

To: Dr. Barbara Schneeman
Director, Office of Nutritional Products Labeling and Dietary Supplements
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

To: Dr. Edward Scarborough
U.S. CODEX Manager - U.S. CODEX Office
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To: Receiver of Dockets
Dockets Management Branch
Department of Health and Human Services
Food and Drug Administration
Room 1061, 5630 Fishers Lane
Rockville, MD 20852

**Second Amendment to
CITIZEN PETITION
for Furtherance of Dietary Supplement Harmonization Policy
by the U.S. CODEX Delegation and Food and Drug Administration,
in Harmony with DSHEA and 19 USC 3512**

This Second Amendment is submitted with regard to the Citizen Petition of June 1, 2005, (Amended June 14, 2005) urging the US Codex Office to further, as its policy, harmonization with the CODEX Vitamin and Mineral Guideline (VMG) only in conformity with existing US Law and includes the issues raised therein by reference and to refrain from harmonization via either legislative or regulatory means with any standard, guideline or regulation which conflicts with or violates US current Law. Attached hereto and made a part hereof is a copy of the VMG, marked for amendment to conform to existing United States laws and regulations.

This Petition is further addressed to the Food and Drug Administration, as the agency responsible for US Policy on food and nutrient safety at the International Food Safety Agency, including herein, by reference the original Petition and the First Amendment thereto, copies of which are appended hereto.

Further the Petitioner states:

Factual Background

1. (a) The Vitamin and Mineral Guideline adopted by CODEX on July 4 2005 uses inappropriate science (i.e., Risk Assessment procedures [Toxicology]) rather than appropriate science (i.e., Nutritional Science [Biochemistry]) which is very likely to inappropriately mandate maximum permissible levels of nutrients so low that they are, by intention, without impact on any human being, the intended outcome of Risk Assessment procedures; a Fact Hearing must be, and petitioner hereby requests that a fact hearing be, held to determine the scientifically factual and appropriate basis for the use of Risk Analysis [Toxicology] rather than more appropriate nutritional [Biochemistry] scientific standards in all decisions pertaining to nutrition.

(b) Codex has accepted the use of Risk Assessment procedures for nutrients. However, Risk Assessment is a methodology relevant only to toxicology and both irrelevant and antithetical to Nutritional Science and biochemistry. The Risk Assessment methodology employed by CODEX has been arbitrarily modified without scientific validation or professional consensus to restrict permissible dosages of nutrients essential to life to levels which can, by intent, have no impact on any human being, no matter how sensitive. This misapplication, distortion and misconstruction of Risk Assessment is in clear contradiction to the principles of toxicology and scientific Risk Assessment procedures which have been developed to determine the highest dosages of dangerous industrial and natural toxins to which humans can be exposed to without discernable effect. For this reason, instead of evaluating vitamin and mineral upper limits using inappropriately modified and unscientific Risk Analysis, US Policy must further the use of Nutritional Science to support the liberal access to nutrients enjoyed under legislative protection in the US. Under the Dietary Supplements Health and Education Act, passed by unanimous Congressional consent in 1994, while a nutrient may be dealt with by the FDA if it is shown to pose a significant risk to health and safety, nutrients are treated as foods which, as such, may have no upper limits set upon their use.

(c) The United States has failed to oppose the use of these scientifically unsupported and unverified Risk Assessment techniques in the CODEX Committee on Nutrition and Foods for Special Dietary Uses. It has failed to note or oppose these procedures on the basis of the substantial Conflict of Interest represented by the publicly acknowledged personal, professional and financial involvement in commercial Risk Assessment by the Chairman of the Codex Committee on Nutrition and Foods for Special Dietary Uses as the head of the BfR, a commercial Risk Assessment company. The United States has failed to oppose the classification of nutrients as toxins in 1994, by that same committee despite the clear violation of US law which that classification represents. And, since 1994, the United States has failed to present any opposition to the use of Risk Analysis and other attempts to limit access to nutrients in order to prevent the restrictive (and illegal under US law) Vitamin and Mineral Guideline from reaching Step 8 and from being ratified on July 4, 2005 at the 28th CODEX ALIMENTARIUS Commission meeting in Rome, Italy, contrary to DSHEA (Dietary Supplement health and Education Act of 1994) and the unanimous determination of Congress that Dietary Supplements are Foods, not toxic substances and, as foods, can have no upper limit set upon their intake or use.

