

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 6

CX/NFSDU 06/28/6-Revised  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES 28<sup>th</sup> Session

Chiang Mai, Thailand, 30 October - 3 November 2006

#### PROPOSED DRAFT REVISION OF THE ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN AT STEP 3

(Prepared by Germany)

Governments and interested international organizations are invited to submit comments or information on the document at Step 3 and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Fifteenth Edition*), to: Dr Rolf Grossklaus, Director and Professor, Federal Institute for Risk Assessment (BfR), P.O. Box 33 00 13, 14191 Berlin, Germany (Fax: +49 1888 529-4965; email: [ccnfsdu@bmelv.bund.de](mailto:ccnfsdu@bmelv.bund.de)), with a copy to: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by FAX +39-06-5705-4593 or email [codex@fao.org](mailto:codex@fao.org) by **September 30, 2006**.

#### Background

At its last session, the Committee agreed that in the absence of internationally recognised purity criteria national references for purity criteria should be accepted. In order to avoid that a large number of nutrients, for which no internationally recognised criteria exist, be removed from the Lists, Member Countries were requested to submit national purity criteria. Furthermore, along with their proposals for inclusion or deletion of nutrient compounds, member countries were to provide information on how the respective compound satisfies or does not satisfy the criteria defined in Section 2.1.

The Committee also agreed to reintroduce List D, although there were contradictory views as to the substances to be included. The committee recognised that it could not take a final decision on this question until it had received the advice from the CCFAC on how to address carriers.

The following document was prepared taking into account the comments submitted by Argentina, Australia, Costa Rica, the European Community, USA, Venezuela, and ISDI in response to CL

2005/53-NFSDU, part D. For better clarity, nutrient compounds that are still in square brackets are highlighted in **grey**.

### General Comments:

Although the Committee had already agreed upon the wording of the title, **AUSTRALIA** requests that it be changed to read:

‘ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR ~~USE~~ CONSUMPTION BY INFANTS AND YOUNG CHILDREN’.

Furthermore, **AUSTRALIA** considers that the headline of the column ‘*Use in food categories for infants and young children*’ should be changed to read ‘Use in Codex Food Standards Applicable to Infants and Young Children’, to ensure a consistent and clear interpretation of the permissions provided in the advisory lists:

Nutrient Source	Purity Requirements by		Use in <u>Codex Food Categories for Standards Applicable to Infants and Young Children</u>				
	CAC <sup>1</sup>	international and/or national bodies	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>

The **USA** requests clarification of whether nutrient compounds, which may be used for nutritional purposes in formula for special medical purposes intended for infants, are included in the Advisory List under the column for IF or FSMP. Given the special nature of formula for special medical purposes intended for infants, the USA suggest they be included under the column for FSMP even though the term “foods for special medical purposes” remains to be defined.

**Taking into account** the comments submitted by AUSTRALIA and the USA the Committee needs to resolve whether the headline of the column of the lists should refer to

- (a) Food Categories for Use by Infants and Young Children, or
- (b) Codex Food Standards Applicable to Infants and Young Children.

Provided that the Committee approves option (a), the IF column will then refer only to foods for infants in good health, while the FSMP column will <sup>7</sup>comprise foods for special medical purposes for infants and young children. Up till now, the Committee has, however, not considered whether requirements for FSMP intended for use by infants differ from those for use by young children. To make this transparent, the headline of the FSMP column could be changed to read "FSMP for infants":

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<sup>3</sup> FUF = follow-up formula

<sup>4</sup> PCBF = processed cereal based food

<sup>5</sup> CBF = canned baby food

<sup>6</sup> FSMP = food for special medical purposes

<sup>7</sup>

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup> [for infants]

If the Committee favours option (b), the IF column will refer to Section A of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes for Infants, whereas the FSMP column would then refer to Section B of that standard. Thus, the IF column would have to be subdivided into "IF Section A" and "IF Section B", and the present FSMP column be moved to "IF Section B". Furthermore, the Committee would need to consider whether an additional column "FSMP for young children" should be added.

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC <sup>1</sup>	international and/or national bodies	IF <sup>2</sup>		FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup> for young children
			Section A	Section B				

## ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

### 1. PREAMBLE

These lists include nutrient compounds, which may be used for nutritional purposes in foods for special dietary uses intended for use by infants and young children in accordance with 1) the criteria and conditions of use identified below and 2) other criteria for their use stipulated in the respective standards. In addition, the sources from which the nutrient compound is produced may exclude the use of specific substances where religious or other specific dietary restrictions apply. As noted in the respective standards, their use may either be essential or optional.

### 2. CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS

2.1 Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:

- (a) they are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children
- (b) it is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available
- (c) the purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognised specification. If there is no internationally

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recognised specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered

- (d) the stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated
- (e) the fulfilment of the above criteria shall be demonstrated by generally accepted scientific criteria.

2.2 Nutrient compounds may be added to the Lists based on the criteria above. Nutrient compounds shall be deleted from the Lists if they are found no longer to meet the above criteria.

The USA proposes the following addition to the paragraph:

2.2 Nutrient compounds . . . if they are found no longer to meet the above criteria. If a country proposes to add or delete a nutrient compound to a list, the country should provide information that addresses how the nutrient compound satisfies/does not satisfy the criteria in Section 2.1.

## A: ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

### 1. Calcium

**ARGENTINA** considers that sources of calcium should only include those with high solubility/bioavailability. Some sources, as phosphates, especially calcium phosphate, tribasic (1.11) and calcium pyrophosphate (1.12), have low bioavailability and thus do not comply with the criterion b) in section 2.1. Also calcium sulphate (1.13) should only be included if it is bioavailable and if it can be scientifically justified.

