codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/NFSDU 05/27/8**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-seventh Session
Bonn, Germany, 21- 25 November 2005

ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN AT STEP 3[1]

(Prepared by Germany)

Governments and interested international organizations are invited to submit comments or information on the attached document at Step 3 (see Appendix) 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, Fourteenth 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@bmvel.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 **by August 31, 2005.**

BACKGROUND

Due to time constraints the document "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)) has not been discussed in detail during the last session of the CCNFSDU. However, the Committee focused on the following issues raised for discussion by the German Delegation:

1. Should in absence of purity criteria elaborated by JECFA other references for purity criteria be accepted?

   ➔ The Committee agreed that in the absence of purity criteria elaborated by JECFA and/or other recognized international organizations also national requirements could be used. The Delegation of the United States suggested that the identity and purity specifications for food additives accepted by the Commission should be considered.

2. Should the use of nutrient compounds also be indicated for the category of "foods for special medical purposes"?

[1] Prevously considered as the 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).

➔ The Committee agreed to allow the use of these substances for foods for special medical purposes, therefore decided to delete the square brackets around the column containing FSMP.

3. Should food additives for nutrient carriers be included again?

➔ The Committee agreed to reintroduce the table containing additives used for special vitamin form carriers and to keep it only for the purpose of nutrient carriers. However, it 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 Delegation of the United States proposed to support establishment by the CCFAC of an additive functional class for nutrient carriers.

The Committee also agreed to change the title of the document to read:

"Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children".

On the basis of written comments and comments brought up at the 26th session and in view of the comments received from Cuba, EC, Norway, South Africa, Switzerland, USA as well as DSM Nutritional Products and ISDI, Germany made the following modifications:

- In accordance with the criteria 2.2 approved by the CCNFSDU, all nutrient compounds, for which no internationally (or nationally) recognised purity requirements exist, have been removed from the lists (a separate table listing all those compounds is attached at the end).

  However, with respect to the criteria under 2.1, Germany wants to draw the Committee's attention to the fact that there seems to be a misinterpretation of the idea behind the term "purity requirements":

  Some of the nutrient compounds removed from the Lists because of lacking purity requirements are actually included in EC legislation. Therefore, Switzerland, EC and ISDI requested that those compounds also be added to the Lists. But, even though all nutrient compounds listed in annex II of directive 2001/15/EC are deemed to be safe and appropriate for the intended use as nutrient sources for infants and young children, it is not clear to Germany whether all of them have officially recognised purity requirements. Furthermore, safety evaluations by EFSA are generally based on purity criteria submitted by a petitioner, but this does not mean that the criteria are established in an internationally recognised specification.

  So far, only purity requirements referring to identity and purity of a nutrient compound have been included in the Advisory Lists, with the exception that JECFA does not only elaborate specifications for the identity and purity, but also evaluates the toxicological data and estimates acceptable intakes by humans. Thus, from the point of view of Germany, nutrient compounds that are accepted under EC legislation or that have been evaluated by EFSA should only be included in the Advisory Lists if they meet officially recognised purity requirements.

- The Lists A, B, and C have been extended to foods for special medical purposes (FSMP).

- As proposed by the USA, an additional column has been introduced under purity requirements identifying nutrient compounds for which the Codex Alimentarius Commission has established identity and purity specifications ("purity requirements determined by CAC"). Furthermore, in accordance with this, the criteria in Section 2.1 (c) has been slightly reworded in order to explicitly identify Codex specifications in addition to other internationally recognised specifications and national references.

- Trimagnesium dicitrate" has been removed from List A because the term "Magnesium salts of citric acid" does include all forms of "Trimagnesium dicitrate" ("anhydrous" as well as "9-hydrat", and "14-hydrat").

- The "Advisory List of additives for special vitamin forms" has been reintroduced and revised according to the comments received at the 25th Session.