(d) U.S. District Court Judge Tena Campbell stated in the Ephedra Decision, April 2005 (*Nutraceutical Corporation and Solaray, Inc. v. Lester Crawford, Acting Commissioner, U.S. Food and Drug Administration*, Case No. 2:04CV409 TC, USDC, Utah Central Division),

“...the legislative history of the DSHEA indicates that Congress generally intended to harmonize the treatment of dietary supplements with that of foods when it added the dietary supplement subsection...”

(e) The CODEX Technical Report discussing the application of Risk Assessment to nutrients makes it clear that this procedure does not apply to nutrients because, unlike drugs, they have minimum intake limits that are required for life and health. Risk Assessment procedures were modified for application to vitamin and mineral supplements without scientific validation, peer review or clinical testing. There is a considerable body of literature supporting the nutritional harm caused by low-level intake of essential and vital nutrients. Has the United States held a public fact finding hearing to determine if this jerry-rigged statistical system has any applicability to Nutritional Science and what the risks to the US and global population are when Risk Assessment is applied to nutrients? If not, why has the US supported the use of this technique in the nutritional determinations made by the CCNFSDU when so many lives are at stake in this issue, estimated by public health scientists to exceed 3 Billion consequential deaths world-wide? Why has the US supported and adopted this scientifically, biologically and factually indefensible Policy which should be abandoned in favor of a Policy which supports and promotes nutrients as foods, as DSHEA mandates, as the domestic and international standard which are so strongly supported by both science and US Law? A fact Hearing must be, and petitioner hereby request that a fact hearing be, held to determine the impact on public health in the United States from the use of Risk Analysis [Toxicology] rather than more appropriate nutritional [Biochemistry] scientific standards.

(f) We have appended hereto, and make part hereof, the Alliance for Natural Health (ANH) and Citizens for Health (CFH) comments on the failure of toxic Risk Assessment to conform to standards of science.

Legal Authority

2. (a) The US Codex Office, the FDA and all other involved agencies have legal authority to further international harmonization only in conformity with US law:

Title 19, Section 3512, forbids the US from harmonizing with standards which violate US law;

The Dietary Supplement Health Education Act (DSHEA), 1994 classifies supplements as foods which therefore may have no Safe Upper Limits, Maximum Permissible Upper Limits or other restrictions upon their use.

(b) FDA has adopted a policy of harmonization with International Standards, even where those standards are not finalized. “In a notice published in the Federal Register of October 11, 1995 (60 FR 53078), FDA articulated its policy regarding the development and use of standards with respect to the harmonization of various national and international regulatory requirements and guidelines” - <http://www.cfsan.fda.gov/~lrd/fr970707.html> .

(c) The adoption of the Risk Assessment Model and the anti-DSHEA harmonization Policy are *ultra vires* and premature; have occurred without sufficient

Public Hearings and in direct contravention of the Public Policy of the United States as enacted by Congress. The appropriate US agencies must therefore assert a Nutritional Standard as the only lawful alternative to the inappropriate and unscientific use of toxicological Risk Assessment with regard to Dietary Substances. It is incumbent upon the United States therefore to ensure that the proper science is presented and considered in the process of attempting to set upper limits for nutrient supplements and to vigorously support the reopening of the Vitamin and Mineral Guideline to correct its scientific deficiencies since the science upon which it is based, relying on toxicology while ignoring the appropriate science, biochemistry, is flawed, creating a position that is contrary to US legal requirements and domestic (as well as global) health and well being of every man, woman and child on the planet.

(d) The Natural Solutions Foundation, in cooperation with Citizens for Health, has caused its attorneys to prepare a Revised Version of the Vitamin and Mineral Guideline more in conformity with the requirements of Law. A copy of the Revised Version is attached hereto and made a part hereof (together with a comparison copy, showing the specific changes requested).

Environmental Statement

3. (a) Environmental Impact information is generally required only if the petition requests approval of food or color additives, drugs, biological products, animal drugs, or certain medical devices, or for a food to be categorized as GRAS (generally recognized as safe) under the Procedures for preparing environmental impact statements found in Title 21, Part 25 of the Code of Federal Regulations. An environmental impact statement is therefore not required.

