

# 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 7

CX/NFSDU 01/7  
September 2001

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

#### Twenty-third Session

Berlin, Germany, 26-30 November 2001

### PROPOSAL FOR 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)<sup>1</sup>

*(prepared by Germany)*

The Committee on Nutrition and Foods for Special Dietary Uses at its 22<sup>nd</sup> Session, held in Berlin from 19 to 23 June 2000, considered the Proposed Draft Revision of the Advisory List(s) of Mineral Salts and Vitamin Compounds for the Use in Foods for Infants and Children. During the discussion it was emphasised that criteria for inclusion in and/or deletion from the Advisory List(s) were essential in order to ensure that the respective nutrients be safe and appropriate for the dietary use by infants and young children. Furthermore, it was discussed if other nutrient categories apart from vitamin compounds and mineral salts should be included in the Lists.

It was agreed that a Circular Letter would request comments from delegations concerning the criteria for inclusion and deletion of mineral salts and vitamin compounds adopted by the 18<sup>th</sup> Session of the CCNFSDU (ALINORM 87/26, App. XII). In addition, for a thorough revision of the Lists the following aspects would need to be evaluated and commented:

- the objective and the title of the list
- the structure of the list
- the choice of nutrients
- the purity requirements
- use in different types of foods for infants and children.

Until 31 July Germany had received nine comments, from Australia, Cuba, Hungary, Malaysia, Mexico, Spain, USA, EU, and ISDI. Based on those comments, Germany has prepared the following document for consideration by the Committee at the forthcoming session.

#### 1) Comments concerning the Criteria for inclusion and deletion of nutrient sources

With respect to the **criteria** for inclusion and/or deletion of mineral salts and vitamin compounds in the List(s), the following proposals were submitted:

---

<sup>1</sup> Based on comments received to the CL 2001/7-NFSDU.

Ad 1 (a)

- Australia: The use of the word “suitable” is unclear in this criterion. – Does it refer to nutritional or technological suitability or both?
- Mexico: The term “nutrient sources” should be replaced by “nutrients”, as reference is made to the nutrients themselves in their chemical composition.
- Spain: The wording “for infants and children” should be added to make clear that this population group is targeted.
- USA: points out that the nutrient sources should be appropriate for “use as a sole source of nutrition”.

Ad 1 (b)

- Australia: ADIs have not been determined for all current compounds or categories of compounds that might be added to the List in future.
- EU: It should not be necessary for a nutritional substance to be a recognised food additive → it is proposed that this requirement should be deleted from the criteria.
- Mexico: ADI (Acceptable Daily Intake) refers to additives, while RDI refers to nutrients. The criteria for additives are different from those for nutrients. The main objective of the vitamin compounds and mineral salts refers to the addition for nutritional purposes, but not for their use for technological purposes. → “its use does not exceed the ADI” should be removed
- USA: According to the JECFA, the ADI should not be considered applicable to neonates and young children below the age of 12 weeks. The following wording is proposed: “the use of an anion (or acid from which the anion is derived) does not exceed a daily intake that is safe and appropriate for a young infant”.
- ISDI: The aim of this criterion is questioned. JECFA evaluations are only done for additives and contaminants, but not for nutritional substances.

Ad 1 (c)

- EU: The definition of appropriate studies on the biological availability of substances should be extended to allow consideration of other appropriate studies apart from those in animals or infants, for example in children or adults.
- Mexico proposes the following wording: “there is evidence for the existence and amount of the bioavailability of each vitamin and mineral”

Ad 1 (e)

- Malaysia: An additional criterion should be included regarding the stability of a nutrient: “the stability of nutrient(s) in the food(s) in which it is to be used can be demonstrated”

Ad 2

- EU, ISDI, and Mexico proposed to delete the second part of the criterion: “if there is no evidence of their continued commercial application”.

→ Taking the above comments into consideration, Germany proposes the following amendment of the criteria (changes are printed in bold) and invites the Committee to discuss this proposal at the forthcoming session.

1. **Substances 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** as nutrient sources **for infants and young children**
  - (b) Regarding this criterion, several delegations proposed to remove the reference to ADI. The wording proposed by the USA is already included in criterion (a). → Thus, Germany proposes to **remove this criterion**.
  - (c) it is demonstrated by appropriate studies in animals and/or **humans** that the **substances** are biologically available

- (d) the purity requirements of the **substances** are established in an internationally recognised specification **or, if there is no internationally recognised specification, national purity requirements may be considered**
- (e) **the stability of nutrient(s) in the food(s) in which it is/they are to be used can be demonstrated**

2. **Substances** shall be deleted from the List if they are found no longer to meet the above criteria.