**MEXICO** proposes to remove the square brackets from calcium pyrophosphate (1.12) and calcium sulphate (1.13).

**ISDI** reiterates its request to include calcium sulphate (1.13) for use in IF and FSMP.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>1. Source of Calcium (Ca)</b>							
1.1 Calcium carbonate	√ (1981)	JECFA (1973), Ph Int, FCC, USP, NF, Ph Eur, BP, DAB	√	√	√	√	√
1.2 Calcium chloride	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, JP, BP, DAB	√	√	√	√	√
1.3 Tricalcium dicitrate (Calcium citrate)	√ (1979)	JECFA (1975), FCC, USP, DAC	√	√	√	√	√

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Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
1.4 Calcium gluconate	√ (1999)	JECFA (1998), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
1.5 Calcium glycerophosphate		FCC, Ph Eur, Ph Franc	√	√	√	√	√
1.6 Calcium L-lactate	√ (1978)	JECFA (1974), FCC, USP, Ph Eur (tri- and pentahydrate), BP, DAB	√	√	√	√	√
1.7 Calcium hydroxide	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP	√	√	√	√	√
1.8 Calcium oxide	√ (1979)	JECFA (1975), FCC, DAC	-	-	√	√	√
1.9 Calcium dihydrogen phosphate (Calcium phosphate, monobasic)	√ (1997)	JECFA (1996), Ph Int, FCC	√	√	√	√	√
1.10 Calcium hydrogen phosphate (Calcium phosphate, dibasic)	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
1.11 Tricalcium diphosphate (Calcium phosphate, tribasic)		JECFA (1973), Ph Int, FCC, BP	√	√	√	√	√
Malaysia, Mexico: [1.12 Calcium pyrophosphate]	√ (2001)	JECFA (1982), FCC	?	?	?	?	?
New Zealand, Malaysia, Mexico, ISDI: [1.13 Calcium sulphate]	√ (1979)	JECFA (1975), Ph Int, FCC, Ph Eur (dihydrate), DAB	<b>ISDI:</b> [√]	-	-	-	[√]

## 2. Iron

**ARGENTINA** considers the use of elementary sources of iron, i.e. reduced, electrolytic and carbonyl (2.9 - 2.11) only to be justified in CBF, but not in PCBF and FSMP, as their bioavailability is low. Furthermore, ferrous succinate (2.15) and ferrous biglycinate (2.16) should only be included if they are bioavailable and if it can be scientifically justified.

**AUSTRALIA** requests the inclusion of ferrous citrate (2.14) and ferrous succinate (2.15), as they are permitted in Australian New Zealand food regulation, and they are also included in the current Codex advisory list (CAC/GL 10-1979). In the past, inclusion of ferrous succinate was also requested by NEW ZEALAND.

**MEXICO** requests deletion of square brackets from ferrous citrate (2.14), ferrous succinate (2.15), and ferrous bisglycinate (2.16).

**ISDI** proposes that ferric orthophosphate (2.17) should only be permitted for use in PCBF.

In addition, **ISDI** reiterates its request to include sodium ferric diphosphate (2.13) as source of iron for use in PCBF, CBF and FSMP. In the past, this had also been requested by the **EUROPEAN COMMUNITY**.

Furthermore, **ISDI** requests the inclusion of ferrous citrate (2.14), ferrous succinate (2.15) and ferrous bisglycinate (2.16) as sources of iron as they are stable and have been shown to be bioavailable. But, contrary to **AUSTRALIA**, **ISDI** considers that only ferrous citrate should be permitted for use in all food categories, whereas the use of ferrous succinate and ferrous bisglycinate should be limited to PCBF.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>2. Source of Iron (Fe)</b>							
2.1 Ferrous carbonate, stabilised with saccharose		DAB	-	-	√	√	√
2.2 Ferrous fumarate		Ph Int, FCC, USP, Ph Eur, BP	√	√	√	√	√
2.3 Ferrous gluconate	√ (2001)	JECFA (1999), FCC, USP, Ph Eur, DAB, BP	√	√	√	√	√
2.4 Ferrous lactate	√ (1991)	JECFA (1989), FCC, NF	√	√	√	√	√
2.5 Ferrous sulphate	√ (2001)	JECFA (1999), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
2.6 Ferric ammonium citrate	√ (1987)	JECFA (1984), FCC, DAC	√	√	√	√	√
2.7 Ferric citrate		FCC	√	√	√	√	√
2.8 Ferric diphosphate (pyrophosphate)		FCC	√	√	√	√	√
2.9 Hydrogen reduced iron		FCC, DAB	-	-	√	√	√
2.10 Electrolytic iron		FCC	-	-	√	√	√
2.11 Carbonyl iron		FCC	-	-	√	√	√
2.12 Ferric saccharate		Ph Helv, DAB, ÖAB	-	-	√	√	√
2.13 Sodium ferric diphosphate		FCC	-	-	√	√	√
2.14 Ferrous citrate		FCC, FSANZ	√	√	√	√	√
Australia, New Zealand, ISDI: [2.15 Ferrous succinate]		MP, MI, FSANZ	[√]	[√]	[√]	[√]	[√]
South Africa, ISDI: [2.16 Ferrous bisglycinate]		JECFA (2003)	-	-	ISDI: [√]	-	-
ISDI: [2.17 Ferric orthophosphate]		FCC	-	-	ISDI: [√]	-	-

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### 3. Magnesium

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>3. Source of Magnesium (Mg)</b>							
3.1 Magnesium hydroxide carbonate		JECFA (1979), USP, BP, DAB	√	√	√	√	√
3.2 Magnesium chloride	√ (1979)	JECFA (1979), FCC, USP, Ph Eur (-4,5-hydrate), BP, DAB	√	√	√	√	√
3.3 Magnesium gluconate	√ (2001)	JECFA (1998), FCC, DAC	√	√	√	√	√
3.4 Magnesium glycerophosphate		Ph Eur, BPC	-	-	√	√	√
3.5 Magnesium hydroxide	√ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
3.6 Magnesium lactate	√ (1987)	JECFA (1983) (Mg-DL-Lactate, Mg-L-Lactate)	-	-	√	√	√
3.7 Magnesium oxide		JECFA (1973), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
3.8 Magnesium hydrogen phosphate (Magnesium phosphate, dibasic)	√ (1985)	JECFA (1982), FCC, DAB	√	√	√	√	√
3.9 Trimagnesium phosphate (Magnesium phosphate, tribasic)	√ (1981)	JECFA (1982), FCC	√	√	√	√	√
3.10 Magnesium sulphate		Ph Eur (heptahydrate), FCC, USP, JP, BP, DAB, DAC	√	√	√	√	√
3.11 Magnesium acetate		Ph Eur, DAC	-	-	-	-	√
3.12 Magnesium salts of citric acid		USP, DAC	√	√	√	√	√
3.13 Magnesium carbonate		JECFA (1973), FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√

### 4. Sodium

**ARGENTINA** comments that sodium sulphate (4.12) and sodium tartrate (4.13) should only be included if they are bioavailable and if it is scientifically justifiable.