Actions requested

4. The Petitioner requests the following Actions by the agencies, with regard to CODEX and the International Food Safety Agency:

(a) The opening of an appropriate Docket for this Petition and for consideration of the Revised Version of the Vitamin and Mineral Guideline.

(b) The holding of Public Hearings on following Questions of Fact:

1. Whether or not the use of Toxic Risk Assessment to determine the allowable forms and dosages of Vitamins and Minerals will promote public health. Petitioners assert it will not, as the use of Risk Assessment is inappropriate science with reference to Foods, including Vitamins and Minerals

2. Whether forms and dosages of Vitamins and Minerals determined through Toxic Risk Assessment will adversely impact on the health and well-being of the residents and Citizens of the United States.

(c) (1) The adoption of the Revised Version of the Vitamin and Mineral Guideline (attached hereinafter) to promote harmonization in conformity with United States Law, and (2) support for such harmonization at future CODEX and International Food Safety Agency meetings.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitions that are unfavorable to the petition.

Dated: October 14, 2005

Natural Solutions Foundation

Cc: George W. Bush, President
Richard B. Cheney, Vice President
Secretary of HHS

Secretary of Commerce
Ret.)
Secretary of Agriculture
Secretary of Transportation
Commissioner of EPA
Commissioner of FDA
Barbara Schneeman, FDA
Sen. William Frist, MD

Maj. Gen. Albert N. Stubblebine III (US Army,
President
Natural Solutions Foundation

Rep. Dennis Hastert
Sen. Harry Reid
Rep. Nancy Pelosi

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Procedural Advisor:
Jim Turner, JD

Revised Version
Text of final Codex Vitamin and Mineral Guideline.
Marked for Amendment

Deletions ~~struck through~~; additions underlined.

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

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.~~

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 8 and 10

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 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 ~~These~~ 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 as well as that additionally include other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in these Guidelines 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. ~~These Guidelines only apply in those jurisdictions where products defined in 2.1 are regulated as foods.~~ 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 ~~not~~ covered by this framework and its guidelines ~~these Guidelines~~.

2. DEFINITIONS

2.1 Vitamin and mineral food supplements for the purpose of ~~these~~ 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 ~~these~~ 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 ~~but~~ 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 should contain vitamins/provitamins and/or minerals whose nutritional value for human beings has been proven established by clinical and scientific data and whose status as vitamins and minerals is recognized by FAO, and 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 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~~ 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 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.~~

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 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

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. Beeking 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. Beeking 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.”

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.

~~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).~~

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

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

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) 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 ~~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 to assist in preventing choking injuries.

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. 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.”

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http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/005/Y2770E/y2770e06.htm

Text prepared by James Turner, JD, Rima Laibow, MD and Ralph Fucetola,
JD

10/14/05

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:

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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.

⁴ 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

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 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),⁵ between known deficiency and established toxicity, each based on clinical observation and/or laboratory assessment, that can be considered a range of optimal

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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 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

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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.

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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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5.4 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

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Reference Intakes for example), as the case may be, in the Codex Guidelines on Nutrition Labeling.

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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.

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. 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 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

Text prepared by James Turner, JD, Rima Laibow, MD and Ralph Fucetola, JD
10/14/05

June 14, 2005

To: Dr. Edward Scarborough
U.S. CODEX Manager
U.S. CODEX Office
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**AMENDMENT to CITIZEN PETITION
to U.S. CODEX Office for
Adoption of Dietary Supplement Harmonization Policy
by the U.S. CODEX Delegation
in Harmony with DSHEA and 19 USC 3512**

This AMENDMENT is submitted with regard to the Citizen Petition of June 1, 2005, urging the US Codex Office to adopt, as its policy, harmonization with international standards only in conformity with existing US Law, further now stating:

1. The CODEX Vitamin and Mineral Standard uses inappropriate science (Risk Assessment procedures [toxicology] rather than nutritional science [biochemistry]) to mandate maximum permissible levels of nutrients so low that they are, by intention, without impact on any human being; a Fact Hearing must be held to determine the scientifically factual basis for the use of Risk Analysis in decisions pertaining to nutrition.

The US Codex Office has accepted the use of Risk Assessment procedures for nutrients although Risk Assessment is a methodology relevant to toxicology and both irrelevant and antithetical to nutritional science and biochemistry. Over the past many years, the United States has failed to oppose the use of Risk Assessment techniques in the CODEX Committee on Nutrition and Foods for Special Dietary Purposes and, since 1994, has failed to make its opposition to the use of Risk Analysis or any other attempt to limit access to nutrients clear in order to prevent the restrictive, and, because of US law, the illegal Vitamin and Mineral Standard from moving forward via consensus to Step 8 in preparation for ratification.

