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Roche Vitamins Ltd.

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Comments for the

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU)

Bonn, November 2003

Proposed Draft Guidelines for Vitamin and Mineral Supplements (VMS)

(Alinorm 03/26A, Paras 87-100 and Appendix IV)

- Comments at step 3 of the Procedure -

Reference: CAC CL 2002/51-NFSDU, November 2002, inviting comments to the "Proposed Draft Guidelines for Vitamin and Mineral Supplements". Comments from Governments are requested for submission to Prof. Dr. Rolf Grossklaus, Federal Institute for Risk Assessment, D- Berlin, with copy to the Secretary, Codex Alimentarius Commission, FAO, Rome.

Introduction

Our company is a main manufacturer of some nutrient categories, in particular vitamins, carotenoids and polyunsaturated fatty acids (PUFAs). Our comments concern a number of matters, which are related to the mentioned nutrients.

We appreciate the work of the Codex Alimentarius regarding the "Proposed Draft Guidelines" as we see the necessity of international harmonization of rules in this area in order to achieve a high level of consumer information, to avoid substantial barriers to trade and to ensure fair competition in the area of food supplements. Food supplements are an important product category with a high benefit for consumers:

- **Scientific perspective:** It is well established that diet and nutrition are important factors in the promotion and maintenance of good health throughout the entire life course. Vitamins play an important role, as they are essential for healthy growth, vitality and physical well being. In addition there is strong scientific evidence/it is scientifically proven
  - 1) that the intake of vitamins has additional health benefits (e.g. protection against osteoporosis, birth defects, normalizing homocystein levels etc.),
  - 2) there are benefits of vitamin intake in amounts higher than the RDA.
- **Consumer perspective:** It is worldwide accepted that a link between diet/life-style and risk factors of several chronic diseases exists. Therefore consumers are more and more interested regarding their diet, its relationship to health and in particular in additional health benefits of nutrients as supported by science and mainly supplement their diet in order to achieve an optimum state of health, rather than just preventing deficiencies. We believe that in light of the scientific evidence (please see above) regular intake of food supplements makes good sense for various population groups (e.g. the growing number of elderly people, pregnant women, or any group with increased requirements or difficulty to have an adequate intake).

Regarding the "Proposed Draft Guidelines" under discussion we have general and specific comments, which are presented below:

A. General Comments

- We support the development of "Codex Guidelines for Vitamin and Mineral Supplements" in order to harmonize their regulatory status globally (for background see footnote 1 on page 3) and regulate them under food regulations.
- As we understand the development of "Codex Guidelines for Vitamin and Mineral Supplements" is only a first step for the development of Codex Guidelines for the whole food supplements field (dietary supplements) (including other nutrients).
- Food supplements (dietary supplements) under food law should
  - comply with the food regulations applicable to this category of products,
  - be a category clearly separated from products under medicinal and pharmaceutical law.

B. Specific Comments

The following table summarizes our specific comments. The original text (full version) of the "Codex Proposed Draft Guidelines for Vitamin and Mineral Supplements " (which will be discussed at the next CCNFSDU session) is presented in the second column (normal format). **Our proposed amendments** are included in **bold** letters. In addition detailed argumentation (rationale) is given in the third column.

	Proposed Draft Guidelines for Vitamin and Mineral Supplements (proposed amendments by Roche Vitamins Ltd are included in bold letters)	**Rationale**
PREAMBLE	Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food ~~**before considering any vitamin and mineral supplement**~~. In cases where the intake from the diet is insufficient or where consumers consider their diet requires supplementation, vitamin and mineral supplements serve to supplement the daily diet.	Deletion of *"before considering any vitamin and mineral supplement"* is proposed. Rationale: The current wording of the Preamble is rather restrictive and gives the impression that supplementation detracts from good diet. It does not reflect the following matters: ▪ Consumers mainly supplement their diet in order to achieve an optimum state of health, rather than just preventing deficiencies. ▪ Additional supplementation of the diet is of high benefit for various population groups (e.g. growing number of elderly people, pregnant women, or any group with increased requirements or difficulty to have an adequate intake). There is growing scientific evidence supporting health benefits of vitamin intake in amounts higher than the RDA.
1. SCOPE	1.1 These guidelines apply to vitamin and mineral supplements intended for use in supplementing the daily diet with vitamins and/or minerals.	
	~~**1.2 It is left to national authorities to decide whether vitamin and mineral supplements are drugs or foods. These Guidelines do apply in those jurisdictions where products defined in 2.1 are regulated as foods.**~~	Deletion is proposed. Rationale: ▪ As Codex guidelines apply only to products regulated as foods reference to drugs is unnecessary. Furthermore, as the term "drug" is not defined within Codex (only on country level) "drug" should not be referred to in Codex texts. ▪ This paragraph contradicts to the objective of the international harmonization efforts/goals[1] and could lead to barriers in international trade (by classification as drugs in some countries). Food supplements complying, with these guidelines should be regulated as food.