## 2) **The objective and the title of the List(s)**

Germany states that the objective of the lists is to indicate nutrients, which may be added to foods intended for infants and children for nutritional purposes.

Australia and the EU proposed to extend the scope of the List(s) by increasing the range of nutrients in order to cover nutrients other than vitamin compounds and mineral salts, e.g. essential fatty acids, amino acids, and other nitrogenous substances such as nucleotides, taurine, and carnitine. Along with this, Germany proposes to adjust the title of the List(s) as follows:

**“Advisory List(s) of Nutrient Compounds for the Use in Foods for Infants and Children”.**

## 3) **The objective and the structure of the List(s)**

As it is envisaged to include other nutrient categories apart from vitamin compounds and mineral salts, the structure of the List(s) should be continued in such way that a separate table is composed for each nutrient category. Germany proposes the following structure:

- A: Advisory List of mineral salts and trace elements for use in foods for infants and children
- B: Advisory List of vitamin compounds for use in foods for infants and children
- C: Advisory List of amino acids and other nutrients for use in foods for infants and children
- D: Advisory List on Food Additives for Special Vitamin Forms

Regarding the internal structure of the Lists, Germany proposes that each table should consist of three columns, as shown below. The purity requirements and the use of each nutrient source should be indicated for each nutrient by use of specific abbreviations.

Nutrient source	Purity requirements	Use in food categories for infants and children
-----------------	---------------------	---

With respect to the use of the nutrient sources, Germany proposes to consider the following as possible food categories:

- Infant formula (IF)
- Follow-up formula (FUF)
- Complementary foods, processed cereal-based (PCBF) as well as canned baby foods (CBF) (Codex-Stan 73-1981)
- Foods for special medical purposes (FSMP)

For the above food categories for infants and children codex standards are available, while the following three categories are not mentioned in codex standards.

- Toddlers milk (TM)
- Oral rehydration solution (ORS) (these are partially identified as pharmaceutical products)
- Dietary supplements (DS) for infants and young children

#### **4) Comments and proposals regarding the Advisory List(s) and the inclusion and/or deletion of vitamin compounds and minerals salts in the List(s)**

Germany proposes that the Advisory List(s) be preceded by the following preamble:

“These lists include nutrient compounds, which may be used for nutritional purposes in dietary foods for infants and young children. The criteria for the composition of such foods stipulated in the respective standards shall be adhered to.”

Some of the proposals for inclusion and/or deletion of nutrient sources submitted by member delegations were in accordance with the List(s) of nutrient sources proposed by Germany at the last session (CX/NFSDU 00/8). For easy reference, these lists are included in the annex I of this discussion paper.

**Additional proposals:** Apart from the Lists attached in the annex, it was proposed to include the following nutrients in the respective lists:

##### **A: Advisory List of Mineral Salts for Use in Foods for Infants and Children**

###### **Potassium (K)**

- Australia: Potassium phosphate (tribasic)
- EU, ISDI: Potassium hydroxide

###### **Sodium (Na)**

- Australia: Sodium phosphate (monobasic)
- Australia: Sodium phosphate (tribasic)

###### **Iron (Fe)**

- ISDI: Ferric saccharate - FCC
- ISDI: Ferric orthophosphate - FCC

###### **Magnesium (Mg)**

- EU, ISDI: Magnesium hydroxide
- EU: Magnesium salts of citric acid
- ISDI: Magnesium acetate

###### **Selenium (Se)**

- ISDI: Sodium hydrogen selenite

###### **Chromium (Cr III)**

- ISDI: Chromium (III) chloride
- ISDI: Chromium (III) sulphate:

###### **Molybdenum (Mo VI)**

- ISDI: Sodium molybdate
- ISDI: Ammonium molybdate:

###### **Fluoride (F)**

- ISDI: Potassium fluoride
- ISDI: Sodium fluoride

##### **C: Advisory List of Amino Acids and Other Nutrients for Use in Food for Infants and Children:**

###### **Choline**

- Australia: Choline bitartrate
- EU, ISDI: Choline

**Nucleotide**

- Australia: Cytidine5-monophosphate (CMP)  
Cytidine5-monophosphate sodium salt  
Uridine5-monophosphate (UMP)  
Uridine5-monophosphate sodium salt  
Adenosin5-monophosphate (AMP)  
Adenosin5-monophosphate sodium salt  
Guanosine5-monophosphate  
Guanosine5-monophosphate sodium salt  
Inosine5-monophosphate  
Inosine5-monophosphate sodium salt

