Roche

Vitamins

August 22,2002

17

Ms. Nancy Crane
CFSAN
Harvey W. Wiley Federal Building PK1/4D015
HFS-832

5100 Paint Branch Parkway
College Park, Maryland 20740-3835

02-022N
02-022N-17
Alberto Davidovich, DVM, Ph.D.

Reference:CCNFSDU 24th Session, U.S. Draft Positions, as of July 2002 – Comments prepared by Roche Vitamins Inc

Dear Ms. Crane

This message is in response to your e-mail of July 30, 2002 requesting written comments from US interested parties for the U.S. Draft Positions for the CCNFSDU 24th Session. "Comments shall be submitted electronically by 23 August 2002 to Ms. Nancy Crane so that they may be considered in preparing the U.S. positions for Conference Room Documents and responses to Codex Circular Letters prior to the forthcoming CCNFSDU meeting in Berlin."

Our company, a main manufacturer of vitamins and special vitamin forms, has expertise in these nutrients and their uses in the US, as well as abroad.

We take the opportunity to submit our comments, which are outlined below. To facilitate the review of our comments, we have also included them in blue *italics* throughout the text of the US Draft Position Papers.

The page numbers given below refer to the original draft document issued by FDA (i.e. not to the attached document that includes our comments)

Proposed draft standard for infant formula

- p. 14. We support the designation "Vitamin C" when referred to as nutrient (instead of Ascorbic Acid).

- p. 15. We agree with the proposal to delete "niacin equivalents'; in the column of vitamin designation as this designates a reference unit but not a vitamin.

  "Niacin" is the term used, mainly in the US, for both Nicotinic Acid and Nicotinamide/Niacinamide. For nutrition labeling purposes, a differentiation is not important. However, Nicotinamide is generally better tolerated without the side effect of "flushing". Therefore, food manufacturers use and state in the ingredients' list "Nicotinamide". To facilitate consumer understanding, it is preferred to use consistency of terms within a food label (see next paragraph).

  The names "Vitamin B_1", 'Vitamin B_2", "Vitamin PP" etc. are still widely used and better known by consumers in many countries than the "chemical" terms (national provisions may

allow both designations). In our opinion the term "Vitamin x" should be acceptable as alternative designations where these traditional names are common. This concerns primarily with the Codex Guidelines on Nutrition Labeling (CAC/GL 2-1985 [Rev. 1-1993]) which serve as a model; an explanatory footnote to this effect would solve the matter. This draft Guideline uses "Vitamin" and chemical names somewhat arbitrarily.

- p. 16. We support the designation "Vitamin K (instead of Vitamin K_1).

- p. 19. Phytases. If phytases are used in soy-based infant formulas the enzymes have to be included in section "4. Food Additives" and must be labeled. To our knowledge, phytases have not been evaluated and accepted as food additives for this purpose and they have not been allocated INS numbers. - Same comment on p. 21 to zinc.

- p. 26 in 4.1-4.4. Maximum levels of food additives. We understand the intention of "3) maximum use levels that would reflect the minimum level necessary to achieve the intended technical effect", however, we feel the wording will need some modification. The needed level depends on the desired properties of the final product, the composition, and the manufacturing process, and not the last of the properties of the food additive itself, e.g. within the group of modified starches. The determination of the maximum use levels is always somewhat arbitrary. - Same comment on p. 31 (regarding the draft revised standard for processed cereal-based foods for infants and young children)

- p. 26 in 9.1.5. Products of this Codex Standard are for "meeting the normal requirements of infants" (Scope of the Standard), i.e. for healthy infants only (U.S. Draft Positions p. 9 "1. The goal ... requirements of healthy infants"). Therefore, point 9.1.5 may either be deleted or be formulated shorter e.g. "9.1.5 Products for infants with special nutritional requirements are not covered in this Standard and their labeling is provided in relevant Codex standards".

Proposed draft revision of the advisory list(s) of mineral salts and vitamin compounds for the use in foods for infants and children

- p. 33f. Preamble and Scope. WTO refers to Codex norms as "reference standards" without differentiating between Standards, Guidelines, Code of Practice and other norms. The Codex Procedure Manual, p. 78 (12th edition, 2001) "Format for Codex Commodity Standards" does not foresee a Preamble. The Scope section often repeats main parts of the Preamble. For the Advisory List of Nutrient compounds the term Preamble could be substituted with Scope. (see also p. 37 for Vitamin and Mineral Supplements).

