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TO: Dr. Elizabeth A. Yetley, Chief Scientist CFSAN/FDA/H&HS
FR: Karl Riedel
02-022N
02-022N-8
Karl Riedel

RE: Comments on the Draft Codex Guidelines on Vitamin and Mineral Supplements

We sincerely appreciate this opportunity to provide comments on these important guidelines. As we have provided extensive comments to you in past years on these same issues, we apologize in advance for any egregiously repetitive comments.

The most significant change to the current draft is the 2001 proposal of the European Commission to revise point 3.2.2. In the context of the recently adopted European Directive on Food Supplements, for which the proposed wording was *developed*, the compromise text provided a political solution acceptable to EU Member States which facilitated the parliamentary adoption of that Directive. However, for the purposes of Codex, we believe that their proposed text provides insufficient clarity on the process to be used in, and inadequate scientific justification for, setting maximum nutrient levels for vitamin and mineral supplements.

Reference intake values may be a useful marker which may help a risk assessor to establish the range of minimal safe intake, below which intake range there is an increased risk of deficiency. Reference intake values, however, have no direct relationship with the range of optimal safe intake of supplemental vitamins and minerals. The setting of upper tolerable intake levels (UL) and maximum supplement levels, if and where necessary, should be a nutrient appropriate scientific assessment which needs to be undertaken by qualified scientific bodies. In order to reduce trade barriers, these assessments should not be subject to national interpretations, unless risk managers document valid safety concerns from national dietary patterns.

The EC 3.2.2. proposal also fails to adequately define the scientific body responsible for establishing Upper Safe Levels. The proposal also includes the dangerously malleable term "generally accepted scientific data", which has caused considerable difficulty in its application here in the US in relation to dietary supplements, and should be eschewed by the CCNFSDU.

Attached for your review and use are our detailed comments and recommendations on the current draft Guidelines and we again thank you for your consideration of our input.

- Regards & Health

- 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.
- We absolutely support the principle that *people should be encouraged to select a balanced diet from food.* The preamble, however, implies that supplementation detracts from good diet by inclusion of the statement *"before considering any vitamin and mineral supplement"*. Existing evidence suggests that supplement consumers are very conscious of their nutrient intake and supplement their diet with the aim of achieving an optimal state of health, rather than just preventing deficiency diseases. Moreover, NAS/IOM/F&NB reports validate that only a small percent of the US population actually obtains 100% of the RDA micro-nutrients from a normal diet. Evidence is also clear that sub-optimal, but RDA adequate vitamin/mineral intake is associated with chronic disease. (Ref: *"Vitamins for Chronic Disease Prevention in Adults"* - Journal of the American Medical Association - Vol. 287, No. 23, June 19, 2002. We therefore strongly recommend that *"before considering any vitamin and mineral supplement"* be deleted, or at the least, be placed in square brackets.
1. Scope
- 1.1 These guidelines apply to vitamins and minerals intended for use in supplementing the daily diet [if and where necessary] with vitamins and/or minerals.
- Delete the bracketed [if and where necessary] as redundant and superfluous. We strongly urge adding [in foods] at the end of 1.1 to preclude the need for 1.2.**
- 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.]
- The Codex Alimentarius mandate is limited to food products. It is also committed to reducing existing barriers to trade. In some countries trade barriers are caused by the classification of food supplements as drugs. Some countries assume that supplements not considered foods are automatically classified as drugs, and some have stated that as vitamin/mineral supplements are not foods, then they are prohibited as drugs.
- If the guidelines are to be of practical value, and hold to Codex General Principles, they should at least ensure minimum standards for opportunities to trade on a global basis. Any reference to national classification should therefore be removed from the guidelines as a barrier to trade
- We therefore strongly recommend deletion of the entire 1.2 as it violates Codex General Principles.
- 1.3 Foods for special dietary uses as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are not covered by these Guidelines.
- No comment on 1.3

<p>Definitions</p>	<p>2.1 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.]</p>	<p>We urge deletion of “and do not provide a significant amount of energy”, as many of the most popular vitamin/mineral supplements are blended with sweeteners and are sold as powders, liquids concentrates, chewable tablets, lozenges and bars; many of which have “significant” amounts of energy, usually as carbohydrates.</p> <p>We recommend deleting the first sentence as the “purpose” of vitamin and mineral supplements is already covered in the preamble, making this sentence redundant.</p> <p>We recommend removing the square brackets from the last sentence.</p>
<p>Composition</p>	<p>3.1 Selection of vitamins and minerals</p> <p>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 and minerals is recognized by FAO and WHO.</p> <p>3.1.2. The selection of admissible ingredient sources of nutrient or compounds should be based on criteria such as safety and bio-availability. In addition, purity criteria should take into account the FAO/WHO or Pharmacopeias [and national legislation where applicable].</p> <p>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.]</p> <p>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.</p>	<p>No comment</p> <p>We strongly recommend deletion of 3.1.2 as 3.1.1 already defines vitamins and minerals selection criteria according to Codex standards. Limitations imposed on the use of individual vitamins and minerals for reasons of safety must be based on adequate scientific risk assessment, which for essential nutrients does not vary significantly based on regional or national ‘peculiarities’, with the possible exception of selenium. National exemptions pre-empt and emasculate the entire Codex process and violate Codex General Principles.</p> <p>We strongly recommend deletion of 3.1.2 as the right of any health authority to act to protect consumer health is implicit and embodied in Codex. Limitations imposed on the use of individual vitamins and minerals for reasons of safety must be based on adequate scientific risk assessment, which for essential nutrients does not vary significantly based on regional or national ‘peculiarities’, with the possible exception of selenium National exemptions pre-empt and emasculate the entire Codex process and violate Codex General Principles.</p> <p>No Comment</p>

