

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 99N-0391]

**International Standard-Setting Activities; Codex Alimentarius Commission;
Committee on Nutrition and Foods for Special Dietary Uses; Background Paper to
Identify Perspectives and Issues Pertaining to International Guidelines on Vitamin
and Mineral Supplements**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is asking interested persons to submit comments that will be used by the U.S. delegate to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to prepare a background paper to be considered by the CCNFSDU prior to its considering the appropriateness of establishing guidelines for vitamin and mineral supplements for the purposes of international trade. The background paper will discuss the range of concerns and the differences in rationales on this topic. The United States, which has indicated its opposition to the development of such guidelines, has been asked to participate in the development of this background paper along with other governments. FDA is accepting this request in its role as the agency representing the United States in the CCNFSDU.

DATES: Submit written comments by (*insert date 60 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments and recommendations to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS-456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4605.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Codex Alimentarius Commission (Codex) is the joint food standards program of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). This program was established in 1962 and develops food standards, codes of practice, and other guidelines to help protect the health and economic interests of consumers and to facilitate and encourage fair international trade in food. The Codex accomplishes these actions through the use of subordinate committees that develop food standards, codes of practice, and other guidelines for consideration and adoption by the Codex and member countries.

In the United States, the U.S. Department of Agriculture (USDA), FDA, and other agencies manage and carry out U.S. Codex activities. Executive direction of this effort comes from the U.S. manager for Codex, a responsibility of the Food Safety and Inspection Service (FSIS) of USDA. For more information on U.S. Codex activities and the responsibilities of the U.S. delegates to Codex committees, see the **Federal Registers** of May 27, 1998 (63 FR 28966), and February 12, 1998 (63 FR 7118), respectively. Under section 491 of the Trade Agreements Act of 1979 (19 U.S.C. 2578), as amended, and the Uruguay Round Agreements Act, Pub. L. 103-465, 108 Stat. 4809, FSIS must inform the public of the sanitary and phytosanitary standard setting activities of international standard-setting organizations, such as Codex. The most recent annual notice was published in the May 27, 1998, **Federal Register**. That notice identified FDA as the responsible agency for the United States with respect to the activities of the CCNFSDU (63 FR 28966 at 28973). Accordingly, the U.S. delegate to the CCNFSDU is from FDA.

This notice solicits information and comments relative to the content of a background document that is intended to identify the nature of and basis for differences in perspectives on

establishing guidelines for vitamin and mineral supplements in international trade. This document is a component of the sanitary and phytosanitary standard-setting activities of the CCNFSDU with regard to its consideration of guidelines for vitamin and mineral supplements (Ref. 1).

II. Background

Germany proposed a process to consider the development of guidelines for vitamin and mineral supplements at the October 1995 meeting of the CCNFSDU. Germany submitted the draft proposed guidelines (Ref. 2), which were intended to address such issues as the composition and labeling of vitamin and mineral supplements, including lists of allowable vitamins and minerals and their sources, minimum and maximum levels, permissible additives, packaging, labeling requirements, and permissible claims. Codex circulated the proposal to member governments for comment, and it was considered at the October 7 to 11, 1996, CCNFSDU committee meeting (Ref. 3).

At that meeting, the United States, through its delegate, indicated its opposition to the development of the guidelines. Such guidelines would not affect dietary supplements within the United States, whose sale and marketing is regulated under the Federal Food, Drug, and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act of 1994. However, such guidelines, were they developed and adopted by other countries, could affect international trade in vitamin and mineral supplements. In particular, such guidelines could have ramifications for those U.S. manufacturers of dietary supplements that export their products to countries that adopt such guidelines.

CCNFSDU did not reach consensus on many aspects of the draft proposed guidelines, but nonetheless, they forwarded the draft proposed guidelines to Codex and recommended that the draft proposed guidelines be advanced to the next level of consideration. Codex considered the recommendation of the committee at its June 23 to 28, 1998, meeting in Rome, Italy (Ref. 4). The United States, through its delegate, again indicated its opposition to the advancement of the guidelines during the Codex meeting.

Codex did not advance the draft proposed guidelines to the next level of consideration, but instead Codex returned them to the CCNFSDU for further discussion and consideration. Codex also advised the CCNFSDU to reconsider whether there was a need to proceed with the development of the guidelines.

