

CRS Report for Congress

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Dietary Supplements: International Standards and Trade Agreements

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Summary

The dietary supplement industry has long been concerned about international activities that could have a potential impact on supplement trade. As originally proposed, FDA reform legislation contained provisions on mutual agreements and global harmonization that would have applied to most products under FDA jurisdiction. However, Congress explicitly exempted supplements from the final provisions of the Food and Drug Administration Modernization Act of 1997 (P.L. 105-115), which means that these products are not part of on-going trade discussions. However, the perception of supplement proponents at that time was that such harmonization efforts would limit access and availability of supplement products and was a harbinger of their reaction to other international supplement agreements ever since. The European Commission adopted a directive on vitamin and mineral supplements in 2002. Although in April 2005, the Advocate General declared it invalid, in July 2005 the European Court judges ruled in favor of upholding the directive. In July 2005, the United Nations' Codex Alimentarius Commission voted to adopt the guidelines on the composition of certain vitamin and mineral supplements. Once adopted, however, Codex guidelines are not binding on any country, unless the provisions are incorporated into the laws of that country. More recently, questions have been raised about the impact on supplements of actions by the World Trade Organization (WTO) and implementation of the Central American Free Trade Agreement (CAFTA). This report will be updated if the status of the issues changes.

Food and Drug Administration Modernization Act of 1997 (FDAMA97)

At the time of passage of the Food and Drug Administration Modernization Act of 1997 (FDAMA97, P.L. 105-115, enacted November 21, 1997), considerable interest was raised about the potential impact of trade talks on dietary supplements. Supplement proponents were concerned that agreements with other governments that were perceived to have more stringent regulation of supplements than the United States would adversely affect exports of U.S. products. While not mentioned in the original bill, provisions were

added to the final Act that specifically excluded dietary supplements from consideration in mutual recognition agreements and global harmonization initiatives. Those activities are intended to facilitate trade through discussion and subsequent consensus among governments on agreements that approximate the laws of the participating countries. Such agreements generally require consensus on the general standards and selected peripheral issues on the subject under discussion. The FDAMA97 provisions, as passed, affect drugs, medical devices and foods. (See CRS Report 98-263.)

The final language in Section 410 of FDAMA97, entitled Mutual Recognition Agreements and Global Harmonization, amended the existing provisions on good manufacturing practice requirements to ensure that FDA regulations conform, to the extent possible, with internationally recognized standards for defining quality systems for medical device production. In addition, the law directed the Secretary of Health and Human Services to support the Office of the U.S. Trade Representative, in consultation with the Secretary of Commerce, in harmonization meetings with representatives of other countries. The Secretary was required to determine whether such harmonization would continue consumer protection consistent with U.S. law. In addition, the Secretary was directed to support efforts toward the acceptance of mutual recognition agreements related to the regulation of drugs, biological products, devices, foods, food and color additives, and good manufacturing practices between the European Union (EU) and the United States. And finally, the Secretary was further directed to participate regularly in meetings with representatives of foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements. FDAMA97 directed the Secretary to publish a plan that established a framework for achieving mutual agreement on inspections for good manufacturing practices.

The supplement industry's concern about the original FDAMA97 global harmonization provisions was based on its view that, through participation in harmonization discussions, the United States would be required to meet the perceived strict regulations for dietary supplements of the EU or its member countries. However, the conference committee compromise resulted in dietary supplements being expressly exempted from the requirements of the harmonization provisions. The final language in Section 410 states that the four provisions on mutual agreements and global harmonization do not apply to products defined as dietary supplements in Section 201(ff) of the Dietary Supplement Health and Education Act of 1994 (DSHEA, P.L. 103-417, enacted October 25, 1994).

The exemption of supplements from the harmonization provisions of FDAMA97 resulted, at least in part, from concerns raised by dietary supplement proponents that the legislation would somehow limit access to and availability of supplements in the United States. The conference report provides no explanation of the congressional intent regarding the mutual recognition agreements and global harmonization provisions or the explicit exemption of supplements.¹ There is no evidence that restricting access and availability was ever intended. Generally, the intent of the harmonization efforts is to facilitate trade and eliminate nontariff trade barriers that otherwise can limit access to products in international trade. However, the perception that these harmonization

¹ Conference Committee, *Food and Drug Administration Modernization Act of 1997*, 105th Congress, 1st session, H.Rept. 105-399.

provisions would have limited access and availability of supplements was not assuaged by their exemption and was the forerunner to the continuing concerns raised for the same reasons by supplement proponents about the European Commission directive, the Codex Alimentarius Commission guidelines, and the potential actions of the World Trade Organization and Central American Free Trade Agreement, discussed in the rest of this report.

