

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**Agenda Item 8**

**CX/NFSDU 03/8**  
**September 2003**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

#### **Twenty-fifth Session**

**Bonn, Germany, 3- 7 November 2003**

### **PROPOSED DRAFT REVISION OF THE ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR THE USE IN FOODS FOR INFANTS AND CHILDREN (CAC/GL 10-1979, amended 1983, 1991)**

*(Proposal for revision prepared by Germany)*

The Committee agreed on the following amendment of the Title:

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

Furthermore, during the last Session the preamble and the "criteria for the inclusion and deletion of nutrient compounds from the Advisory Lists" were revised as follows:

#### **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. 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 are established in an internationally recognised specification or, if there is no internationally recognised specification, national purity requirements may be considered

(d) the stability of nutrient compounds 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 shall be deleted from the Lists if they are found no longer to meet the above criteria. Nutrient compounds may be added to the Lists based on the criteria above.

#### **A: ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR INFANTS AND YOUNG CHILDREN**

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
1. Source of Calcium (Ca)						
1.1 Calcium carbonate	Ph Eur (2002), USP/NF, FCC IV, DAB, BP, JECFA (1973)	√	√	√	√	[√]
1.2 Calcium chloride	Ph Eur (2002), USP, FCC IV, DAB, JP, BP, JECFA (1975)	√	√	√	√	[√]
1.3 Tricalcium dicitrate (Calcium citrate)	USP, FCC IV, DAC, JECFA (1975)	√	√	√	√	[√]
1.4 Calcium gluconate	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1998)	√	√	√	√	[√]
1.5 Calcium glycerophosphate	Ph Eur (2002), FCC IV, Ph Franc	√	√	√	√	[√]
1.6 Calcium lactate*	Ph Eur (2002) (Tri- and Pentahydrate), USP, FCC IV, BP, DAB, JECFA (1974)	√	√	√	√	[√]
1.7 Calcium hydroxide	Ph Eur (2002), USP, FCC IV, BP, JECFA (1975)	√	√	√	√	[√]
1.8 Calcium oxide	FCC IV, DAC, JECFA (1975)	-	-	√	√	-
1.9 Calcium dihydrogen phosphate (Calcium phosphate, monobasic)	FCC IV, JECFA (1996)	√	√	√	√	[√]
1.10 Calcium hydrogen phosphate (Calcium phosphate, dibasic)	Ph Eur (2002), USP, FCC IV, BP, DAB, JECFA (1975)	√	√	√	√	[√]
1.11 Tricalcium diphosphate (Calcium phosphate, tribasic)	BP, FCC IV, JECFA (1973)	√	√	√	√	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>Other calcium compounds proposed for inclusion:</b>						
<b>ISDI (1.12 - 1.15):</b> 1.12 Calcium salts of orthophosphoric acid	identical with 1.9, 1.10, 1.11 ?	√	√	√	√	[√]
1.13 Calcium citrate malate	?	-	-	-	-	[√]
1.14 Calcium enriched yeast	?	-	-	-	-	[√]
1.15 Calcium pyruvate monohydrate	?	-	-	-	-	[√]
<b>Malaysia:</b> 1.16 Calcium pyrophosphate	FCC IV, JECFA (1980)	?	?	?	?	?
<b>Neuseeland, Malaysia, ISDI:</b> 1.17 Calcium sulphate <sup>1</sup>	Ph Eur (2002) (Dihydrate), FCC IV, DAB, JECFA (1975)	-	-	-	-	[√]
<b>2. Source of Iron (Fe)</b>						
2.1 Ferrous carbonate, stabilised with saccharose	?	-	-	√	√	[√]
2.2 Ferrous fumarate	Ph Eur (2002), BP, USP, FCC IV	√	√	√	√	[√]
2.3 Ferrous gluconate	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1999)	√	√	√	√	[√]
2.4 Ferrous lactate	NF, FCC IV, JECFA (1989)	√	√	√	√	[√]
2.5 Ferrous sulphate	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1999)	√	√	√	√	[√]
2.6 Ferric ammonium citrate	DAC, FCC IV, JECFA (1984)	√	√	√	√	[√]
2.7 Ferric citrate	FCC IV	√	√	√	√	[√]
2.8 Ferric diphosphate (pyrophosphate)	FCC IV	√	√	√	√	[√]
2.9 Hydrogen reduced iron	FCC IV, DAB	-	-	√	√	[√]
2.10 Electrolytic iron	FCC IV	-	-	√	√	[√]
2.11 Carbonyl iron	FCC IV	-	-	√	√	[√]
2.12 Ferric saccharate	?	-	-	√	√	[√]
2.13 Ferric orthophosphate	FCC IV	?	?	?	?	?