The CCNFSDU considered the draft proposed guidelines again at its September 21 to 25, 1998, meeting (Ref. 1). A copy of this document may be downloaded from the internet at “www.fao.org/es%2A/esn/codex/reports.htm”. The CCNFSDU discussed the draft proposed guidelines and decided that while it was premature to stop work on the draft proposed guidelines, there was not enough agreement to advance the proposed draft guidelines for vitamin and mineral supplements to the next level of consideration. Consequently, the draft proposed guidelines remained at their current level of consideration. Because there was no consensus on the need for the proposed guidelines or what they should contain, the CCNFSDU decided that it would be useful to reconsider the basis for continuing work on the draft proposed guidelines. The CCNFSDU believed that it would facilitate its work if it could prepare a background paper that would: (1) Provide “a neutral and objective presentation on the issues that should be considered on this subject”, (2) “help understand the rationale behind the different approaches”, and (3) “be useful to study in depth the principles justifying each particular position in order to find a common ground for discussion” (Ref. 1).

The CCNFSDU chair asked the U.S. Government to contribute to this background paper, which will be considered at the next meeting of the CCNFSDU in the year 2000. The U.S. delegate agreed to this request. The U.S. delegate concluded that there is value in assisting with the development of an objective background paper that addresses the various perspectives, approaches, and difficulties associated with developing guidelines for international trade in vitamin and mineral supplements. This activity is consistent with the U.S. interests in this matter and will facilitate the decisionmaking process of the CCNFSDU.

III. Request for Comments

Interested persons may, on or before (*insert date 60 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Based on the interest of the CCNFSDU in identifying the pros and cons of developing guidelines for vitamin and mineral supplements and in identifying the various factors and principles pertaining to international guidelines for vitamin and mineral supplements, FDA is asking for comments that identify the range of perspectives associated with the manufacture, use, and regulation of such products, as well as the specific issues that the paper should address. Moreover, the CCNFSDU intends to develop a paper that considers only issues relevant to vitamin and mineral supplements. The CCNFSDU does not intend that the paper will consider the addition of vitamins and minerals to conventional foods nor products containing other ingredients or substances, for example herbs or other botanicals. Accordingly, comments on such matters will not assist the U.S. delegate to contribute to the CCNFSDU paper.

For the purposes of international trade, FDA has identified topics that should be addressed in the background paper. The topics identified for comment are as follows: (1) Topic 1 focuses on terminology, such as the use of the terms “food supplements” or “dietary supplements,” as compared to “vitamin and mineral supplements;” (2) topic 2 focuses on the purpose and role of vitamin and mineral supplements; (3) topic 3 focuses on the concept of “approved nutrients” (i.e., a positive or negative list of nutrients for use in the supplements of issue); (4) topic 4 focuses on setting maximum levels for vitamins and minerals in supplement form; (5) topic 5 focuses on setting minimal limits for vitamins and minerals in such products; (6) topic 6 focuses on purity

and good manufacturing practices; (7) topic 7 focuses on labeling, warning statements, and claims; and (8) topic 8 focuses on packaging and marketing.

For each topic, specific comments would be most helpful if they addressed the following:

(1) Is there a need for the topic? (2) What are the various perspectives on the topic and what the difficulties in addressing these perspectives? and (3) What are the options for making decisions about the topic?

We also welcome comments on the inclusion of additional topics. It would be most helpful if the additional topic(s) could be addressed in a fashion so as to respond to the three basic questions identified for the other topics listed previously.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

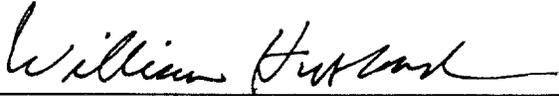
1. Codex Alimentarius Commission, "Report of the Twenty-First Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses," ALINORM 99/26, FAO/WHO, Rome, 1998.

2. Codex Alimentarius Commission, "Report of the Twentieth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses," ALINORM 97/26, FAO/WHO, Rome, 1996.

3. Codex Alimentarius Commission, "Report of the Nineteenth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses," ALINORM 95/26, FAO/WHO, Rome, 1995.

4. Codex Alimentarius Commission, "Report of the Twenty-Second Session of the Codex Alimentarius Commission," ALINORM 97/4, FAO/WHO, Rome, 1997.

Dated: April 2, 1999



William K. Hubbard
Acting Deputy Commissioner for Policy

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