

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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ORGANIZATION



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Agenda Item 8

CX/NFSDU 00/8
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Twenty-second Session

Berlin, Germany, 19-23 Juni 2000

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)

- Comments at Step 3 of the Procedure-

Comments from:

BRAZIL
CUBA
GERMANY
KOREA, REPUBLIC OF
MALAYSIA
NORWAY
PARAGUAY
POLAND
SINGAPORE
SOUTH AFRICA
SPAIN
UNITED KINGDOM

IDF/FIL -INTERNATIONAL DAIRY FEDERATION

BRAZIL

We are favorable to the integral text of the CL 1999/21-NFSDU.

CUBA

We have been informed by the competent national authorities that the Republic of Cuba has no objections to the proposed draft of the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children.

GERMANY

1. Germany supports the proposal to revise this list.
2. However, **some basic changes** will become **necessary** due to this revision.

They concern

- a) the **objective** of this list, i.e. its title;
- b) its **structure**;
- c) the **choice of nutrients**;
- d) the **purity requirements**;
- e) the **use in foods** to be indicated respectively.

3. The **objective**, i.e. the **title** of the list has to be adapted accordingly.

Justification: The objective of this list was and is to indicate compounds which may be added to foods intended for infants and children for nutritional purposes. Due to the latest findings and provisions e.g. in the Draft Amendment on the Standard for Infant Formula, these compounds do no longer only comprise vitamins and mineral salts, but also substances such as amino acids and related compounds, nucleotides and possibly long-chain, highly unsaturated fatty acids.

Thus the German proposal already takes into consideration amino acids, carnitine and taurine.

The question as to whether requirements should be formulated for long-chain, highly unsaturated fatty acids of the n-6 and n-3 series has to be discussed at the Codex Committee on Nutrition and Foods for Special Dietary Uses.

Proposal on a new title: *Advisory Lists for Nutrient Compounds for Use in Foods for Infant and Children*

4. Germany proposes the following structure of the lists:
 - **A: advisory list of mineral and trace element compounds**
 - **B: advisory list of vitamin compounds**

- **C: advisory list of amino acids and other nutrients**
- **D: advisory list on food additives for special nutrient forms** (vitamins)

5. The **choice of nutrient compounds** is done on the basis of provisions applicable in the European Union for infant formula and follow-up formula as well as for additional food and which are included in the respective individual directives.

In future, this list could possibly be enlarged by adding further nutrient compounds, which become necessary, e.g. in balanced diets (foods for special medical purposes) for infants and young children, e.g. dispensable amino acids.

The Advisory List applicable thus far explicitly includes **source of chloride** and **source of phosphorus**. It should be discussed whether these data are necessary. The compounds mentioned are all indicated as sources of other mineral salts and trace elements, except for hydrochloric acid and phosphoric acid. We hold the view that probably **hydrochloric acid** and **phosphoric acid** as well as **potassium** and **sodium hydroxide** are mainly used for pH adjustment, i.e. for **technological purposes** and not for the supply of nutrients. We therefore suggest to put "source of phosphorus" and "source of chloride" **in square brackets**.

The **nomenclature** of the International Union of Pure and Applied Chemistry (**IUPAC**) should be used for the nutrient compounds and for the purpose of exact **identification** the numbers of the European Inventory of Existing Chemical Substances (**EINECS**) or of the Chemical Abstract Service (**CAS**) should also be indicated in a separate column.

With regard to the mineral salts the following proposals are made:

Calcium	1.11	Calcium sulphate should be deleted and the individual calcium phosphates should be indicated.
Iron	4.1	Ferrous (II) carbonate, stabilized with saccharose should be indicated.
	4.2	Ferrous (II) citrate should be deleted because of missing purity requirements
	4.6	Ferrous (II) succinate should be deleted.
	4.10	Ferric (III) gluconate should be deleted
Magnesium	5.1	Magnesium carbonate should be replaced by magnesium hydroxide carbonate.
	5.6	Trimagnesium dicitrate should be included in the list as well as magnesium gluconate, magnesium glycerophosphate, magnesium hydroxide and magnesium lactate.
Sodium	6.11	Sodium sulphate and
	6.12	sodium tartrate should be deleted. Sodium hydroxide should be included in the list.
Potassium		Potassium lactate should be included in the list.
Iodine		Sodium iodate should be included in the list.
Zinc		Zinc citrate, zinc lactate and zinc gluconate should be included in the list.
Manganese		Manganese gluconate and manganese glycerophosphate should be included in the list.