[1] Background: Currently food supplements are regulated as foods in some countries and as drugs in others. The differing national regulations contribute to technical barriers to international trade, create unequal conditions of competition and restrict consumers' freedom of choice in food supplements. This contradicts the aim of open markets and free exchange of goods. Therefore, supranational organizations and authorities like the Codex Alimentarius (CA), the European Union (EU), the Trans Atlantic Business Development (TABD), producers' associations (e.g. IADSA, CRN) and others started initiatives to harmonize the regulatory status of supplements under food law and containing vitamins and minerals as main nutrients.

	Proposed Draft Guidelines for Vitamin and Mineral Supplements (proposed amendments by Roche Vitamins Ltd are included in bold letters)	**Rationale**
	1.3 Foods for special dietary uses as defined in the General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are not covered by these Guidelines.	
2. DEFINITIONS	Vitamin and mineral supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in capsules, tablets, powders, solutions etc., not in a conventional food form and do not provide a significant amount of energy. [They serve to supplement the daily diet with these nutrients in cases when the intake from food is insufficient or where the consumers consider their diet requires supplementation.]	
3. COMPOSITION	3.1 SELECTION OF VITAMINS AND MINERALS 3.1.1 Vitamin and mineral supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins or minerals is recognized by FAO and WHO.	
	3.1.2 The selection of admissible vitamin and mineral sources should be based on criteria such as safety and bioavailability. In addition, purity criteria should take into account **the specifications by** FAO/WHO or Pharmacopoeias [and national legislation, where applicable[1]]. **Footnote:** **[1] "i.e. where no purity criteria are laid down by FAO/WHO or Pharmacopoeias"**	▪ Re: *"The selection of admissible vitamin and mineral sources……"*. We believe that this is a repetition of 3.1.1 (as it is part of the FAO/WHO assessment process) and therefore is redundant. ▪ Re: *"In addition, purity criteria should take into account….."* For reasons of clarity we propose to add the term *"the specifications by"*. ▪ Re: *"and national legislation, where applicable":* For definition of the term "applicable" we propose to add the following footnote: *"i.e. where no purity criteria are laid down by FAO/WHO or Pharmacopoeias"*. Rationale: Purity criteria laid down by FAO/WHO or Pharmacopoeias should have precedence over national legislation. Otherwise this would contradict to the international harmonization efforts (see footnote 1 on page 3) and could lead to barriers of trade (in case of a more restrictive national legislation).
	~~**[3.1.3 The use of individual vitamins and minerals in supplements can be [limited] for reasons of health protection and consumer safety, taking into account regional or national peculiarities concerning the supply situation of the population].**~~	Deletion is proposed. Rationale: Limitations on the use of individual vitamins and minerals are a matter of adequate scientific risk assessment, which is already covered under paragraph 3.2.