Furthermore, Australia requested that the following nutrients be retained in the Advisory Lists:

**A: Advisory List of Mineral Salts**

Calcium sulphate  
Ferrous citrate  
Ferrous succinate  
Sodium sulphate  
Sodium tartrate

**B: Advisory List of Vitamin Compounds**

Retinol propionate  
Cholecalciferol-cholesterol  
d-alpha-tocopheryl succinate  
dl-alpha-tocopheryl succinate

**References**

European Commission (1999). Opinion on substances for nutritional purposes which have been proposed for use in the manufacture of foods for particular nutritional purposes (PARNUTS). Scientific Committee for Food. Brussels, Belgium.

Codex Alimentarius Commission (ALINORM 01/26). Report of the 22<sup>nd</sup> session of the Codex committee on Nutrition and Foods for Special Dietary Uses. 19 – 23 June 2000, Berlin, Germany.

Commission Directive 96/5/EC, Euratom of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children. Official Journal L 049, 28/02/1996: (17-28), including Amendments OJ L 167, 12/06/1998: (23-24) and OJ L124, 18/05/1999: (8-10).

Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae Official Journal L 175, 04/07/1991: (35-49), including Amendments OJ L 049, 28/02/1996: (p.12) and OJ L 139, 02/06/1999: (p.29).

Nestle P(ed.). Proceedings: Interventions for Child Survival. OMNI Manual. May 17-18, 1995 London, United Kingdom: Blum M.. Overview of Iron Fortification of Foods. F. Hoffmann-La Roche Ltd. Basel, Switzerland.

Raiten D J, Talbot J M and Waters J H (Editors): Executive Summary for the Report: Assessment of Nutrient Requirements for Infant Formulas. Life Sciences Research Office, American Society for Nutritional Sciences. Supplement to The Journal of Nutrition 1998, vol. 128;11:(2059S - 2294S).

WHO/EMRO. Joint World Health Organisation/UNICEF/Micronutrient Initiative Strategic Development Workshop on Food Fortification with Special Reference to Iron Fortification of Flour, Muscat, Oman, from 26 to 30 October 1996. WHO, 1998.

## ANNEX I

**ADVISORY LISTS OF NUTRIENT COMPOUNDS  
FOR USE IN FOODS FOR INFANTS AND CHILDREN**

**A: Advisory List of Mineral Salts and Trace Elements for Use in Foods for Infants and Children**

Mineral Salts	Purity Requirements	Use in Foods for Infants and Children
<b>1. Source of Calcium (Ca)</b>		
1.1 Calcium carbonate	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
1.2 Calcium chloride	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
1.3 Tricalcium dicitrate (Calcium citrate)	USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
1.4 Calcium gluconate	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
1.5 Calcium glycerophosphate	Ph Eur, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
1.6 Calcium lactate	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
1.7 Calcium hydroxide	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
1.8 Calcium oxide	FCC	PCBF; CBF; TM; FSMP; DS
1.9 Calcium dihydrogen phosphate (Calcium phosphate, Monobasic)	FCC	PCBF; CBF; TM; FSMP; DS
1.10 Calcium hydrogen phosphate (Calcium phosphate, Dibasic)	Ph Eur, USP, FCC	PCBF; CBF; TM; FSMP; DS
1.11 Tricalcium diphosphate (Calcium phosphate, Tribasic)	FCC	PCBF; CBF; TM; FSMP; DS
<b>[2. Source of Phosphorus (P)]</b>		
2.1 Calcium phosphate, monobasic	FCC, FAO/WHO	Milk substitute and low sodium formulae
2.2 Calcium phosphate, dibasic	FCC	Milk substitute and protein hydrolysate formulae
2.3 Calcium phosphate, tribasic	FCC: FAO/WHO	Milk substitute, protein hydrolysate and premature formulae; infant cereals
2.4 Magnesium phosphate, dibasic	FCC	Milk substitute and lactose-free formulae
2.5 Magnesium phosphate, tribasic	FCC, FAO/WHO	
2.6 Potassium phosphate, monobasic	FCC, FAO/WHO	Protein hydrolysate formulae
2.7 Potassium phosphate, dibasic	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae
2.8 Sodium phosphate, dibasic	FCC, FAO/WHO	Electrolyte mixture supplement
2.9 Phosphoric acid	FCC, FAO/WHO	All infant and follow-up formulae; cereal-based foods for infants and children

