

CODEX OVERVIEW

What is the current status on Codex?

Has it passed congress?

This document from the US FDA, seems to put all the concerns about CODEX behind us, as just a bad dream. It is VERY well worth reading, as it seems to claim that there is no way that CODEX can override DSHEA.

FDA US Food and Drug Administration CFR/Office of Nutritional Products, Labeling and Dietary Supplements March 2005

Responses to Questions about Codex and Dietary Supplements

Many U.S. consumers have expressed concerns about the development of the Codex Draft Guidelines for Vitamin and Mineral Food Supplements. Some are concerned that these Guidelines, if adopted by Codex, will restrict consumers' access to the wide range of vitamin and mineral supplements of varying potencies legally sold in the United States.

Others are concerned that the Guidelines will limit the amount and type of information on the labels of dietary supplements sold in the United States. Still others believe that the Guidelines will require dietary supplements to be sold as drugs in the United States.

We hope the responses below help you understand why the adoption of Draft Guidelines for Vitamin and Mineral Food Supplements by Codex will not restrict U.S. consumers' access to vitamin and mineral supplements or impose any restrictions that go beyond those established by U.S. law. We also hope the responses help explain why the U.S. participates in the Codex process and how you can keep abreast of Codex activities.

What is Codex?

The Codex Alimentarius Commission, or Codex, was created in 1963 by two U.N. organizations, the Food and Agriculture Organization and the World Health Organization. Its main purpose is to protect the health of consumers and to ensure fair practices in international trade in food through the development of food standards, codes of practice, guidelines and other recommendations. Codex standards and guidelines are developed by committees, which are open to all member countries. Member countries

review and provide comments on Codex standards and related texts at several stages in the development process. In the United States, public meetings are held to receive comments on Codex drafts and comments are invited from all interested parties (See U.S. Codex Office web site). Codex standards and related texts are voluntary; member countries are not bound by or required to adopt them. You can obtain more information about Codex at the Rome Codex web site. You can also obtain information about U.S. Codex activities at the U.S. Codex Office web site.

What work has Codex undertaken on vitamin and mineral supplements?

In the early 1990's, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) began discussions on guidelines for vitamin and mineral supplements. This Committee is responsible for studying nutritional issues referred by the Codex Alimentarius Commission; drafting provisions, as appropriate, on the nutritional aspects of all foods; and developing standards, guidelines, or related texts for foods for special dietary uses. Germany is the host government for the Committee, which has met either every year or every other year since 1966. At its most recent session (Bonn, November 1-5, 2004), the Committee completed work on Draft Guidelines for Vitamin and Mineral Food Supplements and submitted them for adoption by the Codex Alimentarius Commission at the Commission's July 2005 meeting.

What is the scope and content of these Guidelines?

The Guidelines apply only to supplements that contain vitamins and/or minerals, where these products are regulated as foods. The Guidelines address the composition of vitamin and mineral supplements, including the safety, purity, and bioavailability of the sources of vitamins and minerals.

The Guidelines do not specify upper limits for vitamins and minerals in supplements. Instead, they provide criteria for establishing maximum amounts of vitamins and minerals per daily portion of supplement consumed, as recommended by the manufacturer. The criteria specify that maximum amounts should be established by scientific risk assessment based on generally accepted scientific data and taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups.

The Guidelines also address the packaging and labeling of vitamin and mineral supplements. We encourage you to read the complete text of the Guidelines, which is found in Appendix II of the report of the most recent

session of the CCNFSDU. See ALINORM 05/28/26 on the page of Full Reports of Recent Sessions .

What has been the U.S. position on these Guidelines?

The U.S. supports consumer choice and access to dietary supplements that are safe and labeled in a truthful and non-misleading manner. The Dietary Supplement Health and Education Act of 1994 (DSHEA) ensures that a broad array of dietary supplements are available to U.S. consumers. The Codex Guidelines for Vitamin and Mineral Food Supplements will not, in any way, affect the availability of supplement products to U.S. consumers. On the contrary, the absence of science-based Codex guidelines could adversely affect the ability of U.S. manufacturers to compete in the international marketplace.

