codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 **CX/NFSDU 03/5-Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-fifth Session
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PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS

– Comments at Step 3 of the Procedure -
(in response to CL 2002/51-NFSDU Part 3)

Comments from:

United States of America

CRN – COUNCIL FOR RESPONSIBLE NUTRITION

European Community

United States of America

General Comments

Since this is a guideline, rather than a standard, we recommend changing "shall" and "must" to "should" throughout the document.

Comments on Specific Sections

1. SCOPE

1.2 ~~It is left to national authorities to decide whether vitamin and mineral supplements are drugs or foods.~~ These Guidelines ~~do~~ apply **to** ~~in those jurisdictions where~~ **food** products defined in 2.1. ~~are regulated as foods.~~

Rationale:

Codex Alimentarius guidelines only apply to products in international trade and that are regulated as foods. Therefore, reference to regulation as drugs or deference to national authorities are unnecessary.

2. DEFINITIONS

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, **or** solutions**, and are not**

represented for use as conventional foods. ~~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.]~~

Rationale:

a) The current language of "not in a conventional food form" would appear to be unnecessary given previous language as to marketed forms (e.g., capsules, tablets). The suggested language of "not represented for use as conventional foods" would seem to support the Preamble concept that these products are supplements and should not be a substitute for a balanced diet.
b) The meaning of the phrase "do not provide a significant amount of energy" is not clear and appears unnecessary. Moreover, we are unaware of an accepted definition of the concept of "a significant amount of energy".
c) The last sentence is unnecessary. It is redundant with the information in the Preamble.

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.2 The ~~selection of admissible~~ ***chemicals used as sources of*** *vitamin**s** and mineral**s** ~~sources~~ should be based on* ***considerations*** *~~criteria~~ such as safety and bioavailability. In addition, purity criteria should take into account ~~the~~ FAO/WHO* ***standards,*** *or**,** **if FAO/WHO standards are not available, international*** *Pharmacopoeias* ***or recognized international standards. In the absence of criteria from these sources, national legislation may be used.*** *~~[and national legislation, where applicable].~~*

Rationale:

a) The word "admissible" does not seem necessary.
b) Reference to "chemicals used as sources" should clarify the differences between 3.1.1 and 3.1.2.

c) Specific reference to national legislation runs contrary to the spirit of international fair trade practices. Specific reference is not necessary because it is protected under provisions of the WTO agreements. Any reference to national legislation should only be made when international standards are not available.

[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].~~

Rationale:

The intent of this provision is not clear. If it is intended to limit the levels of vitamins and minerals in a product based on safety considerations, then it is more appropriately addressed in provisions covered by Section 3.2 on "Contents" than in section 3.1 on "Selection".

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 **equal to or greater than** ~~[~~15% ~~to 33%]~~ of the recommended **nutrient** ~~daily~~ intake**s (RNIs)** as determined by FAO/WHO.

Comments:

a) Under nutrition labeling standards, a level of 15% of the NRV for a vitamin and mineral is generally deemed necessary to support a nutrient content claim. This suggests that it is a meaningful amount and therefore provides a rational basis for a minimum level for vitamin and mineral supplements, if a minimum level is deemed necessary. We are unaware of a logical basis for the 33% level.
b) The minimum level of 33% may be difficult to achieve for some minerals (e.g., calcium and magnesium) where their bulk alone may make it difficult to achieve a 33% level, particularly where several of these minerals are present in a product.
c) We also recommend the removal of the square brackets around the 15% level.
d) The use of the term "nutrient" in place of "daily" is consistent with the terminology used in the FAO/WHO expert consultations on vitamin and mineral requirements.

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.]~~

Rationale:

We believe that the setting of maximum levels, when needed, should be derived from science-based risk assessments of safety (as is done in the second option for 3.2.2 below). Moreover, the recommended daily intakes as determined by FAO/WHO are inappropriate in this context as safety considerations are not used in their development. We also recommend the removal of the square bracket around the second option for 3.2.2 below.

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 should ~~shall be set~~, take~~ing~~ the following criteria into account:

Rationale:

As a guideline rather than a standard, the use of "should" rather than "shall" is appropriate.