Selenium Sodium selenate and sodium selenite should be included in the list.
The numbering has been changed according to the proposals.

The following items of the list of admissible vitamin compounds should be changed:

Vitamin A Retinyl propionate should be deleted.

Vitamin D Cholecalciferol-cholesterol should be deleted.

Vitamin E d-alpha-tocopheryl succinate and dl-alpha tocopheryl succinate should be deleted.

Vitamin B₆ Pyridoxal 5-phosphate and pyridoxal dipalmitate should be included in the list.

Pantothenic acid Sodium-D-pantothenate should be included in the list.

Vitamin C Potassium-L-ascorbate should be included in the list.

Furthermore, it is proposed to include **choline** and **inositol** in advisory **list C** for amino acids and other nutrients. Thus far the draft amendment for the standard on infant formula has not explicitly stipulated the addition of nucleotides. Further to the indispensable and partially indispensable amino acids which may be added to improve the protein quality we propose to also include **carnitine** and **taurine**.

The **additives** needed for **technological reasons** for the manufacture of useable **preparations of certain vitamins** are furthermore mannitol, trisodium citrate and citric acid.

6. **Purity requirements**, if available, are indicated in this proposal with the abbreviation of their respective source.
7. In the present advisory list for mineral salts the admissible **intended use** has been respectively indicated. However, in this context, there are names and differentiations which cannot be systematically derived from the Codex Standards or Guidelines and/or which have not been defined there.

Therefore, the following **scope** is suggested:

- **breast milk substitutes** (infant formula) (**IF**)
- **follow-up foods** (**FUF**)
- **additional foods** both cereal-based (**PCBF**) as well as others (**CBF**) (in the Codex "canned, baby food", Codex-Stan 73-1981)
- **infant milk** (toddlers milk; **TM**)
- **balanced diets** (foods for special medical purposes **FSMP**)
- **oral rehydration solutions** (**ORS**) (these are partially identified as pharmaceutical products)
- where necessary **dietary supplements** for infants and young children (**DS**).

8. A proposal for a **revised version of the Advisory Lists** is submitted below:

This list shall be preceded by a **preamble**: *"These lists include nutrient compounds which may be used for nutritional purposes in dietary foods for infants and young children. When they are used, the criteria for their composition stipulated in the respective standards shall be observed"*.

Advisory lists of nutrient compounds for use in foods for infants and children

A: Advisory list of mineral salts and compounds for use in foods for infants and children

Salts	Purity Requirements	Use in Foods for Infants and Children*
1. Source of Calcium (Ca)		
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
[2. Source of Phosphorus (P)]		
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

Salts	Purity Requirements	Use in Foods for Infants and Children*
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
[3. Source of Chloride (Cl)]		
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
4. Source of Iron (Fe)		
4.1 Ferrous carbonate, stabilized 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

Salts	Purity Requirements	Use in Foods for Infants and Children*
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
5. Source of Magnesium (Mg)		
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
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 Sulfate	FCC	
6. Source of Sodium (Na)		
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

Salts	Purity Requirements	Use in Foods for Infants and Children*
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
7. Source of Potassium (K)		
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
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
8. Source of Copper (Cu)		
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
9. Source of Iodine (I)		
9.1 Potassium iodide	Ph Eur, USP, FCC	IF; FUF; PCBF; CBF; TM; FSMP; DS

