codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/NFSDU 02/7**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-forth Session
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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:

COSTA RICA
CUBA
GERMANY
NEW ZEALAND
SWITZERLAND
UNITED STATES OF AMERICA

EUROPEAN COMMUNITY

COSTA RICA

Title: No objections.

Section 1. Preamble: Delete the word "dietary", as it has not been defined in any food standard for infants and young children and would therefore cause confusión. It could be interpreted as if the Advisory List was exclusively intended for weight control diets.

Section 2. Criteria for the inclusion or deletion of nutrient compounds from the Advisory Lists:

Section 2.1: Put the word "sólo" before the word "pueden" so that it reads as follows: "...sólo pueden incluirse en las listas dadas las ...." (*Applies to Spanish version only, the Translator*).

Subparagraphs a, b and d: It should be clarified which organization evaluates the safety, the studies regarding the biological availability and the stability of nutrient sources for infants and young children. There should be an organization that confirms such statements because otherwhise it would not be worthwhile establishing criteria as they would not not be met.

Subparagraph c: This is in contradiction to the document as there are many compounds for which no purity requirements have been established so that they could not be included in the Lists. (List A: 2.1, 2.7, 3.3, 3.7, 3.12, 3.13, 3.14, 4.10, 5.10, 5.11, 6.1, 6.2, 6.4, 8.1, 8.3, 8.5, 9.1, 9.3, 9.6, 10.1, 10.3, 11.1, 11.2, 12.1, 12.2, 13.1, and 13.2, List C: 4.4, 4.5, and 6.1 to 6.10). As far as compounds are concerned for which no purity requirements have been established, we propose to include them in an appendix and indicate this accordingly.

Setion 2.2: It should be indicated who is to express the opinion that substances no longer meet the criteria. In addition, the criteria for the deletion of nutrient compounds should be mentioned or it should be indicated that the respective compounds are deleted because they no longer meet the criteria for their inclusion.

List A. Differences were found between the [current] Advisory List of Mineral Salts for the Use in Foods for Infants and Children and the [proposed] Advisory List of Mineral Salts and Trace Elements for Use in Foods for Infants and Children.

Therefore, it should be clarified, if the criteria used for the inclusion or deletion of compounds are those established in Section 2 of the document, to which the comments made apply.

In some countries, mineral salts such as sodium sulphate and iodized sodium chloride are still used, although have been deleted from the current list. Moreover, iron amino acid chelate and polymaltosed iron are used in our country and in Europe, respectively, in some foods for infants and young children. For that reason we suggest that those compounds be revised in view of their inclusion in the List or that the reasons be given why they are not included.

In the compound 4.7 potassium is to be replaced by sodium because Section 4 refers to sources of sodium (Na). (*Applies to Spanish version only, the Translator*)

List B. Differences were found between the [current] Advisory List of Vitamin Compounds for Use in Foods for Infants and Children and the [proposed] Advisory List of Vitamin Compounds for Use in Foods for Infants and Children.

Therefore, it should be clarified if the criteria used for the inclusion and deletion of compounds are those established in Section 2 of the document, to which the comments made apply.

As regards the compounds which are sources of Vitamin K the name 2-Methyl-3-phytyl-1,4-naphthoquinone should be corrected as follows: 3-phytyl should be deleted so that the name reads 2-Methyl-1,4-naphthoquinone.

Furthermore, the categories of foods in which the compounds may be used are not indicated (although they are indicated in the current lists). It should, however, be made clear that the substances included in this List may be used in all categories of foods for infants and young children.

List C. In the current document purity requirements are indicated for the sources of choline. Such requirements are, however, not indicated in the proposed list. We therefore ask that it be revised.

List D. Given the fact that at present some vitamins are stabilized with tocopherols, the latter should be mentioned in List D or it should be clarified if it is sufficient for them to be mentioned in List B as permitted substances.

Moreover, other coating agents are used which are not included in the List, e.g. fish gelatine, bovine gelatine, EC: ethylcellulose, FC: glyceryl tristearate, SC: silicone, BHA/BHT (as stabilizer) and peanut oil (as stabilizer). We therefore ask that these special forms be revised in order to evaluate the possibility to include them in the list.

CUBA

1. We agree with the proposed new title as it mentioned in the document.
2. We approve the criteria for the inclusion or deletion of nutrient compounds from the advisory lists proposed in the document.
3. We agree with the proposal for the inclusion of the substances indicated in Lists A, B and C. We will go on analysing the aspects regarding the purity requirements and their feasibility for use in foods for infants and children, given the fact that, for lack of time, we have not yet been able to obtain the opinion of all investigators who are working on these aspects.