Mineral Salts	Purity Requirements	Use in Foods for Infants and Children
<b>[3. Source of Chloride (Cl)]</b>		
3.1 Calcium chloride	FCC, FAO/WHO	Milk-based, milk substitute and protein supplement formulae; electrolyte mixture supplement
3.2 Choline chloride	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae
3.3 Magnesium chloride	FCC, FAO/WHO	Milk-based, milk substitute and lactosefree formulae
3.4 Manganese chloride	FCC	Milk-based formulae
3.5 Potassium chloride	FCC, FAO/WHO	
3.6 Sodium chloride	FCC, FAO/WHO	Milk-substitute formulae, baby foods and electrolyte mixture supplement
3.7 Sodium chloride, iodized	FCC	Milk substitute formulae
3.8 Hydrochloric acid	FCC, FAO/WHO	All infant and follow-up formulae; cereal-based foods for infants and children
<b>4. Source of Iron (Fe)</b>		
4.1 Ferrous carbonate, stabilised with saccharose		PCBF; CBF; TM; FSMP; DS
4.2 Ferrous fumarate	Ph Eur, FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
4.3 Ferrous gluconate	Ph Eur, USP, FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
4.4 Ferrous lactate	NF, FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
4.5 Ferrous sulphate	Ph Eur, USP, FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
4.6 Ferric ammonium citrate	DAC, FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
4.7 Ferric citrate		IF, FUF, PCBF, CBF, TM, FSMP, DS
4.8 Ferric diphosphate (pyrophosphate)	FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
4.9 Hydrogen reduced iron	FCC	PCBF; CBF
4.10 Electrolytic iron	FCC	PCBF; CBF
4.11 Carbonyl iron	FCC	PCBF; CBF
<b>5. Source of Magnesium (Mg)</b>		
5.1 Magnesium hydroxide carbonate	Ph Eur, USP, FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
5.2 Magnesium chloride	PH.Eur, USP, FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
5.3 Trimagnesium dicitrate (Magnesium citrate)		IF, FUF, PCBF, CBF, TM, FSMP, DS

Mineral Salts		Purity Requirements	Use in Foods for Infants and Children
5.4	Magnesium gluconate	FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
5.5	Magnesium glycerophosphate	BPC	PCBF, CBF, TM, FSMP, DS
5.6	Magnesium hydroxide	Ph Eur, USP, FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
5.7	Magnesium lactate		PCBF, CBF, TM, FSMP, DS
5.8	Magnesium oxide	Ph Eur, USP, FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
5.9	Magnesium hydrogen phosphate (Magnesium phosphate, Dibasic)	FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
5.10	Trimagnesium diphosphate (Magnesium phosphate, tribasic)	FCC	IF, FUF, PCBF, CBF, TM, FSMP, DS
5.11	Magnesium sulphate	FCC	
<b>6. Source of Sodium (Na)</b>			
6.1	Sodium carbonate	Ph Eur, FCC	IF, FUF, FSMP
6.2	Sodium hydrogen carbonate (Sodium bicarbonate)	Ph Eur, USP, FCC	IF, FUF, FSMP, ORS
6.3	Sodium chloride	Ph Eur USP, FCC	IF, FUF, FSMP, ORS
6.4	Trisodium citrate (Sodium citrate)	Ph Eur, USP, FCC	IF, FUF, FSMP, ORS
6.5	Sodium gluconate	USP, FCC	IF, FUF, FSMP
6.6	Sodium lactate	Ph Eur, USP, FCC	IF, FUF, FSMP
6.7	Sodium dihydrogen phosphate (Sodium phosphate, Monobasic)	Ph Eur, USP, FCC	IF, FUF, FSMP
6.8	Disodium hydrogen phosphate (Sodium phosphate, Dibasic)	Ph Eur, USP, FCC	IF, FUF, FSMP
6.9	Trisodium phosphate (Sodium phosphate, Tribasic)	FCC	IF, FUF, FSMP
6.10	Sodium hydroxide	-	IF, FUF, FSMP
<b>7. Source of Potassium (K)</b>			
7.1	Potassium carbonate	Ph Helv, USP, FCC	IF; FUF; FSMP
7.2	Potassium hydrogen carbonate (Potassium bicarbonate)	Ph Eur, USP, FCC	IF; FUF; FSMP; ORS
7.3	Potassium chloride	Ph Eur, USP, FCC	IF; FUF; FSMP; ORS; PCBF; CBF; TM
7.4	Tripotassium citrate (Potassium citrate)	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; ORS
7.5	Potassium gluconate	USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP
7.6	Potassium glycerophosphate	FCC	PCBF; CBF; TM; FSMP
7.7	Potassium lactate	FCC	IF; FUF; PCBF; CBF; TM; FSMP