Salts	Purity Requirements	Use in Foods for Infants and Children*
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
10. Source of Zinc (Zn)		
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
11. Source of Manganese (Mn)		
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
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
12. Source of Selenium (Se)		
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 ₂	Ergocalciferol	Ph Eur, USP, FCC, NF
3.2 Vitamin D ₃	Cholecalciferol	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 FCC NF
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 ₁	Thiaminchloride hydrochloride Thiamin mononitrate	Ph Eur, USP, FCC Ph Eur, USP, FCC
7. Vitamin B ₂	Riboflavin Riboflavin-5'-phosphate sodium	Ph Eur, USP, FCC Ph Eur, USP, FCC
8. Niacin	Nicotinicacid amide (Nicotinamide) Nicotinic acid	Ph Eur, USP, FCC Ph Eur, USP, FCC
9. Vitamin B ₆	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 ₁₂	Cyanocobalamin Hydroxocobalamin	Ph Eur, USP, FCC Ph Eur, USP, NF
13. Vitamin K ₁	Phytomenadione (2-Methyl-3- phytyl-1,4-naphthoquinone) (Phylloquinone)	Ph Eur, USP, FCC
14. Biotin	D-Biotin	Ph Eur, USP, FCC

C: Advisory list für amino acids and other nutrients for use in foods for infants and children

1. Source of Amino acids		
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
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
2. L- Carnitine and its hydrochloride	USP	IF; FUF; FSMP; DS
3. Taurine	JP	IF
4. Source of Choline		
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
5. myo-Inositol (=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: Special Vitamin Forms

For reasons of stability and safe handling, some vitamins have to be converted into suitable preparations, e.g. stabilized 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 ₁₂ dry rubbing 0,1 %)	10 mg/kg
(e) Trisodium citrate (B ₁₂ acidic preparation 0,1 %)	260 mg/kg
(f) Citric acid (B ₁₂ acidic preparation 0,1 %)	90 mg/kg

KOREA, REPUBLIC OF

Referring to GL 10, We would like to add 3 items in the Lists.

1. Ferric phosphate

Source : Fe

Government permitting use : Korea, Australia, USA

2. Manganese gluconate

Source : Mn

Government permitting use : Korea, USA, EU

3. Zinc gluconate

Source : Zn

Government permitting use : Korea, USA, EU

MALAYSIA

Advisory list of mineral salts for the use in foods for infants and children

Malaysia would like to propose the addition of the following to the current Advisory Lists Of Mineral Salts :

calcium pyrophosphate, ferric phosphate, sodium pantothenate.

Advisory list of vitamin compounds for use in foods for infants and children

Malaysia would like to propose the addition of the following to the current Advisory Lists Of Vitamin Compounds :

vitamin A alcohol, thiamine, thiamine hydrochloride, D-pantothenic acid, D-pantothenyl alcohol, tocopherols, tocotrienol, pyridoxine, pyridoxal, pyridoxamine.

Special Vitamin Forms

Malaysia is of the view that the title "Special Vitamin Forms" does not reflect the content of the table. We propose to amend the title to "Permitted Stabilizer For Vitamins" or a title of a similar meaning.

NORWAY

General comments on iron compounds used in infants cereals:

The iron compounds used in infant cereals should be of good bioavailability and should not result in increased fat oxidation and changes in colour. Changing in colour is mostly seen in infant cereals with added sourish fruitpowder. Based on scientific knowledge Norway suggest following changes in the column «Use in Foods for Infants and Children»:

4.3 Ferrous fumarate - *add «infant cereals»* (good bioavailability)

4.4 Ferrous succinate - *add «infant cereals»* (good bioavailability)

- 4.11 Sodium ferric pyrophosphate - *add «Not recommended for use in infant cereals»* (low bioavailability)
- 4.12 Hydrogen reduced iron - *delete «infant cereals» and add «Not recommended for use in infant cereals»* (low bioavailability)
- 4.14 Carbonyl iron - *add «Not recommended for use in infant cereals»* (low bioavailability)
- 4.15 Ferric pyrophosphate - *add «Not recommended for use in infant cereals»* (low bioavailability).

PARAGUAY

Paraguay is satisfied with the proposed draft in its current version and has no significant objections regarding this topic.

POLAND

p.2.9 and 3.8

We think that phosphoric acid and hydrochloric acid shouldn't be used in products for infants and children up to 3 years.

p.9

Potassium iodate is using to the salt (NaCl), occasionally to the production of foods for special dietary uses for adults.