- Following the recommendation of the USA, "Calcium lactate", "Sodium lactate", and "Potassium lactate" have been changed into the respective L- forms "Calcium L-lactate", "Sodium L-lactate", and "Potassium L-lactate". Consequently, the footnote included in the previous revision of the Advisory List(s) ("Nutrient compounds that should not be used in infant foods, as proposed by the United States during the 24th Session of the CCNFSDU") has been removed.

- The EC points out that L-glutamic acid and L-glutamine should not be permitted for use in infant formula and follow-on formula. This is justified by the general provision indicating that essential amino acids may only be added to improve the quality of the protein. Thus, the indication of permitted use in IF and FUF is kept in square brackets.

APPENDIX

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. 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

➔ The USA suggested that 2.1 (c) be reworded as follows:

(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, ~~are established in an~~ with another 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

➔ DSM argued that it is the manufacturer's responsibility to guarantee the content of the nutrient until the Use-by-Day of the final product, and therefore proposed to remove point 2.1 (d).

(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.

➔ DSM proposed to change the order of the sentences in 2.2 to read:

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.

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

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[2]	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
1. Source of Calcium (Ca)							
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	√	√	√	√	√
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	√	√	√	√	√
Other calcium compounds proposed for inclusion:							

[2] CAC = Codex Alimentarius Commission

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[2]	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
Malaysia: [1.12 Calcium pyrophosphate]	√ (2001)	JECFA (1982), FCC	?	?	?	?	?
New Zealand, Malaysia, ISDI: [1.13 Calcium sulphate]	√ (1979)	JECFA (1975), Ph Int, FCC, Ph Eur (dihydrate), DAB, MP	-	-	-	-	[√]
2. Source of Iron (Fe)							
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 Ferric orthophosphate		FCC	?	?	?	?	?
Other iron compounds proposed for inclusion:							

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[2]	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
EU, ISDI: [2.14 Sodium ferric diphosphate]		FCC	-	-	[√]	[√]	[√]
ISDI: [2.15 Ferrous citrate]		FCC	[√]	[√]	[√]	[√]	[√]
New Zealand: [2.16 Ferrous succinate]		MP, MI	?	?	?	?	?
South Africa: [2.17 Ferrous bisglycinate]		JECFA (2003)	?	?	?	?	?
3. Source of Magnesium (Mg)							
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	-	-	-	-	√

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[2]	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
3.12 Magnesium salts of citric acid		USP, DAC	√	√	√	√	√
Other magnesium compounds proposed for inclusion:							
3.13 Magensium carbonate		JECFA (1973), FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
4. Source of Sodium (Na)							
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	√	√	-	-	√
Other sodium compounds proposed for inclusion:							
New Zealand: [4.11 Sodium chloride (iodised)]		USP, Ph Eur, BP, JP	?	?	?	?	?

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[2]	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
New Zealand: [4.12 Sodium sulphate]		JECFA (2000), Ph Int, FCC, USP, Ph Eur, BP, DAB	?	?	?	?	?
New Zealand: [4.13 Sodium tartrate]		JECFA (1963)	?	?	?	?	?
5. Source of Potassium (K)							
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	√	√	-	-	√
6. Source of Copper (Cu)							
6.1 Cupric gluconate (Copper gluconate)		FCC, USP	√	√	√	√	√
6.2 Cupric sulphate (Copper sulphate)	√ (1981)	JECFA (1973), FCC, USP, Ph Eur, DAB	√	√	√	√	√

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[2]	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
7. Source of Iodine (I)							
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	√	√	√	√	√
8. Source of Zinc (Zn)							
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 oxide		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
8.5 Zinc sulphate		FCC, USP, Ph Eur, BP	√	√	√	√	√
Other zinc compounds proposed for inclusion:							
EU, ISDI: [8.6 Zinc carbonate]		BP (hydroxide carbonate)	-	-	-	-	[√]
9. Source of Manganese (Mn)							
9.1 Manganese(II) chloride		FCC	√	√	√	√	√
9.2 Manganese(II) citrate		FCC	√	√	√	√	√
9.3 Manganese(II) glycerophosphate		FCC	-	-	√	√	√
9.4 Manganese(II) sulphate		FCC, USP, Ph Eur (monohydrate)	√	√	√	√	√
9.5 Manganese(II) gluconate		FCC	√	√	√	√	√
10. Source of Selenium (Se)							
10.1 Sodium selenate		MI	√	√	NZ: [√]	-	√
10.2 Sodium selenite		DAC, MP, MI	√	√	NZ: [√]	-	√