The Technical Report discussing the application of Risk Assessment to nutrients makes it clear that this procedure does not apply to nutrients because, unlike drugs, they have minimum intake limits which are required for life. Risk Assessment procedures were modified without scientific validation or clinical testing. Has the United States held a public fact finding hearing to determine if this jerry-rigged statistical system has any applicability to nutritional science? If not, why has the US supported the use of this technique in the nutritional determinations made by the

CCNFSDU when so many lives are at stake in this issue? Why has the US adopted this scientifically factually indefensible policy which should not be abandoned in favor of a policy which supports and promotes DSHEA as the international standard?

2. The US Codex Office and all other involved agencies are without legal authority to set, as was announced at the Public Hearing of June 9, 2005, as its Policy for the United States Government, and its Delegates to the 28th CAC meeting next month, a Policy which explicitly and specifically violates US law as set forth in the Natural Solutions Foundation's Citizen's Petition presented to the US Codex Office on June 1, 2005:

Title 19, Section 3512, forbids the US from harmonizing with standards which violate US law;

The Dietary Supplement Health Education Act (DSHEA), 1994 classifies supplements as foods which therefore may have no Safe Upper Limits, Maximum Permissible Upper Limits or other restrictions upon their use.

The adoption of the Risk Assessment Model and the anti-DSHEA harmonization Policy are *ultra vires* and premature; have occurred without sufficient Public Hearings and in direct contravention of the Public Policy of the United States as enacted by Congress.

Dated: June _____, 2005

Natural Solutions Foundation

Cc:
CODEX Office via facsimile and email
George W. Bush, President
Secretary HHS

Secretary of Commerce
Ret.)
Secretary of Agriculture
Secretary of Transportation
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Commissioner of FDA

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June 1, 2005

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**CITIZEN PETITION to U.S. CODEX Office for
Adoption of Dietary Supplement Harmonization Policy
by the U.S. CODEX Delegation in Harmony with DSHEA and
19 USC 3512**

I. Introduction

The Natural Solutions Foundation of 88 Batten Road, Croton on Hudson NY 10520 hereby PETITIONS the U.S. CODEX Office to adopt as the policy of the U.S. CODEX Delegation support for international harmonization only as it conforms to United States law and practice. This policy should be adopted on an emergent basis, prior to the 28th General Sessions of the CODEX Commission scheduled for July 4-9, 2005 in Rome, Italy. This Petition is posted on the Internet at www.HealthFreedomUSA.org/petition.

The Dietary Supplement industry has responded with growth and expansion to substantial consumer demand since the adoption of the Dietary Health and Education Act of 1994 (DSHEA). Much of this growth may be attributed to the Free Market in Dietary Supplements that was established by DSHEA. As U.S. District Court Judge Tena Campbell stated in the Ephedra Decision last month (Nutraceutical Corporation and Solaray, Inc. v. Lester Crawford, Acting Commissioner, U.S. Food and Drug Administration, Case No. 2:04CV409 TC, USDC, Utah Central Division), “the legislative history of the DSHEA indicates that Congress generally intended to harmonize the treatment of dietary supplements with that of foods when it added the dietary supplement subsection...”

At this point, many people in the industry, Health Freedom Advocates and consumers, fear that the CODEX ALIMENTARIUS process may, over time, reverse these positive developments. There is public perception and concern that international agencies are seeking to harmonize Dietary Supplement regulations with restrictive rules and practices prevalent in certain countries outside the United States, rather than with the Freedom of Access guaranteed by DSHEA. Since most of the world’s Dietary Supplement

consumption and demand takes place in the United States, our law should be the basis for international harmonization.

The CODEX Commission is scheduled to adopt standards regarding Dietary Supplements at the July meeting that will lead to violations of United States law and practice and therefore the U.S. CODEX Delegation should be instructed to vigorously oppose the adoption of such standards by using every legal means at their disposal to oppose such adoption.

