

TABD DIETARY SUPPLEMENTS

A Report from the CEOs on their Expert Group Agreements

Issue Summary

The Dietary Supplements Sector Working Group has sought to achieve a United States of America (US) and European Union (EU) understanding on the establishment of the common components for a regulatory framework for Dietary Supplements. The ultimate aim was to define a compatible environment for a transatlantic marketplace for these products. The need for dialogue was due to the differences in the current regulatory environments in the US, the EU, and individual EU Member States. The US Congress has legislated that dietary supplements shall be regulated as foods and, thus, their regulatory structure exists in accordance with US food law. These regulations maintain safety as a primary principle while acknowledging the specific benefits of these products. In Europe, particularly in the EU, various national laws of the EU Member Countries regulate dietary supplements. In May 2000 the EU-Commission presented to the European Parliament and to the Council of the European Union a proposed “EU-Directive on the approximation of the laws of the Member States relating to vitamin and mineral food supplements,” based on safety as a primary principle. A complex process to reach a final agreement on the directive is underway. Notably, the near-final draft that may be approved by April 2002 retained the term “physiological effect” in the definitions section, and specified the primacy of risk assessment in determining upper limits.

Mandate

The dietary supplements sector of TABD was initiated in the Rome CEO meeting in November 1997 and the inaugural communiqué agreed on the need to define supplements as a class of food. In the report from the 1999 Mid Year meeting in Washington the EU and the US issues managers agreed to set up a common regulatory framework for dietary supplements, based on agreed principles and components, to allow the European and the US dietary supplements industry market access on either side of the Atlantic.

The 1999 Mid Year report recommended the development of science-based documents providing details on definitions, safety, claims, and Good Manufacturing Practices (GMPs), taking into account the underlying principles of consumer access, consumer protection, the roles of the dietary supplement industry, and compliance with appropriate regulations.

Later, at the 1999 Annual TABD CEO Conference, a joint EU and US government and industry expert working group was established and began in 2000 to draft documents to form the basis of understanding and consensus on the four components in an acceptable regulatory framework.

Process

Recognizing the underlying challenges to this vitamin and mineral dietary supplements dialogue, the expert group accepted the importance of step-by-step progress to ensure a strong foundation for lasting success in developing a transatlantic consensus on the regulation of dietary supplements. The expert group projected that such consensus would allow the US and European

dietary supplement industry full market access on either sides of the Atlantic. Specifically, the joint EU and US working group, involving both government and industry experts, set out to achieve these objectives:

- Define vitamin and mineral dietary supplements presented in specific forms including, but not limited to, tablets, capsules, powders, and liquids.
- Work out methodologies and criteria to set upper safe levels for vitamins and minerals through nutrient-appropriate scientific risk assessment.
- Define criteria for label claims with the objective of giving consumers science-based accurate, truthful and non-misleading information on nutritional and health benefits to make informed choices.
- Work out principles for Good Manufacturing Practices (GMPs) that ensure safety, quality, and uniformity of the products delivered to the consumer.

The working group also took due consideration of ongoing work and discussion in other organizations like the Codex Alimentarius Commission, the European Commission, the US National Academy of Sciences, and other credible organizations.

Agreements

During the last two years, the experts and industry representatives appointed by the CEOs have met approximately every six months to develop, discuss and improve draft documents that were exchanged electronically during the entire period. Agreements have been reached and approved by the CEOs on all four components as indicated below. Copies of the entire documents are found in Attachments 1-4.

1. Definitions of Vitamin and Mineral Supplements (the Definitions document).

The CEO GROUP unanimously approved the Definitions document (Attachment 1) in November 2000 during the TABD Annual CEO Conference in Cincinnati, encouraged its support by the industry on both sides of the Atlantic, and acknowledged the following circumstances of application:

These products are known as dietary supplements in the United States of America, and are generally known as food supplements in the European Union. In addition, the term “dietary supplement” is used in the European Union for products regulated as Foods for Particular Nutritional Uses (PARNUTS).

2. Methods for Setting Tolerable Upper Intake Levels of Supplemental Vitamins and Minerals (the Safety document).

The Safety document (Attachment 2) has been under development since 1999 and has gone through several rounds of discussion and updating by the experts and industry representatives. The CEO group unanimously approved this document on March 2, 2002 at their meeting in Reston, Virginia, and approved the following resolution:

The TABD dietary supplements sector recommends that the EU and USA identify appropriate scientific bodies by November 2002, and report their identification at the 2002 Annual TABD CEO Conference, to collaborate for the purpose of setting Upper Levels for Supplement (ULS^{*}) values for vitamins and minerals through the scientific approaches prescribed by the TABD as detailed in the attachment. The proposals on ULS values by these scientific bodies will be completed by November 2003 and will be reported to the 2003 Annual TABD CEO Conference. (*Concept proposed in EU food supplement directive under the description: “maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer.”)

3. Good Manufacturing Practices for Dietary Supplements (the GMPs document).

The GMPs document has been under development since 1999 and has gone through several rounds of discussion and redrafting by the experts and industry representatives. The CEO group unanimously approved this document on March 2, 2002 at their meeting in Reston, Virginia, and passed the following resolution:

The TABD dietary supplements sector recommends that the EU and USA implement dietary supplement GMP rules as described in the attached document. The TABD dietary supplement sector urges the US FDA to publish proposed GMPs for dietary supplements by June 2002. The parties to TABD support the attached guidelines and will use this document as a basis for further comment on the FDA proposal. The attached document is in line with the ANPR previously published by FDA but is somewhat strengthened and has been carefully considered by both US and European participants.

4. Claims for Dietary Supplements (the Claims document).

The Claims has been under development since 1999 and has gone through several rounds of discussion and redrafting by the experts and industry representatives. The CEO group unanimously approved this document on March 2, 2002 at their meeting in Reston, Virginia, and passed the following resolution:

The TABD dietary supplements sector recommends implementation of provisions permitting content claims, comparative claims, function claims and risk reduction claims for foods and dietary supplements similar to those described in the attached TABD document, which also sets forth substantiation requirements for such claims. The approach described in this document is in line with models already in place in a number of EU member states and in the US. The parties to TABD should use these concepts in implementing a harmonized claims policy based on sound scientific substantiation.

Next Steps

The CEOs directed the Dietary Supplements group to develop and document plans for the following initiatives:

FIRST LEVEL OF PRIORITY—Implementation of agreements on vitamin and mineral supplements

The CEOs directed the Dietary Supplements group to take steps to promote acceptance of the concepts and recommendations described in supporting documents behind the agreements in the four topic areas described in the four attached documents. The steps are to include a strategy and the necessary actions to gain recognition and acceptance by regulatory authorities in the EU and USA. Likely opportunities for in-person follow up will include the TABD Mid Year meeting, anticipated to be held in Europe in June 2002 and the Annual TABD CEO Conference, anticipated to be held in the USA in November 2002. The Issues Managers will lead the development of a detailed implementation plan.

SECOND LEVEL OF PRIORITY—New topics to be addressed

The CEOs approved the direction of future work by the TABD Dietary Supplements group on two issues: (a) botanical (herbal) dietary supplements, and (b) Genetically Modified Organism (GMO) ingredient policy position and recommendations. A first draft was prepared but not discussed or approved at the March 2002 meeting. However, the CEOs recognized that their initial comments were to put a “place marker” on the issue for TABD.