Mineral Salts		Purity Requirements	Use in Foods for Infants and Children
7.8	Potassium dihydrogen phosphate (Potassium phosphate, Monobasic)	Ph Eur, FCC	IF; FUF; FSMP
7.9	Dipotassium hydrogen phosphate (Potassium phosphate, dibasic)	FCC	IF; FUF; FSMP
<b>8. Source of Copper (Cu)</b>			
8.1	Cupric carbonate		IF; FUF; PCBF; CBF; TM; FSMP; DS
8.2	Cupric citrate		IF; FUF; PCBF; CBF; TM; FSMP; DS
8.3	Cupric gluconate (Copper gluconate)	FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
8.4	Copper-lysine-complex		IF; FUF; PCBF; CBF; TM; FSMP; DS
8.5	Cupric sulphate (Copper sulphate)	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
<b>9. Source of Iodine (I)</b>			
9.1	Potassium iodide	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
9.2	Sodium iodide	Ph Eur	IF; FUF; PCBF; CBF; TM; FSMP; DS
9.3	Potassium iodate	Ph Eur, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
9.4	Sodium iodate	Ph Eur	IF; FUF; PCBF; CBF; TM; FSMP; DS
<b>10. Source of Zinc (Zn)</b>			
10.1	Zinc acetate		IF; FUF; PCBF; CBF; TM; FSMP; DS
10.2	Zinc chloride	Ph Eur, USP, JP	IF; FUF; PCBF; CBF; TM; FSMP; DS
10.3	Zinc citrate		IF; FUF; PCBF; CBF; TM; FSMP; DS
10.4	Zinc gluconate	FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
10.5	Zinc lactate		IF; FUF; PCBF; CBF; TM; FSMP; DS
10.6	Zinc oxide	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
10.7	Zinc sulphate	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
<b>11. Source of Manganese (Mn)</b>			
11.1	Manganese(II) carbonate		IF; FUF; PCBF; CBF; TM; FSMP; DS
11.2	Manganese(II) chloride	FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
11.3	Manganese(II) citrate		IF; FUF; PCBF; CBF; TM; FSMP; DS

Mineral Salts	Purity Requirements	Use in Foods for Infants and Children
11.4 Manganese(II) glycerophosphate	FCC	PCBF; CBF; TM; FSMP; DS
11.5 Manganese(II) sulphate	USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS
11.6 Manganese(II) gluconate		IF; FUF; PCBF; CBF; TM; FSMP; DS
<b>12. Source of Selenium (Se)</b>		
12.1 Sodium selenate		IF; FUF; FSMP
12.2 Sodium selenite	DAC	IF; FUF; FSMP

- \* IF = infant formula  
 FUF = follow-up formula  
 PCBF = processed cereal based food  
 CBF = canned baby food  
 TM = toddlers' milk  
 FSMP = food for special medical purposes  
 DS = dietary supplement  
 ORS = oral rehydration solution

#### B: Advisory List of Vitamin Compounds for Use in Foods for Infants and Children

Vitamin	Vitamin Form	Purity Requirements
1. Vitamin A	all trans Retinol Retinyl acetate Retinyl palmitate	Ph Eur, FCC Ph Eur, USP, FCC Ph Eur, USP, FCC
2. Provitamin A	beta-Carotene	Ph Eur, USP
3. Vitamin D 3.1 Vitamin D <sub>2</sub> 3.2 Vitamin D <sub>3</sub>	Ergocalciferol Cholecalciferol	Ph Eur, USP, FCC, NF Ph Eur, USP, FCC
4. Vitamin E	D-alpha-Tocopherol DL-alpha-Tocopherol D-alpha-Tocopheryl acetate DL-alpha-Tocopheryl acetate	Ph Eur, USP Ph Eur, USP Ph Eur, USP Ph Eur, USP
5. Vitamin C	L-Ascorbic acid Calcium-L-ascorbate Potassium-L-ascorbate 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate) Sodium-L-ascorbate	Ph Eur, USP, FCC Ph Eur, USP, FCC  Ph Eur, USP, FCC USP, FCC
6. Vitamin B <sub>1</sub>	Thiaminchloride hydrochloride Thiamin mononitrate	Ph Eur, USP, FCC Ph Eur, USP, FCC