II. Action Requested

The Petitioners urge the U.S. CODEX Office and all other Agencies and government instrumentalities to adopt as the policy of the U.S. CODEX Delegation and Agencies support only for international harmonization that conforms to United States law and practice, at the 28th General Session of the CODEX ALIMENTARIUS Commission, and in all further deliberations, considerations, CODEX Committee and CODEX Commission policy positions, dealings and meetings going forward from this time and specifically to:

1. Reject any international standard that is inconstant with DSHEA or with 19 USC 3512,
2. Support the Congressional determination that vitamins and minerals are foods, not drugs or toxic chemicals, and, therefore,
3. Support the use of nutritional science, a branch of biochemistry, not risk assessment science, a branch of toxicology, to determine optimal levels, since toxicity is virtually unknown in nutrients but is part of the definition of a “toxin.” Since optimal levels vary based on complex and interweaving factors such as age, diet, nutrient absorption, the presence or absence of co-factors, genetic makeup, underlying nutritional status, disease state, toxic burden and biochemical individuality, no maximum intake levels are meaningful for nutrients although they are highly significant for toxins.
4. Support the biochemical reality embodied in DSHEA’s protection of all supplements and categories of nutrients which the CODEX Vitamin and Mineral Standard violates when it states that the principal nutritional value of foods comes from its vitamins and minerals. Exemplary and abundant scientific and clinical evidence supports the importance of essential fatty acids, oils, complex plant residues with physiological impact in foods, flavinoids, antioxidants, amino acids and other vital factors, essential to health, in food. These compounds are protected under DSHEA but ignored or prevented from being part of the supplemental feeding list if a “Positive List” is enacted by the CODEX ALIMENTARIUS Commission when it seeks to ratify the vitamin and mineral standard this July in Rome.

5. “Take Care that the Laws be faithfully executed” (Article II, Section 3, United States Constitution) as established by DSHEA that, as foods, nutritional supplements do not require safe upper limits, maximum potencies, maximum permissible upper limits or similar constraints on their use and that any such limits are antithetical to the legislative intent and guarantees of DSHEA.

III. Statement of Grounds

A. Factual Grounds

The 28th meeting of The CODEX ALIMENTARIUS Commission in Rome July 4-9, 2005, will consider adopting vitamin and mineral guidelines based on regulatory principles that may, over time limit access to dietary supplements of consumers in the United States, and that could significantly restrict access to vitamin and mineral supplements worldwide.

Based on public statements of the Chairman of the CODEX Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), Bonn, 2004, it is the intent and understanding of that Committee (which has prepared the Vitamin and Mineral Standard for ratification by the CODEX ALIMENTARIUS Commission in July, 20) that, despite the limited title of the proposed Standard, it will, because of the legal structure under which the CODEX ALIMENTARIUS Commission operates, restrict all classes of nutrients, not just those classed as Vitamins and Minerals.

Ratification by the CODEX ALIMENTARIUS Commission of the Vitamin and Mineral Standard as proposed by CCNFSDU will amount to approving a blank check since the actual limits and specific items which it will restrict have not been specified or proposed. The positions of decision makers on the CCNFSDU, which would have the authorization to select nutrients and levels without oversight or review once the Vitamin and Mineral Standard has been ratified, are antithetical to the use of nutrients for the “prevention, treatment or cure of any disease or conditions” and include the publicly stated position that “Nutrition has no place in medicine”. These positions and trends are both antithetical to the will of the American people as expressed in their buying habits (i.e., approximately \$20 billion in after-tax, unreimbursable dollars for supplements in 2004) and in DSHEA.

This summer the Commission will meet to approve vitamin and mineral guidelines that were finalized by the CODEX Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in Bonn, Germany last November. These standards, as noted above, have neither specificity nor precision: the vitamin and mineral standard has no content and, if ratified, would not be subject to further review by a governing body and cannot be modified by countries like the United States whose laws it violates. If the Commission moves forward and approves these guidelines, CODEX will restrict access to vitamins and minerals in several ways:

1. Setting upper safe limits (maximum potencies, maximum permissible upper limits or similar limitations) for each vitamin and mineral based on inappropriate scientific risk assessment from the science of toxicology, not the science of nutrition; this violates scientific sense and clinical experience. “Optimum levels” are a much more reasonable, clinically and scientifically supported standard and must be individually determined for each individual.
2. Setting any upper limits on supplements and nutrients; this violates the legislative intent and provisions of DSHEA that Dietary Supplements are Foods, not Drugs.
3. Marginalizing the nutrient supplement possibilities for the nearly 1 billion people worldwide, who, by international standards and the assessments of the World Health Organization and the Food and Agriculture Organization, now experience devastating widespread under nutrition and go hungry. In addition, the population-based CODEX standards under-appreciate the nutritional status of the world’s remaining 4.6 billion people, a majority of whom lack the recommended amount of one or more essential nutrient.
4. Creating, through setting maximum vitamin and mineral consumption limits, an approach to regulating dietary supplements which is consistent with and leading the way toward, if not itself directly establishing, prior restraint.
5. Narrowing substantially the amount of nutrition and health information about vitamins and minerals consumers will be allowed to receive, asserting that only drugs can contain label claims for products that are suitable for the prevention, alleviation, treatment or cure of disease, disorder or particular physiological conditions; this violates the Right of Free Speech guaranteed by the First Amendment.
6. Fostering the worldwide health assumption that sufficient levels of nutrients can be found in a regular diet; this is unsupported by an abundant body of scientific literature and clinical experience as well as the repeated findings of international organizations like the World Health Organization, UNESCO and the Food and Agriculture Organization.

Natural health consumers are becoming active and organized to protect and expand their health rights. Worldwide health could be significantly undermined by the CODEX-created limits to nutrients available in many countries according to official documents prepared jointly by the World Health Organization and the Food and Agriculture Organization. Codex, by itself, may change U.S. laws. Codex's upper potency limits, established for vitamins and minerals, may restrict U.S. consumer access to high-potency vitamins and minerals to which they are accustomed. U.S. companies may choose to “dumb down” their potencies to mirror their international formulations.

CODEX ALIMENTARIUS standards and guidelines are enforced at the international level via trade sanctions imposed by the World Trade Organization (WTO) through its dispute resolution process. However, there is grave concern in many quarters, including an opinion created by the Congressional Research Service for two members of Congress, that because of the Sanitary and Phytosanitary Agreement, Article 3, it shall be incumbent upon each member nation of the WTO to bring its domestic standards into conformity with CODEX standards and guidelines in order to avoid the creation of a hidden barrier to international trade. This would be in clear violation of both DSHEA and with 19 USC 3512. CODEX misapplies an inappropriate toxic chemicals risk assessment model to regulate helpful nutrients which have virtually no established toxicity and therefore, present virtually no consumer danger. Although any assessment of vitamin and mineral usage should evaluate nutrients using nutritional science rather than with the toxicological science used to evaluate toxin and dangerous industrial chemicals, since supplements, including vitamins and minerals, are defined as foods under DSHEA, upper limits of any type are inappropriate and should be opposed by the United States with vigor both in CODEX meetings and otherwise.

The human body is able to rid itself of excess doses of nutrients or store them for future use in times of shortfall, whereas it is not able to rid itself adequately of toxic and dangerous chemicals. This difference, coupled with differential impact of nutrients and detrimental impact of toxins, is precisely the distinction upon which the determination that the latter are, in fact, toxic while the former are clearly non-toxic. The CODEX Vitamin and Mineral Standard disregards the unique biological individuality which determines the basic nutritional needs of each individual.

Biological requirements can vary widely (by orders of magnitude) during the life span since nutritional requirements are affected by climate, dietary supply, genetics, energy output, toxic load, emotional, organ and immune health, electromagnetic and geopathic stress as well as normal and pathological aging processes and enzymatic decline with aging. CODEX disregards this and all other short and long term biological individuality. CODEX fails in this fundamental requirement by erroneously disregarding biological, physiological and pathophysiological variation in nutrient needs. CODEX documents make it clear that the process of risk assessment does not properly apply to nutrients and that the process must be modified to account for the differences between nutrients and toxins. The procedures employed to accomplish that modification are untested through scientific or clinical evaluations and are entirely theoretical. Their impact upon the earth's population, however, will be practical and devastating. CODEX also fails in this fundamental requirement by erroneously applying toxic chemical risk assessment principles to nutrients which are foods, not toxins, erroneously asserting that

1. Nutrients should be treated and evaluated as toxins.
2. Such evaluation requires new and untested procedures whose accuracy and utility have not been evaluated through appropriate studies and trials.

