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FILE: ▪Codex Alimentarius
▪Food and Dietary Supplement Standards
▪International Harmonization

HC 050151-283

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RE: Clarifying Codex: Herb and Dietary Supplement Trade Associations Combat Confusion on Codex Alimentarius

AHPA. Codex Alimentarius and dietary supplements. April 2005. Washington, DC: American Herbal Products Association, April 21, 2005. Available at: <http://www.ahpa.org/05_0413_CodexAndDS.pdf>.

Hathcock J. Myths and Facts on Codex and WTO. Washington, DC: Council for Responsible Nutrition, March 2005. Available at: http://www.crnusa.org/leg_CODEX_mythsandfacts.html

Hathcock J, LeDoux M, Mansour M. CRN Comment on European Court of Justice Ruling. Washington, DC, Council for Responsible Nutrition, April 5, 2005. Available at: http://www.crnusa.org/pdfs/CRN_Comments_ECJ_040504.pdf

The Codex Alimentarius Commission (Codex) was founded in 1963 as a joint project by the United Nations (UN) and the World Health Organization (WHO). The Codex is recognized by the World Trade Organization (WTO) as the authority for food safety standards and has created almost 250 standards in the past 42 years. Currently, much concern has been generated over proposed rules for regulating international trade in dietary supplements, which are being defined by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

There has a significant amount of e-mail and Internet-based communications in the past several months regarding concerns that the increased activity of Codex in the area of dietary supplements will adversely affect consumer choices and freedom of health care in the United States. The American Botanical Council has long held that Codex has little implications for herbs and phytomedicines as these products are regulated as various types of "traditional medicines" or nonprescription drugs in most nations of the EU and elsewhere in the world. In most cases, Codex has deferred to the WHO which has published as series of guidelines on various aspects of herb quality and safety, including Good Agricultural Practices (GAPs), as well as three volumes of monographs on herb quality and therapeutics (The third volume is in press.).

The summary below is based on three publications — one by the American Herbal Products Association (AHPA) and two by the Council for Responsible Nutrition (CRN), two leading herb and dietary supplement and herbal trade associations. These documents attempt to clarify some of the current issues and concerns over the proposed Codex standards for dietary supplements.

As noted, one primary concern being spread on the Internet is that the Codex rules would limit consumer access to dietary supplements in the United States. Both AHPA and CRN dispute this assertion. According to the commentaries, the Codex rules will not force countries to make their laws more restrictive. For example, if a country currently allows the manufacturing and distribution of capsules containing 1000 mg of vitamin C, and the Codex places a limit on vitamin C at 500 mg per capsule (a completely hypothetical example), the country would not be forced to limit sales of vitamin C to 500 mg capsules, but could continue to sell the 1000 mg capsules. However, if a member country simply allowed only 250 mg capsules to be sold, it would have to relax its standard to allow 500 mg capsules of vitamin C to be sold or face possible WTO sanctions. "No country is required to adopt Codex guidelines as its domestic regulations," writes John Hathcock, PhD, of CRN. "WTO [World Trade Organization] sanctions apply only when a country fails to allow imports that meet Codex guidelines." AHPA's president, Michael McGuffin agrees, writing, "The U.S. is under absolutely no obligation to change its existing laws and replace them with Codex guidelines, but is required to accept for import any products that conform to such guidelines."

Codex will establish maximum limits based on risk assessment and a determination of "safe upper limits." Hathcock (March 2005) states that CRN "strongly supported the risk assessment approach." He believes that the current Recommended Daily Allowance (RDA), which is used as the basis for limits in many countries but not in the United States as the guideline for dietary supplements is too restrictive. "With RDA-based limits you automatically get the wrong answer," he writes, but also cautions that "we must now guard against arbitrarily restrictive risk assessment."

How these regulations will affect member countries' domestic laws remains to be seen. Hathcock et al. address this concern in their commentary on the recent European Court of Justice Ruling. The European Union (EU) issued a directive in 2002 that "would limit vitamin and mineral supplements to an approved list as of August 2005." The ruling struck down this directive on the grounds that the directive "was 'seriously deficient' because it did not give a norm for decisions to add supplements to the approved list; did not make it clear if firms could submit substances for approval; and gave no clear procedure for any such submission." Additionally, the ruling objected to the lack of guidelines for "'how interested parties could be heard, set any deadlines for decision making or even guarantee decisions on proposed substances would be taken.'" CRN's position is that this ruling protects the Draft Standard for Vitamin and Mineral Supplements agreed upon by the Codex Commission on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

Some past Codex rules have set standards for agricultural production; however, "there are no Codex activities related to herbal products," according to the AHPA commentary. Therefore, none of the Codex rules should affect importation or access to herbal dietary supplements in the United States.

While these articles go to great lengths to answer some of the public's concerns over Codex and how it will affect access to dietary supplements, some questions remain unanswered. How will "upper safe limit" be defined, and will it be defined for just a single nutrient or a combination of nutrients? Will international laws create a de facto change in access to dietary supplements? This conceivably could result from manufacturing changes to conform to the stricter Codex rules in international companies that supply the U.S. market, resulting in a lack of availability of some dietary supplements. Will safe upper limits be determined for just single vitamins and minerals or combinations of vitamins and minerals, which might alter the safety profile of single agents?

Codex may not be the only organization whose actions might affect the future of dietary supplements in the U.S. "There are several federal and state legislators, as well as organizations like the American Medical Association, that continue to advocate for more restrictive laws that might have the effect of reducing consumer choices," writes AHPA's McGuffin. While the information provided by AHPA and CRN is reassuring, and some proposals contained in Codex may improve current international rules governing the trade in vitamins and minerals, it is still not possible to predict with certainty how Codex will affect access to dietary supplements in the U.S if it does at all.

Note: On May 20, 2005 the National Nutritional Foods Association, another trade association representing the dietary supplement industry, primarily independent health food retailers, issued a release announcing its new Codex Alimentarius Online Resource Center to help combat "widely circulated misinformation" on this issue. According to a press release from NNFA, "The purpose of the center, which will be regularly updated, is to provide members and others with accurate information that dispels the increasing number of erroneous reports stating that sales of dietary supplements in the United States will be halted this summer as a result of international decisions." The new Center is available at <www.nnfa.org/codex/>.

—John Neustadt, ND and Mark Blumenthal

Enclosure: Referenced articles reprinted with permission from the American Herbal Products Association and the Council for Responsible Nutrition.