

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 6

CX/NFSDU 00/6-Add. 1
April 2000

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES **Twenty-second Session** **Berlin, Germany, 19-23 June 2000**

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA **(CODEX STAN 72-1981)**

THE USE OF ADDITIVES IN INFANT FORMULA

Prepared by the Netherlands, Canada, China, France, Germany, Romania, Spain, Switzerland, United Kingdom, the United States of America (USA), Uruguay, Slovakia, EC, and ISDI

Since the present standards on infant formula (Codex stan 72-1981) came into effect, there has been a tremendous product development. This means that the present paragraphs on additives do not reflect the situation on the market any more.

Regarding the lay-out of the paragraphs in the annex it can be noted that the additives which are part of the present paragraphs on additives are presented in the annexes in regular characters. Following the room documents of the last meeting of the Committee and the request of several delegations new additives have been inserted in italics. The comments of the working group regarding the use of specific additives are given in the annexes preceded by an asterisk. ISDI suggested a number of additives to be added to the paragraphs, these insertions are marked with two asterisks. The working group did not have the opportunity to comment these additions.

Besides the comments regarding specific additives the working group has the following comments of a more general nature.

1. The general view is that the use of additives in foodstuffs for young children should be as restricted as possible. The question is whether this should be achieved by limiting the absolute number of additives permitted in these foodgroups or whether the insertion of several additives with a comparable function is acceptable.
2. Many remarks concerned the units to be used in which the use of additives is expressed. Most members of the working group supported the use of mg/kg or mg/l of ready to use formula or babyfood. The presentation has been adapted to this suggestion.

3. The use of thickening agents in infant formula is questioned.
4. It is suggested that locust bean gum in anti-reflux formula should not be regulated via a list of additives included for technological purposes.
5. Section 4.5 Carry-over of food additives should be modified as follows:
No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:
 - of food additives listed above within the limits of the maximum levels stipulated in this Standard; and
 - 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.

ANNEX

**Proposed draft revised Standard for Infant formula
(Codex stan 72-1981)**

Paragraph 4: Food additives, flavours and enzymes

| | | INS | Max. level per l of kg of formula as consumed | Status/ remarks |
|---------------------|-------------------------------|------|--|-----------------|
| 4.1 | Thickening agents | | | |
| 4.1.1 <i>new</i> | Guar gum | 412 | 1 g in all types of infant formula *delete <i>1 g in hydrolyzed protein and/or amino-acid based liquid infant formula</i> <i>10 g in medical infant formula</i> | ADI: n.s. |
| 4.1.2 <i>new</i> | Locust bean gum | 410 | 1 g in all types of infant formula *delete <i>10 g in infant formula for the reduction of gastro-oesophagel reflux</i> | ADI: n.s. |
| 4.1.3 <i>new</i> | Distarch phosphate | 1412 | 5 g singly or in combination in soy-based infant formulae *delete <i>25 g in hydrolyzed protein and/or amino-acid based liquid infant formula</i> *delete | ADI: n.s. |
| 4.1.4 | Acetylated distarch phosphate | 1414 | 5 g singly or in combination in soy-based infant formulae *delete 25 g in hydrolyzed protein and/or amino-acid based liquid infant formula *delete | ADI: n.s. |
| 4.1.5 | Phosphated distarch phosphate | 1413 | 5 g singly or in combination in soy-based infant formulae *delete 25 g in hydrolyzed protein and/or amino-acid based liquid infant formula *delete | ADI: n.s. |
| 4.1.6 | Hydroxypropyl starch | 1440 | 25 g singly or in combination in hydrolyzed protein and/or amino acid-based infant formulae only *delete | ADI: n.s. |

| | | INS | Max. level per l of kg of formula as consumed | Status/ remarks |
|------------|--|------|--|-----------------|
| | <i>Starch sodium octenyl succinate</i> | 1450 | 20 g in medical infant formula *in formulae which contain extensively hydrolysed protein and/or amino acids | ADI: n.s. |
| 4.1.7 | Carrageenan | 407 | 3 g in regular, milk- and soy-based liquid infant formulae only *delete 1 g in hydrolyzed protein and/or amino acid-based liquid infant formulae only *delete | ADI: n.s. |
| new | <i>Xanthan gum</i> | E415 | 0,12 g in hydrolyzed protein and/or amino acid-based infant formula or infant formula for inborn errors of metabolism *1,2 g | ADI: n.s. |
| new | <i>Pectines</i> | 440 | 10 g in infant formula for disturbed functioning of the gastrointestinal tract | ADI: n.s. |
| new | <i>Sodium carboxymethylcellulose</i> | 466 | 10 g in infant formula for the dietary management of inborn errors of metabolism | ADI: n.s. |
| * new | <i>Arabic gum</i> | 414 | | |
| 4.2 | Emulsifiers | | | |
| 4.2.1 | Lecithin | 322 | 5 g in all types of infant formulae *1 g 10 g in medical infant formula *delete | ADI: n.l. |
| new | | | | |
| 4.2.2 | Mono- and diglycerides | 471 | 4 g in all types of infant formulae *5 g 40 g in medical infant formulae *5 g | ADI: n.l. |
| new | | | | |
| new | <i>Citric acid esters of mono- and diglycerides</i> | 472c | 7,5 g in powdered products 9 g in liquid hydrolyzed protein and/or amino acidbased infant formulae only | ADI: n.l. |
| ** new | <i>Diacetyl Tartaric acid esters of mono- and diblycerides</i> | 472e | 4 g in hydrolyzed protein, peptides and/or amino acid based infant formula | |
| new | <i>Tartaric acid esters of mono- and diglycerides</i> | 472f | 4 g in hydrolyzed protein and/or amino acid based infant formulae only * delete | ADI: n.l. |

