



By James J. Gormley, Policy Advisor, Citizens for Health, March 25, 2005

MYTH: Your right to sell or buy supplements will end in summer of 2005

FACT: No. In fact, there are two completely different events that some have mixed together.

First, in July 2005, the United Nations Food and Agriculture Organization (FAO) and World Health Organization's (WHO) Codex Alimentarius Commission is set to ratify vitamin and mineral guidelines that were finalized in Bonn, Germany, in November 2004.

Second, as of August 1, the European Food Supplements Directive (EFSD), "the Directive"—a European Community (EC) not Codex directive—will restrict the sale in (or into) Europe of dietary supplements that contain any of hundreds of ingredients or forms of ingredients not on the EFSD "approved lists" (Annex I or II), except for ingredients that have received "derogation" (approval for continued sale) until 2009 in one of 25 European countries (member states) and which are being considered for addition to one of the approved lists by the European Food Safety Authority (EFSA).

Aside from a potential one-year sell/buy-through grace period, taken together with upcoming dosage limit guidelines to be set by the FAO/WHO Nutrient Risk Assessment Project [see below], European retailers and consumers will most assuredly have their choice of innovative, high-potency dietary supplements greatly curtailed, officially, as of August 1, 2005.

MYTH: Dosage limits that will be set are going to be based on an acknowledgment that dietary supplements are inherently benign

FACT: False. The dosage levels that Codex will set are going to be largely based on the findings of the FAO/WHO Nutrient Risk Assessment Project, the key event related to which is an international risk assessment workshop scheduled for May 2005. The framework upon which this project is based is one that is typically used for toxic chemicals and environmental hazards, not, say many, the best model upon which to develop a liberal set of recommended upper levels. To view Citizens for Health's comments on this, please [click here](#).

MYTH: The Directive on supplements will have no impact on U.S. products

FACT: False, by omission. The scenario that is often overlooked is that some U.S. companies which export into Europe now---but which do not wish to have

two entirely separate “catalogs” of products with very different formulations---may voluntarily decide to either no longer sell in Europe or may, for economic reasons, decide to “dumb down” all of its formulations to meet both the EFSD and the to-be-established FAO/WHO dosage level guidelines.

In addition, according to the U.S. Food and Drug Administration (FDA), “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.”

MYTH: Codex is part of some huge conspiracy to take away our health freedom and our supplements

FACT: No---a complex web of forces, interests and connections does not necessarily a “conspiracy” make. Codex was originally formed with the best of intentions. In fact, according to Codex, “The highest priority of the Codex Alimentarius Commission, as stated in Article 1 of its statutes, is to protect the health of consumers and ensure fair practices in the [sic] food trade.”

Nevertheless, what consumer protection means to European regulators is, in many ways, quite different from what that means to American consumers. In Europe, regulators have traditionally over-regulated dietary supplements, in many cases classifying supplements as drugs, partly due to what some regard as a coddling, paternalistic “nanny state” approach to consumer protection and, therefore, to dietary supplements. In addition, there are many international treaties that recognize Codex as the authority on food safety and dietary supplements within the context of an intricate matrix of global treaties and agreements that will, at least theoretically, provide “teeth” to Codex’ regulation-like “guidelines.”

MYTH: The FDA would never modify its regulations (through rulemaking) to adjust U.S. law to international standards

FACT: Maybe, maybe not. On October 11, 1995, the FDA stated, referring to an earlier notice, that “it is the intent of this policy to enable the FDA to “increase its efforts to harmonize its regulatory requirements with those of foreign governments.” In the October 1995 notice, the FDA asked the following question: “If the agency concludes that it is appropriate to propose to revise its regulations to accommodate consideration of Codex standards, FDA plans to [...] outline specific revisions.” According to attorney Justin J. Prochnow, these 1995 statements, “are not akin to [currently] mandated FDA policy.”

In 2005, the FDA wrote the following, however: “Failure to reach a consistent, harmonized set of laws, regulations and standards within the free trade agreements and the World Trade Organization Agreements can result in considerable economic repercussions.”

MYTH: Codex will never get involved in WTO's international trade disputes

FACT: False, according to the WTO. The WTO writes that Codex “can be called in as experts to give advice to WTO dispute settlement panels.”

MYTH: Codex, like other international guidelines, is just voluntary

FACT: False by omission, according to the WTO. The WTO writes: “Before the entry into force of the WTO, international standards, guidelines, recommendations and other advisory texts could be adopted by governments on a voluntary basis. Although these norms remain voluntary, a new status has been conferred on them by the SPS [emphasis ours] [Agreement on the Application of Sanitary and Phytosanitary Measures]. A WTO Member country adopting such norms is presumed to be in full compliance with the SPS Agreement.”

According to a March 22, 2005 white paper by attorney Justin J. Prochnow, “of particular relevance to this discussion is Article 3 of the SPS Agreement, which reads: *To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members **shall** [emphasis ours] base their [food safety] measures on international standards, guidelines or recommendations.*” According to Prochnow, “These provisions, with the use of the term ‘shall,’ effectively make the ‘voluntary’ Codex guidelines mandatory for Member Nations of the WTO,” including the U.S.

MYTH: If the WTO, several years from now, imposes sanctions on the U.S., the U.S. would have to automatically change its laws to comply

FACT: False, technically. If the WTO Dispute Settlement Body imposed sanctions against the U.S. for a specific case of non-adherence to Codex guidelines in international trade, the U.S., according to Justin J. Prochnow, “would have to determine whether it could absorb the sanctions or whether the sanctions were onerous enough to force a change in the law to conform to the Codex guidelines. In order to adopt new legislation, Congress would have to use the standard legislative process.

MYTH: The FDA can just adopt Codex guidelines as new regulations

FACT: False. To attempt to issue new more “Codex friendly” regulations regarding dietary supplements that wouldn’t undermine the Dietary Supplement Health & Education Act of 1994 (DSHEA), the FDA would have to go through the usual deliberative process starting with a Notice of Proposed Rulemaking, a public notice that would likely generate massive consumer response, depending on what is proposed.

MYTH: There is nothing that I can do before July to help the U.S. delegation represent my interests in Rome

FACT: *Not true!* You can create your own health action letter [click](#) that will go to chief delegates at the U.S. Codex Office, or you can create your own. You can also be heard at an important pre-Rome Public Meeting on June 9, 2005, in Washington D.C. <[Read more](#)>