3. Supplements, including vitamins and minerals are toxins, not foods, and therefore require upper limits on ingestion
4. Foods and nutrients are not useful in treating disease.
5. Supplements have little value because people can get the limited amounts they need from food.
6. The nutritional quality of foods is due primarily to the vitamin and mineral content of those foods.
7. Rigid, low limits should be set for vitamins and nutrients because nutritional requirements do not change with biochemical, age-related, genetic and other assaults and do not vary from person to person, despite abundantly documented genetic and environmental variations within and between populations.
8. Theoretical reference values are more important than unique individual nutrient needs and clinical requirements.
9. Toxicology science is preferred to individual choice as the best control on access to foods such as Dietary Supplements.
10. Dietary supplements require control on access despite the fact that they are foods under DSHEA.

The well documented safety of Dietary Supplements, as foods, is documented by La Leva di Archimede at http://www.laleva.cc/petizione/english/ronlaw_eng.html (with particular reference to http://www.laleva.cc/petizione/ron_law_tables/tabella.html, http://www.laleva.cc/petizione/ronlaw/australia_societal_vs_individual_risks2.pdf, http://www.laleva.cc/supplements/medical_injury_law.pdf, http://www.laleva.cc/petizione/ronlaw/leape_relative%20risks1.pdf, http://www.laleva.cc/petizione/ronlaw/relative_risk_boeing72.pdf, http://www.laleva.cc/petizione/ronlaw/relative_risks_bubbles3.pdf) and Dr. Andrew Saul's presentation to the Canadian Parliament, "*Where Are The Bodies?*", <http://www.doctoryourself.com/testimony.htm>.

CODEX reinforces, in its vitamin and mineral guidelines, its existing prohibition on preventing truthful information about the ability of foods and nutrients to treat, diagnose, prevent, mitigate and cure disease. CODEX prohibits supplemental nutritional feeding world wide, and the dissemination of information on the positive impact of nutritional supplementation and support on chronic, degenerative disease. CODEX rejects without scientific basis or support the position supporting access to nutrients strongly documented and endorsed by joint publications of the World Health Organization and the Food and Agriculture Organization which detail the contribution of nutrition to the prevention and treatment of chronic diseases in both the developing and developed world. World hunger experts recognize that nutrient supplementation can be extraordinarily useful in improving world health and eliminating disease (vitamin A supplements in developing countries can offer 30 times as much social improvement as \$1 of development aid), a

fact CODEX vitamin and mineral guidelines ignore without scientific support for their position.

CODEX ignores, in its vitamin and mineral guidelines, the high costs in loss of life, degraded quality of life and economic loss created by the chronic diseases of nutrient-deficiency although they are abundantly documented in clinical, biochemistry and epidemiological literature. The human and economic impact and costs of under nutrition are recognized by the World Health Organization and the Food and the Food and Agriculture Organization who document that chronic disease (e.g., heart disease and stroke, diabetes, obesity, cancer, etc.) is a non-contagious epidemic problem which can be prevented, treated and cured only through adequate nutrition. They further document that nutrition cannot always be provided by diet. Clinically necessary nutrient intake is, however, prohibited under the proposed CODEX vitamin and mineral standard. The United States Supreme Court has spoken forcefully, enforcing consumers' right to truthful information about health care issues. See: *Thompson v Western States Medical Centers*, where Justice O'Connor wrote,

"If the First Amendment means anything, it means that regulating speech must be a last - not first - resort. . . We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information. . . Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring . . . a warning that . . . its risks were unknown."

The basic rule, announced by the case, to determine constitutionally permitted government restrictions on Commercial Speech (speech that makes or is about an offer for a transaction, such as the sale of Dietary Supplements) is a Two Prong Test: the first prong is to ask two questions: (1) is the speech in question about unlawful activity and (2) is the speech misleading. If "no" to both, the speech is entitled to protection unless the Government can carry its burden and prove (1) the governmental interest involved is "substantial", (2) the regulation must "directly advance" the governmental interest and (3) the regulation of Commercial Speech cannot be "more extensive than is necessary to serve that interest" (quoting *Central Hudson v Public Service*, 447 US 557, at 566). We submit that the standards proposed for adoption at the 28th General Session cannot withstand legal scrutiny under the Supreme Court Test.