Mineral salts and vitamins for use in foods for infants and children should meet requirements of health quality. So we propose to add a list of requirements of health quality to this document.

SINGAPORE

Singapore would also like to recommend that levels of mineral salts and vitamin compounds in foods for infant and children be made flexibel so that individual governments may adjust accordingly, based on the respective nutritional status of infants and children in their countries.

SOUTH AFRICA

We request that the amino acid chelate forms of the following minerals be included in the list:

- Calcium
- Copper
- Iron
- Magnesium
- Manganese

SPAIN

Concerning the list of mineral salts:

We propose the inclusion of the following mineral salts for use in foods for infants and young children:

- **Source of Calcium:** Calcium hydroxide, for cereal-based foods and other foods for infants and young children.
- **Source of Phosphorus:** Iron diphosphate (ferric pyrophosphate), for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
- **Source of Chlorine:** Zinc chloride, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
- **Source of Magnesium:** Magnesium hydroxide, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
Magnesium lactate and magnesium glycerophosphate, for cereal-based foods and other foods for infants and young children.
- **Source of Iron:** Ferrous gluconate, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
- **Source of Sodium:** Sodium hydroxide, for infant and follow-on formulae.
- **Source of Potassium:** Potassium hydroxide, for infant and follow-on formulae.
Potassium lactate and potassium glycerophosphate, for cereal-based foods and other foods for infants and young children.
- **Source of Copper:** Copper-lysine complex, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
- **Source of Zinc:** Zinc lactate, zinc gluconate and zinc citrate, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
- **Source of Manganese:** Manganese gluconate, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
Manganese glycerophosphate, for cereal-based foods and other foods for infants and young children.

- **Source of Thiamin/
Vitamin B₁:** Thiamin hydrochloride, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
- **Source of Vitamin B₆:** Pyridoxine-5-phosphate, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
- **Source of
Pantothenic acid:** Sodium D-pantothenate, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.
- **Choline sources:** Choline citrate, for infant and follow-on formulae as well as for cereal-based foods and other foods for infants and young children.

Concerning the special vitamin forms:

In our opinion the maximum levels for gum arabic (100 mg/kg) and for silicon dioxide (10 mg/kg) are too high. In Spain the maximum level for gum arabic is 10 mg/kg and for silicon dioxide 0.152 mg/kg. We therefore propose reconsidering the proposed levels and analysing the possibility of limiting their use for vitamin E as there is no reference in the literature regarding their use for other vitamins.

We further propose authorising the use of the additives gum arabic and silicon dioxide in weaning foods only.

UNITED KINGDOM

Rules which specify the nutritional substances which may be added to infant formula, follow-on formula and baby foods are harmonised at European Community (EC) level by directives 91/321/EEC (as amended) and directive 96/5/EC (copies enclosed). The UK propose that the Advisory List should be amended to reflect the wider range of vitamin and mineral sources permitted by European legislation. A list of these additional nutritional substances is attached at Annex 1.

The UK requests the following amendments to the Advisory List:

- it is unnecessary to include salts such as calcium chloride twice, as a source of both calcium and chloride. One entry is sufficient, preferably for the first named element i.e. calcium;
- 'Panthenol' should be replaced by 'Dexpanthenol';
- 'Phytlmenaquinone' should be replaced by 'phylloquinone (phytomenadione)';
- the reference to 'thaimin chloride hydrochloride' should be replaced by 'thaimin hydrochloride';
- the use of calcium oxide should be limited to baby foods;
- the reference to 'potassium citrate' is too restrictive and the UK propose that it should be replaced by 'Potassium salts of citric acid';
- for calcium, magnesium, potassium and sodium, the UK would prefer a reference to 'salts of orthophosphoric acid' rather than individual references to the relevant mono- di- and tri-basic forms. The use of the potassium and sodium salts however should be restricted to infant and follow-on formulae only;

- If choline and inositol are to be included in the list they should appear under a separate category entitled OTHERS, and a list of permissible amino acids should be included with them.