(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 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.]~~

Comment:

We are unclear as to the meaning or purpose of this last statement. It would appear to already be an integral part of the scientific processes involved in both options stated above. In the absence of a clear need for this sentence, we recommend deleting it.

3.2.3 ~~For vitamins an 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.~~

Rationale:

a) Safety issues, including those relating to vitamins and minerals with a narrow safety margin, would be covered by the provisions in 3.2.2.
b) If a particular nationality has an unusually high dietary level of a particular nutrient with a narrow safety range, provisions under the WTO agreements already allow that nation to deviate from international standards based on scientific justification. Thus, this provision is unnecessary.

4. PACKAGING

4.1 The product **should** ~~shall~~ be packed in containers which will safeguard the hygienic and other qualities of the food.

4.2 The containers, including packaging material, **should** ~~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.

5. LABELLING

5.1 Vitamin and mineral supplements **should be** ~~are~~ labeled according to the Codex Standard for the Labelling 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 **should** ~~shall~~ be "vitamin and mineral supplement", or "dietary mineral/vitamin preparation to supplement the diet with …" with an indication of the nutrients contained therein, **or "food supplement", or "dietary supplement".**

Rationale:

Specific identification of "vitamin and mineral" in the name is unnecessary as the nutrient declaration in the labeling will make clear that the product contains vitamins and minerals.

~~[~~5.3 The amount of the vitamins and minerals present in the product **should** ~~shall~~ be declared in the labeling in numerical form. The units to be used **should** ~~shall~~ be ~~units of weight.~~ **consistent with the Codex Guidelines on Nutrition Labelling.**

Comment:

We also recommend the removal of the square bracket for 5.3.

5.4 The amounts of the vitamin and minerals declared **should** ~~shall~~ be those **amounts** per portion of the product ~~as~~ recommended **on the labeling** for daily consumption**, and if different, the amounts per single use.** ~~on the labelling and per unit dose form as appropriate.~~

Rationale:

The use of the term "dose" inappropriately implies a drug use instead of a food use.

5.5 **Numerical** Information on vitamins and minerals **should** ~~shall~~ also be expressed as a percentage of the reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labelling.]

Rationale:

Provides clarification as to the intent of this provision and is consistent with the Codex Guidelines on Nutrition Labeling, para 3.4.4 (CAC/GL2-1985(Rev 1-1993)).

5.6 The label **should** ~~must~~ indicate the recommendations on how to take the product (quantity, frequency, special conditions).

~~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.]~~

Rationale:

There is no need for a warning statement relative to nutrient levels because a product that meets the provisions in 3.2.2 would not contain unsafe nutrient levels.

[5.8 The label ~~must~~ **should not state or imply that** ~~contain a statement:~~ supplements can ~~not~~ be used for the replacement of meals **or a varied diet**. ~~on long term basis~~.

Rationale:

With limited label space, prevention of misleading information is more practical than requiring additional information. Moreover, crowded labels may lead to consumer confusion or failure to read all information. We also recommend the removal of the square bracket for 5.8.

~~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.]~~

Rationale:

This statement is not necessary because products that meet the provisions in this Guideline would be safe, truthfully labeled, and suitable as foods. Moreover, reference to use on the advice of health professionals may mislead consumers into believing it is useful as a drug rather than as a food product.

CRN – COUNCIL FOR RESPONSIBLE NUTRITION

ARE RDA-BASED UPPER LIMITS LOGICAL AND APPROPRIATE?

While the use of the RDA to set upper limits for vitamins and minerals in supplement products has been seen by some governments as convenient, RDA-based limits have no scientific validity for this purpose. Risk assessment is the scientifically valid approach to identification of maximums.

The imposition of drug regulations on products with amounts of nutrients higher than the RDA serves no health purpose, and may preclude certain benefits. Also, imposing drug regulations on supplements with amounts of nutrients above the RDA is disproportionate to the regulation of conventional foods, some of which contain many multiples of the RDA of certain vitamins.