	Proposed Draft Guidelines for Vitamin and Mineral Supplements (proposed amendments by Roche Vitamins Ltd are included in bold letters)	**Rationale**
	3.1.4 Vitamin and mineral supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1, a single vitamin and/or mineral or an appropriate combination of vitamins and/or minerals.	
	3.2 CONTENTS OF VITAMINS AND MINERALS 3.2.1. The minimum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should be **25% ~~[15% to 33 %~~]** of the recommended daily intake as determined by FAO/WHO.	For vitamins we support a level of 25 % of the Recommended Daily Intake (RDI) as we consider this as an appropriate amount for information of the consumer. Rationale: ▪ The rationale for 25 % is that there are 4 meal occasions during the day. ▪ Supplements should contain reasonable levels of vitamins as 1) they are taken for reasons of supplementing the daily diet [meeting the RDIs] or 2) because of the benefits of vitamins in amounts higher than the RDI . ▪ A level of 15% of the RDI for vitamins is a very low amount for supplementing the daily diet and therefore is not very significant for the consumer.
	~~**3.2.2 [The maximum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should not exceed [100%] of the recommended daily intake as determined by FAO/WHO].**~~ ~~**or**~~ 3.2.2 [Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:: 1. A) **upper safe levels of vitamins and minerals established** by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups; 2. B) the daily intake of vitamins and minerals from other dietary sources When the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population]	We propose to delete option 1. Option 2 is strongly supported. Rationale: ▪ Option 1 is proposed for deletion as Recommended Daily Intake (RDI) values were established to indicate the required levels in order to avoid deficiency diseases. Since RDIs were not defined to address safety, and none of the data used to establish RDIs are pertinent to safety, we do not support this approach. Using RDIs as a basis would be arbitrary and would exclude the potential benefits of nutrients at intakes above the current RDI. ▪ Option 2 is strongly supported, since the scientific risk assessment (i.e.science-based assessment of safety; upper safe levels) should be the basis for setting maximum amounts (which is risk management) for nutrients.
	~~**3.2.3 For vitamins and minerals with a narrow safety margin between the recommended daily intake and the adverse effect level, different maximum limits for the daily dose may be established at the national level.**~~	We propose deletion, as safety issues would be covered by the provisions in 3.2.2.

	Proposed Draft Guidelines for Vitamin and Mineral Supplements (proposed amendments by Roche Vitamins Ltd are included in bold letters)	**Rationale**
4. PACKAGING	4.1 The product shall be packed in containers, which will safeguard the hygienic and other qualities of the food.	
	4.2 The containers, including packaging material, shall be made only of substances, which are safe and suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging material, that standard shall apply.	
	4.3 Vitamin and mineral supplements should be distributed in child-resistant packagings, if necessary.	
5. LABELLING	5.1 Vitamin and mineral supplements are labeled according to the Codex Standard for the Labeling of Prepackaged Foods (Codex-Stan 1-1985, Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979).	
	[5.2 The name of the product shall be "vitamin and mineral supplement" or "dietary mineral/vitamin preparation to supplement the diet with ...", with an indication of the nutrients contained therein	
	[5.3 The amount of the vitamins and minerals present in the product shall be declared in the labeling in numerical form. The units to be used shall be units of weight.]	
	[5.4 The amounts of the vitamin and minerals declared shall be those per portion of the product as recommended for daily consumption on the labeling and per unit dose form, as appropriate.]	
	[5.5 Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labeling.]	
	5.6 The label must indicate the recommendations on how to take the product (quantity, frequency, special conditions).	

		Rationale
	5.7 ~~**The label must contain a warning statement' [if the product contains a significant amount of a nutrient with respect to the toxicity level]**~~ **Where it can be scientifically demonstrated that the use of a food supplement may lead to adverse effects for a particular population group, appropriate cautionary statements should be made.**	Modification of section 5.7 is proposed. Rationale: ▪ **Replacement of the term** ***"warning"*** by *"cautionary statement"* is proposed as this term should be preferred over negative warning statements. Warning statements could cause misunderstanding with consumers. ▪ In order to be more precise we propose to focus on adverse effects.
	[5.8 ~~**The label must contain a statement: supplements can not be used for the replacement of meals on long term basis**~~.] **The labelling of a food supplement may not state or imply that these products are a substitute for a varied diet.**	Modification is proposed. Rationale: ▪ We agree that supplements should not be used as a substitute for a varied diet. However we do not agree to the need of a general statement (*"The label must contain a statement..."*) as existing evidence suggests that many consumers of supplements are particularly conscious of their nutrient intake and supplement their diet with the aim of achieving an optimum state of health rather than substituting their diet. ▪ We believe that it would be more beneficial to modify the current wording as proposed in order to prohibit the use of any statement, which implies that supplements may be a substitute for a varied diet.
	~~**[5.9 All labels shall bear a statement that the supplement should be taken on an advice of a nutritionist, a dietician or a medical doctor.]**~~	Deletion is proposed. Rationale: Vitamin and mineral supplements under these guidelines will be regulated as safe food products (for self-selection) which do not need advice as proposed. This requirement is impractical for foodstuffs. Appropriate labelling information is sufficient.

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