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Roche Vitamins Ltd
Comments for the
CODEX COMMITTEE ON NUTRITION AND FOODS
FOR SPECIAL DIETARY USES (CCNFSDU)

Bonn, November 2003

Agenda item 8: 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

References: ALINORM 03/26A¹ (agenda item 7/paras 101-112), CL 2002/7-NFSDU (March 2002), CX/NFSDU 02/7 (September 2002) and CX/NFSDU 02/7-Add. 1 (October 2002).

Our company is a main manufacturer of some nutrient categories, in particular vitamins, carotenoids and polyunsaturated fatty acids (PUFAs) and therefore has expertise in these nutrients and their uses. Our comments concern a number of matters, which are related to the mentioned nutrients. We do not comment in detail on the lists of mineral salts, amino acids and other nutrients.

The Advisory List(s) date(s) from 1979 with amendments from 1983 and 1991. We welcome the opportunity of a review and revision in conjunction with the revision of the Codex Standard on Infant Formulae (CODEX STAN 72-1981 as amended) and the Codex Standard on Processed Cereal-based Food for Infants and Young Children (CODEX STAN 74-1981 as amended).

1. General Comments

- **Title:**
 - We agree to the proposed new title (as agreed at the 24th session of the CCNFSDU) "*Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children*" as this is in correspondence with the title of the Codex Standards currently under revision (see above) (ALINORM 03/26A).
 - We propose to adapt the titles of the specific advisory lists (A, B and C) to be in line.
- **Preamble:** We agree to the proposed new wording of the Preamble as agreed at the 24th session of the CCNFSDU (ALINORM 03/26A).
- **Criteria for the Inclusion and Deletion of Nutrient Compounds from the Advisory Lists:** We agree to section 2 as agreed at the 24th session of the CCNFSDU (ALINORM 03/26A). The lists shall be open lists, i.e. new nutrients and nutrient sources (chemical substances) may be added, if complying with the requested criteria.
- **Lists on nutrients other than minerals and vitamins:** We support the proposal to include lists on nutrients other than minerals and vitamins, i.e. amino acids and other nutrients. For clarity and systematic reasons amino acids and other nutrients shall be given in separate lists (CL 2002/7-NFSDU).
- **Specifications/purity requirements:** Substances included (or to be included) in the lists shall have approved specifications (purity requirements). These specifications should be a) for food uses and/or b) for medicinal preparations, and shall be c) global, regional or national (in this order). Thus *preference* should be given to specifications adopted by FAO/WHO (JECFA), the International Pharmacopoeia (WHO), FCC, USP, Ph. Eur. (see also below 2. Specific Comments "*B. Advisory List of Vitamin Compounds*" and the attached table in the **Annex** of these comments).

¹ ALINORM 03/26A: Report of the 24th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (November 2002)

- **Designation(s):** The designation(s) of the nutrient compounds should be harmonized with designations in other Codex norms (e.g. General Standard of Food additives [GSFA]), thus avoiding different descriptors and creating uncertainties as to the substance (CL 2002/7-NFSDU).
- **Abbreviations:** We support that all used abbreviations are explained (CL 2002/7-NFSDU).
- **Reference to “Foods for Special Medical Purposes (FSMP)” within the Advisory Lists:** We suggest to delete the reference to “FSMP” as the Advisory List(s) is/are only *advisory* for this product category, but not exclusive.
 - **Rationale:** These foods are for a very limited group with specific physiological and/or medical needs and may need the use of other compounds either for physiological and/or technological reasons (CL 2002/7-NFSDU).
- **Number of references:** We suggest to limit the number of references. E.g. if “Ph Eur” includes a monograph that is identical or includes all requirements in a hierarchically subordinated compendia (e.g. BP, Ph Franç, DAB, Ph Helv) the latter should not be cited because being redundant (CL 2002/7-NFSDU). Reference should be given without quoting years (e.g. Ph Eur [2000]) or editions (e.g. FCC IV).
 - **Rationale:** The reference Ph Eur (FCC respectively) (without year) is more appropriate as this stands for the most recent edition of the monograph or specification. Years may be indicated only if an earlier edition shall be referenced.