GERMANY

2. CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS

2.1 (b):

This sentence should read as follows:

"it is demonstrated by appropriate studies in animals and/or humans that the substances are of **suitable biological availability**"

Reason: The meaning of "biologically available" is not clear. In the present case, one might even understand that the biological availability is 1%.

2.1 (d):

This sentence should be changed as follows:

"**the** stability" is to be replaced by "**an adequate** stability".

Reason: "an adequate" should be added, because test conditions have not been specified for the determination of stability, neither have any precise statements been made regarding any permissible deviations of nutrient levels.

NEW ZEALAND

1. Advisory list of mineral salts and trace elements for use in foods for infants and children:

Point 1: Please add calcium sulphate to the list.

Point 2: Please add ferrous succinate.

Point 4: Please add sodium chloride (iodised), sodium iodide, sodium sulphate and sodium tartrate to the list.

Point 10: Selenium: we propose that the scope be expanded to include PDBF (processed cereal based food) for sodium selenate and sodium selenite.

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

For clarification purposes, we propose including a statement that vitamin compounds are permitted in all categories.

Please add cholecalciferol cholesterol to the list.

Please add d α tocopheryl succinate and dl α tocopheryl succinate to the list.

3. Advisory list of amino acids and other nutrients for use in the foods for infants and children

Point 4: Taurine – propose that the scope should be expanded to include Follow-up Formula (FUF) as well as Infant Formula (IF).

Point 6: Nucleotides – propose that the scope should be expanded to include FUF as well as IF.

SWITZERLAND

GENERAL COMMENTS

1. Switzerland supports the new title proposed in CL 2002/7-NFSDU i.e. Advisory Lists of Nutrient Compounds.
2. Furthermore, we also agree with the proposal to include lists on nutrients other than minerals and vitamins, i.e. amino acids (preferably a separate list), and other nutrients.
3. Switzerland also supports the inclusion on the list of substances with approved specifications (purity criteria). These specifications should be according to the following criteria:
    a) food uses
    b) medicinal preparations
    c) global, regional or of national reference. Therefore, preference should be given to specifications adopted by FAO/WHO (JECFA), the International Pharmacopoeia, FCC, USP, Ph Eur, Japanese Food Standard.
4. Switzerland would like to encourage the CCNFSDU to harmonise with other Codex Standards, and in particular with the Codex General Standard on Food Additives, the designation of the nutrient compounds. This will indeed avoid having different descriptors for the same substances thereby leading to uncertainties and confusion as regards these substances.
5. We would like to draw your attention to the fact that the Ph Eur is missing from the list of Abbreviations given on Page 8 of the CL 2002/7-NFSDU.

SPECIFIC COMMENTS

ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN (Letter B, page 5, CL 2002/7-NFSDU)

6. The order of the purity criteria has been rearranged in order to bring it in line with the criteria outlined in our comments (see point 3 above) i.e. food specifications preceding those for medicinal preparations, whereas global specifications precede the regional and national ones.
7. We would like to propose the deletion of the following compounds due to the fact that they lack official purity criteria: Potassium L-ascorbate, all Pyridoxal Derivatives. There is the special case of Sodium D-pantothenate which is only found in the Japanese Food Standard.
8. In the Annex to these comments, we have attached an amended Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (***see Annex***). We have included references to the International Pharmacopoeia published by the WHO, Geneva, Switzerland. These are specifications which are intended for medicinal preparations parallel to the monographs for food uses as adopted by FAO/WHO. Volume 5 of the International Pharmacopoeia, which will soon be published, may include additional monographs.
9. We would like to draw to your attention a possible editorial error: for Vitamin B6, the compound "pyridoxal hydrochloride" should probably read "pyridoxine hydrochloride".

ADVISORY LIST OF FOOD ADDITIVES/CARRIERS FOR SPECIAL VITAMIN FORMS (Letter D, page 8, CL 2002/7-NFSDU)

10. It is our understanding that Part D of the Advisory List of Food Additives relates to specified use of food additives and carriers that need to be permitted specifically for special vitamin forms or for which a Maximum Level needs to be set in Ready-to-Use Foods for Infants and Children. However, the current wording of the leading paragraph under D is not easily understandable and therefore, it might lead to misunderstandings or misinterpretations. We would therefore like to propose that the following sentence be

included at the end of that paragraph: "In addition, the following food additives/carriers are permitted". We need to use the term Carriers in addition since Maltodextrins aren't food additives.