**AUSTRALIA** requests the inclusion of sodium chloride (iodised) (4.11), sodium sulphate (4.12), and sodium tartrate (4.13), as they are permitted in Australian New Zealand food regulation, and they are also included in the current Codex advisory list (CAC/GL 10-1979). In the past, this request had also been supported by NEW ZEALAND.

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**MEXICO** requests deletion of square brackets from sodium chloride (iodised) (4.11), sodium sulphate (4.12), and sodium tartrate (4.13).

Contrary to AUSTRALIA and NEW ZEALAND, **ISDI** requests to remove sodium chloride (iodised) (4.11) from the list because the iodine content of Foods for Special Dietary Uses is to be monitored closely and iodine should therefore not be added through iodised salt, but rather by use of specific iodine compounds.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>4. Source of Sodium (Na)</b>							
4.1 Sodium carbonate	√ (1979)	JECFA (1975), FCC, USP, NF, Ph Eur, BP, DAB	√	√	-	-	√
4.2 Sodium hydrogen carbonate (Sodium bicarbonate)	√ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	-	-	√
4.3 Sodium chloride		Ph Int, FCC, USP, Ph Eur, JP, BP, DAB	√	√	-	-	√
4.4 Trisodium citrate (Sodium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	-	-	√
4.5 Sodium gluconate	√ (1999)	JECFA (1998), FCC, USP, DAC	√	√	-	-	√
4.6 Sodium L-lactate	√ (1978)	JECFA (1974), FCC, USP, Ph Eur, BP, DAB	√	√	-	-	√
4.7 Sodium dihydrogen phosphate (Sodium phosphate, monobasic)	√ (1995)	JECFA (1963), FCC, USP, Ph Eur (dihydrate)	√	√	-	-	√
4.8 Disodium hydrogen phosphate (Sodium phosphate, dibasic)		JECFA (1975), Ph Int, FCC, USP, BP	√	√	-	-	√
4.9 Trisodium phosphate (Sodium phosphate, tribasic)		JECFA (1975), FCC, DAC	√	√	-	-	√
4.10 Sodium hydroxide	√ (1979)	JECFA (1975), Ph Int, FCC, USP, NF, Ph Eur, JP, BP, DAB	√	√	-	-	√
Australia, New Zealand: [4.11 Sodium chloride (iodised)]		USP, Ph Eur, BP, JP, FSANZ	[√]	[√]	[√]	[√]	[√]
Australia, New Zealand: [4.12 Sodium sulphate]		JECFA (2000), Ph Int, FCC, USP, Ph Eur, BP, DAB, FSANZ	[√]	[√]	[√]	[√]	[√]
Australia, New Zealand: [4.13 Sodium tartrate]		JECFA (1963), FSANZ	[√]	[√]	[√]	[√]	[√]

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## 5. Potassium

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>5. Source of Potassium (K)</b>							
5.1 Potassium carbonate	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, DAC	√	√	-	-	√
5.2 Potassium hydrogen carbonate (Potassium bicarbonate)	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	√	√	-	-	√
5.3 Potassium chloride	√ (1983)	JECFA (1979), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
5.4 Tripotassium citrate (Potassium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
5.5 Potassium gluconate	√ (1999)	JECFA (1998), FCC, USP, DAC	√	√	√	√	√
5.6 Potassium glycerophosphate		FCC	-	-	√	√	√
5.7 Potassium L-lactate	√ (1978)	JECFA (1974), FCC, DAB	√	√	√	√	√
5.8 Potassium dihydrogen phosphate (Potassium phosphate, monobasic)	√ (1979)	JECFA (1982), FCC, NF, Ph Eur, BP, DAB	√	√	-	-	√
5.9 Dipotassium hydrogen phosphate (Potassium phosphate, dibasic)	√ (1979)	JECFA (1982), FCC, BP	√	√	-	-	√
5.10 Potassium phosphate, tribasic	√ (1979)	JECFA (1982)	√	√	-	-	√
5.11 Potassium hydroxide	√ (1979)	JECFA (1975), FCC, NF, Ph Eur, JP, BP, DAC	√	√	-	-	√

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## 6. Copper

GERMANY proposes that Copper-lysine-complex be included, although it lacks official purity requirements. It is permitted in Europe in food for particular nutritional uses.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>6. Source of Copper (Cu)</b>							
6.1 Cupric gluconate (Copper gluconate)		FCC, USP	√	√	√	√	√
6.2 Cupric sulphate (Copper sulphate)	√ (1981)	JECFA (1973), FCC, USP, Ph Eur, DAB	√	√	√	√	√
6.3 Cupric carbonate		MI	√	√	√	√	√
6.4 Cupric citrate		FCC, USP	√	√	√	√	√
[6.5 Copper-lysine-complex]	?	?	[√]	[√]	[√]	[√]	[√]

## 7. Iodine

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	International and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>7. Source of Iodine (I)</b>							
7.1 Potassium iodide		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
7.2 Sodium iodide		Ph Eur, USP, BP, DAB	√	√	√	√	√
7.3 Potassium iodate	√ (1991)	JECFA (1988), FCC	√	√	√	√	√
7.4 Sodium iodate		FCC	-	-	√	√	√

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## 8. Zinc

**ARGENTINA** notes that zinc oxide (8.4) and zinc carbonate (8.6) do not comply with the criterion b) in section 2.1 because they are insoluble and poorly bioavailable.

