NATURAL
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PROPOSED FRAMEWORK FOR TRADE IN VITAMIN AND MINERAL FOOD SUPPLEMENTS

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

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]

[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 2 and 11

Codex Alimentarius Commission July 4, 2005

Ratified by the Codex Alimentarius Commission July 4, 2005

PREAMBLE

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.

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.

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. SCOPE

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 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 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 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/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.

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.

2. DEFINITIONS

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 quantities 1 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.

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 (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

3.2.1 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.

[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.

[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."

3.1.2 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 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 nutritient intakes (e.g. Population Reference Intake or Recommended Daily Allowance values).

[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.

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 scientific evidence.

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 labelled according to the Codex Standard for the Labelling of Prepackaged Foods (Codex-Stan 1-1985 Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979).

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 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).

[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

5.2 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.

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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 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.

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.

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.

5.9 The label shall contain a statement that the product should be stored out of the reach of young children.

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

NATURAL
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SAMPLE INTERNATIONAL DIETARY SUPPLEMENT ACT

Sample International Dietary Supplement Act

Source: Dietary Supplement Health and Education Act of 1994

Modified for Conformity with the Revised Vitamin and Mineral Guideline.
For adoption by national legislatures.

§1. Short Title; Reference; Table Of Contents.

(a) Short Title.

This Act may be cited as the "International Dietary Supplement Act of [Year]".

(b) Table of Contents.

The table of contents of this Act is as follows:

§2. Findings.

The Government finds that -

(1) improving the health status of citizens ranks at the top of the national priorities of the Government;

(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented in numerous scientific studies;

(3) (A) there is a link between certain nutrients or dietary supplements and the prevention of hunger and chronic diseases and

(B) clinical research has shown that many chronic diseases can generally be prevented by a healthful diet with a high proportion of plant-based foods and dietary supplements

(4) healthful diets may mitigate the need for expensive, dangerous and invasive medical procedures, such as coronary bypass surgery or angioplasty and expensive, toxic and dangerous pharmaceuticals which can suppress symptoms rather than correct or prevent underlying causes of chronic degenerative disease;

(5) preventive health measures, including education, good nutrition, and appropriate use of nutritional supplements will reduce the incidence of chronic diseases, and reduce human suffering, hunger, preventable death and long-term health care expenditures;

(6) (A) promotion of good health and healthy lifestyles improves and extends life and health while reducing health care expenditures; and

(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

(7) there is a growing public health requirement for the dissemination of information supporting the connection between nutrition, dietary supplementation and long-term good health;

(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements, traditional medical wisdom and clinical practice;

(9) surveys have revealed that many consumers use dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;

(10) studies indicate that consumers are placing increased reliance on the use of traditional, non-allopathic health care providers to avoid the dangerous toxic allopathic alternatives and their excessive costs and to participate in holistic, rather than symptom-suppressive allopathic health care;

(11) a significant amount, representing a high percentage, of a nation's financial capacity is spent on allopathic health care and both this amount and percentage will continue to increase to the detriment of the national economy, without commensurate health benefits for the population unless significant efforts are undertaken to reverse the increase, support nutrition and supplementation as primary medical modalities;

(12) (A) the nutritional supplement industry can, and should be, an integral and important part of the national economy;

(B) in addition to increasing the health, and decreasing the preventable deaths of the nation, the dietary supplement industry can be expected to provide a positive trade balance and

(C) domestic dietary supplement manufacturers could produce a significant number of products improving the balance of trade;

(13) although the Government should take swift action against products that are unsafe or adulterated, the Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

(14) unlike pharmaceuticals, dietary supplements are safe within a broad range of intake, and safety problems with supplements are if not non existent then extremely rare; and

(15) (A) legislative action that protects the right of access of consumers to safe dietary supplements and truthful information is necessary in order to promote wellness; and

(B) a rational framework should be established to spell out a regulatory policy on dietary supplements that promotes easy consumer access to healthful and properly labeled dietary supplements.

§3. Definitions.

(a) Definition of Certain Foods as Dietary Supplements.

