

American Holistic Health Association Position Paper November 2004 Codex Meeting

Written by American Holistic Health Association

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The following are the AHHA comments submitted to the FDA representative, Dr. Barbara Schneeman, to be considered when drafting the United States' position related to the *Proposed Draft Guidelines for Vitamin and Mineral Food Supplements* that will be discussed at the 26th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to be held in Bonn, Germany, November 1-5, 2004.

September 9, 2004

Comments for U.S. Head Delegate, Dr. Barbara Schneeman, to be considered when finalizing the United States' position related to the *Proposed Draft Guidelines for Vitamin and Mineral Food Supplements* that will be discussed at the 26th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to be held in Bonn, Germany, November 1-5, 2004.

As a consumer education organization, the American Holistic Health Association (AHHA) has been working to increase the American public's awareness of the *Codex Alimentarius*. *The highest consumer interest has been in the Guidelines for Vitamin and Mineral Food Supplements* being developed by the CCNFSDU.

It is our understanding that the WTO expects the Codex Alimentarius to draft food standards for international trade regulations and for food safety. In order to resolve international trade disputes these standards need to be applicable in all situations and for all countries. In the case of vitamin and mineral supplements there are so many variables and exceptions that it is not possible to present the WTO with *one trade standard that could be applied to every nation*.

* If you survey all of the countries around the globe, you will find that they designate vitamin and mineral supplements in one of the following three ways:

as food

as drugs

as food at a lower level; as drugs at a higher level

* Another variable is that vitamin and mineral supplement products can have natural and/or synthetic ingredients as the source of the nutrients.

* To complicate the situation even further, the same vitamin and mineral products can be used for different purposes:

Prevent nutritional deficiencies

Health enhancement

Disease prevention

Treatment

The key concern expressed by the American public is that there are conflicting indications for how the *Guidelines for Vitamin and Mineral Food Supplements* document will be used after it has been finalized. AHHA urges the U.S. Delegation to spearhead an effort to verify how the WTO will use these *Guidelines*. Currently, it appears that those drafting this important document are misinformed as to how it will actually be used.

Firsthand experience talking with delegates at CCFSDU sessions in Germany and members of the German Codex staff indicates strong convictions that the *Guidelines* is a document with optional suggestions to be used by those countries needing this type of data. Delegates seem to believe that because the document is entitled "Guidelines" it is only guidelines, or suggestions. However, in 1998 the WTO informed Codex that it does not differentiate between *standards* and *guidelines*. Both will be used as **mandatory standards**.

http://docsonline.wto.org/gen_search.asp?searchmode=simple
Search for documents numbered 98-0462 and 98-1071.

A. STATUS OF CODEX STANDARDS, GUIDELINES AND OTHER RECOMMENDATIONS CX/EXEC 98/45/9 April 98

The 22nd CAC Session had requested the WTO Committee on Sanitary and Phytosanitary Measures (the SPS Committee) to clarify how the Committee would differentiate "standards, guidelines and other recommendations" in relation to the SPS Agreement by WTO Members. The WTO letter of response dated March 1998 included "The definition makes no distinction between standards, guidelines and recommendations. The SPS Agreement does not provide specific definitions for the terms 'standards', 'guidelines' or 'recommendations'."

"In no case do these provisions differentiate between the three terms 'standards', 'guidelines' or 'recommendations'"
"...how a Codex text was applied depended on its substantive content

rather than the category of that text (eg., commodity standards, MRLs, codes of practice, guidelines)."

The content of the *Codex Guidelines for Vitamin and Mineral Food Supplement* specifically excludes the roles of prevention and treatment. It also limits application to only countries designating vitamin and mineral supplements as food. The wording of the Guidelines has been changed to have should, not shall. References have been made in 25th CCFNSDU session report to CAC that "as the text was not a standard". However, under SCOPE 1.2 the text states "These Guidelines do apply..." To clear up any future confusion, if the CCFNSDU does intend for the *Guidelines* to **not** be a mandatory standard, this needs to be stated within the document, most appropriately under the SCOPE section. This would be in keeping with the WTO clarifications to Codex "**...how a Codex text was applied depended on its substantive content rather than the category of that text.**"

Otherwise, once the *Guidelines* are finalized, the WTO might decide that, since there is no international standard, it will use the *Guidelines for Vitamin and Mineral Food Supplements* as a mandatory standard and apply to all countries, perhaps even those designating these supplements as drugs. The WTO might even decide to use the *Guidelines* to apply to all uses of vitamins and minerals, even those used for therapeutic purposes.