The European Commission

In 2000, the European Commission (EC) announced that it had adopted a proposal for a directive on food supplements setting out harmonized rules for the sale of vitamins and minerals as dietary supplements.² The initiative was driven by concerns about the need for informed consumer choice and safety. The objectives were to set a general framework and safety rules for vitamins and minerals in the European Union, and to provide consumers with detailed information through labeling on recommended daily consumption, warnings on side effects from excessive use, and a statement that the pills are not a substitute for a varied diet. Under this directive, health claims are prohibited, and products packaged in a way that resembles a pharmaceutical product must carry the statement that “this is not a medicinal product.” The proposal contained a positive list of chemical substances authorized for the production of vitamins and minerals, and was part of a package of measures being considered on food safety. The European Parliament and Council of Ministers had to agree to this directive for it to be implemented, allowing the marketing of products complying with its provisions as of June 2002 and prohibiting the marketing of products that do not respect its rules no later than June 2004. The directive was adopted and took immediate effect on June 10, 2002, allowing the statements to appear on products as stated in the directive and requiring them to appear by June 2004.

On April 5, 2005, the Advocate General in an Opinion to the European Court of Justice declared invalid the European Union’s directive on food supplements.³ According to the opinion, the directive lacked clearly defined rules and norms for the EC to decide whether a food supplement should be allowed and lacked a clearly defined system for companies to appeal bans or request approval of new products. The case was brought by a group of United Kingdom supplement manufacturers and health food stores, who believe that the directive would ban the use of about 200 nutrients, affecting up to 5,000 products sold in the United Kingdom. While the Advocate General’s opinion on the directive is not legally binding on the rest of the European Court judges, these opinions generally are followed by the full court in a majority of final rulings. However, on July 12, 2005, the full court ruled in favor of the European Commission (EC), upholding the validity of the food supplement directive, its legal base, and the positive list system. The EC is now expected to study the details of the court’s judgment and comments on the procedure and seek ways to ensure that the directive is implemented in a manner that is

² The European Commission, Health and Consumer Protection, Press Release: *Consumer Safety and Choice Are Paramount in New Rules on Vitamin and Mineral Food Supplements*, Brussels, May 10, 2000.

³ See [U.K.] Food Standards Agency, Occasional Paper, *Advocate General’s Opinion on the Food Supplements Directive*, June 3, 2005, [<http://www.food.gov.uk/aboutus/ourboard/boardmeet/occasionalpapers/foodsuppdirective>]; Nikki Tait, “Suppliers Hail Vitamin Sales Decision,” *Financial Times*, April 6, 2005.

transparent and timely and minimizes the restrictions on businesses while maintaining protection of public health based on science.

Codex Alimentarius Commission

In a separate but related issue, efforts are ongoing to develop international guidelines for certain dietary supplements, specifically those containing vitamins and minerals. The United Nations' Codex Alimentarius Commission is an international intergovernmental body responsible for the implementation of the Joint Food and Agriculture Organization/World Health Organization's Food Standards Program. The primary objectives of the Codex for food products are to protect consumer health and facilitate world trade by establishing uniform international food standards. Those standards can be in the form of guidelines, codes of practice, and other advisory provisions aimed at promoting the standard's objective. Codex committees meet on a regular basis to draft standards and guidelines that affect various aspects of food trade, such as labeling and commodity standards.

The Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is responsible for determining the need to develop standards and guidelines on the nutritional quality of foods, including dietary supplements. At the 1995 CCNFSDU meeting, the German delegation proposed that the committee consider the development of guidelines for dietary supplements of vitamins and minerals. Such guidelines would include recommendations for minimum and maximum dosages, approved and prohibited ingredients, and labeling claims. Although the U.S. delegation voted against undertaking that task, the majority of delegations voted for drafting proposed guidelines. The document, as drafted by the German delegation, was circulated by the Food and Drug Administration (FDA) for comments to interested parties in the United States. The comments received were then used in preparing FDA's response to the draft guidelines.

At the October 1996 CCNFSDU meeting where the draft document was discussed, the member countries, including the United States, reached agreement on most issues. However, unresolved was the method to use in setting safe upper dosage levels for vitamins and minerals, in part because different methods result in different levels. The document was sent forward to the Commission for its June 1997 meeting; however, the Commission returned the document to the committee because the critical issue of setting maximum dosages had not been resolved.

Because of this protracted debate, a discussion paper on guidelines for vitamins and minerals was drafted to facilitate consideration of this issue at the June 2000 CCNFSDU meeting in Berlin.⁴ The document was prepared with the cooperation of five delegations (Brazil, Canada, European Commission, Mexico and the United States) as a summary of the range of issues and perspectives that had arisen in discussions on regulation of vitamin

⁴ United Nations, Food and Agriculture Organization/World Health Organization, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses, *Discussion Paper on Issues Surrounding Elaboration of a Codex Guideline for Vitamin and Mineral Supplements*, prepared by representatives of Brazil, Canada, European Commission, Mexico and the United States of America. February 2000. 34 pp. [<http://vm.cfsan.fda.gov/~dms/sdultr.html#ccnfsdu>]

and mineral supplements. The following issues were reviewed in the discussion paper: purpose and role of vitamin/mineral supplements; products to be covered by a guideline and terminology used to describe them; positive and negative lists (ingredients allowed and not allowed); maximum and minimum levels; purity criteria; good manufacturing practices; labeling; packaging; and marketing. FDA convened two meetings in May 2000 to take comments and assist in developing its position paper on the issues for the June Codex meeting. At the June 2000 meeting, the Committee decided that, based on the debate that surrounded the discussion paper, it would continue to work toward completing the guidelines on vitamin and mineral supplements. In November 2004, the Committee adopted the guidelines on vitamin and mineral supplements, having finally resolved the outstanding issue on the method for setting safe upper levels for individual vitamins and minerals in supplement products.⁵ The full Commission voted to adopt the guidelines on July 4, 2005.