<sup>1</sup> Calcium sulphate had been deleted from the List after 1999. What is the justification for including it again?

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>Other iron compounds proposed for inclusion:</b>						
<b>EU, ISDI:</b> 2.14 Sodium ferric diphosphate	FCC IV	-	-	√	√	[√]
<b>ISDI:</b> 2.15 Ferrous citrate	FCC IV	√	√	√	√	[√]
<b>Malaysia:</b> 2.16 Ferric phosphate	identical with 2.13?	?	?	?	?	?
<b>New Zealand:</b> 2.17 Ferrous succinate	?	?	?	?	?	?
<b>3. Source of Magnesium (Mg)</b>						
3.1 Magnesium hydroxide carbonate	BP, USP, DAB, JECFA (1983)	√	√	√	√	[√]
3.2 Magnesium chloride	Ph Eur (2002) (-4,5-hydrate), USP, FCC IV, DAB, BP, JECFA (1983)	√	√	√	√	[√]
3.3 Trimagnesium dicitrate (Magnesium citrate)	DAC	√	√	√	√	[√]
3.4 Magnesium gluconate	FCC IV, DAC, JECFA (1999)	√	√	√	√	[√]
3.5 Magnesium glycerophosphate	Ph Eur (2002), BPC	-	-	√	√	[√]
3.6 Magnesium hydroxide	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1975)	√	√	√	√	[√]
3.7 Magnesium lactate	JECFA (Mg-DL-Lactat, Mg-L-Lactat: 1983)			√	√	[√]
3.8 Magnesium oxide	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1973)	√	√	√	√	[√]
3.9 Magnesium hydrogen phosphate (Magnesium phosphate, dibasic)	FCC IV, DAB, JECFA (1982)	√	√	√	√	[√]
3.10 Trimagnesium diphosphate (Magnesium phosphate, tribasic)	FCC IV, JECFA (1973)	√	√	√	√	[√]
3.11 Magnesium sulphate	Ph Eur (2002) (Heptahydrate), BP, USP, JP, FCC IV, DAB, DAC	√	√	√	√	[√]
3.12 Magnesium acetate	DAC	-	-	-	-	[√]
3.13 Magnesium salts of citric acid	?	EU:√	EU:√	EU:√	EU:√	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>Other magnesium compounds proposed for inclusion:</b>						
3.14 Magnesium carbonate	DAB, Ph Eur (2002), BP, USP, FCC IV, JECFA (1973)	√	√	√	√	[√]
<b>ISDI:</b> 3.15 Magnesium salts of orthophosphoric acid	identical with 3.9 and 3.10?	√	√	√	√	[√]
<b>4. Source of Sodium (Na)</b>						
4.1 Sodium carbonate	Ph Eur (2002), BP, NF, FCC IV, DAB, USP, JECFA (1975)	√	√	-	-	[√]
4.2 Sodium hydrogen carbonate (Sodium bicarbonate)	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1975)	√	√	-	-	[√]
4.3 Sodium chloride	Ph Eur (2002), BP, JP, USP/NF, FCC IV, DAB	√	√	-	-	[√]
4.4 Trisodium citrate (Sodium citrate)	Ph Eur (2002), USP, FCC IV, BP, DAB, JECFA (1975)	√	√	-	-	[√]
4.5 Sodium gluconate	USP, FCC IV, DAC, JECFA (1998)	√	√	-	-	[√]
4.6 Sodium lactate*	Ph Eur (2002), BP, USP, FCC IV, DAB, JECFA (1974)	√	√	-	-	[√]
4.7 Sodium dihydrogen phosphate (Sodium phosphate, monobasic)	Ph Eur (2002) (Dihydrate), USP, FCC IV, JECFA (1963)	√	√	-	-	[√]
4.8 Disodium hydrogen phosphate (Sodium phosphate, dibasic)	USP, FCC IV, BP, JECFA (1975)	√	√	-	-	[√]
4.9 Trisodium phosphate (Sodium phosphate, tribasic)	FCC IV, DAC, JECFA (1975)	√	√	-	-	[√]
4.10 Sodium hydroxide	Ph Eur (2002), DAB, NF, JP, BP, USP, FCC IV, JECFA (1975)	√	√	-	-	[√]
<b>Other sodium compounds proposed for inclusion:</b>						
<b>New Zealand:</b> 4.12 Sodium chloride (iodised) <sup>2</sup>	Ph Eur (2002), BP, JP, USP	?	?	?	?	?

