

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 3a

CRD15rev

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Forty-Ninth Session

Macao SAR, China, 20-24 March 2017

MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE 82ND MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

Prepared by the JECFA Secretariat

Overview on JECFA assessments of food additives used in infant formulas

At the 47th session of the CCFA it was requested to verify the status of JECFA assessments of all food additives listed in foods category 13.1.1 infant formulae and 13.1.3 formulae for special medical purposes for infants of the GSFA, that were endorsed by CCFA at its 39th and subsequent sessions.

As detailed in the guidance on the principles and methods for the risk assessment of chemicals in food (EHC 70 and EHC 240, published in 1987¹ and in 2009²) the ADI does not apply to infants below the age of 12 weeks who might be at risk at lower levels of exposure compared with older age groups. Very young infants are a particularly sensitive subgroup because their metabolic capacities are not yet fully developed. Accordingly, risk characterization of exposure of such infants to chemicals (e.g. in infant formula or occurring as contaminants) has to be considered on a case-by-case basis. Moreover, since the usual protocols for toxicological studies do not directly cover the developmental period in question, JECFA noted that toxicological testing strategies for additives to be used in infant formulas require approaches that differ from those generally adopted for food additives.

The table below summarises the current status of JECFA evaluation on the food additives listed in the GSFA for the food categories 13.1.1 infant formulae and 13.1.3 formulae for special medical purposes for infants, and listed in Codex Standard 72-1981 Standard for infant formula and formulas for special medical purposes intend for infants.

INS	Additive	Use level per 100 ml of the product ready for consumption	JECFA status	CCFA adoption
Thickeners				
407	Carrageenan	<u>CODEX STAN 72-1981</u> 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 <u>13.1.1</u> 0.1g for use in liquid infant formulae only <u>13.1.3</u> 0.1 g in hydrolysed protein and/or amino acid based liquid infant formula only	Not of concern at proposed use levels in infant formula (79 th JECFA)	47th
410 ^a	Carob bean gum (locust bean gum)	<u>CODEX STAN 72-1981</u> 0.1g in all types of formulae <u>13.1.1 and 13.1.3</u> 0.1 g	Available studies not sufficient for the evaluation for use in infant formula, further	39th

¹ Environmental Health Criteria 70: Principles for the safety assessment of food additives and contaminants in food. WHO, Geneva 1987

² Environmental Health Criteria 240: Principles and methods for the risk assessment of chemicals in food. WHO, Geneva 2009

INS	Additive	Use level per 100 ml of the product ready for consumption	JECFA status	CCFA adoption
			data requested (82 nd JECFA)	
412	Guar gum	<u>CODEX STAN 72-1981</u> in liquid formulas containing hydrolysed protein 13.1.1 and 13.1.3 0.1 g For use in hydrolyzed protein liquid formula only	19 th JECFA (1975): ADI not specified; not evaluated for use in infant formula	39th
415	Xanthan gum	0.1g in all types of infant formula	No safety concern at proposed uses levels (82 nd JECFA)	Not yet in GFSA or Codex Standard
440	Pectin	0.2g in all types of infants formula	No safety concern at proposed uses levels (82 nd JECFA)	Not yet in GFSA or Codex Standard
1412	Distarch phosphate	<u>CODEX STAN 72-1981, 13.1.1 and 13.1.3</u> 0.5 g singly or in combination in soy-based infant formula only 2.5 g singly or in combination in hydrolyzed protein and/or amino acid based infant formula only	26 th JECFA (1982) ADI not specified; not evaluated for use in infant formula	39th
1413	Phosphated distarch phosphate			
1414	Acetylated distarch phosphate			
1440	Hydroxypropyl starch			
1450 ^a	Starch sodium octenyl succinate	<u>CODEX STAN 72-1981</u> 2 g in hydrolyzed protein and/or amino acid based infant formula only 13.1.3 2 g in hydrolyzed protein and/or amino acid based infant formula only	Not of concern at proposed use levels (79 th JECFA)	47th
Emulsifiers				
322i	Lecithins	<u>CODEX STAN 72-1981</u> 0.5 g in all types of infant formula ^b 13.1.1 and 13.1.3 0.5 g in all types of infant formula	17 th JECFA (1973): ADI not specified; not evaluated for use in infant formula	39th
471	Mono and diglycerides	<u>CODEX STAN 72-1981</u> 0.4 g in all types of infant formula ^b 13.1.1 and 13.1.3 0.4 g in all types of infant formula	17 th JECFA (1973): ADI not specified; not evaluated for use in infant formula	39th
472c ^a	Citric and fatty acid esters of glycerol	<u>CODEX STAN 72-1981, 13.1.1 and 13.1.3</u> 0.9 g in all types of infant formula 0.75 g in all types of reconstituted powder infant formula	Not of concern at proposed use levels (79 th JECFA)	47th