11. The INS numbers of the different food additives should be included:

INS no.	Additive/Carrier	Maximum Level in Ready-to-use Food
	Maltodextrins (in formulae with lactose as only carbohydrate)	500 mg/kg
414	Gum Arabic (gum acacia)	100 mg/kg
551	Silicon Dioxide (for vitamin preparations only)	10 mg/kg
421	Mannitol (B12 dry rubbing 0,1%)	10 mg/kg
331iii	Trisodium Citrate (B12 acidic preparation 0,1%)	260 mg/kg
330	Citric Acid (B12 acidic preparation 0,1%)	90 mg/kg

12. We would like to propose the inclusion of Starch Sodium Octenyl Succinate INS no. 1450 with a Max. level of use of 100 mg/kg in the ready-to-use food, in the Advisory List of Food Additives for Special Vitamin Forms. This additive is indeed used as a carrier in some vitamin compounds.

ANNEX

Amended Advisory List of Vitamin Compounds for Use in Foods for Infants and Children

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

Vitamin	VITAMIN FORM	FAO/WHO	Intern Ph	FCC	USP	Ph Eur	Jap Food Stan	Other
1. Vitamin A	all-trans Retinol			FCC	USP	Ph Eur		
	Retinyl acetate			FCC	USP	Ph Eur	Jap Food Stan	
	Retinyl palmitate			FCC	USP	Ph Eur	Jap Food Stan	
2. Provitamin A	beta-carotene	FAO/ WHO		FCC	USP	Ph Eur	Jap Food Stan	
3. Vitamin D								
3.1 Vitamin D2	Ergocalciferol		Int Pharm	FCC	USP	Ph Eur	Jap Food Stan	
3.2 Vitamin D3	Cholecalciferol (Colecalciferol)		Int Pharm	FCC	USP	Ph Eur	Jap Food Stan	
4. Vitamin E	D-alpha Tocopherol (concentrate)	FAO/WHO		FCC	USP	Ph Eur		
	DL-alpha Tocopherol	FAO/WHO		FCC	USP	Ph Eur	Jap Food Stan	
	D-alpha Tocopheryl acetate			FCC	USP	Ph Eur		
	DL-alpha Tocopheryl acetate			FCC	USP	Ph Eur		
5. Vitamin C	L-Ascorbic acid	FAO/WHO	Int Pharm	FCC	USP	Ph Eur	Jap Food Stan	
	Calcium L-ascorbate	FAO/WHO		FCC	USP	Ph Eur		
	Potassium L-ascorbate1							
	Sodium L-ascorbate	FAO/WHO		FCC	USP	Ph Eur	Jap Food Stan	
	6-Palmitoyl-L-ascorbate (Ascorbyl palmitate)	FAO/WHO		FCC	USP/NF	Ph Eur	Jap Food Stan	
6. Vitamin B1	Thiaminchloride hydrochloride		Int Pharm	FCC	USP	Ph Eur	Jap Food Stan	
	Thiamin mononitrate		Int Pharm	FCC	USP	Ph Eur	Jap Food Stan	
7. Vitamin B2	Riboflavin	FAO/WHO	Int Pharm	FCC	USP	Ph Eur	Jap Food Stan	
	Riboflavin-5'-phosphate sodium	FAO/WHO		FCC	USP	Ph Eur	Jap Food Stan	
8. Niacin	Nicotinic acid amide (Nicotinamide)		Int Pharm	FCC	USP	Ph Eur	Jap Food Stan	
	Nicotinic acid		Int Pharm	FCC	USP	Ph Eur	Jap Food Stan	
9. Vitamin B6	Pyrodixin hydrochloride		Int Pharm	FCC	USP	Ph Eur	Jap Food Stan	
	Pyridoxal hydrochloride[1]							
	Pyridoxal 5-phosphate[1]							
	Pyridoxal dipalmitate[1]							
10. Folic acid	N-Pteroyl-L-glutamic acid			FCC	USP	Ph Eur	Jap Food Stan	
11. Pantothenic acid	Calcium-D-pantothenate			FCC	USP	Ph Eur	Jap Food Stan	
	Sodium-D-panthotenate						Jap Food Stan	
	D-Panthenol (* DL-Panthenol, ** Dexpanthenol)			FCC	USP *	Ph Eur**		
12. Vitamin B12	Cyanocobalamin			FCC	USP	Ph Eur		
	Hydroxocobalamin				USP	Ph Eur		
13. Vitamin K1	Phytomenadione (2-Methyl-3phytyl-1,4-naphtoquinone) (Phylloquinone)			FCC	USP	Ph Eur		
14. Biotin	D-Biotin			FCC	USP	Ph Eur		

1 No official purity criteria could be found; therefore should be deleted

UNITED STATES OF AMERICA

GENERAL COMMENTS

Sections to be included in the advisory list. We support the inclusion of sections that provide for a preamble and listing of criteria with this advisory list. We also support the addition of a section to identify the scope of foods and substances to be covered by this list.