<sup>2</sup> Sodium chloride, sodium sulphate, and sodium tartrate had been deleted from the Lists in 2001. What is the justification for including them again?

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
4.13 Sodium sulphate <sup>2</sup>	Ph Eur (2002), DAB, BP, FCC IV, USP, JECFA (2000)	?	?	?	?	?
4.14 Sodium tartrate <sup>2</sup>	JECFA (1963)	?	?	?	?	?
<b>5. Source of Potassium (K)</b>						
5.1 Potassium carbonate	Ph Eur (2002), USP, FCC IV, DAC, JECFA (1975)	√	√	-	-	[√]
5.2 Potassium hydrogen carbonate (Potassium bicarbonate)	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1975)	√	√	-	-	[√]
5.3 Potassium chloride	Ph Eur (2002), USP, FCC IV, BP, DAB, JECFA (1979)	√	√	√	√	[√]
5.4 Tripotassium citrate (Potassium citrate)	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1975)	√	√	√	√	[√]
5.5 Potassium gluconate	USP, FCC IV, DAC, JECFA (1998)	√	√	√	√	[√]
5.6 Potassium glycerophosphate	FCC IV	-	-	√	√	[√]
5.7 Potassium lactate*???	FCC IV, DAB, JECFA (1974)	√	√	√	√	[√]
5.8 Potassium dihydrogen phosphate (Potassium phosphate, monobasic)	Ph Eur (2002), FCC IV, NF, BP, DAB, JECFA (1976)	√	√	-	-	[√]
5.9 Dipotassium hydrogen phosphate (Potassium phosphate, dibasic)	FCC IV, BP, JECFA (1975)	√	√	-	-	[√]
5.10 Potassium phosphate, tribasic	JECFA (1975)	√	√	-	-	[√]
5.11 Potassium hydroxide	Ph Eur (2002), BP, JP, NF, FCC IV, DAC, JECFA (1975)	√	√	-	-	[√]
<b>Other potassium compounds proposed for inclusion:</b>						
<b>ISDI:</b> 5.12 Potassium salts of orthophosphoric acid	identical with 5.8, 5.9, 5.10?	√	√	-	-	[√]
<b>6. Source of Copper (Cu)</b>						
6.1 Cupric carbonate	?	√	√	-	-	[√]
6.2 Cupric citrate	FCC IV	√	√	-	-	[√]
6.3 Cupric gluconate (Copper gluconate)	FCC IV	√	√	-	-	[√]
6.4 Copper-lysine-complex	?	√	√	-	-	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
6.5 Cupric sulphate (Copper sulphate)	Ph Eur (2002), USP, FCC IV, DAB, JECFA (1973)	√	√	-	-	[√]
<b>7. Source of Iodine (I)</b>						
7.1 Potassium iodide	Ph Eur (2002), BP, USP, FCC IV, DAB	√	√	√	√	[√]
7.2 Sodium iodide	Ph Eur (2002), USP, BP, DAB	√	√	√	√	[√]
7.3 Potassium iodate	FCC IV, JECFA (1988)	√	√	√	√	[√]
7.4 Sodium iodate		-	-	√	√	[√]
<b>8. Source of Zinc (Zn)</b>						
8.1 Zinc acetate	Ph Eur (2002) (Dihydrate), USP	√	√	-	-	[√]