The current recommendations for use of individual salts and vitamins are unnecessarily complex. The UK's preferred approach would be to indicate broad categories of products in which these substances may be used, for example:

Salt, Vitamin	Purity Requirement	FOODSTUFF			
		Infant formula	Baby foods	Medical foods	Other
X	FCC	√		√	

ANNEX 1

Table 1: Nutritional substances permitted for addition to foods for infants and young children by EC legislation which are not included in the Codex Advisory List

Salt/Vitamin	Infant Formula and Follow-on formula	Baby foods
VITAMINS		
<i>Vitamin A</i>		
Retinol	√	√
<i>Vitamin B6</i>		
Pyridoxine-5-phosphate	√	√
Pyridoxine dipalmitate		√
<i>Vitamin C</i>		
Potassium ascorbate	√	√
<i>Pantothenic Acid</i>		
D-pantothenate, sodium	√	√
SALTS		
<i>Calcium</i>		
Calcium hydroxide	√	√
<i>Copper</i>		
Copper-lysine complex	√	√
<i>Iodine</i>		
Sodium iodate		√
<i>Iron</i>		
Ferric saccharate		√
<i>Magnesium</i>		
Magnesium gluconate	√	√
Magnesium glycerophosphate		√
Magnesium hydroxide	√	√
Magnesium lactate		√
Magnesium salts of citric acid	√	√
<i>Manganese</i>		
Manganese gluconate	√	√
Manganese glycerophosphate		√

Salt/Vitamin	Infant Formula and Follow-on formula	Baby foods
Potassium		
Potassium lactate	√	√
Potassium hydroxide		
Selenium		
Sodium selenate	√	
Sodium selenite	√	
Sodium		
Sodium hydroxide	√	√
Zinc		
zinc citrate	√	√
Zinc gluconate	√	√
Zinc lactate	√	√
OTHERS		
Choline	√	√
Choline citrate	√	√
L-carnitine	√	√*
L-carnitine hydrochloride	√	√*
L-arginine♣		
L-cystine♣		
L-histidine♣		
L-isoleucine♣		
L-leucine♣		
L-lysine♣		
L-cysteine♣		
L-methionine		
L-phenylalanine		
L-threonine		
L-tryptophan		
L-tyrosine		
L-valine		
cytidine 5'-monophosphate**	√	
uridine 5'-monophosphate**	√	
adenosine 5'-monophosphate**	√	
guanosine 5'-monophosphate**	√	
inosine 5'-monophosphate**	√	

* The addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein present, and only in the proportions necessary for that purpose.

♣ and their hydrochlorides

** and its sodium salts

IDF/FIL -INTERNATIONAL DAIRY FEDERATION

The International Dairy Federation is concerned about the use of dairy terms in the advisory lists of mineral salts and vitamin compounds for use in foods for infants and children (CAC/GL 10-1979 (amended 1983, 1991). The list make uses of the term “milk substitute” in reference to products which do not necessarily contain milk and milk products or which may have some of the milk component replaced by some non-dairy food products and are intended for use in foods for infants and children.

In July 1999, the Codex Alimentarius Commission adopted the General Standard for the Use of Dairy Terms *CODEX STAN 206-1999* (GSUDT). The GSUDT states in its section 4.6 "Use of Dairy Terms for other foods" that the names referred to in section 4.2 "Use of the term milk" and in section 4.5 " Use of terms for composite products" may only be used as names or in the labelling of milk, milk products or composite milk products. In section 4.6, a provision is made for products “the exact nature of which is clear from traditional usage or when the name is clearly used to describe a characteristic quality of the non-milk product”. However, in “respect of a product which is not milk, a milk product or a composite milk product, no label, commercial document, publicity material or any form of point of sale presentation shall be used which claims, implies or suggests that the product is milk, a milk product or a composite milk product, or which refers to one or more of these products”.

The International Dairy Federation would like to assist in finding terms which could accommodate the needs of CCNFSDU in developing standards for products imitating milk and dedicated to specific dietary groups while at the same time respecting Codex decisions in relation to the use of dairy terms, as laid down in the General Standard for the Use of Dairy Terms. The Codex Committee for Nutrition and Food for Special Dietary Uses may also wish to consider consulting the Codex Committee on Milk and Milk Products on that question.