The term "dietary supplement" ("food supplement" or "nutritional supplement") -

"(1) means a product (other than tobacco or alcoholic beverages) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

"(A) a vitamin;

"(B) a mineral;

"(C) an herb or other botanical;

"(D) an amino acid;

"(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

"(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

"(2) means a product that -

"(A) is intended for ingestion through oral use, inhalation, absorption [or in a form described in section (7)(d)(5) hereof;] and

"(B) is not represented for use as a conventional food [with the exception of functional foods which can be used as dietary replacements] or as a sole item of a meal or the diet; and

"(C) is labeled as a dietary supplement or "food supplement"; and

"(3) may -

"(A) include an article that is approved as a new drug, certified as an antibiotic, or licensed as a biologic if same was, prior to the effective date of this Act or the date of such approval, certification, or license, marketed as a dietary supplement or as a food unless the supervising authority has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is by clear and convincing evidence, not safe; and

"(B) not include an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and

for which the existence of such investigations has been made public, unless same was, prior to the effective date of this Act, marketed as a dietary supplement or as a food which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the appropriate authority, has issued a regulation, after notice and comment, finding it reasonable that the article would be lawful under this Act.

(b) A dietary supplement shall be deemed to be a food. Such foods may not be subject to upper limits.

§4. Safety of Dietary Supplements and Burden of Proof.

(1) If a dietary supplement contains a dietary ingredient that

(A) presents, by clear and convincing evidence, a significant and unreasonable risk of illness or injury under -

"(i) conditions of use recommended or suggested in labeling, or

"(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary, predictable conditions of use; or

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present, by reasonable evidence, a significant and unreasonable risk of illness or injury; or

(C) the authority declares to pose, by clear and convincing evidence, an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Director of the Office of Dietary Supplements shall promptly after such a declaration initiate a proceeding to affirm or withdraw the declaration within a reasonable period of time not to exceed 60 days; or

"(D) is or contains an ingredient that renders it adulterated under the conditions of use recommended or suggested in the labeling of such dietary supplement, the Director of the Office of Dietary Supplements may seek relief from the courts. In any proceeding under this Act, the Government shall bear the burden of proof on each element to show that a dietary supplement is adulterated or unsafe. The court shall decide any issue under this paragraph on a de novo basis. No decision under this provision may be based upon the use of Toxic Risk Analysis.

(2) Before the Director of the Office of Dietary Supplements may report a violation of this Act for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding, except in an emergency duly declared by the Director of Dietary Supplements under Section (1)(C) hereof.

§5. Dietary Supplement Information.

(a) IN GENERAL.- A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it -

(1) is not false or misleading;

(2) does not promote a particular manufacturer or brand of a dietary supplement;

(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

(4) if displayed in an establishment, is physically separate from the dietary supplements, or if on the Internet, on a separate page;

(5) does not have appended to it any information by sticker or any other method that does not conform to this Act; and

(6) is made as a testimonial or personal, clinical or other history of experience unrelated to, unsolicited by, or unknown to the manufacturer, marketer, seller or other person with a commercial interest in the problem.

(b) Application. - Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.

(c) Burden of Proof. - In any proceeding brought under subsection (a), the burden of proof shall be on the Government to establish that an article or other such matter is false or misleading.

§6. Statements of Nutritional Support.

A statement for a dietary supplement may be made if -

(A) the statement claims a benefit related to a nutrient deficiency, including classic nutrient deficiency disease, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to prevent and mitigate physical, emotional, attentional and psychological conditions, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Office of Dietary Supplements. This product is not intended to diagnose, treat, mitigate or cure any disease"

If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence (A) of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Director of the Office of Dietary Supplements in writing setting forth the claims being made for each dietary ingredient and combination of ingredients, certifying that the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, no later than 30 days after the first marketing of the dietary supplement with such statement.

§7. Dietary Supplement Ingredient Labeling and Nutrition Information Labeling.