8.2 Zinc chloride	Ph Eur (2002), USP, BP, JP, DAB	√	√	-	-	[√]
8.3 Zinc citrate	FCC IV	√	√	-	-	[√]
8.4 Zinc gluconate	USP, FCC IV, DAC	√	√	-	-	[√]
8.5 Zinc lactate	?	√	√	-	-	[√]
8.6 Zinc oxide	Ph Eur (2002), BP, USP, FCC IV, DAB	√	√	-	-	[√]
8.7 Zinc sulphate	Ph Eur (2002), BP, USP, FCC IV	√	√	-	-	[√]
<b>Other zinc compounds proposed for inclusion:</b>						
<b>EU, ISDI:</b>						
8.8 Zinc carbonate	?	-	-	-	-	[√]
<b>9. Source of Manganese (Mn)</b>						
9.1 Manganese(II) carbonate	?	√	√	-	-	[√]
9.2 Manganese(II) chloride	FCC IV	√	√	-	-	[√]
9.3 Manganese(II) citrate	FCC IV	√	√	-	-	[√]
9.4 Manganese(II) glycerophosphate	FCC IV	-	-	-	-	[√]
9.5 Manganese(II) sulphate	Ph Eur (2002) (Monohydrate), USP, FCC IV	√	√	-	-	[√]
9.6 Manganese(II) gluconate	FCC IV	√	√	-	-	[√]
<b>10. Source of Selenium (Se)</b>						
10.1 Sodium selenate	?	√	√	New Zealand: √	-	[√]
10.2 Sodium selenite	DAC	√	√	New Zealand: √	-	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
10.3 Sodium hydrogen selenite	?	ISDI: √	ISDI: √	ISDI: √	ISDI: √	[√]
<b>Other selenium compounds proposed for inclusion:</b>						
<b>ISDI:</b> 10.4 Selenium enriched yeast <sup>3</sup>	?	-	-	-	-	[√]
<b>11. Chromium (Cr III)</b>						
11.1 Chromium (III) sulphate	?	-	-	-	-	[√]
11.2 Chromium (III) chloride	?	-	-	-	-	[√]
<b>Other chromium compounds proposed for inclusion:</b>						
<b>EU:</b> 11.3 Chromium (III) sulphate hexahydrate	identical with 11.1?	-	-	-	-	[√]
11.4 Chromium (III) chloride hexahydrate	identical with 11.2?	-	-	-	-	[√]
<b>ISDI:</b> 11.5 Chromium enriched yeast <sup>3</sup>	?	-	-	-	-	[√]
<b>12. Molybdenum (Mo VI)</b>						
12.1 Sodium molybdate	Ph Eur (2002) (Dihydrate), BP, DAB	-	-	-	-	[√]
12.2 Ammonium molybdate	USP, FCC IV	-	-	-	-	[√]
<b>13. Fluoride (F)</b>						
13.1 Potassium fluoride	?	-	-	-	-	[√]
13.2 Sodium fluoride	Ph Eur (2002), BP, USP, DAB, FCC IV	-	-	-	-	[√]
<b>Other fluoride compounds proposed for inclusion:</b>						
<b>ISDI:</b> 13.3 Calcium fluoride	DAB	-	-	-	-	[√]

\* Nutrient compounds that should not be used in infant foods, as proposed by the United States during the 24<sup>th</sup> Session of the CCNSF DU.

<sup>3</sup> ISDI: These substances are currently under evaluation by the European Scientific Committee (SCF).