<p>Composition</p>	<p>3.2 Contents of vitamins and minerals</p> <p>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 [15% to 33%] of the recommended daily intake as determined by FAO/WHO.</p> <p>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 <i>daily</i> intake as determined by FAO/WHO]</p> <p style="text-align: center;"><u>or</u></p> <p>3.2.2 [Maximum amounts of vitamins and minerals in vitamin and mineral supplements per <i>daily portion</i> of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:</p> <ul style="list-style-type: none"> 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; b) the <i>daily</i> intake of vitamins and minerals from other dietary sources. <p>When the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population.]</p> <p>3.2.3 For vitamins and minerals with a narrow safety margin between the recommended <i>daily</i> intake and the adverse effect level, different maximum limits for the <i>daily</i> dose may be established at the national level.</p>	<p>In principle, we consider that a minimum level of 10% of the RDI should be established for the inclusion of the vitamin or mineral on the statement of nutritional content to prevent misrepresentation however, the practical implications of the bulk effect of certain nutrients, such as Ca, Mg, K and Na should be considered carefully before setting minimum levels.</p> <p>RDI's were established to indicate required levels in order to avoid deficiency diseases. They do not reflect significant scientific research supporting the health benefits of intakes much higher than the RDI. To ensure the availability of supplements that reflect the scientific & validated benefits of higher than RDI intakes, the maximum limit cannot be linked to RDI's, but must only be established by nutrient appropriate scientific risk assessment as specified in Codex General Principles. Strongly urge that the text after "exceed" be revised as: "the Upper Safe Levels determined by nutrient-appropriate scientific risk assessments of the FAO/WHO".</p> <p>If the above 3.2.2. version is unacceptable, then we strongly urge sub-point a) be simplified to read "upper safe levels of vitamins and minerals established by nutrient-appropriate scientific risk assessment." and delete the balance of the sub-point as inappropriate for composition, and better addressed in Section 5. Labelling. Also delete sub-point b) in its entirety, as irrelevant and beyond the control of manufacturers or governments, who set dietary guidelines but do not monitor, and therefore should not consider, individual <i>daily</i> nutrient intakes. Likewise, delete the final 3.2.2. sentence As an inapplicable criteria to set Upper Safe Levels, as it is based on policy, not science.</p> <p>Add 'only if the national authority can scientifically validate a lower level than that established by Codex' at the end of paragraph 3.2.3. to preclude national authorities placing unscientific technical barriers to trade based on policy. Unedited, this point may be used to contravene any Upper Safe Levels established by Codex or FAO/WHO.</p>
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<p>4. Packaging</p>	<p>4.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.</p> <p>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.</p> <p>4.3 Vitamin and mineral supplements should be distributed in child-resistant packagings, if necessary.</p>	<p>No Comment</p> <p>No comment</p> <p>Correct “packagings” to packages”</p>
<p>5. Labelling</p>	<p>5.1. Vitamin and mineral supplements are labelled according to the Codex Standard for the Labelling of Pre-packaged Foods (Codex-Stan 1-1985, Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979).</p> <p>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.</p> <p>[5.3 The amount of the vitamins and minerals present in the product shall be declared in the labelling in numerical form. The units to be used shall be units of weight.]</p> <p>5.4 The amounts of the vitamins and minerals declared shall be those per portion of the product as recommended for daily consumption on the labelling and per unit dose form, as appropriate.3</p> <p>[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 Labelling.]</p> <p>5.6 The label must indicate the recommendations on how to take the product (quantity, frequency, special conditions).</p> <p>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]</p>	<p>No comment</p> <p>We urge revision and simplification as: “The product shall be declared as a ‘vitamin & mineral supplement’ or ‘food supplement’ or ‘dietary Supplement’ on the principal display panel, with allowable declarations of nutrients contained therein.</p> <p>We recommend replacing ‘weight’ by ‘amount’ to allow for liquids, and specifying “metric” units.</p> <p>We recommend deleting the brackets around 5.4 and replacing ‘and’ by ‘or’ to ensure clear consumer choice on multiple-unit daily dosages.</p> <p>We recommend deleting the brackets around 5.5. and changing “Information” to “Declarations” as ‘information’ is insufficiently specific. to clarify which information should be expressed as a & of the reference values.</p> <p>We recommend adding ‘otherwise referred to as ‘suggestion of use’ or ‘usage suggestions’ at the end of the sentence to clarify the information’s intent.</p> <p>We strongly urge replacement of ‘if the product contains a significant amount of a nutrient with respect to the toxicity level’ by ‘where appropriate, based on the recommended portion for daily</p>

[5.8 The label must contain a statement: supplements cannot be used for the replacement of meals ~~on~~ long term basis

[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.]

We agree that supplements should not be used **as** a substitute for a diversified diet. However, crowded labels *can* possibly confuse the consumer, and there is no evidence that the health-conscious consumers that **purchase** supplements confuse supplements with meals. **We therefore request deleting 5.8, and failiig that, strongly recommend replacing 5.8 with 'The labelling of vitamin and mineral supplements may not state or imply that these products are a substitute for a diversified diet.'** as more useful to prohibit the use of any statement ~~which~~ implies that sup lements *may* be a substitute for a diversi ~~ed~~ diet, than the currently drafted 5.8.

We recommend deletion of 5.9. Under these Codex guidelines vitamin and **mineral** supplements will be regulated **as** foods, and **as** such do not require advice, professional or otherwise, **beyond** labeling **information.**