2. Specific Comments

B. Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (please see attached Table in the Annex)

- **Title:** Should be adapted to the proposed new general title as agreed at the 24th session of the CCNFSDU (see our comment above) i.e. “*B: Advisory List of Vitamin Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children*”; (same for lists A and C).
- **Specifications/purity requirements:**
 - We support the decision of the 24th session of the CCNFSDU to accept the *format* proposed by the European Union (ALINORM 03/26A para 111). In addition we propose that the order of the purity criteria be rearranged as there should be a kind of *ranking* i.e. preference should be given to specifications adopted by FAO/WHO (JECFA), the International Pharmacopoeia (WHO), FCC, USP, Ph. Eur. (in this order) (see also our comment under “General Comments”).
 - We suggest that compounds lacking *official purity criteria* should not be included (or should be deleted) (CL 2002/7-NFSDU). In the enclosed table (see **Annex** of these comments) monographs were checked in compendia and the sources noted in the table; several compounds lack purity requirements and therefore should be deleted from the list (=> potassium L-ascorbate, all pyridoxal derivatives). A special case is sodium-D-pantothenate which is used but lacks specifications in the listed compendia and thus specifications should be adopted officially.
 - Included in the table (see **Annex** of these comments) are references to “The International Pharmacopoeia” by WHO (Geneva) [available are volumes 1 to 5.]. These specifications intended for medicinal preparations parallel the monographs for food uses as adopted by FAO/WHO (JECFA).

- **Editorial:** In CL 2002/7-NFSDU for vitamin B6 the compound "pyridoxal hydrochloride" should probably read "pyridoxine hydrochloride".

D. Advisory List of Food Additives for Special Vitamin Forms

- **Title:** We support the ISDI proposal (CX/NFSDU 02/7-Add.1) for replacement of the term "VITAMINS" by "NUTRIENTS", as the list should be applicable for special forms in general, e.g. forms of minerals, of amino acids etc.. In addition we propose adaptation to the proposed new general title as agreed at the 24th session of the CCNFSDU (see our comment above) i.e. "*D: Advisory List of Food Additives for Special Nutrient Forms for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children*".
- **Proposal for deletion of section D:** We do not agree to the proposal to delete section D and regulate the substances (food additives) in the respective Codex Standards (CX/NFSDU 02/7). This would mean that additional details on food additives for nutrient forms have to be laid down in the respective Codex Standards for Foods for Infants and Children. We understand that food additives regulated in the respective Codex Standards are automatically permitted in these special forms.
- **First sentence after the title of "section D" as proposed by CL 2002/7-NFSDU (see below third paragraph):** In general we support the proposed sentence ("*For reasons of stability and safe handling,....*" [for full wording please see below]). In addition we propose the following modifications:
 - Replacement of the term "VITAMINS" by "NUTRIENTS".
 - Rationale: The list should be applicable for special forms in general, e.g. forms of vitamins, minerals, amino acids etc..
 - Inclusion of the following sentence at the end of the text: "*In addition the following food additives are permitted:....*".
 - Rationale: Clarification is needed, as the current wording is not easy understandable and therefore misunderstanding/misinterpretation is possible. We understand that food additives regulated in the respective Codex Standards are automatically permitted in special nutrient forms for the use in the respective foodstuffs. Therefore there is no need nor justification to do a duplication of work by listing again the same additives in a specific list for vitamin formulations.
 - This would result in the following wording [**proposed changes are included in bold letters**]: "*For reasons of stability and safe handling, some **vitamins nutrients** have to be converted into suitable preparations, e.g. stabilized oily solutions, gelatin 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. **In addition the following food additives are permitted:...** [List of food additives]."*
- **List of food additives (permitted in addition to food additives regulated in the respective Codex Standards):**
 - We propose to include the INS numbers with respect to the listed food additives.
 - Only food additives should be included as the title refers to "Food Additives" specifically. The list should **not** include foods and food ingredients (e.g. oils, gelatin, sucrose, starch, maltodextrins etc.) having either a Codex Standard or other monograph.



- We propose to add “(g) *INS 1450 Starch sodium octenyl succinate (INS 1450) with a maximum level of 100 mg/kg in the ready-to-use food*” (in addition to the food additives as listed in CL 2002/7-NFSDU). Rationale:
 - In some special vitamin forms used in foods for infants and young children “*INS 1450 starch sodium octenyl succinate*” is used for technological reasons.
 - “*INS 1450 starch sodium octenyl succinate*” is not listed in the food additive sections of the two Codex Standards for Food for Infants and Young Children currently under revision. As a consequence the use of vitamin forms containing INS 1450 in these foods for infants and young children would not be possible any more (currently possible, see below).
 - This listing of INS 1450 would be in line with a currently proposed draft amendment of the EC Directive 95/2/EC on food additives other than colours and sweeteners (final adoption expected in September 2003).
 - Section D of the Advisory List in force lists “*modified starches*” and thus permits their use. However “*modified starches*” are not mentioned in the current version of the Advisory List under revision. *Modified starches is the general term for the following substances: INS Nos. 1400, 1401, 1402, 1403, 1404, 1405, 1410, 1412, 1413, 1414, 1420, 1422, 1440, 1442, 1450, and 1451.*

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Annex:

B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

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

² No official purity criteria could be found; therefore proposed to be deleted