## B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN

All vitamin compounds are now categorised according to their use in food categories for infants and young children, as proposed by several delegations.

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Children				
		IF	FUF	PCBF	CBF	FSMP
1. Vitamin A						
1.1 all trans Retinol	Ph Eur (2002) (vitamin A), USP, FCC IV (vitamin A)	√	√	√	√	[√]
1.2 Retinyl acetate	Ph Eur (2002) (vitamin A), USP, FCC IV (vitamin A), Jap Food Stan	√	√	√	√	[√]
1.3 Retinyl palmitate	Ph Eur (2002) (vitamin A), USP, FCC IV (vitamin A), Jap Food Stan	√	√	√	√	[√]
2. Provitamin A						
2.1 Beta-Carotene	Ph Eur (2002), USP, FCC IV, Jap Food Stan, JECFA (1987)	√	√	√	√	[√]
Other provitamin A carotenoids proposed for inclusion:						
ISDI: 2.2 Provitamin A other than beta-carotene	FCC IV (□-apo-8-carotenal), JECFA (1984)	√	√	√	√	[√]
3. Vitamin D						
3.1 Vitamin D2 = Ergocalciferol	Int.Pharm, Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB	√	√	√	√	[√]
3.2 Vitamin D3 = Cholecalciferol	BP, USP, Int.Pharm, FCC IV, Jap Food Stan, DAB	√	√	√	√	[√]
Other vitamin D compounds proposed for inclusion:						
New Zealand: 3.3 Cholecalciferol cholesterol	?	?	?	?	?	?
4. Vitamin E						
4.1 D-alpha-Tocopherol	Ph Eur (2002), USP, FCC IV, JECFA (2000)	√	√	√	√	[√]
4.2 DL-alpha-Tocopherol	Ph Eur (2002), USP, FCC IV, Jap Food Stan, JECFA (1986)	√	√	√	√	[√]
4.3 D-alpha-Tocopheryl acetate	Ph Eur (2002), USP, FCC IV	√	√	√	√	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Children				
		IF	FUF	PCBF	CBF	FSMP
4.4 DL-alpha-Tocopheryl acetate	Ph Eur (2002), USP, FCC IV; NF, BP	√	√	√	√	[√]
<b>Other tocopheryl compounds proposed for inclusion:</b>						
<b>ISDI, EU, New Zealand:</b> 4.5 D-alpha-Tocopheryl acid succinate	NF, FCC IV	-	-	-	-	[√]
4.6 DL-alpha-Tocopheryl acid succinate	?	-	-	-	-	[√]
<b>5. Vitamin C</b>						
5.1 L-Ascorbic acid	Ph Eur (2002), BP, USP, JP, FCC IV, Int. Pharm, Jap Food Stan, DAB, JECFA (1973)	√	√	√	√	[√]
5.2 Calcium-L-ascorbate	Ph Eur (2002), USP, FCC IV, JECFA (1981)	√	√	√	√	[√]
5.3 Potassium-L-ascorbate**	?	√	√	√	√	[√]
5.4 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate)	Ph Eur (2002), BP, NF, FCC IV, USP/NF, Jap Food Stan, DAB, JECFA (1973)	√	√	√	√	[√]
5.5 Sodium-L-ascorbate	DAC, Ph Franc, USP, FCC IV, Ph Eur (2002), Jap Food Stan, JECFA (1973)	√	√	√	√	[√]
<b>6. Vitamin B<sub>1</sub></b>						
6.1 Thiaminchloride hydrochloride	Int. Pharm, Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB	√	√	√	√	[√]
6.2 Thiamin mononitrate	Int. Pharm, Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB	√	√	√	√	[√]
<b>7. Vitamin B<sub>2</sub></b>						
7.1 Riboflavin	Ph Eur (2002), BP, JP, USP, Int. Pharm, FCC IV, Jap Food Stan, DAB, JECFA (1987)	√	√	√	√	[√]
7.2 Riboflavin-5'-phosphate sodium	Ph Eur (2002), BP, JP, USP, Jap Food Stan, DAB, JECFA (1987)	√	√	√	√	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Children				
		IF	FUF	PCBF	CBF	FSMP
8. Niacin						
8.1 Nicotinic acid amide (Nicotinamide)	Ph Eur (2002), BP, USP, FCC IV, Int. Pharm, Jap Food Stan, DAB	√	√	√	√	[√]
8.2 Nicotinic acid	Ph Eur (2002), BP, USP, Int. Pharm, FCC IV, Jap Food Stan, DAB	√	√	√	√	[√]
9. Vitamin B <sub>6</sub>						
9.1 Pyridoxine hydrochloride	Int. Pharm, Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB	√	√	√	√	[√]
9.2 Pyridoxal 5-phosphate**	?	√	√	√	√	[√]
9.3 Pyridoxal dipalmitate**	?	√	√	√	√	[√]
<i>Other pyridoxine compounds proposed for inclusion:</i>						
Malaysia:						
9.4 Pyridoxamine	?	?	?	?	?	?
10. Folic acid						
10.1 N-Pteroyl-L-glutamic acid	Ph Eur (2002), USP, FCC IV, Jap Food Stan	√	√	√	√	[√]
11. Pantothenic acid						
11.1 Calcium-D-pantothenate	Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB	√	√	√	√	[√]
11.2 Sodium-D-pantothenate	Jap Food Stan, DAB	√	√	√	√	[√]
11.3 D-Panthenol/ DL-Panthenol	Ph Eur (2002), USP, FCC IV	√	√	√	√	[√]
12. Vitamin B <sub>12</sub>						
12.1 Cyanocobalamin	Ph Eur (2002), BP, USP, FCC IV, DAB	√	√	√	√	[√]
12.2 Hydroxocobalamin	Ph Eur (2002) (Hydrochloride), USP, NF	√	√	√	√	[√]
13. Vitamin K <sub>1</sub>						
13.1 Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/ Phylloquinone)	Ph Eur (2002), BP, USP, FCC IV ( <u>vitamin K</u> )	√	√	√	√	[√]
14. Biotin						
14.1 D-Biotin	Ph Eur (2002), USP, FCC IV	√	√	√	√	[√]