Vitamin	Vitamin Form	Purity Requirements
7. Vitamin B <sub>2</sub>	Riboflavin Riboflavin-5'-phosphate sodium	Ph Eur, USP, FCC Ph Eur, USP, FCC
8. Niacin	Nicotinic acid amide (Nicotinamide) Nicotinic acid	Ph Eur, USP, FCC Ph Eur, USP, FCC
9. Vitamin B <sub>6</sub>	Pyridoxal hydrochloride Pyridoxal 5-phosphate Pyridoxal dipalmitate	Ph Eur, USP, FCC
10. Folic acid	N-Pteroyl-L-glutamic acid	Ph Eur, USP, FCC
11. Pantothenic acid	Calcium-D-pantothenate Sodium-D-pantothenate D-Panthenol	Ph Eur, USP, FCC Ph Eur, USP, FCC
12. Vitamin B <sub>12</sub>	Cyanocobalamin Hydroxocobalamin	Ph Eur, USP, FCC Ph Eur, USP, NF
13. Vitamin K <sub>1</sub>	Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone) (Phylloquinone)	Ph Eur, USP, FCC
14. Biotin	D-Biotin	Ph Eur, USP, FCC

### C: Advisory List of Amino Acids and Other Nutrients for Use in Foods for Infants and Children

Nutrient	Purity Requirements	Use in Foods for Infants and Children*
<b>1. Source of Amino Acids</b>		
1.1 L- Arginine and its hydrochloride	Ph Eur, USP, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.2. L-Cystine and its dihydrochloride	Ph Eur, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.3 L-Cysteine and its hydrochloride	FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.4 L- Histidine and its hydrochloride	Ph Eur, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.5 L-Isoleucine and its hydrochloride	FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.6 L-Leucine and its hydrochloride	Ph Eur, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.7 L-Lysine and its monohydrochloride	Ph Eur, USP, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP

Nutrient	Purity Requirements	Use in Foods for Infants and Children*
1.8 L-Methionine	Ph Eur, USP, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.9 L-Phenylalanine	Ph Eur, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.10 L-Threonine	Ph Eur, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.11 L-Tryptophan	DAB, Ph Eur, USP, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.12 L-Tyrosine	Ph Eur, USP, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
1.13 L-Valine	Ph Eur, FCC	only for improving the nutritional quality of the protein in IF; FUF; FSMP
<b>2. L- Carnitine</b> and its hydrochloride	USP	IF; FUF; FSMP; DS
<b>3. Taurine</b>	JP	IF
<b>4. Source of Choline</b>		
4.1 Choline chloride	DAB, FCC	IF; FUF; PCBF; CBF; FSMP
4.2 Choline citrate	NF	IF; FUF; PCBF; CBF; FSMP
4.3 Choline hydrogen tartrate	DAB, FCC	IF; FUF; PCBF; CBF; FSMP
<b>5. myo-Inositol</b> (=meso-Inositol)	FCC	IF; FUF; PCBF; CBF; FSMP

**Abbreviations:**

BPC	=	British Pharmaceutical Codex	DAB	=	Deutsches Arzneibuch
DAC	=	Deutscher Arzneimittel Codex	FCC	=	Food Chemicals Codex
JP	=	The Pharmacopoeia of Japan	NF	=	The National Formulary
USP	=	United States Pharmacopeia	Ph Helv	=	Pharmacopeia of Helvetica

**D: Advisory List on Food Additives for Special Vitamin Forms**

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.

**Maximum Level in Ready-to-use Food**

(a) Maltodextrins (in formulae with lactose as only carbohydrate)	500 mg/kg
(b) Gum arabic (gum acacia)	100 mg/kg
(c) Silicon dioxide (for vitamin preparations only)	10 mg/kg

---

(d) Mannit (B <sub>12</sub> dry rubbing 0,1 %)	10 mg/kg
(e) Trisodium citrate (B <sub>12</sub> acidic preparation 0,1 %)	260 mg/kg
(f) Citric acid (B <sub>12</sub> acidic preparation 0,1 %)	90 mg/kg