DEPARTMENT OF HEA H & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 1 2001

01-010N
01-010N-1
Melinda K. Plaisier

The Honorable Peter J. Visclosky
House of Representatives
Washington, D.C. 20515-1401

Dear Mr. Visclosky:

Thank you for your letter of March 21, 2001, on behalf of your constituent, Mr. John G. Clemmons of Hobart, Indiana, who expressed several concerns regarding Codex Alimentarius Commission (Codex) vitamin issues. We address his concerns with relevance to the Food and Drug Administration's (FDA) role in Codex. As you requested, we also will submit Mr. Clemmons' correspondence to the Public Docket Number 01-010N, FSIS Docket Clerk, Food Safety and Inspection Service (FSIS), Cotton Annex, Room 102, Washington, D.C. 20250-3700, for the Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU).

Mr. Clemmons is concerned that the statement that "U.S. domestic vitamin laws are "protected" from Codex harmonization by Federal Statute 19 USC 3512 (a)(1) and (a)(2)" is not factual.

Federal statute, Title 19, United States Code (U.S.C.) 3512(a)(1) reflects U.S. law with regard to the GATT Uruguay Round Trade Agreements. That section provides that no provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have any effect. As a trade agreement, the Uruguay Round Agreements were submitted to Congress along with a bill (called the Uruguay Round Agreements Act, or URAA) to amend U.S. law to bring it into conformity with the Agreements. The statute further states that nothing in the URAA "shall be construed. . . to amend or modify any law of the United States, including any law relating to. . . the protection of human, animal, or plant life or health, the protection of the environment, or worker safety, or to limit any authority conferred under any law of the

United States. . . unless specifically provided for in this Act." 19 U.S.C. 3512(a)(2). Simply put, the World Trade Organization (WTO) has no power to change U.S. law. Similarly, WTO dispute settlement panels do not have any power to change U.S. law or to order such a change. With regard to a panel decision that is adverse to the U.S., only Congress and the Administration can decide whether to implement a WTO panel recommendation and, if so, how to implement it. This is true even when the basis of a panel recommendation is based on the harmonization provisions in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

With regard to specific concerns regarding harmonization and international standard-setting organizations such as the Codex, 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 introduce 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). International standards, guidelines and recommendations with regard to food safety are defined as those established by Codex. SPS Agreement, Annex A). A member's food safety measure that conforms to a Codex standard shall be deemed to be necessary to protect human or animal health, and shall be presumed to be consistent with the provisions of the SPS Agreement and the GATT 1994 (SPS Agreement, Article 3(2)).

Members are free to deviate from Codex's standards to attain a higher level of public health protection. In addition, the SPS Agreement does not require a country to adopt any international standard at all. Therefore, any standards established by Codex, including any relating to dietary supplements, do not automatically result in a change to U.S. laws or regulations concerning dietary supplements.

Mr. Clemmons is concerned that vitamin consumers, health food stores, and small manufacturers can not trust the vitamin trade associations NNFA, UNPA, AHPA, CRN, and IADSA to properly defend the interests of consumers, health food stores, and small manufacturers before Congressional Oversight Committees and at Codex Meetings.

We will address Mr. Clemmon's concerns regarding participation at Codex Meetings. The duties of the United States delegates and delegation members, including non-government members are specified in a notice published in the Federal Register (Vol. 63, No. 29 (February 12, 1998), pages 7118-7120) (Copy enclosed). The U.S. delegate and alternate delegate are full-time Federal government employees. They represent the United States Government at all Codex committee sessions and present the United States' position on each agenda item at Codex committee sessions. Representatives of vitamin trade associations do not represent U.S. positions at CODEX Committee meetings, nor speak on behalf of the U.S. delegate.

In preparing the U.S. positions on various Codex agenda items, the delegate takes into account U.S. statutes, regulations, and policy. The delegate also solicits comments on draft position statements from interested stakeholders via written comments and oral comments expressed at one or more public meetings held prior to a Codex committee meeting. Generally, comments are received from a broad range of interested parties including consumers, health professionals, other government agencies, and industry groups.

A limited number of non-government members also can participate in an advisory role to the U.S. delegate, as members of the United States delegation to a Codex committee meeting. Prior to a Codex Committee meeting, the U.S. delegate solicits requests from interested parties for membership on the delegation. In selecting the delegation members, the U.S. delegate will strive to form a delegation that: (1) has expertise relevant to the items on the agenda of, or likely to be discussed at, the particular Codex committee session; (2) can assist the United States delegate with items on the agenda of, or likely to be discussed at, the particular Codex committee session; (3) is representative of the individuals, groups, and organizations that have an interest in the items on the agenda of, or likely to be discussed at, the particular Codex committee session; and (4) is representative of the individuals, groups, and organizations that could be affected by standards to be considered at the Codex session.

With regard to selection of non-government members to delegations, the United States delegate considers the following: (1) the necessity of obtaining the informed views

of non-government individuals during the Codex committee session; (2) whether consultations or opportunities to provide written comments prior to the Codex committee session would be an adequate alternative to including non-government members on the United States delegation; and (3) the number of non-government members that would be required on the United States delegation to provide balanced representation of the individuals, groups, and organizations that have an interest in the items on the agenda or could be affected by standards to be considered at the Codex session. In the case where the delegation size may exceed the guideline limit of 25, the delegate assesses whether non-governmental interest can be adequately represented through approved Codex international non-governmental organizations.

The delegation members for the Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU), where the proposed standard for vitamin/mineral dietary supplements is currently under consideration, has traditionally represented a broad range of perspectives and interests. (Copy enclosed of the list of participants, including the U.S. delegation membership, for the last meeting of the CCNFSDU). Only once has a person who requested membership on the delegation of the CCNFSDU been denied this privilege. The reasons for this denial were based on inappropriate behavior at a prior CCNFSDU meeting.

Mr. Clemmons is concerned that the National Academy of Sciences paper titled, "A Risk Assessment Model for Establishing Safe Upper Levels for Nutrients" which was put on the table at Codex does not represent the "best science we can get" to protect our business interests.

The National Academy of Sciences (NAS) is an organization with internationally recognized scientific capability and integrity. NAS has available a public document on a science-based risk assessment approach to the setting of safe upper limits of nutrients. This paper is relevant to several CCNFSDU agenda items and provides a scientific reference for the Committee's discussion on the issues at hand.

Thanks again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

for Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosures

cc: Food Safety and Inspection Service
Public Docket Number 01-010N
Cotton Annex, Room 102
Washington, D.C. 20250-3700
ATTN: FSIS Docket Clerk