

**COUNCIL FOR RESPONSIBLE NUTRITION (CRN)  
WASHINGTON, DC, USA**

**Response to**

**CX 5/20.2**

**CL 2004/53-NFSDU**

**REQUEST FOR COMMENTS AND INFORMATION AT STEP 8 OF THE  
PROCEDURE**

**Draft Guidelines for Vitamin and Mineral Food Supplements (ALINORM 05/28/26  
para. 35 and Appendix II)**

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The Codex Alimentarius Commission (CAC) should expeditiously approve and adopt this document because:

1. The Draft Guideline recognizes that vitamin and mineral food supplements can be appropriately regulated as food.
2. It recognizes that risk assessment is the only scientifically valid method for identifying maximums, and it adopts this approach.
3. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) considered and rejected the identification of maximums based primarily on population reference intakes (recommended dietary allowances) because such values do not relate to safety.
4. Valid, science-based guidelines are needed to eliminate unjustified non-tariff barriers to international trade in supplement products.
5. The draft guidelines will provide consumer protection in a manner that is minimally disruptive of international trade.

**Discussion**

1. The Codex Alimentarius is, by name and definition, a food code. The adoption of vitamin and mineral food supplement guidelines will overtly recognize that these products and their ingredients can be properly and effectively regulated as “food” if this guideline and other related guidelines, such as those on labeling, and standards, such as those on composition and purity, are followed. The adoption of Codex guidelines will allow the proper regulation and control of supplement products marketed and used as food without resorting to more onerous and expensive regulations that could not only unnecessarily increase costs and decrease consumer choice and access but actually compromise consumer health by forcing regulatory officials to focus on extraneous matters that have no bearing on safety.
2. Several authoritative bodies (e.g., U.S. Institute of Medicine, European Commission Scientific Committee on Food and European Food Safety Authority, and U.K. Expert

Group on Vitamins and Minerals) have adopted the application of risk assessment to the identification of the maximum quantities of vitamins and minerals that can be safely consumed. The Tolerable Upper Intake Level (UL) method has been developed, refined, and widely adopted for this purpose. The U.N. Food and Agriculture Organization and World Health Organization have a current project underway to establish an internationally accepted approach to nutrient risk assessment, and this approach should be available soon for use by Codex in the identification of maximums for vitamins and minerals in food supplement products.

3. The population reference intakes (PRI) and recommended dietary allowances (RDA) are based on nutritional need, and are not scientifically valid for assessing safety and setting maximums. The draft guideline at Step 8 recognizes these conclusions and recommends that maximums be set through a risk assessment process.
4. Members of the World Trade Organization are obliged to have trade (import) policies that conform to the Sanitary and Phytosanitary Standards (SPS Agreement). This agreement specifies that standards and guidelines for foods in international trade will be no more restrictive than necessary to protect the health of consumers. For this purpose, WTO recognizes the Codex Alimentarius as the international authority on food safety. Any national policy on imports more restrictive than Codex guidelines or standards could be contested under the SPS Agreement. A Codex Alimentarius guideline on vitamin and mineral food supplements would help eliminate the uneven and unjustified differences in trade standards now in place, while protecting consumer safety and health by focusing on appropriate issues.
5. Similarly, WTO members are obliged to have trade (import) policies that conform to the Technical Barriers to Trade Agreement (TBT Agreement). The objective of the TBT Agreement is to prevent the use of national or regional technical requirements, or standards in general, as unjustified technical barriers to trade. The agreement covers standards relating to all types of products and quality requirements for foods, except those requirements which are related to SPS measures. In essence, the TBT Agreement provides that all technical standards and regulations for imports must have a legitimate purpose and that the impact or cost of implementing the standard must be proportional to the purpose of the standard. It also states that if there are two or more ways of achieving the same objective, the least trade restrictive alternative should be followed. The agreement also places emphasis on international standards, specifically that WTO members are encouraged to use international standards in decisions on imported products, except where the international standard would be ineffective or inappropriate in the national situation. Arbitrary use of national PRI (or RDA)-based standards as maximums for supplements and other foods represent precisely the types of measures that the TBT Agreement meant to preclude. Such standards lack a legitimate purpose, so that their cost of implementation is by its nature disproportionate. If the objective is a healthy population, there are many more effective and less trade restrictive alternatives. Thus, the use of PRI (RDA)-based limits is inconsistent with both the spirit and the letter of the conclusions in favor of the risk assessment approach to maximums reached by the CCNFSDU at its past two meetings.