**GERMANY** proposes that Zinc citrate (8.8) be included, although it lacks official purity requirements. It is permitted in Europe in food for particular nutritional uses

**MEXICO** requests deletion of the square brackets from zinc carbonate (8.7).

In contrast to ARGENTINA, **ISDI** reiterates its request for inclusion of zinc carbonate (8.7) for use in FSMP. The compound is authorised for this use in Europe. In the past, the EUROPEAN COMMUNITY also had requested to include zinc carbonate.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>8. Source of Zinc (Zn)</b>							
8.1 Zinc acetate		USP, Ph Eur (dihydrate)	√	√	√	√	√
8.2 Zinc chloride		USP, Ph Eur, JP, BP, DAB	√	√	√	√	√
8.3 Zinc gluconate		FCC, USP, DAC	√	√	√	√	√
8.4 Zinc lactate		FCC	√	√	√	√	√
8.5 Zinc oxide		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
8.6 Zinc sulphate		FCC, USP, Ph Eur, BP	√	√	√	√	√
8.7 Zinc carbonate		USP, BP (hydroxide carbonate)	-	-	-	-	√
[8.8 Zinc citrate]		?	[√]	[√]	[√]	[√]	[√]

## 9. Manganese

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>9. Source of Manganese (Mn)</b>							
9.1 Manganese(II) chloride		FCC	√	√	√	√	√
9.2 Manganese(II) citrate		FCC	√	√	√	√	√
9.3 Manganese(II) glycerophosphate		FCC	-	-	√	√	√

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Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
9.4 Manganese(II) sulphate		FCC, USP, Ph Eur (monohydrate)	√	√	√	√	√
9.5 Manganese(II) gluconate		FCC	√	√	√	√	√
9.6 Manganese(II) carbonate		MI	√	√	√	√	√

## 10. Selenium

**MEXICO** requests deletion of the square brackets from sodium selenate (10.1) and sodium selenite (10.2).

**ISDI** supports that both sodium selenate (10.1) and sodium selenite (10.2) be permitted for use in PCBF, as was requested by **NEW ZEALAND** in the past.

ISDI further requests that sodium hydrogen selenite should be included in the lists, although it lacks official purity requirements. Sodium hydrogen selenite is authorised in Europe.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>10. Source of Selenium (Se)</b>							
10.1 Sodium selenate		MI	√	√	[√]	-	√
10.2 Sodium selenite		DAC, MP, MI	√	√	[√]	-	√
[10.3 Sodium hydrogen selenite]			ISDI: [√]	ISDI: [√]	ISDI: [√]	ISDI: [√]	[√]

## 11. Chromium

**AUSTRALIA** suggests that the column headed 'IF' (infant formula) would refer to the Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, i.e., both Sections A and B upon adoption by the Commission. As AUSTRALIA requested that only infant formulas regulated under Section B be permitted to contain added chromium, it requests to add ticks in the column headed "IF" together with the footnote: "Section B only of the Codex Standard on infant formula and formulas for special medical purposes intended for infants".

It should be considered that the issue raised by AUSTRALIA does refer to the general question whether the heading of the Advisory Lists A, B, C should refer to (a) Food Categories for Use by Infants and Young Children, or (b) Codex Food Standards Applicable to Infants and Young Children (see page 2). As long as the current headline is kept, the FSMP column refers to Section B of the Infant Formula Standard and thus no further ticks in the IF column are needed.

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**ISDI** requests the permission of chromium (III) chloride for use in infant formula.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>11. Chromium (Cr III)</b>							
11.1 Chromium (III) sulphate		USP, MI	-	-	-	-	√
11.2 Chromium (III) chloride		USP, MI	ISDI: [√]	-	-	-	√

## 12. Molybdenum

**AUSTRALIA'S** comment on chromium sources and the reflections above also apply to sources of molybdenum.

**ISDI** supports the permission of sodium molybdate for use in infant formula.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>12. Molybdenum (Mo VI)</b>							
12.1 Sodium molybdate		Ph Eur (dihydrate), BP, DAB	ISDI: [√]	-	-	-	√
12.2 Ammonium molybdate		FCC, USP	-	-	-	-	√

## 13. Fluoride

**ARGENTINA** comments that calcium fluoride (13.2) should only be included in the list if it is scientifically justifiable, and if the compound is bioavailable.

**MEXICO** requests deletion of the square brackets from calcium fluoride (13.2).

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ISDI reiterates its request to include calcium fluoride for use in FSMP.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>13. Fluoride (F)</b>							
13.1 Sodium fluoride		FCC, USP, Ph Eur, BP, DAB	-	-	-	-	√
[13.2 Potassium fluoride]		FCC, DAB	-	-	-	-	[√]
[13.3 Calcium fluoride]		DAB	-	-	-	-	[√]

## B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

### 1. Vitamin A

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>1. Vitamin A</b>							
1.1 all trans Retinol		FCC (vitamin A), USP, Ph Eur (vitamin A)	√	√	√	√	√
1.2 Retinyl acetate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	√	√	√	√	√
1.3 Retinyl palmitate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	√	√	√	√	√

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## 2. Provitamin A

**ISDI** clarifies that in the year 2004 it had already withdrawn its request to include  $\beta$ -apo-8-carotenal. - This has now been removed from the list.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>2. Provitamin A</b>							
2.1 Beta-Carotene	√ (1991)	JECFA (1987), FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√

## 3. Vitamin D

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>3. Vitamin D</b>							
3.1 Vitamin D <sub>2</sub> = Ergocalciferol		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√
3.2 Vitamin D <sub>3</sub> = Cholecalciferol		Ph Int, FCC, USP, Jap Food Stan, BP, DAB	√	√	√	√	√

## 4. Vitamin E

**ARGENTINA** comments that D-alpha-tocopheryl acid succinate (4.6) should only be included in the list if it is bioavailable and if it is scientifically justifiable.

**MEXICO** requests to delete square brackets from D-alpha-Tocopheryl acid succinate (4.6).

**ISDI** reiterates its request for the inclusion of D-alpha-tocopheryl acid succinate for use in FSMP. It is authorised for this use in Europe. In the past, this request had also been supported by the **EUROPEAN COMMUNITY** and **NEW ZEALAND**.

Furthermore, **ISDI** provides the following justification for its request to include DL-tocopheryl polyethylene glycol 1000 succinate (4.7) for use in FSMP:

As DL-tocopheryl polyethylene glycol 1000 succinate is water soluble, it can be used for the preparation of diets for children with cholestatic disorders. In cholestasis, intraluminal bile acid deficiency causes defects in fatty acid emulsification and results in altered absorption of fat and vitamins. Steatorrhea is a constant occurrence in cholestasis and fat malabsorption also includes fat

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soluble vitamin malabsorption and deficiency. In particular vitamin E deficiency causes ataxia, hyporeflexia and polyneuropathy.