INS	Additive	Use level per 100 ml of the product ready for consumption	JECFA status	CCFA adoption
Acidity Regulators				
524	Sodium hydroxide	<p><u>CODEX STAN 72-1981, 13.1.1 and 13.1.3</u> 0.2 g singly or in combination and within the limits for sodium, potassium and calcium in all types of infant formula</p>	<p>9th JECFA (1965): ADI not specified; not evaluated for use in infant formula</p>	39 th
525	Potassium hydroxide			
526	Calcium hydroxide			
500i	Sodium carbonate			
500ii	Sodium hydrogen carbonate			
501i	Potassium carbonate			
501ii	Potassium hydrogen carbonate			
270	L(+) lactic acid	<p><u>CODEX STAN 72-1981, 13.1.1 and 13.1.3</u> Limited by GMP in all types of infant formula</p> <p>none evaluated for use in infant formula</p>	23 th JECFA (1979): ADI not specified	
330	Citric acid		17 th JECFA (1973): ADI not specified	
331i	Sodium dihydrogen citrate		23 th JECFA (1979): ADI not specified	
331iii	Trisodium citrate		17 th JECFA (1973): ADI not specified	
332i	Potassium dihydrogen citrate		23 th JECFA (1979): ADI not specified	
332ii	Tripotassium citrate		17 th JECFA (1973): ADI not specified	
339 i, ii and iii	Sodium dihydrogen phosphate, disodium hydrogen phosphate and trisodium phosphate		<p><u>CODEX STAN 72-1981</u> 45 mg as phosphorus 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</p>	
340 i, ii and iii	Potassium dihydrogen phosphate, dipotassium hydrogen phosphate and tripotassium phosphate			
Antioxidants				
304	Ascorbyl palmitate	<p><u>CODEX STAN 72-1981</u> 1 mg in all types of infant formula</p>	17 th JECFA (1973): ADI 0-1.25 mg/kg bw	39 th

INS	Additive	Use level per 100 ml of the product ready for consumption	JECFA status	CCFA adoption
305	Ascorbyl stearate	singly or in combination	(as the palmitate or stearate or the sum of both); not evaluated for use in infant formula	
307b	Mixed tocopherol concentrate	<u>CODEX STAN 72-1981</u> 1 mg in all types of infant formula singly or in combination	17th JECFA (1973): ADI 0-bw2 mg/kg for alpha-Tocopherol and mixed tocopherols concentrate not evaluated for use in infant formula	Not listed in the GSFA
Packaging Gases				
290	Carbon dioxide	<u>CODEX STAN 72-1981, 13.1.1 and 13.1.3</u> GMP	29th JECFA (1985): ADI not specified; not evaluated for use in infant formula	39th
941	Nitrogen		24th JECFA (1980): no ADI necessary not evaluated for use in infant formula	39th

a Specifications for lead reviewed at the 82th JECFA meeting

b if more than one of the substances INS 322, 471 are added the maximum level for each of those substances is lowered with the relative part as present of the others substances