\*\* Switzerland proposed that compounds should be deleted from the lists if they lack official purity criteria.

# **C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR INFANTS AND CHILDREN**

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Children				
		IF	FUF	PCBF	CBF	FSMP
1. Amino acids						
1.1 L-Arginine	Ph Eur (2002), BP, USP, FCC IV, DAB	}	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) <sup>4</sup>			[√]
1.2 L-Arginine hydrochloride	Ph Eur (2002), BP, USP, FCC IV, DAB					[√]
1.3 L-Cystine	Ph Eur (2002), USP, FCC IV					[√]
1.4 L-Cystine dihydrochloride	?					[√]
1.5 L-Cysteine	DAB					[√]
1.6 L-Cysteine hydrochloride	Ph Eur (2002), FCC					[√]
1.7 L- Histidine	Ph Eur (2002), USP, FCC IV, DAB					[√]
1.8 L- Histidine hydrochloride	Ph Eur (2002), FCC IV, DAB					[√]
1.9 L-Isoleucine	Ph Eur (2002), USP, FCC IV, DAB					[√]
1.10 L-Isoleucine hydrochloride	?					[√]
1.11 L-Leucine	Ph Eur (2002), USP, FCC IV, DAB	}	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) <sup>4</sup>			[√]
1.12 L-Leucine hydrochloride	?					[√]
1.13 L-Lysine	USP					[√]
1.14 L-Lysine monohydrochloride	Ph Eur (2002), USP, FCC IV, DAB					[√]
1.15 L-Methionine	Ph Eur (2002), USP, FCC IV, DAB					[√]
1.16 L-Phenylalanine	Ph Eur (2002), USP, FCC IV	}	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) <sup>4</sup>			[√]
1.17 L-Threonine	Ph Eur (2002), USP, FCC IV, DAB					[√]
1.18 L-Tryptophan	Ph Eur (2002), USP, FCC IV, DAB	}	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) <sup>4</sup>			[√]
1.19 L-Tyrosine	Ph Eur (2002), USP, FCC IV, DAB					[√]
1.20 L-Valine	Ph Eur (2002), USP, FCC IV, DAB					[√]

