Codex - Bridging the Great Divide

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It lies from Heaven across the flood
Of ether, as a bridge.
Beneath, the tides of day and night
With flame and darkness ridge
The void, as low as where this earth
Spins like a fretful midge.
---The Blessèd Damozel, Dante Gabriel Rossetti (1828–1882)

The Codex Alimentarius Commission (CAC) was officially created in 1963 by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) to "develop food standards, guidelines and related texts such as codes of practice." The main purposes of this commission are now said to be: "protecting health of the consumers,""ensuring fair trade practices in the food trade," and "promoting coordination of all food standards."

Codex & CCNFSDU

There are 20 main Codex committees ("subsidiary bodies") hosted by different countries, including: the Codex Committee on Food Additives and Contaminants (Netherlands), the Codex Committee on Food Labelling (Canada), the Codex Committee on Cereals, Pulses and Legumes (U.S.) and, perhaps most importantly right now, the Codex Committee on Nutrition and Foods for Special Dietary Uses [CCNFSDU] (Germany).

The CCNFSDU is a pivotal committee that has responsibility for several vitally important areas that impact consumer health, including (but not limited to):

- guidelines for vitamin and mineral supplements;
- infant formula standards;
- foods for infants and children
- scientific basis of health claims;
- risk analysis; and
- trans fats.

www.citizens.org), I had the opportunity to address the U.S. Codex delegation to CCNFSDU, which is headed by Dr. Barbara O. Schneeman, director of the FDA's Office of Nutritional Products, Labeling and Dietary Supplements.

I expressed serious concern over a number of especially troubling guidelines in the pre-Bonn version of this committee's draft text and worked with non-governmental organization (NGO) representatives to develop a letter to the U.S. delegation (www.healthactioncenter.org/action/index.asp?step=2&item=21232). More importantly, many of these same questions were echoed by at least 5,000 consumers who e-mailed letters to Dr. Schneeman before the official U.S. delegation finalized its recommendations prior to Bonn. Consumers focused on the following:

- **"Upper safe limits" for vitamins and minerals.** *Consumer concern:* Sub-optimal upper levels of vitamins and minerals, perhaps eventually a restricted list à la the European Food Supplements Directive (EFSD), should never be allowed.
- **Infant formula and foods for infants/children:***Consumer concern:* DHA and ARA are listed as "optional additions" to infant formula (not required), even though the UN/WHO itself has recommended that all infant formula contain these necessary fatty acids.
- **Health claims:***Consumer concern:* According to the pre-Bonn draft, the Codex text read: "Health claims should be forbidden if they cannot be substantiated." Who is establishing what constitutes "substantiation"?
- **Risk analysis:***Consumer concern:* The concept of "risk analysis" refers to toxic chemicals not to nutritional supplements.
- **Trans fatty acids:***Consumer position:* There is no place for unhealthful hydrogenated fat or trans fat in human nutrition.

So what happened in Germany in November?

It depends on whom you ask, or more precisely, whether you ask our industry or consumer health advocates.

If you ask U.S. industry, which represents thousands of companies, you are likely to hear the following:

- Government and industry cooperated and came up with a science-based approach to setting upper limits for vitamin and minerals supplements.
- The stage is now set for science-based implementation of the European Food Supplements Directive (EFSD).
- We now have a risk assessment model for supplements.
- Now countries can rest assured that vitamins and minerals are safely regulated in trade.
- Now worldwide consumers are protected.

If you ask U.S. consumer leaders who represent hundreds of thousands of consumers, you're likely to hear:

- Industry caved to the pressure of Germany and the EU bloc and is happy over vitamin and mineral guidelines that will be considered binding by the World Trade Organization (WTO) and international treaties and would likely adopt the

incredibly restrictive EFSD framework; these “guidelines” may potentially lead to the FDA’s eventual harmonization of its regulations to international standards.

- Hello, who asked for a toxic chemical risk assessment model for dietary supplements?
- Thank you, the U.S. has DSHEA and doesn’t need international “guidelines” (read: standards) potentially undermining U.S. law. U.S. products, ergo DSHEA, can be challenged as a “Technical Barrier to Trade” (TBD), the trump card that, along with the threat of trade sanctions, can bend any country to international will - yes including the U.S.
- Considering that U.S. consumers are already protected, and that most overseas consumers are already hyper-protected by drug/medicine standards that regulate supplements as drugs, why do worldwide consumers need a web of international regulation added on to what is already regulated by individual nations and blocs of nations (e.g., the EU)?

Why such a great divide?

In fairness to our industry, there are committed representatives who have worked hard on these issues for years and who did, without a doubt, help consumer groups to achieve important objectives in Bonn, including: (1) establishing that vitamins and minerals are food supplements, (2) stipulating that upper safe limits are to be based on science-based principles rather than the “precautionary principle” (which would have guaranteed arbitrary and capricious standards for setting levels), and (3) stipulating that when maximum levels are set, this provision “should not lead to setting of maximum levels that are solely based on recommended nutrient intakes.”

It, likewise, should be noted that the official U.S. delegation did take a good stand on certain key points, and prevailed on a few of these along with countries such as South Africa and Zimbabwe.

U.S. consumer health-freedom leaders also made profoundly important contributions in Bonn, too, especially but not limited to the National Health Federation (www.thenhf.com) (Scott Tips and Paul Anthony Taylor [U.K.]) and the American Holistic Health Association (www.ahha.org/codexwalter2004.htm) (Suzan Walter).

Unasked questions still remain

Nevertheless, we should all be aware that, as the approved CCNFSDU draft stands now, the following provisions are sailing to Rome, July 4-9, 2005, for codification unopposed by industry:

1) The “upper safe levels” principle is approved with a carte blanche on dosage levels that is, according one umbrella trade group, “fully in line with EU developments and science-based implementation of the European Food Supplements Directive.”The Directive has developed a restricted list of approved supplements which will effectively ban about 300 out of the 420 forms of vitamins and minerals now included in supplements overseas as of August 1, 2005 (in the U.K.).

2) DHA and ARA *are not required* for infant formula (only listed as “optional additions”) even though they are recommended as essential nutrients according to the UN/WHO. In addition, GMO-source ingredients are allowed for infant formula and infant’s/children’s foods, as are hydrogenated/trans fats, cheap quality oils, high-fructose corn syrup, and a host of synthetic additives.

Shocking, isn’t it, for the natural products industry? Nevertheless, this is the state of affairs which some of us are applauding. If you are as stunned as I was about what the guidelines will allow, or not exclude, than we all have a lot of work to do before Rome.

In point of fact, in Rome, from July 4-9, 2005, the 28th session of the full Codex commission will formally ratify and adopt the aforementioned CCNFSDU guidelines and many others.

Building a bridge?

How can we bridge the divide, then, between our industry and consumers?

Industry must not lose sight of the consumer and should not assume that U.S. consumers are being protected or will benefit from something of which they have not been part and to which they have not agreed. Consumer health-freedom leaders should be cognizant of industry goals when they rally the grassroots masses.

If consumers blaze a path through the very heart of Codex, then industry can follow without trepidation since it is consumers, after all, that keep our industry in business and give what we do meaning and context.