| | | INS | Max. level per l of kg of formula as consumed | Status/ remarks |
|------------|--------------------------------------|---------------|---|---|
| <i>new</i> | <i>Sucrose-esters of fatty acids</i> | 473 | <i>1,2 in hydrolyzed protein and/or amino acidbased infant formulae only * 0,12 g</i> | <i>ADI: 0-20 mg/kg, bw, day</i> |
| <i>new</i> | <i>Sodium alginate</i> | 401 | <i>1 g in medical infant formulae for metabolic inborn errors of metabolism from 4 months 1) * and for general tube-feeding</i> | <i>ADI: n.s.</i> |
| 4.3 | PH-Adjusting agents | | | |
| 4.3.1 | Sodium hydroxide | 524 | GMP, 1) * delete | ADI: n.l. |
| 4.3.2 | Sodium hydrogen carbonate | 500ii | GMP, 1) * delete | ADI: n.s. |
| 4.3.3 | Sodium carbonate | 500i | GMP, 1) * delete | ADI: n.l. |
| 4.3.4 | Potassium hydroxide | 525 | GMP, 2) * delete | ADI: n.l. |
| 4.3.5 | Potassium hydrogen carbonate | 501ii | GMP, 2) * delete | ADI: n.s. |
| 4.3.6 | Potassium carbonate | 501iii | GMP, 2) * delete | ADI: n.s. |
| 4.3.7 | Calcium hydroxide | 526 | GMP * delete | ADI: n.l. |
| 4.3.8 | Sodium citrate | 331 | GMP, 1) * 2 g/l individually or in combination with 332 | ADI: n.s. |
| 4.3.9 | Potassium citrate | 332ii | GMP, 2) * 2 g/l individually or in combination with 331 | ADI: n.s. |
| 4.3.10 | L(+) Lactic acid | 270 | GMP | ADI: n.l. |
| 4.3.11 | Citric acid | 330 | GMP | ADI: n.l. |
| <i>new</i> | <i>Sodium phosfate</i> | <i>339iii</i> | <i>1 g expressed as P2O5 1) * individually or in combination with 340iii EC</i> | <i>Mtdi 70 mkg/kg b.w day</i> |
| <i>new</i> | <i>Potassium phosfate</i> | <i>340iii</i> | <i>1 g expressed as P2O5 2) * individually or in combination with 339iii EC</i> | <i>Mtdi 70 mkg/kg b.w day</i> |
| <i>new</i> | <i>Phosforic acid</i> | 338 | GMP *only for weaning foods | Mtdi 70 mkg/kg b.w day |

| | | INS | Max. level per l of kg of formula as consumed | Status/ remarks |
|------------------|---------------------------|-------------|---|----------------------|
| 4.4 | Antioxidants | | | |
| 4.4.1 | Tocopherol mix | 307b | 10 mg in all types of infant formulae | Group ADI: 0,15-2 mg |
| <i>new</i> | <i>Alpha-tocopherols</i> | <i>307c</i> | <i>10 mg</i> | |
| <i>new</i> | <i>Gamma-tocopherols</i> | <i>308</i> | <i>10 mg</i> | |
| <i>new</i> | <i>Delta-tocopherols</i> | <i>309</i> | <i>10 mg</i> | |
| | | | <i>* individually or in combination</i> | |
| 4.4.2 | L-Ascorbyl palmitate | 304 | 10 mg in all types of infant formulae | ADI: 1,25 mg |
| 4.5 | Anti-caking agents | | | |
| <i>* new</i> | <i>Siliciumdioxide</i> | <i>551</i> | <i>20 g/kg</i> | <i>ADI: n.s..</i> |
| **new 4.6 | Packaging gases | | | |
| <i>**new</i> | <i>Carbon dioxide</i> | <i>290</i> | <i>GMP</i> | |
| <i>**new</i> | <i>Argon</i> | <i>938</i> | <i>GMP</i> | |
| <i>**new</i> | <i>Helium</i> | <i>939</i> | <i>GMP</i> | |
| <i>**new</i> | <i>Nitrogen</i> | <i>941</i> | <i>GMP</i> | |
| <i>**new</i> | <i>Nitrous oxide</i> | <i>942</i> | <i>GMP</i> | |
| <i>**new</i> | <i>Oxygen</i> | <i>948</i> | <i>GMP</i> | |

- 1) within the limits for sodium in section 3.1.2 (c) in all types of infant formulae
- 2) within the limits for potassium in section 3.1.2(c) in all types of infant formulae