Why won't these Guidelines restrict U.S. consumers' access to vitamin and mineral supplements?

Some consumers mistakenly believe that if Codex should adopt guidelines on vitamin and mineral food supplements that are more restrictive than DSHEA, the U.S. would be required to automatically change its laws and regulations to comply with the international standard. Some consumers have expressed concerns that the World Trade Organization (WTO) and its trade dispute settlement panels may place pressure on the U.S. to change its laws because of international trade agreements such as the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which references Codex as the international organization for food safety standards. We see no basis for these concerns. First, the DSHEA covers a much broader range of dietary supplements than the vitamin and mineral supplements that are the subject of the Codex Guidelines. Moreover, for supplements covered by these Guidelines, we note the following:

- **The SPS Agreement does not require a country to adopt any international standard.**

Rather, the SPS Agreement provides that members may base their Sanitary and Phytosanitary measures either on international standards, guidelines or recommendations, where they exist, or may establish measures that result in a higher level of protection if there is a scientific justification, or if a country determines it to be appropriate in accord with provisions of the SPS Agreement (SPS Agreement, Article 3(1) and (3)).

- **WTO and WTO dispute panels do not have the power to change U.S. law.**

If a WTO decision in response to a dispute settlement panel is adverse to the U.S., only Congress and the Administration can decide whether to implement the panel recommendation, and, if so, how to implement it.

- For dietary supplements, it is unlikely that another country will accuse the U.S. of imposing a trade barrier for the importation of supplement products into the U.S. marketplace because the U.S. laws and regulations are generally broader in scope and less restrictive than the international standard.
- However, other countries with more restrictive laws and regulations for dietary supplement products than the U.S. may create trade barriers to the importation of products manufactured by the U.S. dietary supplement industry. Thus, the U.S. government's involvement in the setting of international standards can help minimize the potential of trade barriers to U.S. products in international trade. Further, there is no basis for the concern that the Codex Guidelines on Vitamin and Mineral Food Supplements would require dietary supplements be sold as prescription drugs in the United States. First, there is nothing in the Guidelines that suggests that supplements be sold as drugs requiring a prescription. Second, U.S. regulatory agencies are bound by the laws established by Congress, not by Codex standards. Third, because of our generally less restrictive standards, it is unlikely that the trade dispute would be brought against the U.S.

In summary, U.S. consumers' access to a broad array of dietary supplements under DSHEA would not be changed in any way by Codex's adoption of guidelines on vitamin and mineral food supplements. The Guidelines also include packaging and labeling provisions for vitamin and mineral food supplement products. Would vitamin and mineral supplements sold in the U.S. be required to comply with these? All Codex standards and related texts are voluntary, and vitamin and mineral food supplement products sold in the U.S. would not be required to comply with provisions that are more restrictive than U.S. law (i.e., DSHEA).

If the U.S. is not trying to harmonize its regulatory framework for dietary supplements with Codex, what are the benefits of our country participating in the process of developing these Codex Guidelines?

Our participation in the Codex process is important to encourage the

development of guidelines on vitamin and mineral supplements that are based on sound science and not on arbitrary criteria. For example, encouraging the use of science-based risk assessment for determining the maximum levels of vitamins and minerals in supplements reduces the chance that arbitrary standards will be used for determining maximum levels.

How can I keep abreast of the work of Codex?

To keep abreast of U.S. Codex activities, you may want to periodically access the U.S. Codex Office website. You can also obtain the agenda and reference documents for Commission and committee meetings and final reports from these meetings from the Rome Codex website. The appendices to the committee reports provide the latest draft versions following a committee meeting of some of the Codex standards that are being developed or revised by the Committee.

You might want to check this link on Codex and dietary Supplements from FDA

<http://www.cfsan.fda.gov/~dms/dscodex.html>