<sup>4</sup> Amendment, as proposed by the USA in CX/NFSDU 02/7

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Children				
		IF	FUF	PCBF	CBF	FSMP
<b>Other amino acids and their derivatives proposed for inclusion:</b>						
<b>ISDI:</b> 1.21 L-Alanine	Ph Eur (2002), USP, FCC IV, DAB	-				[√]
1.22 L-Arginine L-aspartate	?	-				[√]
1.23 L-Aspartic acid	Ph Eur (2002), USP, FCC IV	-				[√]
1.24 L-Citrulline	USP, DAC	-				[√]
1.25 L- Glutamic acid	Ph Eur (2002), USP, FCC IV, JECFA (1987)	ISDI: √	ISDI: √			[√]
1.26 L-Glutamine	USP, FCC IV, DAB	ISDI: √	ISDI: √			[√]
1.27 Glycine	Ph Eur (2002), USP, FCC IV	-				[√]
1.28 L-Lysine acetate	?	ISDI: √	ISDI: √	ISDI: √	ISDI: √	[√]
1.29 L-Lysine L-Aspartate	?	-				[√]
1.30 L-Lysine L-Glutamate dihydrate	?	-				[√]
1.31 L-Ornithine	?	-				[√]
1.32 L-Proline	Ph Eur (2002), USP, FCC IV, DAB	-				[√]
1.33 L-Serine	PH Eur (2002), USP, DAB	-				[√]
1.34 N-Acetyl-L-cysteine	Ph Eur (2002), USP, DAB	-				[√]
1.35 N-Acetyl-L-methionine	FCC IV	-				[√] except infants
1.36 S-Adenosyl-L-methionine	?	-				[√] except infants
<b>2. Carnitine</b>						
2.1 L-Carnitine	USP, FCC IV	√	√	ISDI:√	ISDI:√	[√]
2.2 L-Carnitine hydrochloride	?	√	√	ISDI:√	ISDI:√	[√]
<b>Other carnitine compounds proposed for inclusion:</b>						
<b>ISDI:</b> 2.2 L-Carnitine tartrate	?	-	-	-	-	[√]
<b>3. Taurine</b>						
3.1 Taurine	USP, JP	√	ISDI:√	-	-	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Children				
		IF	FUF	PCBF	CBF	FSMP
4. Choline						
4.1 Choline chloride	DAB 1996, FCC IV, DAC	√	√	-	-	[√]
4.2 Choline citrate	NF	√	√	-	-	[√]
4.3 Choline hydrogen tartrate	DAB 1996, FCC IV, NF	√	√	-	-	[√]
5. Myo-Inositol (=meso-Inositol)	DAC, FCC IV	√	√	-	-	[√]
6. Nucleotides						
6.1 Cytidine 5-monophosphate (CMP)		√	ISDI:√	-	-	[√]
6.2 Cytidine 5-monophosphate sodium salt		√	ISDI:√	-	-	[√]
6.3 Uridine 5-monophosphate (UMP)		√	ISDI:√	-	-	[√]
6.4 Uridine 5-monophosphate sodium salt		√	ISDI:√	-	-	[√]
6.5 Adenosine 5-monophosphate (AMP)		√	ISDI:√	-	-	[√]
6.6 Adenosine 5-monophosphate sodium salt		√	ISDI:√	-	-	[√]
6.7 Guanosine 5-monophosphate (GMP)	JECFA (1985)	√	ISDI:√	-	-	[√]
6.8 Guanosine 5-monophosphate sodium salt		√	ISDI:√	-	-	[√]
6.9 Inosine 5-monophosphate (IMP)	JECFA (1974)	√	ISDI:√	-	-	[√]
6.10 Inosine 5-monophosphate sodium salt		√	ISDI:√	-	-	[√]
ISDI:						[√]
7. Creatine monohydrate						

