Comment from
Council for Responsible Nutrition
Washington, DC USA
31 August 2010

To:
Herr Bernhard Kühnle,
Director-General for Food Safety and Veterinary Affairs
Federal Ministry of Food, Agriculture and Consumer Protection
(Das Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (BMELV)
Abteilung 3, 11055 Berlin, Germany)

Subject:
Your proposal currently before the Bundestag (German Parliament) seeks to change the status of specified food components, namely food supplements, dietetic foods and fortified foods, from food law to additives legislation.

Potential impact:
If adopted and implemented, this proposed change could give Germany the power to require pre-market approval of food supplements, dietetic foods, fortified foods or ingredients contained in such products.

Procedural context:
This proposal was forwarded in July 2010 as a draft of the 2nd reading of the proposed amendment to the German Food and Feed Law (LFGB), with reference to the implementation of the EU Regulation on Additives, Regulation (EC) No 1333/2008. The consultation period for this proposal before the Bundestag closes on August 31, 2010.

Background:
The German implementation of EU Food Additives law previously has been challenged.

- First, a case in the German Federal Administrative Court determined in July, 2007 (BVerwG 3 C 21.06) that food supplements and dietetic foods are legally foods and therefore characteristic ingredients of these foods that do not have a technological role, cannot be considered as additives.
- Second, German authorities recently asked the European Commission to ratify a German position that all energy drinks (Red Bull, etc.) be required to carry health warnings. The EC did not agree with the German Ministry and the proposal was struck down.

By removing the food supplements, dietetic foods and fortified food from the definition of food and moving them to additives legislation, German authorities could require pre-market approval of all these products via a registration system. This would render the 2007 court decision moot and force manufacturers to seek pre-market approval, rather than a notification.

CRN comments:
If passed by the Bundestag, this law will require notification to the European Commission and the other EU Member States. Also, the change would likely require notification under the SPS Agreement of the World Trade Organization. The Council for Responsible Nutrition (CRN, a Codex-recognized NGO) believes that the proposed change to German food law would:

- Conflict with the Food Supplements Directive (2002/46/EC), where food supplements are defined under food law. The overall thrust of the FS Directive is that supplements are

inherently foods. Implementation of this Directive is in progress for vitamins and minerals, but it clearly acknowledges that other ingredients may be included (FSD, Article 2, Paragraph (a)).

- Directly conflict with EC Regulation No 1333/2008 (EU Additives law), where, for example, vitamins and minerals are specifically cited as NOT being additives.
- Directly conflict with the EC Regulation on the Addition of Nutrients to Food (EC Regulation No 1925/2006) and the Directive on PARticular Nutritional Uses for Food (PARNUTS) (Directive 89/398/EEC, with updates).
- Contravene Codex principles; the Codex Vitamin and Mineral Food Supplements Guideline (CAC/GL 55-2005) is nearly identical to the EC FSD, except that the Codex Guideline overtly states that maximum values for vitamins and minerals may not be based solely on the population reference intakes. Section 1.3, which states, "These Guidelines apply only in those jurisdictions where products defined in 2.1 are regulated as foods," does not permit Germany or any other government to exempt itself from application of this guideline to imported products. The escape provision just quoted ignores the overall situation: 1) The existence of this Codex Guideline is *prima facie* evidence that food-based guidelines can be appropriate and sufficient. 2) The World Trade Organization (WTO) Agreements (SPS and TBT) prohibit the application to imports of regulations that are more restrictive than needed to protect the public health. In essence, application of Section 1.3 would mean that an importing country can apply drug-based regulations for no reason beyond its preference. Clearly, the judgment as to whether such an action violates the SPS and/or TBT Agreements is a decision to be made by the WTO, not Codex.

CRN recommends that the Federal Ministry of Food, Agriculture and Consumer Protection withdraw the amendment currently in the Bundestag for further study in consultation with stakeholders including industry and consumers. Should that approach not be possible, CRN will recommend that the Bundestag reject this current proposed legislation.