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[2]	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
11. Chromium (Cr III)							
11.1 Chromium (III) sulphate		USP, MI	-	-	-	-	√
11.2 Chromium (III) chloride		USP, MI	-	-	-	-	√
12. Molybdenum (Mo VI)							
12.1 Sodium molybdate		Ph Eur (dihydrate), BP, DAB	-	-	-	-	√
12.2 Ammonium molybdate		FCC, USP	-	-	-	-	√
13. Fluoride (F)							
13.1 Sodium fluoride		FCC, USP, Ph Eur, BP, DAB	-	-	-	-	√
Other fluoride compounds proposed for inclusion:							
ISDI: [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

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
1. Vitamin A							
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	√	√	√	√	√

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
2. Provitamin A							
2.1 Beta-Carotene	√ (1991)	JECFA (1987), FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√
Other provitamin A carotenoids proposed for inclusion:							
ISDI: [2.2 Provitamin A other than beta-carotene: [2.2.1 □-apo-8-carotenal]	√ (1991)	JECFA (1984), FCC	[√]	[√]	[√]	[√]	[√]
3. Vitamin D							
3.1 Vitamin D_2 = Ergocalciferol		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√
3.2 Vitamin D_3 = Cholecalciferol		Ph Int, FCC, USP, Jap Food Stan, BP, DAB	√	√	√	√	√
4. Vitamin E							
4.1 D-alpha-Tocopherol	√ (2001)	JECFA (2000), FCC, USP, Ph Eur	√	√	√	√	√
4.2 DL-alpha-Tocopherol	√ (1989)	JECFA (1986), FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√
4.3 D-alpha-Tocopheryl acetate		FCC, USP, Ph Eur	√	√	√	√	√
4.4 DL-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur, BP	√	√	√	√	√
Other tocopheryl compounds proposed for inclusion:							
ISDI, EU, New Zealand: [4.5 D-alpha-Tocopheryl acid succinate]		FCC, NF	-	-	-	-	[√]

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
5. Vitamin C							
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	√	√	√	√	√
5.4 Sodium-L-ascorbate		JECFA (1973), FCC, USP, Ph Eur, Ph Franc, Jap Food Stan, DAC	√	√	√	√	√
6. Vitamin B_1							
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_2							
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	√	√	√	√	√
8. Niacin							
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	√	√	√	√	√

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	**international and/or national bodies**	**IF**	**FUF**	**PCBF**	**CBF**	**FSMP**
9. Vitamin B_6							
9.1 Pyridoxine hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√
10. Folic acid							
10.1 N-Pteroyl-L-glutamic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√
11. Pantothenic acid							
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/ DL-Panthenol		FCC, USP, Ph Eur	√	√	√	√	√
12. Vitamin B_{12}							
12.1 Cyanocobalamin		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
12.2 Hydroxocobalamin		Ph Int, USP, NF, Ph Eur (hydrochloride)	√	√	√	√	√
13. Vitamin K_1							
13.1 Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/ Phylloquinone/ Phytonadione)		Ph Int, FCC (vitamin K), USP, Ph Eur, BP	√	√	√	√	√
14. Biotin							
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

Nutrient Source	Purity Requirements		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national	IF	FUF	PCBF	CBF	FSMP
1. Amino acids[3]							
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-Leucine		FCC, USP, Ph Eur, DAB					√
1.11 L-Lysine		USP					√
1.12 L-Lysine monohydrochloride		FCC, USP, Ph Eur, DAB					√
1.13 L-Methionine		Ph Int, FCC, USP, Ph Eur, DAB					√
1.14 L-Phenylalanine		FCC, USP, Ph Eur					√
1.15 L-Threonine		FCC, USP, Ph Eur, DAB					√
1.16 L-Tryptophan		FCC, USP, Ph Eur, DAB					√
1.17 L-Tyrosine		FCC, USP, Ph Eur, DAB					√
1.18 L-Valine		FCC, USP, Ph Eur, DAB					√

[3] ISDI proposed to add the following footnote: "As far as applicable, also the sodium, potassium calcium and magnesium salts of the amino acids as well as their hydrochlorides may be used."