Scope of foods to be covered by the advisory list. We do not recommend that this advisory list include the category of "Foods for Special Medical Purposes" until such time as a standard would be under consideration by the CCNFSDU. This food category was not included in the 1991 advisory list. Also, unlike the other food categories referenced in this advisory list, there is no Codex standard for foods for special medical purposes. Furthermore, the users of these products are not limited to infants and young children.

Process for safety evaluations for nutrient compounds. We recommend that the Committee consider a systematic, science-based process and/or criteria for reviewing the scientific evidence for the safety and suitability of nutrient compounds that are used in the manufacture of foods for infants and young children. We note that JECFA does not routinely evaluate the safety of nutrient compounds.

SPECIFIC COMMENTS

Proposal for a new title for the advisory list:

We suggest that the title be revised as follows:

> ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR **USE AS NUTRIENT SOURCES** ~~THE USE IN~~ IN FOODS FOR INFANTS AND **YOUNG** CHILDREN
>
> We suggest adding "as nutrient sources" to clarify that the advisory list is for compounds that are to be used for nutritional purposes as opposed to food additive uses.
>
> We suggest saying "…Young Children" in lieu of "Children". This change would appear to be consistent with introductory text in Sections 1 and 2 of the draft revision, and consistent with the food categories cited in the tables.

1. PREAMBLE

We suggest revising the text as follows:

> "These lists include nutrient compounds, which may be used for nutritional purposes in ~~dietary~~ foods for 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.** ~~When they are used, the criteria for their composition stipulated in the respective standards shall be adhered to.~~ **As noted in the respective standards, their use may either be essential or optional.**

SCOPE *(new)*

We propose adding a new section to address the scope of this advisory list with regard to both foods and substances. For example:

> **The nutrient compounds in these lists apply to one or more of the following food categories and their respective Codex standards: infant formula (IF), follow-up formula (FUF), Processed-Cereal Based Foods for Infants and Young Children (PCPF), and Canned Baby Food (CBF).**
>
> **The nutrient compounds include mineral salts and trace elements, vitamin compounds, and amino acids, and other nitrogenous compounds.**

2. CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS

We propose slightly revising this title to say, "Criteria for the Inclusion of Nutrient Compounds in the Advisory Lists".

2.1 (a)

We recommend revising the text in 2.1(a) as follows:

(a) they are shown to be safe and appropriate **for the intended use, including** as nutrient sources for infants and young children.

Rationale: We have added "for the intended use" to encompass a range of considerations, including intended use levels.

2.2

We recommend adding the following statement:

Substances shall be deleted from the Lists if they are found no longer to meet the above criteria. **Substances may also be added to the lists based on the above criteria.**

Tables A, B, and C:

Food Categories:

We recommend that all references to the category of Foods for Special Medical Purposes (FSMP) be removed from the tables, consistent with our comments on the scope of foods to be covered by this advisory list.

Titles:

We recommend revising the titles to refer to "infants and **young** children", which would be consistent with the introductory text for this advisory list.

We also suggest the following change in the title of Table C:

"….amino acids and other **nitrogenous compounds** ~~nutrients~~…"

Identification of Nutrient Sources:

Some of these nutrient compounds are also used as food additives, and have INS numbers. Would it be useful to include the INS numbers for these compounds in this advisory list?

Abbreviations:

We note that the abbreviation "Ph Eur" is identified in the column on "Purity Requirements" but that this is not included in the section on Abbreviations at the end of this advisory list. We therefore suggest that this be added to this section.

Table A Specific Comments:

calcium lactate, sodium lactate and potassium lactate. We note that JECFA has assigned an ADI for these compounds, but includes in their comments that "Neither D(-)-lactic acid nor (DL)- lactic acid should be used in infant foods". Thus, we recommend that the forms of the above compounds that may be used in infant foods be clarified in this advisory list, either in the listing of the nutrient source or in a footnote.

Table B. Specific Comments

If the intent is that these vitamin compounds be permitted in all food categories for infants and young children, then we recommend that this be stated.