RDA values are set on a very similar basis from one country to another—that basis is a consensus of scientific opinion on the quantities of these nutrients needed to confidently assure the performance of recognized physiological functions related to their essentiality. Thus, the RDA values are related to avoidance of classical nutrient deficiency signs and symptoms. Although this basis for the RDA may be appropriate for undernourished populations, the needs are different for well-nourished and over-nourished populations. A significant fraction of the RDA can be used appropriately to set lower limits for vitamins and minerals in supplements.

RDA-based limits and drug regulations for higher amounts are not appropriate for several important reasons:

1. The RDA is not defined or identified to describe safety or represent a safety limit for total or supplemental intake.

2. RDA-based limits are not possible for nutrients without established RDA values. For example, no RDA has been set for lutein, lycopene, boron, and many other important substances with nutritive value. These substances have beneficial effects, but the available evidence has not been judged appropriate to identify RDAs. Risk assessment can be used to identify appropriate safety limits for these important nutrients, whether or not an RDA has been set.

3. Arbitrary limits at or near the RDA may preclude certain benefits of some nutrients. For example, well-documented benefits of nutrient quantities above the RDA include:
   a. Folic acid, vitamin B6 and vitamin B12 help control plasma homocysteine concentrations. Homocysteine is not yet accepted as a recognized risk factor for heart disease, but there is an ever-increasing body of scientific evidence to support this finding. Supplementation with these three vitamins definitely helps control plasma concentrations of homocysteine, and is likely to prove to reduce risk of heart disease.
   b. Supplementation with 200 micrograms of selenium to diets containing about 100 micrograms has been shown in a long-term, well-conducted clinical trial to reduce the incidence of three important types of cancer. A confirmatory clinical trial is underway that, if positive, would justify a widespread public health policy to increase selenium intake in many populations. In the meantime, there is no reason to deny accurate information about the state of the current evidence and to restrict selenium supplements to the RDA.
   c. Supplementation of diets containing less than 40 micrograms chromium with and additional 200 to 400 micrograms helps maintain normal blood glucose levels and minimize the signs and symptoms of type II diabetes. Clinical trials confirm the safety of up to 1,000 micrograms of supplemental chromium.

4. The imposition of RDA-based upper limits is a disproportionate restriction on supplement products, compared with conventional foods. Certain conventional foods contain many multiples of the RDA of some nutrients. For example, the natural amounts of vitamin B12 in conventional foods such as liver and some shellfish can approach 100 micrograms per 100 gram serving. The adult RDA for this vitamin is commonly set at approximately 2 to 2.5 micrograms. Thus, these ordinary conventional foods may contain upwards of 40 to 50 multiples of the RDA of vitamin B12. There is no known toxicity of oral vitamin B12 in humans. Thus, RDA-based upper limits are not rational, serve no useful purpose, and are a disproportionate response to any hypothetical safety concern about this vitamin.

5. Labeling, not limits, can address proper usage. Labeling can provide information on contents, benefits related to RDA or other measure of benefit, and draw attention to limits imposed on a safety basis, as identified by risk assessment.

European Community

The European Community has the following comments on the proposed draft guidelines for vitamin and mineral food supplements (Alinorm 03/26A Appendix I).

SECTION 1. SCOPE

Insert new paragraph

The present wording of the Scope could be interpreted as the Guidelines applying only to food supplements containing only vitamins and/or minerals. The European Community maintains the view that the provisions on vitamins and minerals included in these Guidelines should also apply to food supplements that contain vitamin and minerals together with other ingredients. It is proposed that this should be included in the Scope as a new paragraph after paragraph 1.1.

" Food supplements containing vitamins and/or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in these Guidelines."

SECTION 2. DEFINITIONS

The first sentence is a statement, which does not belong to the definition and should be deleted. If the statement is to be maintained it should be moved to the preamble. The last sentence in square brackets is already included in the preamble and therefore should be deleted from the definition.

The agreed change to "food supplements" in the title of the proposed draft guideline should also be reflected in the definition. Therefore it is proposed that the word "supplements" should be changed to "food supplements".

An important feature to be included in the definition of these products is that they provide the vitamins or minerals in a dose form and they are designed to be taken in small unit quantities. In addition, it should be clear that the forms given are examples and it may be useful to give more examples of the presentation of food supplements, such as pastilles and ampoules.

