

Green: Citizens for Health Codex
Working Group October 15, 2005

Red: Codex Alimentarius Commission
July 4, 2005

The Citizens for Health Codex Working
Group (CFHCWG) October 15, 2005
Proposed Framework for Trade in
Vitamin and Mineral Food Supplements

**Guidelines for the Use of Food
Supplement Trade in the Effort to
End World Hunger and Promote the
WHO/FAO Global Strategy on Diet,
Physical Exercise and Health**

**Guidelines for Vitamin and Mineral
Food Supplements**

Finalized by the Codex Alimentarius
Commission July 4, 2005

PREAMBLE

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The Food and Agriculture Organization
(FAO) Expert Consultation on Food
Safety: Science and Ethics, held in
Rome, Italy, in September 2002, set out
the following food, nutrition and health
rights:

Most people who have access to a
balanced diet can usually obtain all the
nutrients they require from their normal
diet. Because foods contain many
substances that promote health, people
should therefore be encouraged to select
a balanced diet from food before
considering any vitamin and mineral
supplement. In cases where the intake
from the diet is insufficient or where
consumers consider their diet requires
supplementation, vitamin and mineral
food supplements serve to supplement
the daily diet.

**“The human right to adequate food is
recognized in several instruments
under international law. [...] The
right of every human being to be free
from hunger is fundamental and
uncontested. The most important
implication of the right to adequate
food is that states and peoples must be
supported to enable them to address
situations of food insecurity
themselves. The right to culturally
acceptable food should not be
regarded primarily as a right to
receive a specific type of food aid, but
as a right to be supported so as to
create one's own food security.
Support to address sustainable food
security must therefore also include
ensuring the capacity in recipient
countries for food that is both safe and
nutritious.”¹**

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http://www.fao.org/documents/show_cdr.asp?url

[_file=/docrep/006/j0776e/j0776e01.htm](#) FAO
[Expert Consultation on Food Safety: Science and
Ethics...](#) paragraphs 2 and 11

In today's world, billions of people in wealthy and less wealthy countries lack access to a balanced diet, are beset by challenges of food scarcity and nutritional inadequacy, and therefore fail to obtain all the nutrients they require from their available diet. Although foods contain many substances that promote health, and people should be encouraged to select a balanced diet from food, because of the widespread lack of balanced diets, and the absence of nutrient density or balance in many widely consumed foods, people should also be encouraged to consider using vitamin and mineral supplements; national and global food-relief programs should separately ensure this.

Since, in a vast number of cases, the nutrient intake from the diet is either insufficient or insufficiently nutrient-dense to provide optimal health, and recognizing that consumers often determine that their diet requires supplementation, it is appropriate to ensure that ample amounts of vitamin and mineral food supplements of sufficient quality, variety, and potency are available to effectively supplement the daily diet as required and desired by citizen-consumers of all nation states.

1. SCOPE

1.1 This framework and its guidelines apply to vitamin and mineral food supplements intended for use in supplementing the daily diet with vitamins and/or minerals.

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1.1 These guidelines apply to vitamin and mineral food supplements intended for use in supplementing the daily diet with vitamins and/or minerals.

1.2 They also apply to food supplements containing vitamins and/or minerals that additionally include other ingredients found to be safe (i.e. lack proof of harm presented by appropriate regulatory authorities) and effective for their intended use in accordance with scientifically and legally sound international standards.

1.3. This framework and its guidelines apply in all jurisdictions where products defined in 2.1 are marketed, whether as foods, drugs, natural substances or under any other category name.

1.4 Vitamin and mineral food supplements, when used in or as foods for special dietary uses as defined in the Codex Alimentarius General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985), are covered by this framework and its guidelines.

2. DEFINITIONS

2.1 Vitamin and mineral food supplements for the purpose of this framework and its guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral food supplements are sources of concentrated forms of nutrients, alone or in combinations, marketed in forms such as capsules, tablets, powders, tinctures, solutions, etc., that are designed to be taken in measured small-unit (“small” as in physical size not “low” as in potency or strength) quantities at amounts from low to high potency that are not in a conventional food form and whose purpose is to supplement the intake of

1.2 Food supplements containing vitamins and/or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in these Guidelines

1.3. These Guidelines only apply in those jurisdictions where products defined in 2.1 are regulated as foods.

1.4. Foods for special dietary uses as defined in the General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are not covered by these Guideline.

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2.1 Vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral food supplements are sources of concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions, etc., that are designed to be taken in measured small-unit quantities¹ but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet.

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3. COMPOSITION

3.1 Selection of vitamins and minerals

3.1.1. Vitamin and mineral food supplements are food products (whatever else they may be called) that contain vitamins/pro-vitamins and minerals whose nutritional value for human beings has been established by scientific data, whose status as vitamins and minerals is recognized by FAO, WHO and other appropriate scientific or legal authority applying sound scientific and legal principles, and whose form is that set out in section 2.1 of this framework and guidelines.

3.1.2. The sources of vitamins and minerals may be either natural or synthetic (which should be clearly differentiated in information presented to consumers including information accompanying consumer products) and their selection should be based on considerations such as safety, efficacy and bioavailability. In addition, purity criteria should take into account FAO/WHO determinations, international pharmacopoeias and other scientifically and/or legally sound international standards.

3.1.3 Vitamin and mineral food supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1 in a single vitamin and/or mineral form or an appropriate combination of vitamins and/or minerals.

3.2 Contents of vitamins and minerals

3. COMPOSITION

3.1 Selection of vitamins and minerals

3.1.1. Vitamin and mineral food supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognized by FAO and WHO.

3.1.2. The sources of vitamins and minerals may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability. In addition, purity criteria should take into account FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources, national legislation may be used.

