

Crane, Nancy T

611

From: Michael Traub [traub@hawaii.rr.com]
Sent: Saturday, August 24, 2002 7:47 PM
To: Crane, Nancy T
Subject: Codex Committee Comments 02-022N
Importance: High 02-022N-611
Michael Traub

To: Nancy Crane

From: Michael Traub, N.D.
President, American Association of Naturopathic Physicians

Re: U.S. DRAFT Positions on agenda items for the 24th Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) Session prepared for the purpose of discussion and solicitation of comment at the July 30th, 2002 public meeting, and to also solicit written comments from U.S. Stakeholders.

The Committee is requested to consider the following amendments to the US Draft Position on Proposed Guidelines for Vitamin and Mineral Supplements.

General Comments:

We recommend the following revision after the second paragraph:

Insert: Many vitamins and minerals are used for therapeutic purposes, not merely to meet nutrient needs.

Rationale: These guidelines should acknowledge the importance of such uses. For example, niacin, in doses higher than "the recommended daily intake," is an effective agent for reducing elevated cholesterol.

Preamble:

We recommend deleting the following statement in brackets:
[Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet.]

Rationale: Due to nutrient depletion in soil and animal feed, foods may not contain sufficient amounts of all necessary nutrients, even though the diet may be "balanced." Access to a balanced diet does not ensure that people actually eat a balanced diet. The prevalence of vitamin and mineral deficiencies (such as iron, magnesium, and pyridoxine), even in people who have access to a

balanced diet, is evidence that the above statement is erroneous.

5. LABELLING

5.9 We recommend the following revision:

"All labels shall **should** bear a statement that the supplement should be taken on an advice of a [nutritionist, a dietician or a medical doctor."] **qualified health care practitioner.**"

Rationale: Limiting this statement to nutritionist, dietician and medical doctor is discriminatory. Many other qualified health care practitioners may advise nutritional supplements, including naturopathic physicians, osteopathic physicians, nurse practitioners, physician assistants, and dentists.

Respectfully submitted,

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**CODEX COMMITTEE ON NUTRITION AND FOODS
FOR SPECIAL DIETARY USES
24th SESSION
U.S. DRAFT POSITION
AS OF JULY, 2002
PROPOSED DRAFT GUIDELINES
FOR VITAMIN AND MINERAL SUPPLEMENTS
(AT STEP 4)**

AGENDA ITEM No. 6

BACKGROUND

Reference:

- Report of the 23rd Session (ALINORM 03/26, Paras 18-40 and Appendix II)
- Government comments at Step 3 (CX/NFSDU 02 /6) not yet available

The Committee is invited to consider the proposed draft guidelines as amended during the last Session of the Committee and in light of the government comments received.

U.S. DRAFT POSITION

General Comments:

The United States supports consumer choice and access to dietary supplements that are safe and are labeled in a truthful and non-misleading manner. The United States notes that the Codex Guidelines for Vitamin and Mineral Supplements will not, in any way, adversely affect the availability of safe and truthfully labeled supplement products in the U.S. marketplace or to U.S. consumers. The absence of science-based Codex guidelines, however, could adversely affect the ability of U.S. manufacturers to compete in the international marketplace.

Because foods contain many substances that promote health, consumers should be encouraged to select a wide variety of healthful foods. However, we also note that, from a public health perspective, some people need a vitamin-mineral supplement to meet specific nutrient needs. For example, women who could become pregnant are advised to eat foods fortified with folic acid or to take a folic acid supplement in addition to consuming folate-rich foods to reduce the risk of some serious birth defects. Older adults and people with little exposure to sunlight may need a vitamin D supplement. Health care providers may advise pregnant women to take an iron supplement or adults over the age of 50 to get their vitamin B12 from a supplement or fortified foods.

We also recognize that supplements of some nutrients, such as vitamin A and selenium, can be harmful if taken in large amounts.

In the spirit of the protection of international fair trade practices and the science-based resolution of international trade disputes, we support the development of CODEX guidelines for vitamin and mineral supplements that do not unduly limit consumer access to safe and truthfully labeled dietary supplement products.

Comments on Specific Sections:

NOTE: For all sections of these guidelines in which either "shall" or "must" is now used, we recommend that this be changed to "should", since this is a guideline rather than a Codex standard.