The water-soluble form of vitamin E is an important gain in the management of cholestasis, allowing an avoidance of repeated intramuscular injections in these patients. This benefit cannot be obtained with the classical fat-soluble vitamin E (tocopherol) even given at high doses.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>4. Vitamin E</b>							
4.1 D-alpha-Tocopherol	√ (2001)	JECFA (2000), FCC, USP, NF, Ph Eur	√	√	√	√	√
4.2 DL-alpha-Tocopherol	√ (1989)	JECFA (1986), FCC, USP, NF, Ph Eur, Jap Food Stan	√	√	√	√	√
4.3 D-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur	√	√	√	√	√
4.4 DL-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur, BP	√	√	√	√	√
4.5 D-alpha-Tocopheryl acid succinate		FCC, USP, Ph Eur	-	-	-	-	√
4.6 DL-alpha-Tocopheryl acid succinate		NF, MP, MI, USP, Ph Eur	-	-	-	-	[√]
ISDI: [4.7 DL-alpha-Tocopheryl polyethylene glycol 1000 succinate]		FCC	-	-	-	-	[√]

## 5. Vitamin C

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	International and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>5. Vitamin C</b>							
5.1 L-Ascorbic acid	√ (1981)	JECFA (1973), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√
5.2 Calcium-L-ascorbate	√ (1983)	JECFA (1981), FCC, USP, Ph Eur	√	√	√	√	√
5.3 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate)		JECFA (1973), FCC, USP, NF, Ph Eur, Jap Food Stan, BP, DAB	√	√	√	√	√

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Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	International and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
5.4 Sodium-L-ascorbate		JECFA (1973), FCC, USP, Ph Eur, Ph Franc, Jap Food Stan, DAC	√	√	√	√	√
5.5 Potassium-L-ascorbate		FCC	√	√	√	√	√

## 6. Vitamin B<sub>1</sub>

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>6. Vitamin B<sub>1</sub></b>							
6.1 Thiaminchloride hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√
6.2 Thiamin mononitrate		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√

## 7. Vitamin B<sub>2</sub>

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>7. Vitamin B<sub>2</sub></b>							
7.1 Riboflavin	√ (1991)	JECFA (1987), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√
7.2 Riboflavin-5'-phosphate sodium	√ (1991)	JECFA (1987), USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√

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**8. Niacin**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>8. Niacin</b>							
8.1 Nicotinic acid amide (Nicotinamide)		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	√	√	√	√	√
8.2 Nicotinic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	√	√	√	√	√

**9. Vitamin B<sub>6</sub>**

Although there are no purity criteria for Pyridoxal dipalmitate (9.3), **ISDI** proposes to include it in the list as it has been used for many years.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>9. Vitamin B<sub>6</sub></b>							
9.1 Pyridoxine hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√
9.2 Pyridoxal 5-phosphate		MI, FCC, USP	√	√	√	√	√
[9.3 Pyridoxal dipalmitate]	?	?	-	-	[√]	[√]	-

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**10. Folic Acid**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>10. Folic acid</b>							
10.1 N-Pteroyl-L-glutamic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√

**11. Pantothenic Acid**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>11. Pantothenic acid</b>							
11.1 Calcium-D-pantothenate		FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√
11.2 Sodium-D-pantothenate		Jap Food Stan, DAB	√	√	√	√	√
11.3 D-Panthenol/		FCC, USP, Ph Eur	√	√	√	√	√
11.4 DL-Panthenol		FCC, USP, Ph Eur	√	√	√	√	√

**Vitamin B<sub>12</sub>**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>12. Vitamin B<sub>12</sub></b>							
12.1 Cyanocobalamin		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
12.2 Hydroxocobalamin		Ph Int, USP, NF, Ph Eur (hydrochloride)	√	√	√	√	√

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**13. Vitamin K**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>13. Vitamin K<sub>1</sub></b>							
13.1 Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/Phylloquinone/Phytonadione)		Ph Int, FCC (vitamin K), USP, Ph Eur, BP	√	√	√	√	√

**14. Biotin**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>14. Biotin</b>							
14.1 D-Biotin		FCC, USP, Ph Eur	√	√	√	√	√

**C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN**

**1. Amino Acids**

The **EUROPEAN COMMUNITY** has reservations about the request for the use of L-Glutamic acid (1.25) and L-Glutamine (1.26) in IF and FUF.

The **USA** also request that the proposed use of L-glutamic acid and L-glutamine in infant formula and follow-on formula be removed from this list.

Furthermore, the USA considers that if the footnote proposed by ISDI be added ("*As far as applicable, also the sodium, potassium calcium and magnesium salts of the amino acids as well as their hydrochlorides may be used for FSMP.*"), it should include "*free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids*" (see footnote 7) because there are internationally recognised purity requirements for free, hydrated, and anhydrous forms of amino acids, and their hydrochloride, sodium, and potassium salts, but not for the calcium and magnesium salts of amino acids. Thus, purity requirements should be identified if they are to be included in Advisory List C.

**ISDI:** <sup>7</sup> "As far as applicable, also the sodium, potassium, calcium and magnesium salts of the amino acids as well as their hydrochlorides may be used for FSMP."

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**USA:** “<sup>7</sup> As far as applicable, also the free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids may be used for FSMP.”

**ISDI** agrees that both L-Glutamic acid (1.25) and L-Glutamine (1.26) are no longer considered (semi) essential amino acids and should therefore only be permitted for use in FSMP.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>1. Amino acids<sup>7</sup></b>							
1.1 L-Arginine		FCC, USP, Ph Eur, BP, DAB	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)				√
1.2 L-Arginine hydrochloride		FCC, USP, Ph Eur, BP, DAB					
1.3 L-Cystine		FCC, USP, Ph Eur					
1.4 L-Cystine dihydrochloride		MI					
1.5 L-Cysteine		DAB					
1.6 L-Cysteine hydrochloride		FCC, Ph Eur					
1.7 L- Histidine		FCC, USP, Ph Eur, DAB					
1.8 L- Histidine hydrochloride		FCC, Ph Eur, DAB					
1.9 L-Isoleucine		FCC, USP, Ph Eur, DAB					
1.10 L-Isoleucine hydrochloride		FCC, USP					
1.11 L-Leucine		FCC, USP, Ph Eur, DAB					
1.12 L-Leucine hydrochloride		MI, FCC, USP					
1.13 L-Lysine		USP					
1.14 L-Lysine monohydrochloride		FCC, USP, Ph Eur, DAB					
1.15 L-Methionine		Ph Int, FCC, USP, Ph Eur, DAB					
1.16 L-Phenylalanine		FCC, USP, Ph Eur					
1,17 L-Threonine		FCC, USP, Ph Eur, DAB					
1.18 L-Tryptophan		FCC, USP, Ph Eur, DAB					

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<sup>a)</sup> A list of abbreviations is included at the end of this document.