3.1.3 Vitamin and mineral food supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1. a single and/or mineral or an appropriate combination of vitamins and/or minerals.

3.2 Contents of vitamins and minerals

3.2.1 An acceptable range of oral intake (AROI),² between known deficiency and established toxicity, each based on clinical observation, that can be considered a range of optimal intakes for each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion of consumption as suggested by the manufacturer should be set, taking the following criteria into account:

(a) Consumers should not be led to believe, by the amounts of or information about vitamins and minerals in supplement products, or by officially recommended nutrient intakes (e.g. Population Reference Intake or Recommended Daily Allowance values) that there is exact quantitative knowledge of what individuals should eat in order to maintain health.

²Principles And Methods For The Assessment Of Risk From Essential Trace Elements <http://www.inchem.org/documents/ehc/ehc/ehc228.htm#1.0> and Problems Peculiar to the Setting of Limits for Essential Food Elements G.C. Becking Kingston, Ontario, Canada http://www.nnia.co.za/CPD/articles/risk_assessment.pdf In Risk Assessment in the Food Chain of Children, Edited by Peter J. Aggett and Harry A Kuiper. Nestlé Nutrition Workshop Series, Pediatric Program, Vol. 44, Nestec Ltd., Vevey/Lippincott Williams & Wilkins, Philadelphia © 2000 each discuss AROI. Becking says “The proposed methodology is discussed with regard to its applicability to essential trace elements. However, it should be applicable to all essential food components subject to homeostatic control by the human body.”

3.2.1 The minimum level of each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion of consumption as suggested by the manufacturer should be 15% of the recommended daily intake as determined by FAO/WHO.

3.2.2 Maximum amounts of vitamins and minerals in vitamin and mineral food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

(a) upper safe levels of vitamins and mineral established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) the daily intake of vitamins and minerals from other dietary sources.

When the maximum levels are set, due account may be taken of the reference intake values of vitamins and minerals for the population. This provision should not lead to setting of maximum levels that are solely based on recommended nutrient intakes (e.g. Population Reference Intake or Recommended Daily Allowance values).

(b) Biochemical individuality, stages of life and gender are among the factors considered in establishing reference intake values of vitamins and minerals for populations that require the setting of a broad range, rather than specific upper and/or lower limits, of nutrient intake except to convey an understanding of the quantity of nutrients contained in the product.

(c) the AROI risk factors for vitamins and minerals shall be established by scientific risk analysis consisting of risk assessment, risk management and risk communication based on generally accepted scientific procedures, taking into consideration, as appropriate, the varying degrees of sensitivity of different individual consumers and consumer population groups;

(d) The AROI includes the daily intake of vitamins and minerals from other dietary sources as established by aggregated clinical observations rather than abstract handbooks or other sources of imputed nutrient content of foods.

4. PACKAGING

4.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.

4.2. The containers, including packaging material, shall be made only of substances which are safe and suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any substance used as packaging material, that standard shall apply.

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4.2. The containers, including packaging material, shall be made only of substances which are safe and suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any substance used as packaging material, that standard shall apply.

5. LABELLING

5.1 Vitamin and mineral food supplements should be labeled according to the Codex Standard for the Labeling of Prepackaged Foods (Codex-Stan 1-1985 Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979) with the exception that claims that a balanced diet of ordinary foods cannot supply adequate amounts of all nutrients and that identified amounts of vitamins and minerals may be used in the prevention, alleviation, treatment or cure of disease, disorder or particular physiological condition can be made if substantiated by scientific evidence.

5.2 The name of the product shall be "food supplement" with an indication of the category(ies) of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be.

5.3 The amount of the vitamins and minerals present in the product should be declared in the labeling in numerical form. The units to be used should be units of weight consistent with the Codex Guidelines on Nutrition Labeling with the caveat that all references to the recommended daily intake, Dietary Reference Intakes (DRIs), or other reference intake values, in all sections of this framework and its guidelines are for the purpose of providing consumers with a suitable profile of nutrients contained in the food and considered to be of nutritional importance. The information should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the

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quantity of nutrients contained in the product. A more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labeling, labels or other direct to consumer information.³

5.4 To convey an understanding of the quantity of nutrients contained in the product the amounts of the vitamins and minerals declared should be those per portion of the product as recommended for daily consumption and if different, the amount per unit for single use may also be given.

5.5 Information on vitamins and minerals should also be expressed as a percentage of the nutrient reference values mentioned (in the form of Dietary Reference Intakes for example), as the case may be, in the Codex Guidelines on Nutrition Labeling.

5.6 The label should indicate how the product should be used (quantity, frequency, special conditions).

5.7 The label shall contain advice to the consumer to obtain a personal optimum daily vitamin and mineral intake level and not to unintentionally exceed that one-day amount.

5.8 The label should not state or imply that supplements alone can be used for the replacement of meals or a varied diet.

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5.5 Information on vitamins and minerals should also be expressed as a percentage of the nutrient reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labelling.

5.6 The label should indicate how the product should be used (quantity, frequency, special conditions).

5.7 The label shall contain advice to the consumer not to exceed the maximum one-day amount.

5.8 The label should not state or imply that supplements can be used for the replacement of meals or a varied diet.

³ The text of the caveat is from the Codex Guidelines on Nutrition Labeling http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/005/Y2770E/y2770e06.htm

5.9 The label shall contain a statement that the product should be stored out of the reach of young children to assist in preventing choking injuries.

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¹ This refers to the physical forms of the vitamin and mineral food supplements not to the potency of the supplements.