Revised Version - Text of final Codex Vitamin and Mineral Guideline.
Offered for Amendment on behalf of
Natural Solutions Foundation and Citizens Working Group on Codex

Finalized by the Codex Alimentarius Commission July 4, 2005
Guidelines for Vitamin and Mineral Food Supplements

PREAMBLE

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:

"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]

In today's world, billions of people in wealthy and less wealthy countries lack access to a balanced diet capable of providing optimal nutrition, 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 and health professionals often determine that their diet

[1] 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 8 and 10

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.

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 at commonly employed dosages presented by appropriate regulatory authorities) and effective for their intended use in accordance with clinically, 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 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 vitamins and/or minerals from the normal diet.

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/provitamins and/or minerals whose nutritional value for human beings has been established by clinical and scientific data and whose status as vitamins and minerals is recognized by FAO, WHO and/or other appropriate scientific or legal authority applying sound clinical, 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 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. a single and/or mineral form 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 and/or laboratory assessment, 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

[2]Principles 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. Nestlè 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."

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 attain and maintain optimal health.

(b) Biochemical individuality, stage 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 for vitamins and minerals shall be established by appropriate 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.

5. LABELING

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 clinical and 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 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 and average 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,

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

special conditions) under average expectable circumstances recognizing that biochemical individuality may significantly alter these parameters.

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 can be used for the replacement of meals or a varied diet.

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.

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

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10/14/05