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<sup>3</sup> FUF = follow-up formula

<sup>4</sup> PCBF = processed cereal based food

<sup>5</sup> CBF = canned baby food

<sup>6</sup> FSMP = food for special medical purposes

footnote 7 see above

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
1.19 L-Tyrosine		FCC, USP, Ph Eur, DAB	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)				√
1.20 L-Valine		FCC, USP, Ph Eur, DAB					√

**GERMANY** would like to draw the Committee's attention to the following part of the list of amino acids: Amino acids, from 1.21 through 1.39 have/had been requested for inclusion by ISDI. There are internationally recognised purity requirements for all, but L-Lysine L-aspartate and L-Lysine L-Glutamate dihydrate, which are produced by salification of individual monographed amino acids and are permitted under EU legislation.

➔ **The Committee should approve/ disapprove inclusion of those amino acids at the forthcoming Session of CCNFSDU in order to make some progress on this section of the list.**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>Amino acids proposed for inclusion by ISDI:</b>							
1.21 L-Alanine		FCC, USP, Ph Eur, DAB		-			√
1.22 L-Arginine L-aspartate		FP		-			√
1.23 L-Aspartic acid		FCC, USP, Ph Eur		-			√
1.24 L-Citrulline		USP, DAC		-			√
1.25 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur		-			√
1.26 L-Glutamine		FCC, USP, DAB		-			√
1.27 Glycine		FCC, USP, Ph Eur		-			√
1.28 L-Ornithine		MI, FCC		-			√
1.29 L-Ornithine monohydrochloride		DAB		-			√
1.30 L-Proline		FCC, USP, Ph Eur, DAB		-			√
1.31 L-Serine		USP, Ph Eur, DAB		-			√
1.32 N-Acetyl-L-cysteine		USP, Ph Eur, DAB		-			√
1.33 N-Acetyl-L-methionine		FCC		-			√ not for infants

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<sup>5</sup> CBF = canned baby food

<sup>6</sup> FSMP = food for special medical purposes

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
1.34 L-Lysine acetate		FCC, USP, MP; Ph Eur	√	√	√	√	√
1.35 L-Lysine L-Aspartate	?	?			-		√
1.36 L-Lysine L-glutamate dihydrate	?	?			-		√
1.37 Magnesium L-aspartate		Ph Eur			-		√
1.38 Calcium L-glutamate	√ (1991)	?			-		√
1.39 Potassium L-glutamate	?	?			-		√

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## 2. Carnitine

**MEXICO** requests deletion of square brackets from L-Carnitine tartrate (2.3).

**ISDI** indicates that the use of L-carnitine tartrate in FSMP is authorised in Europe.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>2. Carnitine</b>							
2.1 L-Carnitine		FCC, USP, Ph Eur	√	√	√	√	√
2.2 L-Carnitine hydrochloride		FCC	√	√	√	√	√
2.3 L-Carnitine tartrate		FCC, Ph Eur	-	-	-	-	√

## 3. Taurine

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>3. Taurine</b>							
3.1 Taurine		USP, JP	√	√	-	-	√

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<sup>4</sup> PCBF = processed cereal based food

<sup>5</sup> CBF = canned baby food

<sup>6</sup> FSMP = food for special medical purposes

**4. Choline**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>4. Choline</b>							
4.1 Choline		FCC, USP	√	√	√	√	√
4.2 Choline chloride		FCC, DAC, DAB	√	√	√	√	√
4.3 Choline citrate		NF	√	√	√	√	√
4.4 Choline hydrogen tartrate		DAB	√	√	√	√	√
4.5 Choline bitartrate		FCC, NF, DAB	√	√	√	√	√
[4.6 Lecithin]	√ (1995)	JECFA (1993), FCC	[√]	[√]	[√]	[√]	[√]

**5. Inositol**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>5. Myo-Inositol</b> (=meso-Inositol)]		FCC, DAC	√	√	√	√	√

**6. Nucleotides**

**GERMANY** proposes that the nucleotides 6.8 to 6.10 be included, although they lack official purity requirements. They are permitted in Europe in food for particular nutritional uses.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>6. Nucleotides</b>							
6.1 Adenosine 5-monophosphate (AMP)		FCC, FSANZ	√	√	-	-	√
6.2 Cytidine 5-monophosphate (CMP)		FSANZ, Jap Food Stan	√	√	-	-	√
6.3 Guanosine 5-monophosphate (GMP)		JECFA (1985)	√	√	-	-	√
6.4 Inosine 5-monophosphate (IMP)		JECFA (1974)	√	√	-	-	√

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<sup>6</sup> FSMP = food for special medical purposes



Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
6.5 Uridine 5-monophosphate sodium salt		FSANZ, Jap Food San	√	√	-	-	√
6.6 Guanosine 5-monophosphate sodium salt		FCC, JECFA (2000), FSANZ, Jap Food Stan	√	√	-	-	√
6.7 Inosine 5-monophosphate sodium salt		FCC, JECFA (2000), FSANZ, Jap Food Stan	√	√	-	-	√
[6.8 Cytidine 5-monophosphate sodium salt]	?	?	[√]	[√]	-	-	[√]
[6.9 Uridine 5-monophosphate (UMP)]	?	?	[√]	[√]	-	-	[√]
[6.10 Adenosine 5-monophosphate sodium salt]	?	?	[√]	[√]	-	-	[√]

## 7. Creatine

ISDI requests the inclusion of creatine monohydrate (7.1) for FSMP.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
ISDI: [7.1 Creatine monohydrate]		?	-	-	-	-	[√]