Table C. Specific Comments

In the listing of the amino acids, we recommend that the phrase "only for improving the nutritional quality of the protein" be clarified as follows: "only for improving the nutritional quality of the protein **when the protein is nutritionally inadequate for its intended use".**

Table D. Specific Comments

We recommend that this table be deleted. Among other things, it is beyond the scope of this advisory list which is intended to address nutrient compounds that are used for nutritional purposes (as opposed to food additive uses). These compounds should be covered under the food additive provisions in the respective food standards.

EUROPEAN COMMUNITY

General comments

The EC supports the extension of the lists from mineral salts and vitamin compounds to other nutrient compounds.

The EC supports the simplification of the categories of foods to reflect the foods for which Codex standards or Guidelines exist. It is noted that at the 23rd Session of the Committee there was an extensive debate on whether or not the draft infant formula standard should only cover infant formula intended for healthy infants. The EC considers that the draft standard should only apply to infant formula produced for healthy infants while formulae intended for infants with special medical requirements should be covered by the Codex Standard on Food for Special Medical Purposes. In that case additional nutrient compounds will need to be considered for inclusion in the lists. The EC proposals regarding additional substances for use in FSMP are included in the following comments on the individual lists.

A final general comment is that the presentation of the different lists should, as far as possible, be consistent. It would be easier to see in which foodstuffs a substance can be used if the different categories where shown in columns. A proposed format is included as an annex to this document.

Title

The proposed new title is supported.

Section 2

There is a typographical error in the heading of section 2 – "DELITION" should read "DELETION".

List A: Advisory list of mineral salts and trace elements for use in foods for infants and children

2. Source of Iron (Fe)

It is propose that **sodium ferric diphosphate** should be added as a source of iron for the following categories of foods PCBF, CBF and FSMP.

3. Source of Magnesium (Mg)

It is proposed that **magnesium carbonate** should be added as a source of magnesium for the following categories of foods IF, FUF, PCBF, CBF and FSMP.

3.13 Magnesium salts of citric acid – it is proposed that the following categories of foods should be added IF, FUF, PCBF and CBF.

8. Source of Zinc (Zn)

It is proposed that **zinc carbonate** should be added as a source of zinc for the following categories of foods FSMP.

11. Chromium (CR III)

It is proposed that the **hexahydrate forms** of chromium (III) sulphate and chromium (III) chloride should be included for use in foods for special medical purposes.

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

The categories of foods to which the vitamin compounds can be used in should be added to the list. For the vitamin compounds listed CL 2002/7-NFSDU their use would be permitted in all the categories, namely, IF, FUF, PCBF, CBF and FSMP.

4. Vitamin E

If foods for special medical purposes are included in the food categories then **D alpha-Tocopheryl acid succinate** should be considered as a source of vitamin E in FSMP.

Notes to list A-C

The definition of Ph Eur – European Pharmacopoeia needs to be added to the list of abbreviations.

List D: Advisory list of food additives for special vitamin forms

(a) Maltodextrins –maltodextrins are not included in the General Standard on Food Additives, therefore it needs to be clarified whether they are considered food additives under the Codex standards.

(b) Gum arabic (gum acacia) – It is proposed that the maximum level of carry over into the product ready for consumption should be 10 mg/kg.

Additional food additive - it is proposed that the carry over of **sodium L-ascorbate** to a maximum of 75 mg/kg in ready-to-use-food should be added to list D.

Annex

Examples of proposed format for the advisory list 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

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Children				
		IF	FUF	PCBF	CBF	FSMP
5. Source of Potassium (K)						
5.1 Potassium carbonate	Ph Helv, USP, FCC	√	√			√
5.2 Potassium hydrogen carbonate (Potassium bicarbonate)	Ph Eur, USP, FCC	√	√			√
5.3 Potassium chloride	Ph Eur, USP, FCC	√	√	√	√	√

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

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Children				
		IF	FUF	PCBF	CBF	FSMP
1. Vitamin A						
1.1 all trans Retinol	Ph Eur, FCC	√	√	√	√	√
1.2 Retinyl acetate	Ph Eur, USP, FCC	√	√	√	√	√
1.3 Retinyl palmitate	Ph Eur, USP, FCC	√	√	√	√	√

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

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Children				
		IF	FUF	PCBF	CBF	FSMP
1. Amino acids						
1.1 L-Arginine and its hydrochloride	Ph Eur, USP, FCC	only for improving the nutritional quality of the protein				√
1.2 L-Cystine and its dihydrochloride	Ph Eur, USP, FCC	only for improving the nutritional quality of the protein				√
…						
2. Carnitine						
2.1 L-Carnitine and its hydrochloride	USP	√	√	√	√	√
3. Taurine						
3.1 Taurine	JP	√				√