The Codex document on guidelines for vitamins and minerals reflects the concern of a number of governments about the current level of regulation of dietary supplements. The document represents agreement of the signatory countries that these products should be regulated at some baseline level. The Codex document is not binding on any member country, unless the guidelines are adopted into the laws of that country. Many member countries already have adopted regulatory standards for supplements. In some cases, rules of the member country are more strict than the Codex guideline provisions.

Completion of the Codex guidelines document does not dictate the sale, availability, or content of supplements marketed in the United States, unless its provisions are enacted into law by Congress. The document may serve as a guide for other countries that do not yet have, but wish to develop, their own standards for the regulation of these products within their own borders. The adoption of the guidelines into law by other countries could affect the export of U.S.-produced supplement products to those countries, if U.S.-manufactured supplements do not meet the standards set by the regulations of those countries. There seems to be a perception among supplement advocates that other countries have regulations that adversely affect U.S. manufacturers who wish to export supplements to those countries.

Impact on U.S. Manufactured Supplements

The Codex Alimentarius Commission activities are separate from those harmonization efforts with the European Union addressed in FDAMA97. However, during the debate on FDAMA97, there was some confusion within the supplement industry about the effect on Codex activities of implementation of the new law. The Codex has 156 member nations, including the United States. As already stated, the Codex guidelines are not binding on any nation, unless the guidelines are incorporated into the laws of that nation. The European Union is composed of 15 member nations of western Europe. EU directives are developed by, and applicable only to, its member nations.

⁵ Joint FAO/WHO Standards Programme, *Draft Guidelines for Vitamins and Mineral Food Supplements, Step 8*: Report of the 26th Session of the Codex Committee on Nutrition and Foods For Special Dietary Uses, Bonn, Germany, 1-5 November 2004. Appendix II. 2 p. [<http://www.eas.be/download.cfm?cat=legislation&id=43&file=VMS%20Guidelines%20Nov04%3Bpdf.pdf>]

Codex guidelines or EU directives might affect U.S. manufacturers in situations where their products were being exported to countries that either have adopted the Codex guidelines or are EU members that apply their individual countries' rules to imported supplements.

Since dietary supplements were expressly exempted from the FDAMA97 provisions on mutual recognition agreements and global harmonization, these products are not part of those trade discussions. However, it is unclear at this time what impact the exemption might have on international trade of U.S. supplement products. Ultimately, it is possible that the exemption could have negative consequences for U.S.-made supplements since the Secretary, the U.S. Trade Representative, and the Secretary of Commerce are prohibited from including supplements in their agreements to facilitate trade.

Since FDAMA97 was enacted, the impact of its implementation has yet to be fully realized. Congress is unlikely to make any changes soon in the global harmonization provisions with regards to dietary supplements, unless there is evidence that the current provisions negatively impact the supplement industry. While the Codex guidelines have been adopted, there is no evidence to date that Members in the 109th Congress will take any action to implement the guidelines by adopting them into U.S. law.

Considerable concern has been raised about action on dietary supplements in the World Trade Organization (WTO) as a result of the Codex guidelines. To date, no trade disputes on supplements have been taken up by the WTO, although it is conceivable that the body may do so in the future. Since the Codex guidelines only received the final vote of adoption by the full Codex Commission on July 4, 2005, they have not yet been adopted into the laws of any country to be the basis for such a dispute.

While Congress has been preparing the implementing legislation for the Central American Free Trade Agreement (CAFTA), questions have been raised about the Codex guidelines and CAFTA. Chapter 6 of CAFTA directs that a committee on sanitary and phytosanitary measures be created to provide a forum for the discussion of various matters of mutual interest, including consulting on issues, positions, and agendas for meetings of various international bodies, such as the Codex Alimentarius Commission, on food safety, human, animal, and plant health. Dietary supplements are not mentioned in the provisions on this committee, nor does the language suggest in any way that the committee has the authority to adopt, implement, or mandate any set of guidelines, standards, codes of practice, or other advisory positions of Codex or any other international body that could affect the availability or access to dietary supplements in the United States or elsewhere.

Another issue related to the Codex guidelines concerns U.S. membership in the United Nations (U.N.). Withdrawal of U.S. membership in the U.N. would not change the Codex vitamin and mineral guidelines or the adoption of them into the law of another country. Any country that adopts the guidelines into its laws will apply those laws to any supplement products being imported by the country and would affect U.S. products, regardless of the status of U.S. membership in the U.N. If the U.S. were to withdraw from the U.N., it would no longer be a committee member or have a voice in the development of any guidelines, codes of practice or other advisory provisions developed by the 31 Codex committees or adopted by the full Codex Alimentarius Commission.