- p. 34. A general point: we propose, for consistency, to use always the order "vitamins, minerals" In the Scope minerals are mentioned first followed by vitamins. - See also chapter on Vitamin and Mineral Supplements (p. 38 in 2.1; p. 41 first paragraph).

- p. 35. INS numbers. INS numbers should not be given in the Advisory List of Nutrient Compounds. Added for nutritional purposes, they should only be quoted by their name. INS numbers are intended for food additives only and when used for such purposes.

Our colleagues in Switzerland drafted an amended Advisory List of Vitamin Compounds. In

addition to specifications by FAO/WHO (JECFA) and some Pharmacopoeias. Reference is also included to the International Pharmacopoeia (WHO) (see attached letter by Roche Vitamins Ltd., Basel, dated June 12,2002, and submitted to the Bundesamt fur Gesundheit, Bern, Switzerland) (please see **attachment).**

- p. 35. Table D. Such List/Table D is included in the Advisory List (CAC/GL 10-1979, amended 1983,1991) and shall be included in the new list. It seems convenient to specify carriers, adjuvants and additives in a separate list/Table D of the Advisory List. Thus these allowed substances are all presented in one place to facilitate reference. Special vitamin forms for food for infants and young children are the same. Inclusion in the food additive provisions in the respective food standards would mean repetition of the same information (not all substances are necessarily food additives, e.g. gelatin). Therefore, we support keeping Table D in the Advisory List of Nutrient Compounds (please see attached letter by Roche Vitamins Ltd as indicated above).

Proposed draft guidelines for vitamin and mineral supplements

- p. 37 Preamble: In general, we do not support a Preamble within a Codex Guideline, as the Codex Procedure Manual, p. 78 (12th edition, 2001) "Format for Codex Commodity Standards" does not foresee a Preamble. We are concerned about the intention and the current wording of the Preamble which is rather restrictive and it is does not fully conform with the intention of the international harmonization efforts. Nevertheless some of the countries do object to the deletion of the Preamble. Therefore (if deletion of the Preamble will not be possible) we propose to modify the Preamble by deletion of "before considering any vitamin and mineral supplement". This is appropriate as consumers mainly supplement their diet to achieve an optimum state of health, rather than just preventing deficiencies and also, vitamin and mineral supplements are not promoted as replacement for foods by industry.

- p. 37 in 1.1. We support the deletion as proposed. In addition we propose to delete "with vitamins and/or minerals". Argumentation: The additional wording is superfluous. As it is a Codex Guideline it is clear that it applies to vitamin and mineral supplements which are regulated as foods.

- p. 38 in 1.2. We support deletion of the first sentence as proposed. In addition, we propose to delete also the second sentence i.e. the whole paragraph should be deleted. Argumentation: Reference to drugs is unnecessary as the Codex Guidelines apply only to products regulated as foods. This paragraph, as included in the current text of the Codex Draft Guidelines, does not conform with the goals of the harmonization efforts of the regulatory status of "supplements under food law and containing vitamins and minerals as main nutrients" because it could serve to increase trade barriers rather than to decrease them (by classification as drugs in some countries). Food Supplements, which comply with these Guidelines should be regulated as food. Only if represented as such, a supplement should be a drug.

- 3.1.1. The following additional sentence is proposed at the end: "They should be compiled in open positive lists". Background: The main nutrients for Vitamin and Mineral Supplements

should be compiled in open positive lists. A procedure for inclusion of new substances on this list should be defined.

- p. 38 in **3.1.2.** We propose deletion of the first sentence, because it is part of the FAO/WHO assessment process, as laid down under 3.1.1. The second sentence is supported as vitamins and minerals should be characterized by reference to the chemical form(s)

- permitted for use, and references to official specifications/ monographs (FAONVHO, FCC- Food Chemicals Codex, USP/NF - U.S. Pharmacopoeia/National Formulary, International Pharmacopoeia, Ph. Eur - European Pharmacopoeia) should apply. Chemical forms not complying or without an official reference specification/ monograph should not be used. For other substances of food supplements similar requirements should apply.