Nutrient Source	Purity Requirements		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national	IF	FUF	PCBF	CBF	FSMP
Other amino acids and their derivatives proposed for inclusion:							
ISDI: 1.19 L-Alanine		FCC, USP, Ph Eur, DAB	-				√
1.20 L-Arginine L-aspartate		FP	-				√
1.21 L-Aspartic acid		FCC, USP, Ph Eur	-				√
1.22 L-Citrulline		USP, DAC	-				√
1.23 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur	ISDI:[√]	ISDI:[√]			√
1.24 L-Glutamine		FCC, USP, DAB	ISDI:[√]	ISDI:[√]			√
1.25 Glycine		FCC, USP, Ph Eur	-				√
1.26 L-Proline		FCC, USP, Ph Eur, DAB	-				√
1.27 L-Serine		USP, Ph Eur, DAB	-				√
1.28 N-Acetyl-L-cysteine		USP, Ph Eur, DAB	-				√
1.29 N-Acetyl-L-methionine		FCC	-				√ except infants
2. Carnitine							
2.1 L-Carnitine		FCC, USP, Ph Eur	√	√	ISDI: [√]	ISDI: [√]	√
Other carnitine compounds proposed for inclusion:							
ISDI: [2.2 L-Carnitine tartrate]		FCC, Ph Eur	-	-	-	-	√
3. Taurine							
3.1Taurine		USP, JP	√	ISDI:[√]	-	-	√
4. Choline							
4.1 Choline chloride		FCC, DAC, DAB	√	√	√	√	√
4.2 Choline citrate		NF	√	√	√	√	√
4.3 Choline hydrogen tartrate		DAB	√	√	√	√	√

Nutrient Source	Purity Requirements		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national	IF	FUF	PCBF	CBF	FSMP
4.4 Choline bitartrate		FCC, NF, DAB	√	√	√	√	√
Other compounds proposed for inclusion:							
ISDI: 4.5 Lecithin		JECFA (1993), FCC	√	√	√	√	√
5. Myo-Inositol (=meso-Inositol)]		FCC, DAC	√	√	√	√	√
6. Nucleotides							
6.1 Guanosine 5-monophosphate (GMP)		JECFA (1985)	√	ISDI:[√]	-	-	√
6.2 Inosine 5-monophosphate (IMP)		JECFA (1974)	√	ISDI:[√]	-	-	√

LIST OF NUTRIENT COMPOUNDS THAT LACK OFFICIAL PURITY REQUIREMENTS

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
LIST A:							
[Calcium citrate malate]	?	?	-	-	-	-	[√]
[Calcium enriched yeast]	?	?	-	-	-	-	[√]
[Calcium pyruvate monohydrate]	?	?	-	-	-	-	[√]
[Cupric carbonate]	?	?	[√]	[√]	[√]	[√]	[√]
[Cupric citrate]	?	?	[√]	[√]	[√]	[√]	[√]
[Copper-lysine-complex]	?	?	[√]	[√]	[√]	[√]	[√]
[Sodium iodate]	?	?	-	-	[√]	[√]	[√]
[Zinc citrate]	?	?	[√]	[√]	[√]	[√]	[√]
[Zinc lactate]	?	?	[√]	[√]	[√]	[√]	[√]
[Manganese(II) carbonate]	?	?	[√]	[√]	[√]	[√]	[√]
[Sodium hydrogen selenite]	?	?	ISDI: [√]	ISDI: [√]	ISDI: [√]	ISDI: [√]	[√]
ISDI: [Selenium enriched yeast]	?	?	-	-	-	-	[√]
ISDI: [Chromium enriched yeast]	?	?	-	-	-	-	[√]
[Potassium fluoride]	?	?	-	-	-	-	[√]