PREAMBLE

We recommend that the following revision:

"These guidelines are intended to ensure a high level of protection and to facilitate informed choice for consumers of vitamin and mineral supplements. 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."

Rationale: The preamble should clearly state the purpose of the guideline. The addition of the first sentence to the current Preamble paragraph meets this need.

1. SCOPE

1.1 We recommend the following revision:

"These guidelines apply to vitamin and mineral supplements intended for use in supplementing the daily diet [if and where necessary] with vitamins and/or minerals. These Guidelines apply to vitamin and mineral supplements which are regulated as foods.

Rationale:

1. "if and where necessary" is inconsistent with the Preamble language; Moreover, this phrase is not relevant to this section which addresses the scope of products that are covered.

2. The last sentence is redundant with 1.2 below and is, therefore, unnecessary.

1.2 We recommend the following revision:

"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 **to** products defined in 2.1 are regulated as foods."

Rationale: Codex Alimentarius guidelines only apply to products regulated as foods. Therefore, reference to national authorities which regulate these products as drugs is unnecessary.

2. DEFINITIONS

2.1 We recommend the following revision:

"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 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:

1. The usefulness and meaning of the phrase "do not provide a significant amount of energy" is not clear and appears unnecessary.

2. The last sentence is unnecessary. It is redundant with the Preamble language. If it is retained in 2.1, it should be deleted from the Preamble.

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.2 We recommend the following revision:

"The selection of admissible vitamin and mineral sources should be based on criteria **considerations** such as safety and bioavailability. In addition, **where available**, purity criteria should take into account the FAO/WHO or Pharmacopoeias **purity standards**. [and national legislation, where applicable].

Rationale: We do not believe that it is necessary to include "admissible". Specific reference to national legislation runs contrary to the spirit of international fair trade practices. Moreover, it is unnecessary, since it is protected under provisions of the WTO agreements.

3.1.3 We recommend deleting the following bracketed section:

[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: This section, which limits the levels of vitamins and minerals, is more appropriately addressed in provisions covered by Section 3.2 on "Contents" than it is in section 3.1 on "selection".

3.2. CONTENTS OF VITAMINS AND MINERALS

3.2.1 We recommend the following revision:

"The minimum level of each vitamin and/or mineral 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."

Rationale: The 15% level is consistent with the amount that a food product must contain (per serving or per 100g) to claim on its label that it is a "source" of a vitamin or mineral based on recently adopted Codex provisions for conditions for vitamin and mineral claims.

3.2.2 We recommend deleting the first option:

[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: FDA believes that the setting of maximum levels, when needed, should be based on science-based assessment of safety (as is done in the second option for 3.2.2. below) rather than through an arbitrary application of a % of the recommended daily intake level (as is done in the option directly above).

We recommend retaining the second option with the following revision:

[Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall **should** be set, taking the following criteria into account:

(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.]

Rationale:

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

2. The last sentence seems unnecessary if a science-based risk assessment approach is used to set maximum limits.

3.2.3 We recommend deleting the text in this section.

"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."

Rationale: Safety issues would be covered by the provisions in 3.2.2 (a) and (b).

4. PACKAGING

4.1 We recommend the following revision:

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

4.2 We recommend the following revision:

"The containers, including packaging material, shall **should** 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

[5.2 We recommend the following revision:

[" The name of the product shall **should** be "vitamin and mineral supplement" or "dietary mineral/vitamin preparation to supplement the diet with , with an indication of the nutrients contained therein."]

Rationale: The last phrase is more appropriately addressed in 5.3 below.

[5.3 We recommend the following revision:

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

5.4 We recommend the following revision:

"The amounts of the vitamin and minerals declared shall **should** be those per portion of the product as recommended for daily consumption on the labeling and per unit dose form, as appropriate."

5.5 We recommend the following revision:

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

5.6 We recommend the following revision:

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

5.7 We recommend the following revision:

"The label must **should** contain a warning statement [if the product contains an significant amount of a nutrient **that has been shown through science-based risk assessment to be a health hazard under conditions of use.** with respect to the toxicity level."]

[5.8 We recommend the following revision:

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

5.9 We recommend the following revision:

"All labels shall **should** bear a statement that the supplement should be taken on an advice of a nutritionist, a dietician or a medical doctor."]

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Michael Traub, ND
President, American Association of
Naturopathic Physicians