used in infant formulas, therefore can be deleted.	

³ If more than one of the substances INS 472c, 473 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances.

INS no.	Additive	Maximum level in 100 ml of the ready-to-drink product ⁴	Technological Justification	JECFA status	Comments	Approved in
308	Delta tocopherol	1 mg in all types of infant formula singly or in combination	Protect from oxidation		It is not used in infant formulas, therefore can be deleted.	

Section B Infant Formula as Food for Special Medical Purposes

INS no.	Substance	Maximum level in 100 ml of the ready-to-drink product ⁴	Technological Justification	JECFA Status	Comments	Approved in
Thickeners						
401	Sodium alginate	100 mg	Retains homogeneity		Not supported by ISDI: can be deleted	
405	Propene 1,2-diolsalginate	20 mg	Retains homogeneity		Not supported by ISDI: can be deleted	
410	Carob bean gum (Locust bean gum)	0.5 g	Retains homogeneity		Pending a re-evaluation by JECFA	
412	Guar gum	1 g	Retains homogeneity		Not supported by ISDI: can be deleted	
414	Gum—Arabic (acacia)	GMP	Retains homogeneity		Not supported by ISDI: can be deleted. Deletion does not apply to the use of INS 414 as a carrier of nutrient preparations as authorized in CAC/GL 10-1979	
415	Xanthan gum	0.12 g	Retains homogeneity	30 th JECFA (1986), not specified	Pending a re-evaluation by JECFA Date of placing on the market: 1998	EU 1.2 g/L in FSMP, USA (GRAS for food in general)

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

440	Pectins	1 g	Retains homogeneity	25 th JECFA (1981), not specified	Pending a re-evaluation by JECFA. Date of placing on the market: 2007	Brazil, EU (27 countries in FSMP), Indonesia, USA (GRAS for food in general)
466	Sodium carboxymethyl cellulose	1-g	Retains homogeneity		Not supported by ISDI: can be deleted	
1450	Starch sodium octenyl succinate	2 g	Retains homogeneity.	26 th JECFA (1982), not specified	Pending a re-evaluation by JECFA Date of placing on the market: 1986	EU 20g/L in FSMP, USA exempt IF protein hydrolysate
Emulsifiers⁵						
471	Mono and diglycerides	0.5-g	Retains homogeneity		Not supported by ISDI: can be deleted	
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	17 th JECFA (1973), not limited	Pending a re-evaluation by JECFA Date of placing on the market: before 1995	Australia, Canada, China, EU (27 countries), Malaysia, New Zealand, USA (GRAS for food in general)
473	Sucrose esters of fatty acids	12 mg in formula containing hydrolysed protein, peptides or amino acids	Retains homogeneity	49 th JECFA (1997) :ADI specified at 0-30 mg/kg bw; infants <12 weeks not mentioned	Pending a re-evaluation by JECFA Date of placing on the market: before 1995	Japan, EU (27 countries)

* Generally recognised as safe (GRAS)

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.