

COUNCIL FOR RESPONSIBLE NUTRITION (CRN)

WASHINGTON, DC, USA

Revised June 6, 2003

Comment on

Item 3--CL 2002/51-NFSDU

**PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL
SUPPLEMENTS**

PREAMBLE

The preamble includes so many qualifiers and limitations to justify a vague recommendation against use of supplements that it should be either deleted or extensively revised.

The following points—related to the first sentence only—illustrate the flaws:

- The draft uses the term “most people.” How many is that? Fifty-one percent? All but one in a million?
- The draft uses the phrase “who have access to a balanced diet,” but does not address whether those who have “access” actually consume such a balanced diet. For example, most persons in developed countries have “access” to good diets but many do not actually consume such diets.
- The preamble uses the term “balanced diet” without defining it. Does “balanced” equal “adequate?”
- The preamble indicates that persons who consume “balanced diets” will “usually” obtain all the nutrients they require. What is the probability related to “usually?” Because of the statistical definition of the Recommended Dietary Allowance (RDA), if everyone in a population consumes exactly the RDA, the result is that 2.3 percent of the population would be consuming inadequate quantities of the nutrients.

The second sentence of the preamble properly emphasizes consumption of a variety of foods that constitute a balanced diet. The mistake is to see diet and supplementation as an “either/or” situation. The prudent decision for consumers to protect their health is to consume both a balanced diet and supplement on a rational basis.

The last sentence of the preamble suggests that no one should take a supplement without first doing a detailed dietary intake or nutritional status assessment. This suggestion is not feasible because of the technical or scientific input required. Most consumers are not qualified to do this for themselves. The economic resources available would be better

spent on food and supplements, rather than individual nutritional assessments by a professional.

1. SCOPE

1.2. This sentence is offered, apparently, as an “escape valve” for countries that wish to regulate supplements as drugs. It is self-evident in the name that a guideline by the Codex Alimentarius would not apply to products regulated as drugs. It is not apparent that a country can decide to impose drug regulations as a non-tariff trade barrier on supplements without sanction by the World Trade Organization. This sentence should be deleted because it seems to encourage countries to evade the guidelines by opting for drug regulations for supplements.

2. DEFINITIONS

2.1 The sentence in square brackets reflects the same flaws as the Preamble. It should be deleted.

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.1 This paragraph is restrictive in a way that could compromise the consumer’s health. The word “vitamin” together with the phrase “proven by scientific data” could easily be interpreted in a restrictive manner that could be detrimental to the consumer’s health and benefit— the word “vitamin,” if interpreted literally, would exclude substances lutein and lycopene. Also, these two substances are not “provitamins” but instead are best described as “vitamin like” because they provide nutritional benefits, although they are not “essential” in the usual, restrictive meaning of that word. Such exclusions would not serve the public interest or health.

3.1.2 The total provisions of the Pharmacopoeias must be recognized, including the common separate provisions for the vitamin or mineral source and tablets or capsules that contain it. The sources of vitamin ingredients used in dietary supplements include both natural and synthetic sources. Purity criteria for the concentrated vitamin used as a source for it in the vitamin tablet or capsule cannot be applied to natural sources or the final product. For example, a bulk ingredient identified as ascorbic acid might be required to be 99 percent pure, but the content in an ascorbic acid tablet might be much lower, thereby allowing use of vitamin C sources other than purified ascorbic acid, such as rose hips and acerola cherry. The purity of a tablet is related to the amount of the vitamin stated on the label.

[3.1.3] This section is redundant with 3.2, and should be deleted from 3.1.

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1 Some specified flexibility is needed for the minimum quantity—33 percent is reasonable for the nutrients required in very small quantities (such as vitamins B1, B2 and others) but not for those require in larger quantities (such as calcium). The 15 percent minimum is reasonable for those required in larger quantities.

This flexibility is necessary because, for example, a supplement of 15 percent of the calcium requirement may be very beneficial, but is not feasible for multivitamin/mineral products because the limitations of tablet size.

- 3.2.2 The first option in square brackets for RDA based limits should be deleted. The RDA does not provide all benefits, known with reasonable certainty, for the vitamins and minerals, and the statistical definition of the RDA does not cover 2.3 percent of the population—a terrible public health policy. See the following excerpt from a CRN comment to the US Food and Nutrition Board, November 2002 (indented in *Italics*, below). Most importantly for consideration of maximums, the RDA is not defined or determined to consider safety issues. The second option for maximums based on risk assessment is the current state of the science and should be adopted by Codex.