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<sup>5</sup> CBF = canned baby food

<sup>6</sup> FSMP = food for special medical purposes

**Other Comments:**

ISDI proposes to add the following additional sections:

**[8. Antioxidants]**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>[8. Antioxidants]</b>							
[8.1 Xanthophyll/ Lutein]		US GRAS (2004), JECFA (2004): lutein from tagetes erecta	[√]	[√]	-	-	[√]
[8.2 Mixed Carotenes]		95/45/EC, JECFA (1998): Carotenes (vegetable)	[√]	[√]	-	-	[√]
[8.3 Lycopene]		US GRAS (2005)	[√]	[√]	-	-	[√]

**Justification:**

According to ISDI, antioxidants, i.e. xanthophyll/ lutein, lycopene and mixed carotenes, should be permitted for use in IF, FUF, and FSMP because there was some evidence that suggests that human milk contains a variety of carotenoids that may provide antioxidant benefits to infants.

**[9. Other Compounds]**

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>[9. Other Compounds]</b>							
[9.1 ARA (arachidonic acid-rich single cell oil derived from the soil fungus <i>Mortierella alpina</i> )]		US GRAS (2001), FSANZ	[√]	[√]	-	-	[√]
[9.2 DHA (docosahexanoic acid-rich single cell oil derived from the microalgal species <i>Cryptocodium cohnii</i> )]		US GRAS (2001), FSANZ	[√]	[√]	-	-	[√]

**Justification:**

ISDI points out that there were clinical studies suggesting that the addition of these sources of polyunsaturated fatty acids to formulas for infants and young children improve both visual and mental development, and that they have been approved for use in many countries, including China, Mexico and Saudi Arabia.

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## LIST OF NUTRIENT COMPOUNDS THAT LACK OFFICIAL PURITY REQUIREMENTS

For most of the nutrient compounds purity specifications in internationally recognised publications have been provided. Therefore they are included in the respective lists.

Furthermore **ISDI** withdraws its former request for inclusion of the following compounds:

- calcium citrate malate
- calcium enriched yeast
- calcium pyruvate monohydrate
- selenium enriched yeast
- chromium enriched yeast

For the following compounds no purity requirements were found and/or no comments were submitted.

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC <sup>1</sup>	international and/or national bodies <sup>a)</sup>	IF <sup>2</sup>	FUF <sup>3</sup>	PCBF <sup>4</sup>	CBF <sup>5</sup>	FSMP <sup>6</sup>
<b>LIST B:</b> New Zealand: [Cholecalciferol cholesterol]	?	?	?	?	?	?	?
Malaysia: [Pyridoxamine]	?	?	?	?	?	?	?
<b>LIST C:</b> [S-Adenosyl-L-methionine]	?	?			-		[√] except infants

### D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL VITAMIN FORMS

It had been proposed to amend the title by replacing "vitamin" by "nutrient":

### D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

#### Comments on the title:

**ARGENTINA** agrees with the change of the title of this section, as proposed.

**NEW ZEALAND** also agrees with the amended title, but notes that further changes will be necessary as the list in section D includes ingredients as well as food additives and this should be reflected in the title.

The **USA** proposes the following changes to the title:

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<sup>4</sup> PCBF = processed cereal based food

<sup>5</sup> CBF = canned baby food

<sup>6</sup> FSMP = food for special medical purposes

## D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS FOR USE AS NUTRIENT CARRIERS

### Introduction:

For reasons of stability and safe handling, some vitamins have to be converted into suitable preparations, e.g. stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations, dry rubbed preparations. For this purpose, the edible materials and the additives included in the respective Codex standard may be used.

**SWITZERLAND** and **ISDI** had proposed that the introductory paragraph be amended to read:

For reasons of stability and safe handling, some vitamins and nutrients have to be converted into suitable preparations, e.g. stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations, dry rubbed preparations. For this purpose, the following edible materials and the additives included substances permitted in the respective specific Codex standard respectively may be used:

The **EUROPEAN COMMUNITY** had proposed the following text during the last Session of the CCNFSU:

For reasons of stability and safe handling, some vitamins and nutrients have to be converted into suitable preparations, e.g. stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations, dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used:

### Comments on the Introductory Paragraph:

<p><b>ARGENTINA</b> suggests to delete “vitamins” since it would be included in “nutrients”, and the word “respectively”, since it is redundant and the phrase is confusing:</p>	<p>For reasons of stability and safe handling, some <del>vitamins</del> nutrients have to be converted into suitable preparations, e.g. stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations, dry rubbed preparations. For this purpose, the <u>following edible materials and the additives included substances permitted</u> in the <u>respective specific</u> Codex standard <u>respectively</u> may be used.</p>
<p>The <b>EUROPEAN COMMUNITY</b></p>	<p>The EC supports the above mentioned proposal it put forward during the last Session of the CCNFSU</p>
<p>The <b>USA</b> propose that the CCNFSU identify the criteria for determining maximum levels and offer the following edits to the EC proposal for consideration:</p>	<p>For reasons of stability and safe handling, some vitamins <u>and other nutrients</u> have to be converted into suitable preparations, e.g., <del>stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations,</del> dry rubbed preparations. For this purpose, <del>the food additives included in the respective specific Codex standard may be used,</del> <u>In addition, the following food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used as nutrient carriers.</u>  <u>The maximum levels should be based on the amount needed to achieve the technical effect of a nutrient carrier under good manufacturing practice.</u>  <u>Where a food additive used as a nutrient carrier is also permitted in a Codex food standard for infants and young children for a different technological function, the maximum level in the food should be determined by the function with the highest acceptable maximum use level under good manufacturing practice.</u></p>

<p><b>ISDI</b> maintains its request to amend the introductory paragraph and proposes the following further changes:</p>	<p>For reasons of stability and safe handling, some vitamins <u>and nutrients</u> have to be converted into suitable preparations, e.g. stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations, dry rubbed preparations. For this purpose, the <del>edible materials and the additives included</del> <u>substances permitted in the respective specific Codex standards may respectively be used</u>. In addition, the following food <u>additives may also be used</u>:</p>
--	---

### Comments on the List:

**ARGENTINA** is of the opinion that the function of including this table in this general standard is not clear, and neither is the incorporation of new additives, as was requested by many countries. Since ARGENTINA is not aware of the technological justification for the request of inclusions, as well as of the purpose of adding this table, Argentina can not express an opinion regarding this item and requests, if possible, to receive clarification on this issue.