Increasing numbers of American consumers are becoming aware of what a valuable privilege they have to be able to purchase the vitamin and mineral supplements of their choice. They see the looming restrictions going into effect in the European Union countries and are genuinely concerned that this might happen in the U.S.

While most industry sources are confident there is no reason to be concerned, there are a number of individuals with legal training who are concerned after studying how the WTO handles international trade disputes.

AHHA urges the U.S. Delegation to

* Have legal experts study the following WTO procedures with respect to identifying the circumstances under which these might have the power to force the U.S. to change it's laws, particularly using trade sanctions:

Technical Barriers to Trade

Most-Favoured Nations

Dispute Settlement Body

* Find a source within WTO who can answer these questions:

If the WTO received the *Guidelines for Vitamin and Mineral Food Supplements* in its current form, how could this document be used by WTO?

If the CCFNSDU wanted to guarantee that the *Guidelines for Vitamin and Mineral Food Supplements* is not to be used as a mandatory standard, what does the WTO officially need to have included within the text of the document to ensure this, and where within the document?

AHHA urges the U.S. Delegation to make certain that the CCNFSDU delegates are accurately informed as to the answers to these two questions. How the Guidelines document will be used by the WTO needs to be on record in the CCNFSDU session report - from the WTO, not from a Codex source.

AHHA also urges the U.S. Delegation to take the leadership role supporting the addition of appropriate wording to the *Guidelines* document, stating that this document is not to be a mandatory standard, but only optional suggestions. AHHA will be present to support you in this. Our president, Suzan Walter, will be attending the CCNFSDU session as an observer.

Please make sure the *Guidelines for Vitamin and Mineral Food Supplements* document is not finalized until these matters have been resolved.

In reviewing the preliminary U.S. Positions on the *Guidelines for Vitamin and Mineral Food Supplements* we offer the following comments:

1) 3.1.2 Synthetic sources not food

We are concerned that this reference to synthetic sources for a vitamin or mineral supplement is inconsistent with the scope of Codex in general and this document in particular. The WTO is expecting Codex to provide standards related to **foods**. Synthetic ingredients are not food. Also, in 2003 there was a significant issue made at the CCNFSDU session that the word 'food' must be added to the title of the *Guidelines* document. We urge you to carefully consider all of the ramifications of including synthetic sources in the scope this document. This is one of those variables that make an all-encompassing food standard impossible for dietary supplements. (Reference our comments above on this matter)

2) Work on your rationale for 3.2.2 section deletion

We agree that the statement in square brackets should be deleted. You are encouraged to have stronger arguments to rebut those committed to keeping upper limits on vitamins and minerals as low as possible. They will find numerous reasons to take a safe upper limit and keep lowering it due to possible other sources. This process could easily be abused.

3) Concern about wording of 3.2.2

It is reasonable that a ceiling be established for a nutrient, where more than that amount would be toxic and dangerous for human consumption. This research needs to be done by a fair, qualified scientific process and this information should be made available in the public domain. However, the wording in the *Guidelines* is "Daily portion of consumption as recommended by the manufacturer" We are concerned that implementation is wide open for misinterpretation. As this section is not in square brackets, we are realistic that the CCNFSDU session Chair would most likely refuse to have it addressed. We do urge the U.S. Delegation to be alert and vigilant to matters related to this section. The goal is helpful information related to safety, not setting restrictive international standards.

4) 5.5 should be in square brackets

If you look at the November 2003 CCNFSDU session appendix, which includes the Guidelines, you will note that 5.5 is in square brackets. The initial bracket has been accidentally omitted in the most recent online Codex version, but the end bracket stands. The U.S. Delegation will want to review 5.5 and determine their position on this matter.

These comments submitted by
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