- p. 38 in **3.1.3** We support the deletion as this paragraph limits the levels of vitamins and minerals, which is more properly addressed under paragraph **3.2.**

- p. 39 in **3.2.1.** To prevent misinterpretation and as a minimum level to be established, we consider 15 % of the labeling RDI as appropriate to allow the inclusion of the vitamins and minerals on the statement of nutritional content. Before a decision is taken, the practical implications of the bulk effect of certain nutrients (e.g. calcium, magnesium, potassium, sodium) has to be taken into consideration. In addition we have the following remarks regarding "The minimum level. of the recommended daily intake as determined by FAONVHO." We are not aware whether these FAO/WHO recommendations are now available. If yes, will FAONVHO recommendations be the basis for CCFUCCNFSDU to review the NRVs (with far reaching consequences) ? The FAONVHO expert consultation recommendations are scientific levels and (may) differ for gender and age. We assume the intention is to refer to the Nutrient Reference Values (NRV) for labeling purposes (Codex Guidelines on Nutrition Labeling, CAC/GL 2-1985 (Rev. 1-1993)? This would avoid to have two sets of values and thus confuse consumers. This point should be submitted to CCNFSDU for discussion.

- p. 39 in **3.2.2** We also support option 2 (i.e. "maximum amounts for vitamins and minerals should be set...") as the setting of maximum amounts (when needed) should be based on science-based assessment of safety. However, as this is currently not sufficiently reflected in the current wording of option 2 we propose the addition of the phrase "by the relevant Scientific body taking into account:" after the words "shall be set" (at the end of the first sentence of option 2). Further we support to replace "shall" by "should (as this is rather a guideline than a standard). Option 1 is not favored and should be deleted 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 since 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 at intakes above the current RDI. We therefore also support deletion of the final sentence "when the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population".

- p. 40 in **3.2.3** We support the deletion, as safety issues would be covered by the provisions in **3.2.2.**

- p. **40** in **4.1** and **4.2** Replacement of "shall" by "should" is supported.

- p. **40** in 5.2. It would be sufficient to simply require the term "supplement" on the principal display (front) of the product and not as part of the name of the product. We therefore

- propose to replace the following words: "name" by "labeling" and "be" by "include". Further we support to replace "shall" by "should" (as this is rather a guideline than a standard).

- p. **41** in 5.3. We support the proposed amendments.

- p. **41** in 5.4. We suggest the replacement of "and" by "**or**" as there is no need for both declarations, which is redundant. Again we support to replace "shall" by "should".

- p. **41** in 5.5. We suggest the replacement of "information" by "quantitative **declaration**" , as the term "information" is insufficiently specific. Further we support to replace "shall" by "should".

- p. **41** in 5.6. For reasons of clarity add 'otherwise referred to as 'suggestion of use' or 'usage suggestions' at the end of the sentence. Further we support to replace "must" by "should".

- p. **41** in 5.7. "Instructions for use" should be preferred over negative warning statements. Warning statements could have extremely negative effects for marketing and misunderstanding for consumers. Therefore the replacement of "warning statement" by "Instructions for Use statement" is proposed. In addition we propose to replace "must" by "**should**". The need for specific intake **information/statements** where appropriate is agreed. We propose the following modification because the current wording is rather negative: delete "if the product contains a significant amount of a nutrient with respect to the toxicity level" and replace it by "where appropriate, based on the recommended portion for daily consumption" (**e.g.** by a statement not to exceed the recommended daily dose).

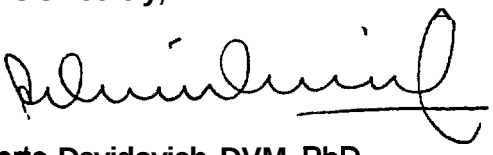
- p. **41** in 5.8. Existing evidence suggests that many consumers of supplements are particularly conscious of their nutrient intake and supplement their diet with the aim of achieving an optimum state of health rather than substituting their diet. We therefore do not see the necessity for the requirement of a statement as included in the current text. We therefore propose to modify the current wording in order to prohibit the use of any statement, which implies that supplements may be a substitute for a varied diet. The modified paragraph would read as follows: "The label should **not** state or imply that supplements are a substitute for a varied diet".

- p. **41** in 5.9. Deletion is suggested as vitamin and mineral supplements under these guidelines will be regulated as safe food products, which do not need advice, by a nutritionist, dietician or medical doctor as proposed **i.e.** labeling information is sufficient.

We hope our comments and suggestions are clear and of use in the further elaboration and revision of the list of nutrient compounds. Should you have questions please feel free to contact us, we will be pleased to give additional information and explanation.

We will send you by express carrier a signed original of this letter (including the comments written into the Draft document) for your file.

Yours sincerely,



Alberto Davidovich, DVM, PhD
Associate Director Regulatory Affairs
Roche Vitamins Inc.

45 Waterview Boulevard
Parsippany, NJ 07054
Telephone (973) 257 8325
Fax (973) 257 8414
alberto.davidovich@roche.com