To take account of the above points the following revised text is proposed as the definition:

"2.1 Vitamin and mineral food supplements are sources in concentrated forms of those nutrients alone or in combination, marketed in dose form, namely forms such as capsules, tablets, pastilles, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders, designed to be taken in measured small unit quantities not in a conventional food form, and do not provide a significant amount of energy."

SECTION 3.1 SELECTION OF VITAMINS AND MINERALS

Paragraph 3.1.1

The section indicates that the nutrients should be recognised by FAO and WHO. Unfortunately this does not make clear which nutrients are recognised as there are different lists of nutrients in FAO or WHO publications. It would be clearer if a list was included in the Guidelines as an annex.

Paragraph 3.1.2

The wording in square brackets is acceptable. The text should be kept and the square brackets should be deleted.

Again it would be clearer if a list of acceptable sources of nutrients were included as an annex. The acceptable sources of nutrients established in other Codex Standards would be a useful basis for elaborating such an annex.

SECTION 3.2 CONTENTS OF VITAMINS AND MINERALS

Paragraph 3.2.1

Coherence between different sections of the Guidelines should be ensured. Paragraph 3.2.1 refers to recommended daily intake as determined by FAO/WHO whereas in 5.5 reference is made to the nutrient reference values of the Codex Nutrition Labelling Guidelines.

It is noted that in the case of the "Guidelines for the use of Nutrition Claims", the nutrient reference values of the Codex Nutrition Labelling Guidelines have been used as reference values. However, the nutrient reference values would need to be updated, not only to include figures for copper and selenium but also to include additional nutrients that are recognised as vitamins and minerals by FAO or WHO.

Paragraph 3.2.2

The first alternative wording for 3.2.2 should be deleted.

The second alternative wording for paragraph 3.2.2 is broadly accepted and the square brackets should be deleted. The final sentence has some typographical errors. The following sentence is proposed as a replacement:

"When maximum levels are set, due account should also be taken of the reference intake values of vitamins and minerals for the population."

SECTION 4. PACKAGING

It is proposed that the text of paragraph 4.3 be deleted and replaced by the following statement on the labelling (to be inserted in section 5):

"The label must contain a statement to the effect that the product should be stored out of the reach of young children."

SECTION 5. LABELLING

Paragraph 5.2

Given that the proposed Guidelines are to apply to vitamin and mineral food supplements it would be appropriate to include the word "food" in the name of the product. In addition the products could be presented as single vitamin or mineral preparations so the description "vitamin and mineral supplement" would not be appropriate.

It is noted that paragraph 4.1.1 of the Codex General Standard for the Labelling and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) prohibits the use of the word "dietary" in products not covered by that Standard. The Committee decided that foods for special dietary uses would not be covered by the Guideline (see paragraphs 25 and 26 of Alinorm 03/26). Therefore the second alternative for the product name should be deleted.

In cases of multi-vitamin and multi-mineral products the name could become extremely long.

Therefore, it is proposed that paragraph 5.2 on the name of the product should read as follows:

"5.2. The name of the product shall be "food supplement", with an indication of the category(s) of the nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product, as the case may be."

Paragraph 5.4

It is considered that the information required should be restricted to the actual amount per recommended portion. The additional information per "unit dose form, as appropriate" would be confusing for the consumer and should be deleted.

Paragraph 5.5

As previously indicated there are likely to be more vitamins and minerals included in food supplements that those listed in the Codex Guidelines on Nutrition Labelling. Therefore it may be necessary to give consideration to updating the list.

Paragraph 5.7

A warning statement should always be included in the labelling. It is proposed that paragraph 5.7 should read as follows:

"5.7. The label must contain a warning statement not to exceed the stated recommended daily dose."

Paragraph 5.8

It is considered that the proposed statement concerning food supplements and replacement of meals implies that food supplements can be taken in place of a meal, this is not the case. Therefore it is proposed to change the wording of paragraph 5.8 to:

"5.8 The label must contain a statement to the effect that food supplements should not be used as a substitute for a varied diet."