**COSTA RICA** supports the proposal made by the EUROPEAN COMMUNITY, provided that no products but rather additives are included in the list. It withdraws its request for inclusion of Fish gelatine, Bovine gelatine, Ethylcellulose, Glycyl tristearate, BHA/BHT, and Peanut oil.

The **EUROPEAN COMMUNITY** notes that not all the current Codex standards on foods intended for infants and young children (infant formula (STAN 72-1981); follow-up formula (STAN 156-1987); processed cereal-based foods for infants and children (STAN 74-1981); and, canned baby foods (STAN 73-1981)) list the additives included in Section D of the Advisory list. Therefore the EC continues to support its request for inclusion of 414 gum arabic, 551 silicon dioxide, 421 mannitol, 1450 starch sodium octenyl succinate and 301 sodium L-ascorbate in this section of the Lists.

The **USA** propose deletion of the table as it lists substances that are outside the scope agreed to by the Committee. The table should be limited to food additives used as nutrient carriers (ALINORM 05/28/26 para 128 and ALINORM 06/29/26 para 137). It is recognised that certain ingredients may also function as nutrient carriers, provided they are safe and suitable for their intended use according to the provisions in the respective standards (i.e., IF, FUF, PCBF, CBF) for 1) quality and purity of all ingredients, and 2) optional ingredients. Consequently, such ingredients are covered under the provisions for safe and suitable use in the respective standards and, therefore, should not be listed in Advisory List D.

For consistency with the food additive provisions in the respective standards, the USA further suggest that

- 1) the maximum levels for food additives used as nutrient carriers be listed separately for each product category, perhaps using a format similar to Advisory Lists A, B, and C, and
- 2) the maximum levels be listed in the same units as food additives listed for other functional purposes in Section 4 of the specific Codex standard. Therefore, the USA propose the following format for List D:

<b>ins no.</b>	<b>name of additive</b>	<b>infant formula (maximum per 100 ml ready-to-consume product)</b>	<b>follow-up formula (maximum per 100 ml ready-to-consume product)</b>	<b>Processed Cereal-Based Foods (maximum per 100 g ready-to-consume product)</b>	<b>canned baby foods (maximum per 100 g of ready-to-consume product)</b>	<b>foods for special medical uses (maximum per 100 ml ready-to-consume product)</b>

Furthermore, the USA propose the following **Working Principles for Food Additive Provisions in Table D:**

- Step 1: Functional Classes. As a first step, the CCNFSDU should resolve questions regarding the technological need for food additives to function as nutrient carriers in each of the five food categories.
- Step 2: Specific Food Additives. Once the need for food additive nutrient carriers in each of these food categories has been resolved, then the CCNFSDU should address questions relating to specific food additives (i.e., revisions to the list of food additives and their maximum use level). This discussion should consider, among other things, the following principles:
- a) Within the needed functional classes, only additives assigned a full ADI by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are eligible for consideration in the standard.
  - b) Food additives that have been allocated a numerical ADI should be assigned a numerical maximum level of use. The lowest level needed to achieve the technical effect under good manufacturing practice should be used for all food additives.

According to ISDI, the maximum level for addition of sucrose needs to be increased since it is exceeded by sucrose diluted carrageenan, which is used in Latin America and Asia. Also encapsulated LCPUFA contain some sucrose.

ISDI also requests that Sorbitol be included as carrier in L-Ascorbic Acid.

Furthermore, ISDI suggests that a maximum level of 250 ppm is more reasonable for sodium L ascorbate as some powders are 2.8% encapsulated LCPUFA and 5% of the encapsulated LCPUFA is sodium ascorbate.

	INS no.	Additive/ Carrier	Maximum Level in Ready-to-use Food [mg/kg]
(a)		Maltodextrins (in formulae with lactose as only carbohydrate)	500
(b)	414	Gum arabic (gum acacia)	100
(c)	551	Silicon dioxide	10
(d)	421	Mannitol (B <sub>12</sub> dry rubbing 0,1%)	10
(e)	331iii	Trisodium citrate (B <sub>12</sub> acidic preparation 0,1%)	260
(f)	330	Citric acid (B <sub>12</sub> acidic preparation 0,1%)	90
(g)		Sucrose (in formulae with lactose as only carbohydrate)	10
(h)	1400-1451	Modified starches (as included in the Supplementary List to section 5.1, Codex Alimentarius Volume 1)	100
(i)	1450	<b>Switzerland:</b> Starch sodium octenyl succinate	100
(k)	420	<b>ISDI:</b> Sorbitol (carrier in L-Ascorbic Acid)	?

**EC Proposal:**

	INS no.	Additive/ Carrier	Maximum Level in Ready-to-use Food [mg/kg]
(a)	414	Gum arabic (gum acacia)	10
(b)	551	Silicon dioxide	10
(c)	421	Mannitol (B <sub>12</sub> dry rubbing 0,1%)	10
(d)	1450	Starch sodium octenyl succinate	100
(e)	301	Sodium L-ascorbate (in coating of nutrient preparations containing PUFAs)	75 [ISDI: 250 ]

**Abbreviations:**

BP	=	British Pharmacopoeia
BPC	=	British Pharmaceutical Codex
DAB	=	Deutsches Arzneibuch
DAC	=	Deutscher Arzneimittel-Codex
FCC	=	Food Chemicals Codex
FSANZ	=	Food Standards of Australia and New Zealand
FU	=	Farmacopoea Ufficiale della Repubblica Italiana
JP	=	The Pharmacopeia of Japan
Jap Food Stan	=	Japanese Food Standard
95/45/EC	=	COMMISSION DIRECTIVE 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs
MI	=	Merck Index
MP	=	Martindale Pharmacopoeia
ÖAB	=	Österreichisches Arzneibuch
Ph Eur	=	Pharmacopoeia Europaea
Ph Franç	=	Pharmacopée Française
Ph Helv	=	Pharmacopoeia Helvetica
Ph Int	=	International Pharmacopoeia
USP	=	The United States Pharmacopoeia