Codex Alimentarius and the US Dietary Supplement Industry

Mark A. Le Doux, Chairman and CEO
Natural Alternatives International, Inc.
Since the first steps were taken in 1961 to establish a Codex Alimentarius, the Codex Alimentarius Commission – the body charged with developing a global food code – has drawn world attention to the field of food quality and safety. Now, for almost 50 years, all important aspects of food pertaining to the protection of consumer health and fair practices in the food trade have come under the Commission’s scrutiny.
“When formulating national policies and plans with regard to food, Governments should take into account the need of all consumers for food security and should support and, as far as possible, adopt standards from the Food and Agriculture Organization’s ... and the World Health Organization’s Codex Alimentarius ...”.

United Nations General Assembly Guidelines for Consumer Protection

1985

Fostering consumer protection worldwide
Agreed that:

...“The process of harmonizing national food regulations to bring them into line with international standards and recommendations was an urgent one, which needed to be accelerated ...” and that: “Provisions essential for consumer protection (health, safety of food, etc.) should be the focus of emphasis in Codex standards ...”.
World Trade Organization - Geneva
Formal Recognition of these International standards, guidelines and recommendations, including the Codex Alimentarius, as reference points for facilitating international trade and resolving trade disputes in international law.
Committed itself to:

“Implement policies aimed at ... improving physical and economic access by all, at all times, to sufficient, nutritionally adequate and safe food and its effective utilization.”

and to:

“Apply measures, in conformity with the Agreement on the Application of Sanitary and Phytosanitary Measures and other relevant international agreements, that ensure the quality and safety of food supply ... “.
Fifty-Third World Health Assembly
Year 2000

Recognized:

“The importance of the standards, guidelines and other recommendations of the Codex Alimentarius Commission for protecting the health of consumers and assuring fair trading practices ...”

and urged Member States to:

“Participate actively in activities in the emerging area of food safety risk analysis.”
Affirmed:

“The Codex system provides an important opportunity for countries to work together to develop international standards in a representative manner. ... Developing countries would benefit from greater use of basic Codex texts when building their food control systems.”
Scientific Principles for Standards-Setting in the Codex Alimentarius System

The first Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account says, “The food standards, guidelines and other recommendations of the Codex Alimentarius shall be based on the principle of sound scientific analysis ...”.
Relevance of Codex Standards in International Commerce

Purpose of the Codex guidelines on nutrition labeling:

To ensure that nutrition labeling is effective and to assist

“In providing the consumer with information about a food so that a wise choice of food can be made ...”

The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.
SPS agreement: agreement on the application of Sanitary and Phytosanitary Measures

Article 2.2 of the SPS Agreement states:

“Members shall ensure that any sanitary and phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence ...”.

Article 3.1 of the SPS Agreement states:

“To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement.”
In the 14 years until December 2008, members submitted 6648 regular notifications and 1086 emergency notifications of measures relating to the SPS agreement.

Since 2005, the toughest policy issue facing the SPS Committee has been the increased use of private standards. With political and consumer pressures for ever-safer food – *sometimes regardless of justification* – retailer and distributors are putting into place their own standards which often exceed national or international norms.
A total of 1,408 notifications of new or proposed SPS measures were submitted to the WTO in 2010.
Some consumers mistakenly believe that with the adoption of the *Guidelines on Vitamin and Mineral Food Supplements*, the U.S. is required to automatically change its laws and regulations to comply with the international standard.

Some 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)).
Codex is quoted in trade agreements
Codex and its work have been quoted in many bilateral and pluri-lateral trade agreements, including:

- Mexico–Bolivia, 1995
- Baltic Area Free Trade Agreement, 1996
- Chile–Mexico, 1997
- Bulgaria–Turkey, 1998
- Central America–Chile, 1999
- Association of Southeast Asian Nations (ASEAN), 2000
- Turkey–Bosnia and Herzegovina, 2002
- Australia–Thailand, 2005
- United States of America–Australia, 2005
TBT agreement: agreement on Technical Barriers to Trade

Article 2.6 of the TBT Agreement states:

“With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they have either adopted, or expect to adopt, technical regulations.”
Harmonization – Possible?

• The stated objective of the Codex work is to foster harmonization of standards globally to enhance international trade and to help alleviate food shortages.

• Other attempts at Harmonization to foster commerce have been undertaken in other trading areas, most notably in the European Community, but the objective has been elusive.

• Additional work is proceeding in other trading blocs, most notably in the ASEAN marketplace, but success at achieving harmonization also appears elusive due to political and market protection issues arising at the eleventh hour.
Relevant Codex Committees

1. CCFL – Codex Committee on Food Labeling, Hosted by Canada – Meets in May

2. CCNSFDU – Codex Committee on Nutrition and Foods for Special Dietary Uses, Hosted by Germany – Meets in November

3. Codex Committee on Pesticide Residues, Hosted by China – Meets in April

4. Codex Committee on Food Hygiene, Hosted by the USA – Meets in December
In the early 1990's, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSUDU) 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 the 26th CCNFSUDU 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 (CAC). The Guidelines were adopted at the 28th CAC Session that was held in Rome on July 4-9, 2005.
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.
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 do 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.
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.

http://www.fda.gov/Food/DietarySupplements/GuidanceComplianceRegulatoryInformation/ucm113860.htm
FDA and WTO
Precaution at Work?

- FDA is on record as saying WTO and WTO dispute panels do not have the power to change US law.

- For Dietary supplements, it is unlikely that another country will accuse the US of imposing a trade barrier for the importation of supplement products into the US because the US laws and regulations are generally broader in scope and less restrictive than the international standard.
Codex and the US Dietary Supplement Industry
Summary of Observations

- Codex has emerged as the pre-eminent standard setting entity for international trade disputes in the field of foods and dietary supplements.

- Continued emphasis on transparency will continue. This will have a potential impact on product label disclosures and country of origin discussions.

- The actions of the European Commission in implementing the Health Claims Directive is forming a pattern for future work for the Codex Commission.

- Do not expect governments to play fair when it comes to market protection of their domestic producers. There will be more and more concerns raised at the WTO under the SPS and TBT complaint systems.

- Despite public pronouncements by the agency, understand that there is considerable interface between government representatives and a continued bias towards pre-market approval.
Thank You

Mark A. LeDoux, Chairman and CEO
Natural Alternatives International, Inc.

mledoux@nai-online.com
(760) 736-7700
1185 Linda Vista Drive, San Marcos CA 92078