The Italicized section that follows is excerpted from a CRN comment to the US Food and Nutrition Board, November 2002

RDA – RECOMMENDED DIETARY ALLOWANCE: What it IS, and What it is NOT

A theoretical risk from intakes near or above the UL is likely to be overemphasized if the risk of inadequacy with intakes near the RDA are not recognized. Consider the following scenario that clearly demonstrates that the RDA is not an ideal intake or an appropriate nutrient intake target for all individuals in a population:

If the mean requirement is known with certainty (by including all members of the population), and the statistical distribution around that mean is exactly Gaussian, thus providing exact quantification of the variance (standard deviation), the RDA identifies an intake that would be sufficient for 97.5 percent of the population—but also insufficient for 2.5 percent of the population. If every member of the population put complete confidence in the sufficiency of the RDA and consumed a diet that provided exactly the RDA level of intake, 2.5 percent of the population would have nutrient intakes that were, by definition, inadequate. A health policy that would result in 2.5 percent of the population having inadequate intakes cannot be justified as a goal—thus the RDA is not an appropriate target intake for the population.

An ideal target intake for a population would be one that is a safe and convenient intermediate between the RDA and the UL. Such an intermediate level of intake could simultaneously provide safety from adverse effects of excess intakes and from risk of inadequacy resulting from insufficient intakes. For example, in contrast to the 2.5 percent inadequacy rate expected for intakes equal to the currently defined RDA, the mean requirement plus four standard deviations would identify intakes that protect all individuals but 1 in 13,000. (Note: a risk of 0.0001 would occur an intake 3.88 SD above the EAR.) It should be recognized, however, that there is no number of SD above the mean that would provide certainty of covering everyone in a population with a true Gaussian distribution.

For adult males, the following would apply:

<i>Nutrient*</i>	<i>EAR</i>	<i>RDA based on + 2SD (as rounded by FNB)</i>	<i>“RDA” based on +4SD (with rounding)</i>	<i>UL</i>
<i>Folate (µg DFE)</i>	320	400	500	1000
<i>Vitamin A (as µg RE)</i>	625	900	1150	3000
<i>Vitamin B-6 (mg)</i>	1.4	1.7	2	100
<i>Vitamin C (mg)</i>	75	90	105	2000
<i>Vitamin E (mg aTE)</i>	12	15	18	1000
<i>Selenium (µg)</i>	45	55	65	400
<i>Zinc (mg)</i>	9.4	11	13	40

* For the nutrients listed, the FNB assumed a 10 % CV, except retinol with a 20% CV.

This scenario comparing the RDA and a value 4 SD above the EAR does not address the issue of whether the endpoints selected by the FNB to serve as the basis of the RDA are the most appropriate ones. If endpoints related to risk of chronic disease (e.g., increased folic acid intake lowering homocysteine levels and the related risk of heart disease, or increased selenium intake decreasing the risk of certain cancers) had been selected as the basis of the RDA (regardless of the 2 SD vs 4 SD issue) the separations of the RDA and the UL would be considerably different. In such a circumstance, these relationships would need to be reexamined.

3.2.2 The second option for maximums based on risk assessment is the current state of the science and should be utilized. The last sentence of the second option for section 3.2.2, however, reflects compromise language that is included in the European Commission Food Supplements Directive. This reference to “population reference intakes” (can this be anything other than the RDA?) seems to be a “back door” to RDA-based limits. From a risk management viewpoint, the range of actual intakes from conventional food sources is relevant to the safety of supplements, but the RDA is not. The last sentence of option 2 should be deleted because it overtly contradicts the method described in sentences (a) and (b) in option 2.

3.2.3 This section should be deleted because it provides an “escape valve” to avoid Codex guidelines. The CCNFSDU should recognize that the Codex Procedural Manual (13th Edition) permits member countries to select one of three levels of acceptance Codex standards—for the purpose of domestic policy. The third of these (“free distribution”) would give the Codex standard no impact on domestic regulations, but it does not exempt the country from its obligations to comply with Codex standards under the international trade rules of the World Trade Organization. In the context of paragraph 3.2.3, maximums might be established as the national level for domestic purposes without input from Codex, but imports would be subject to the Codex guideline.

4 PACKAGING

4.3 The child-resistant provision is appropriate, but the “if necessary” qualifier should be expanded to acknowledge that easy-to-open containers are needed by many elderly consumers.

5 LABELLING

- 5.5 The requirement for labeling with percentages of the RDA should be optional because many consumers believe with considerable scientific justification that the RDA is not the relevant issues for many vitamins and minerals. Certainly, the percentage of the RDA has no meaning for safety.
- 5.7 The term “significant amount” is likely to be interpreted in a kaleidoscope of ways by different countries. Such warning statements are not needed unless the product exceeds the maximum identified through the second option in paragraph 3.2.2. This paragraph should be rewritten to read: “The label must contain a warning statement if the product exceeds the maximum identified through risk assessment as described in paragraph 3.2.2.”
- 5.9 This paragraph should be deleted. Under Codex supplements are to be regulated as “food” and therefore there should be no requirement to seek professional advice before their use. Note that the label itself is professional advice