(a) MISBRANDED SUPPLEMENTS. -

If a product -

(1) is claimed to be a dietary supplement; and

(2)(A) the label or labeling of the supplement fails to list -

"(i) the name of each ingredient of the supplement that is described in section 201(ff); and

"(ii)(I) the quantity of each such ingredient; or

"(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to identify the product by using the term `dietary supplement', 'nutritional supplement' or 'food supplement', which term may be modified with the name of such an ingredient;

(C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

(D) the supplement -

"(i) is covered by the specifications of an official compendium;

"(ii) is represented as conforming to the specifications of an official compendium; and

"(iii) fails to so conform; or

(E) the supplement -

"(i) is not covered by the specifications of an official compendium; and

"(ii)(I) fails to have the identity and strength that the supplement is represented to have; or

"(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.

(b) Supplement Listing on Nutrition Labeling.

A dietary supplement product label shall provide that -

(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.

(v) The manufacturer or distributor shall list any known cautions or special information making a supplement of special concern to a particular population (e.g., “people with dietary sensitivity to phenylketones should avoid this food” or “this food contains wheat products”) on the label.

(c) Percentage Level Claims.

Dietary supplement products may include a statement in the labeling that characterizes the percentage level of a dietary ingredient for which there is no established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

(d) Vitamins and Minerals.

(1) the supervising authority may not establish maximum limits on the potency or dose of any natural or synthetic vitamin, mineral, enzyme, hormone, amino acid or herb within a food to which this law applies; nor classify any natural or synthetic vitamin, mineral, enzyme, hormone, amino acid or herb (or combination thereof) as a drug solely because it exceeds the level of potency which the authority determines is nutritionally rational or useful;

(2) the supervising authority may not limit the combination or number of any synthetic or natural

(i) vitamin,

(ii) mineral, or

(iii) enzyme, hormone, amino acid, herb or other ingredient of food, within a food to which this law applies.

(3) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women unless the manufacturer or distributor has reasonable substantiation for such representation. For purposes of this paragraph, the term ''children'' means individuals who are under the age of twelve years.

(4) Labeling and advertising requirements for dietary supplements

(a) The labeling for any dietary supplement to which this section applies shall list its ingredients, including those which are not dietary supplement ingredients (i) as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations, if any. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulation.

(5) Definitions

(1) For purposes of this section, the term ''food to which this section applies'' means a food for humans which is a food for special dietary use -

(A) which is, or contains any, natural or synthetic vitamin, mineral, enzyme, hormone, amino acid or herb, and

(B) which -

(i) is intended for ingestion or other nutritive assimilation, in tablet, capsule, powder, softgel, gelcap, liquid/salve or similar form, or

(ii) if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form if it is formulated in a fluid carrier and it is intended for ingestion or for administration through the mouth or similar orifice, in daily quantities measured in drops or similar small units of measure, such as ounces, teaspoons, tablespoons, milliliters, centimeters or drama and other similar units.

(3) For purposes of this title, the term ''special dietary use'' as applied to food used by humans means a particular use for which a food purports, or is represented, to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium or other minerals or

(B) Supplying a vitamin, mineral, or other ingredient for use by a human to supplement the diet by maintaining or increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet

(D) Detoxification and removal of toxic substances

(E) Prevention of, or protection against, diseases or conditions.

(e) Effective Date. Dietary supplements -

(1) may be labeled after the date of the enactment of this Act in accordance with the terms hereof.

(2) shall be labeled one year after the enactment of this Act in accordance with the terms hereof.

§8. New Dietary Ingredients.

(a) In general - a dietary supplement that contains a new dietary ingredient shall be deemed adulterated unless it meets one of the following requirements:

(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered since at least the date of the enactment of this Act, or

(2) (i) There is a history of use or other evidence of safety reasonably establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, (ii) at least 60 days before being introduced or delivered for introduction into commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the

supervising authority with information, including any citation to published articles, books, lectures, data bases or other similar materials, which are the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

(3) The authority shall keep confidential any information provided under paragraph (2) for 60 days following its receipt. After the expiration of such 60 days, the authority shall place such information on public display by official notice and posting on the Internet, except matters in the information which are claimed to be trade secrets or otherwise confidential, commercial information.