**Abbreviations:**

IF = infant formula  
 FUF = follow-up formula  
 PCBF = processed cereal based food  
 CBF = canned baby food  
 [FSMP] = food for special medical purposes

BP = British Pharmacopoeia  
 BPC = British Pharmaceutical Codex

DAB	= Deutsches Arzneibuch
DAC	= Deutscher Arzneimittel-Codex
FCC	= Food Chemicals Codex
FU	= Farmacopoea Ufficiale della Repubblica Italiana
JP	= The Pharmacopeia of Japan
Jap Food Stan	= Japanese Food Standard
NF	= The National Formulary/USA
Ph Eur	= Pharmacopoeia Europaea
Ph Franç	= Pharmacopée Française
Ph Helv	= Pharmacopoea Helvetica
Ph Int	= International Pharmacopeia
USP	= The United States Pharmacopeia

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

- The USA proposed to delete this list, as it does not contain nutrient compounds. The substances included in the list should be covered under the food additive provisions in the respective food standard.
- ISDI proposed to amend the title of the list by substituting the term "nutrient" for "vitamin":

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

- Furthermore, ISDI suggests that the introductory paragraph be amended as follows:

*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:*

- Switzerland states that the current wording of the leading paragraph is not easily understandable. They propose that the following sentence be included at the end of the paragraph:  
*"In addition, the following food additives/carriers are permitted".*
- Regarding the list itself, Switzerland recommends that the term "carrier" be introduced besides "additive", since Maltodextrins are not regarded as food additives.
- Furthermore, Switzerland proposes to add the INS numbers of the different food additives and to include "Starch Sodium Octenyl Succinate" (INS no. 1450) with a Max. level of use of 100 mg/kg in the ready-to-use food.
- Costa Rica proposes that other coating agents be included, e.g.: fish gelatine, bovine gelatine, EC: ethylcellulose, FC: glyceryl tristearate, SC : silicone. Furthermore, BHA/BHT and peanut oil should be added to the list as stabiliser.
- ISDI suggests the following modification to the list:
  - the clause "for vitamin preparations only" should be deleted, as Silicon dioxide is not only used for vitamins but also as anticaking agent for potassium chloride in a concentration of 0,2 %
  - Saccharose is used in vitamin mixtures (dry blended) and as spray drying aid in dry preparations of LCPUFA. Infant starting formula, containing only the carbohydrate lactose (claim "lactose only") can contain up to 10 mg saccharose/kg in the ready to use food.
  - Modified starches were listed in the original list CAC/GL 10-1979, they should remain in the revised list

➔ Subsequently, the list should read:

		<b>INS no. Ready-to-use Food</b>	<b>Maximum Level in Additive/Carrier</b>	
(a)		Maltodextrins		
		(in formulae with lactose as only carbohydrate)	500	mg/kg
(b)	414	Gum arabic (gum acacia)	100	mg/kg
(c)	551	Silicon dioxide	10	mg/kg
(d)	421	Mannit (B <sub>12</sub> dry rubbing 0,1%)	10	mg/kg
(e)	331iii	Trisodium citrate (B <sub>12</sub> acidic preparation 0,1%)	260	mg/kg
(f)	330	Citric acid (B <sub>12</sub> acidic preparation 0,1%)	90	mg/kg
(g)		Fish gelatine		
(h)		Bovine gelatine		
(i)		Ethylcellulose (EC)		
(j)		Glycyl tristearate		
(k)		BHA/BHT		
(l)		Peanut oil		
(m)		Saccharose		
		(in formulae with lactose as only carbohydrate)	10	mg/kg
(n)		Modified starches (as included in the Supplementary List to section 5.1, Codex alimentarius Volume 1)	100	mg/kg
(o)	1450	Starch sodium octenyl succinate	100	mg/kg