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 02/7-Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-forth Session
Berlin, Germany, 4 - 8 November 2002

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 to the CL 2002/7-NFSDU -

Comments from:

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

ISDI believes that the following nutritional substances should be authorised for use in infant formula (IF), follow-up formula (FUP), processed cereal-based foods (PCBF), canned baby foods (CBF) and foods for special medical purposes (FSMP).

FSMPs play a vital part in the dietary management of those infants and young children who have special nutritional requirements. Products intended for infants and young children not in good health are highly specific and are designed to meet the particular nutritional requirements resulting from a disease, disorder or medical condition. They are designed to be used for the dietary management of infants suffering from a particular disease e.g. pheylketonuria, galactosemia and other inborn errors of metabolism, malabsorption, allergies.

In many cases, the products are used as the only source of nutrition and are, in fact, substitutes for normal food. Thus a full complement of nutrition in the form of carbohydrate, protein, fat, vitamins, minerals and trace elements must be supplied. It is vital that the vitamins and minerals requested by ISDI for use in FSMPs are accepted, to allow the formulation of these much needed products.

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

Nutrient source	**Purity Requirement**	**Use in Food Categories for Infants and Children**
1. Source of Calcium (Ca)		
Calcium citrate malate [1]		**FSMP**
Calcium enriched yeast [1]		**FSMP**
Calcium pyruvate monohydrate [1]		**FSMP**
Calcium sulphate [1]		**FSMP**
Calcium salts of orthophosphoric acid [3,4]		**IF, FUF, PCBF, CBF, FSMP**
2. Source of Iron (Fe)		
Ferric orthophosphate [1, 2]	FCC	**IF, FUF, PCBF, CBF, FSMP**
Ferrous citrate [3,4]		**IF, FUF, PCBF, CBF, FSMP**
Ferric sodium diphosphate [3, 4]		**PCBF, CBF, FSMP**
3. Source of Magnesium (Mg)		
Magnesium salts of orthophoric acid [3, 4]		**IF, FUF, PCBF, CBF, FSMP**
5. Source of Potassium (K)		
Potassium salts of orthophosphoric acid [3,4]		**IF, FUF, FSMP**
8. Source of Zinc (Zn)		
Zinc carbonate [4]		**FSMP**
10. Source of Selenium (Se)		
Sodium hydrogen selenite [5]		**IF, FUF, PCBF CBF**, FSMP
Selenium enriched yeast [1]		**FSMP**
11. Source of Chromium (CrIII)		
Chromium enriched yeast [1]		**FSMP**
13. Source of Fluoride		
Calcium fluoride [1]		**FSMP**

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

Nutrient source	**Vitamin form**	**Purity Requirement**
2. Provitamin A	Provitamin A other than beta-carotene [5]	
4. Vitamin E	D-alpha-tocopheryl acid succinate [4], only FSMP	NF

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

Nutrient source	**Purity Requirement**	**Use in Food Categories for Infants and Children**
1. Amino acids		
1.1 L-arginine and its hydrochlorid to 1.13 L-Valine		**IF, FUF, PCBF, CBF [3],** FSMP Only for improving the nutritional quality of the protein
L-alanine		**FSMP [4]**
L-arginine L-aspartate		**FSMP [1]**
L-aspartic acid		**FSMP [4]**
L-citrulline		**FSMP [4]**
L-glutamic acid		**IF, FUF [6], FSMP [4]**
L-glutamine		**IF, FUF [6], FSMP [4]**
Glycine		**FSMP [4]**
L-lysine acetate		**IF, FUF, PCBF, CBF [1], FSMP [4]**
L-lysine L-aspartate		**FSMP [1]**
L-lysine L-glutamate dihydrate		**FSMP [1]**
L-ornithine		**FSMP [4]**
L-proline		**FSMP [4]**
L-serine		**FSMP [1]**
N-acetyl-L-cysteine		**FSMP [1]**
N-acetyl-L-methionine		**FSMP except infants [1]**
S-adenosyl-L-methionine		**FSMP except infants [1]**
2. L-Carnitine and its hydrochloride		IF, FUF, **PCBF, CBF [3],** FSMP
L-carnitine tartrate		**FSMP [1]**
3. Taurine		IF, **FUF [3],** FSMP
6. Nucleotides		
6.1 Cytidine 5-monophosphate to 6.10 Inosine 5-monophosphate		IF, **FUF [3],** FSMP
X. Creatine monohydrate		**FSMP [1]**

As far as it is applicable, also the sodium, potassium, calcium and magnesium salts as well as their hydrochlorides may be used [4].

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL VITAMIN FORMS

- Not only vitamins need to be converted into suitable preparation but also other nutrients. Therefore, ISDI suggests to reword the Title of section D and the first paragraph into:

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

  *"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***

substances permitted in the specific Codex standard respectively may be used:. ~~*the edible materials and the additives included in the respective Codex standard may be used*~~*."*

- Regarding the list itself, ISDI suggests the following modification:
  - 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:

	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) Mannitol (B12 dry rubbing 0,1%)	*10 mg/kg*
e) Trisodium citrate (B12 acidic preparation 0,1%)	*260 mg/kg*
f) Citric acid (B12 acidic preparation 0,1%)	*90 mg/kg*
g) Saccharose (in formulae with lactose as only carbohydrate)	*10mg/kg*
h) *Modified starches* (as included in the Supplementary List to Section 5.1, Codex Alimentarius Volume 1)	*100 mg/kg*

JUSTIFICATION for the requested uses

[1] Currently under evaluation by the European Scientific Committee on Food. IDACE File 01/083 available on request

[2] 1985 JECFA evaluation for iron phosphate found an ADI of 70 mg/kg body weight/day.

[3] European Directive 91/321/EEC on infant formula and follow-on formula and Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children.

[4] European Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses

[5] Currently under evaluation by the European Scientific Committee on Food. IDACE File 01/015 available on request

[6] Substances present in breast milk, are approved in Infant formula and Follow-up formula in Hong Kong. More data available on request.