(4) Unless clearly contrary to generally accepted scientific knowledge, such history of use or other evidence of safety shall be deemed acceptable upon the expiration of the 60 day period and the manufacturer or distributor of the dietary ingredient or dietary supplement may proceed to introduce same into commerce. If the Director of the Office of Dietary Supplements finds that there is no reasonable evidence of safety and such evidence as offered is clearly contrary to generally accepted scientific knowledge, the supervising authority may seek relief in any court of competent jurisdiction.

(b) Petition. - Any manufacturer or distributor may file with the supervising authority a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The supervising authority shall make a decision on such petition within a reasonable time. For purposes of appeal by any party to the courts, the decision, or failure to decide (within 120 days of filing of the Petition) of the supervising authority shall be considered final agency action.

(c) Definition. - For purposes of this section, the term "new dietary ingredient" means a dietary ingredient that was not marketed before the enactment of this Act.

§9. Good Manufacturing Practices.

(1) If a dietary supplement has been prepared, packed, or held under conditions that do not reasonably meet current good manufacturing practice regulations, if any, including regulations requiring, when necessary, expiration date labeling, issued by the supervising authority under subparagraph (2), such supplement shall be considered misbranded.

(2) The supervising authority may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food, not pharmaceuticals, and may take traditional techniques of food preparation into account and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment. The methodologies of the science of toxicology may not be used to determine safe upper limits without a showing of actual harm if such limits are exceeded since dietary supplements are, as foods, presumed to be free of the requirement for safe upper limits.

§10. Claims.

(a) A food or dietary supplement for which a claim is made is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made is not a drug under clause solely because the label or the labeling contains such a statement.

(b) The introduction or delivery for introduction into commerce of a dietary supplement that is unsafe is prohibited.

(c) A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.

(d) A dietary supplement may make truthful and not misleading claims that characterize the relationship of a dietary ingredient, or combination of ingredients, (1) to the normal structure and function of the body, (2) to general wellness concerns and (3) to the prevention and mitigation of physical, emotional, attentional and psychological conditions.

§11. Harmonization with International Regulations

It is the intent of this Act that determinations and regulations permitted under its terms be issued in conformity with the Revised Vitamin and Mineral Guideline and Framework where same promotes The Food and Agriculture Organization (FAO) Expert Consultation on Food Safety: Science and Ethics, held in Rome, Italy, in September 2002, which 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."

§12. (a) In general - Office of Dietary Supplements

(a) Establishment. - There is established an Office of Dietary Supplements as the supervising authority under this Act, within the Department/Ministry of _____.

(b) Purpose. - The purposes of the Office are -

(1) to explore more fully the role of dietary supplements to alleviate hunger, improve health and health care; and

(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing hunger, chronic disease and other health-related conditions.

(3) To act as Supervising Authority under this Act.

(c) Duties. - The Director of the Office of Dietary Supplements shall -

(1) conduct and coordinate scientific research relating to dietary supplements and the manner in which the use of dietary supplements can limit or reduce the risk of disease;

(2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from domestic and foreign sources;

(3) serve as the principal advisor to the Government on issues relating to dietary supplements including -

"(A) dietary intake regulations;

"(B) the safety of dietary supplements;

"(C) claims characterizing the relationship between -

"(i) dietary supplements; and

"(ii)(I) prevention of disease or other health-related conditions; and

"(II) maintenance of health; and

"(D) scientific issues arising in connection with the labeling and composition of dietary supplements;

"(4) compile a database of scientific research on dietary supplements and individual nutrients; and

"(5) coordinate funding relating to dietary supplements.

(6) Act as the Supervising Authority under this Act, with all the powers and prerogatives provided herein, under the proper supervision of the judiciary.

§13. Appendix

Appended hereto and made a part hereof as though fully set forth herein: the Revised Vitamin and Mineral Guideline and Framework.

NATURAL
SOLUTIONS
FOUNDATION

Nutrition and Health

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www.HealthFreedomUSA.org
healthfreedom optonline.net

With special thanks to:

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- Andrew Saul, PhD

Nutrition is nothing less than the foundation of medicine, the cornerstone of all medical therapeutics.

— A Forum on Nutrition and Health, JON 2(4), 1993

Prevention cannot start too early. Neither can it start too late.

— Rima E. Laibow, MD, 2005