

**Comment by the
Council for Responsible Nutrition (CRN) on the
CCFNSDU Draft Guideline on Vitamin and Mineral Supplements**

**Codex Alimentarius Commission Meeting
Geneva, 2004**

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) has agreed on a Draft Guideline on Vitamin and Mineral Supplements, at Step 5. The issue of maximum contents has been the most difficult issue in the guideline, but consensus was reached in 2003, after several years of intensive debate. During the same period, this topic has been the subject of major scientific progress by several national and regional scientific bodies. Consequently, this topic is now ready for scientifically-based international harmonization in a manner that will protect consumers' health and facilitate fair practices in food trade in a manner that is consistent with the World Trade Organization's Sanitary and Phytosanitary (SPS) Agreement. Accordingly, CRN urges national delegations to support approval by the Commission for further work on this guideline at Step 5 by the CCFNSDU.

The maximum levels set by Codex or governments for contents of vitamins and minerals in supplements should be based solely and completely on safety, not on nutritional policy in general or the Recommended Dietary Allowances (RDA) in particular. Many conventional foods contain vitamins or minerals far above the RDA, and some nutrients have well-established benefits at intakes far above the RDAs. While the use of the RDA to set upper limits for vitamins and minerals in supplement products has been seen by some governments as convenient, RDA-based limits have no scientific validity for this purpose. Risk assessment is the scientifically valid approach to identification of maximum levels.

The imposition of drug regulations on products with amounts of nutrients higher than the RDA serves no health purpose, and may preclude certain benefits. Also, imposing drug regulations on supplements with amounts of nutrients above the RDA is inconsistent with the regulation of conventional foods, some of which contain many multiples of the RDA of certain vitamins (e.g., 100 g of beef liver may contain 50x the RDA for vitamin B12).

RDA values are set on a very similar basis from one country to another. That basis represents a consensus of scientific opinion on the quantities of these nutrients needed to confidently assure the performance of recognized physiological functions related to their essentiality. Thus, the RDA values are related to avoidance of classical nutrient deficiency signs and symptoms. The RDA is adequate for performance of the functions recognized in setting that value, but higher amounts of specific nutrients may provide additional benefits. For example, the RDA for selenium is generally approximately 50 to 55 µg for adults, but well-designed and conducted clinical trial has shown that 200 µg of supplemental selenium, in addition to a diet containing 100 µg, reduces the incidence of three major types of cancer. The total amount of selenium needed for this purposes is far above the RDA but within the common range of natural occurrence in the diet. These types of benefits will be covered by the Health Claims document from the Codex Committee on Food Labeling, to be considered at Step 8 at this Commission meeting.

A significant fraction of the RDA can be used appropriately to set lower limits for vitamins and minerals in supplements.

RDA-based limits and drug regulations for higher amounts are not appropriate for several

1. The RDA is not defined or identified to describe safety or represent a safety limit for total or supplemental intake.
2. RDA-based limits are not possible for nutrients without established RDA values. For example, no RDA has been set for lutein, lycopene, boron, and many other important substances with nutritive value. These substances have beneficial effects, but the available evidence has not been judged appropriate to identify RDAs. Risk assessment can be used to identify appropriate safety limits for these important nutrients, whether or not an RDA has been set.
3. Arbitrary limits at or near the RDA may preclude certain benefits of some nutrients. For example, well-documented benefits of nutrient quantities above the RDA include:
 - a. Folic acid, vitamin B6 and vitamin B12 help control plasma homocysteine concentrations. Homocysteine is not yet accepted as a recognized risk factor for heart disease, but there is an ever-increasing body of scientific evidence to support this finding. Supplementation with these three vitamins definitely helps control plasma concentrations of homocysteine, and is likely to prove to reduce risk of heart disease.
 - b. Supplementation with 200 micrograms of selenium to diets containing about 100 micrograms has been shown in a long-term, well-conducted clinical trial to reduce the incidence of three important types of cancer. A confirmatory clinical trial is underway that, if positive, would justify a widespread public health policy to increase selenium intake in many populations. In the meantime, there is no reason to deny accurate information about the state of the current evidence and to restrict selenium supplements to the RDA.
 - c. Supplementation of diets containing less than 40 micrograms chromium with and additional 200 to 400 micrograms helps maintain normal blood glucose levels and minimize the signs and symptoms of type II diabetes. Clinical trials confirm the safety of up to 1,000 micrograms of supplemental chromium.
4. The imposition of RDA-based upper limits is a disproportionate restriction on supplement products, compared with conventional foods. Certain conventional foods contain many multiples of the RDA of some nutrients. For example, the natural amounts of vitamin B12 in conventional foods such as liver and some shellfish can approach 100 micrograms per 100 gram serving. The adult RDA for this vitamin is commonly set at approximately 2 to 2.5 micrograms. Thus, these ordinary conventional foods may contain as much as 40 to 50 multiples of the RDA of vitamin B12. There is no known toxicity of oral vitamin B12 in humans. Thus, RDA-based upper limits are not rational, serve no useful purpose, and are a disproportionate response to any hypothetical safety concern about this vitamin.
5. Labeling, not limits, can address proper usage. Labeling can provide information on contents, benefits related to RDA or other measure of benefit, and draw attention to limits imposed on a safety basis, as identified by risk assessment.

These recommendations support the conclusions reached by the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses at Bonn in November 2003, and CRN urges the Codex Alimentarius Commission to ratify for further work at Step 5 the carefully considered outcome on vitamin and mineral supplements.