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
LIST B:							
New Zealand: [Cholecalciferol cholesterol]	?	?	?	?	?	?	?
[DL-alpha-Tocopheryl acid succinate]	?	?	-	-	-	-	[√]
[DL-alpha-Tocopheryl polyethylene glycol 1000 succinate]	?	?	-	-	-	-	[√]
[Potassium-L-ascorbate]	?	?	[√]	[√]	[√]	[√]	[√]
[Pyridoxal 5-phosphate]	?	?	[√]	[√]	[√]	[√]	[√]
[Pyridoxal dipalmitate]	?	?	[√]	[√]	[√]	[√]	[√]
Malaysia: [Pyridoxamine]	?	?	?	?	?	?	?
LIST C:							
[L-Isoleucine hydrochloride]	?	?					[√]
[L-Leucine hydrochloride]	?	?					[√]
[L-Lysine acetate]	?	?	ISDI: [√]	ISDI: [√]	ISDI: [√]	ISDI: [√]	[√]
[L-Lysine L-Aspartate]	?	?	-				[√]
[L-Lysine L-Glutamate dihydrate]	?	?	-				[√]
[L-Ornithine]	?	?	-				[√]
[S-Adenosyl-L-methionine]	?	?	-				[√] except infants
[L-Carnitine hydrochloride]	?	?	[√]	[√]	ISDI: [√]	ISDI: [√]	[√]
[Choline]	?	?	[√]	[√]	[√]	[√]	[√]
[Cytidine 5-monophosphate (CMP)]	?	?	[√]	ISDI: [√]	-	-	[√]
[Cytidine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]
[Uridine 5-monophosphate (UMP)]	?	?	[√]	ISDI: [√]	-	-	[√]
[Uridine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]
[Adenosine 5-monophosphate (AMP)]	?	?	[√]	ISDI: [√]	-	-	[√]
[Adenosine 5-monophosphate sodium	?	?	[√]	ISDI: [√]	-	-	[√]

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
salt]							
[Guanosine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]
[Inosine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]
ISDI: [Creatine monohydrate]	?	?					[√]

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL VITAMIN FORMS

It has been proposed to replace "vitamin" by "nutrient" to read:

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT 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.

ISDI and Switzerland have proposed that the introductory paragraph be amended to read:

➔ 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 <u>following</u> ~~edible materials and the additives included~~ <u>substances permitted</u> in the ~~respective~~ <u>specific</u> Codex standard <u>respectively</u> may be used:

	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	Mannit (B_{12} dry rubbing 0,1%)	10
(e)	331iii	Trisodium citrate (B_{12} acidic preparation 0,1%)	260
(f)	330	Citric acid (B_{12} acidic preparation 0,1%)	90
		Costa Rica:	
(g)		Fish gelatine	

	INS no.	Additive/ Carrier	Maximum Level in Ready-to-use Food [mg/kg]
(h)		Bovine gelatine	
(i)		Ethylcellulose	
(j)		Glycyl tristearate	
(k)		BHA/BHT	
(l)		Peanut oil	
(m)		Saccharose (in formulae with lactose as only carbohydrate)	10
	1400-1451	Modified starches (as included in the Supplementary List to section 5.1, Codex alimentarius Volume 1)	100
		Switzerland:	100
	1450	Starch sodium octenyl succinate	
		EC:	75
(p)	301	Sodium L-ascorbate (in coatings of nutrient preparations containing PUFAs)	

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 Republica Italiana
JP = The Pharmacopeia of Japan
Jap Food Stan = Japanese Food Standard
MI = Merck Index
MP = Martindale Pharmacopoeia
NF = The National Formulary (USA)
ÖAB = Österreichisches Arzneibuch
Ph Eur = Pharmacopoeia Europaea
Ph Franç = Pharmacopée Française
Ph Helv = Pharmacopoeia Helvetica
Ph Int = International Pharmacopoeia
USP = The United States Pharmacopoeia