B. Legal Authority

1. The Legal Basis for this Petition is the First Amendment to the Constitution of the United States: "Congress shall make no law . . . abridging the . . . the right of the people . . .to petition the Government for a redress of grievances."
2. The Legal Basis for the Proposed Policy is Section 3512 of Title 19 and specifically, 19 USC 3512(a)(1) and (a)(2) as applied to the protection of human life through DSHEA. Section 3512. Relationship of agreements to United States law and State law

(a) Relationship of agreements to United States law

(1) United States law to prevail in conflict. No provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.

(2) Construction: Nothing in this Act shall be construed –

(A) to amend or modify any law of the United States, including any law relating to –

(i) the protection of human, animal, or plant life or health,

(ii) the protection of the environment, or

(iii) worker safety, or

(B) to limit any authority conferred under any law of the United States, including section 2411 of this title, unless specifically provided for in this Act.

3. Additionally, the Statutes authorizing the Department contain general provisions that support the actions requested in this petition. Federal Law includes provisions that grant the Secretary broad authority to promulgate rules and regulations “necessary to carry out the Act[s].”

4. The Office Should Promulgate the Requested Policy as an Interim Final Rule Without First Completing Notice and Comment, Risk Assessment, and Cost-Benefit Analysis

Under ordinary circumstances, the agency must comply with procedural requirements under both the Administrative Procedures Act (APA) and the USDA Reorganization Act of 1994, including the use of notice-and-comment rulemaking and the completion of a risk assessment and cost-benefit analysis before issuance of a new rule. However, both acts provide for exceptions to those requirements for circumstances such as those present here, where the new international regulations would constitute an imminent threat to public safety and any delay in policy making would be contrary to the public interest.

The Office should avail itself of those statutory exceptions and promulgate the requested policies without first providing the public with notice and an opportunity for comment and before completing a full risk assessment and cost-benefit analysis. The agency should first adopt the policy as an "interim-final rule," which would become binding upon publication (or shortly thereafter), and subsequently provide for public comment and complete its risk assessment and cost-benefit analysis. As explained below, the Office is authorized to take such an approach under the USDA Reorganization Act of 1994.

a. The Requested Regulations Satisfy the "Good Cause" Exception to the Administrative Procedure Act's Requirement for Notice and Comment. The APA provides that full notice-and-comment rulemaking is not required when an agency "for good cause finds (and incorporates the finding and a brief statement of the reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public

interest." 5 U.S.C. §553(b)(B). The good cause exception "is an important safety valve to be used where delay would do real harm." *United States Steel v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979). According to the legislative history of the provision, "'impracticable' means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings." S. Rep. No. 752, 79th Cong., 1st Sess., at 16 (1945). As one court has held, determining "impracticability" requires "analysis in practical terms of the particular statutory-agency setting and the reasons why agency action could not await notice and comment." *American Transfer & Storage Company v. ICC*, 719 F.2d 1283, 1295 (5th Cir. 1983).

There are numerous instances in which courts have upheld an agency's decision to invoke the "good cause" exception and issue a rule without providing for notice and comment where a delay would threaten public safety or the environment. See, e.g., *Hawaii Helicopter Operators Ass'n v. FAA*, 51 F.3d 212, 214 (9th Cir. 1995) (good cause exception satisfied in view of "the threat to public safety reflected in an increasing number of helicopter accidents"); *Northern Arapahoe Tribe v. Hodel*, 808 F.2d 741, 750-52 (10th Cir. 1987) (good cause exception satisfied in view of urgent need for hunting regulations where herds were threatened with extinction); *Northwest Airlines-v. Goldschmidt*, 645 F.2d 1309, 1321 (8th Cir. 1981) (good cause exception satisfied in view of urgent need to allocate landing slots at major airport).

The rationale underlying those decisions, that compliance with time-consuming procedural requirements would "do real harm" by delaying implementation of urgently needed policies to safeguard public health, is equally applicable here, where international regulations in derogation of United States Law and practice will have a negative impact on U.S. consumers. Clearly, the exigent circumstances necessary to satisfy the APA's good cause exception are present.

b. The Requested Regulations Present a Situation In Which Regulatory Analysis is "Not Practicable Because of Compelling Circumstances" Under the U.S. Department of Agriculture Reorganization Act of 1994.

Under § 2204e of the USDA Reorganization Act of 1994, USDA must complete a risk assessment and cost-benefit analysis for each proposed major regulation that relates to human health, safety, or the environment. 7 U.S.C. § 2204e. That section does provide an exception, however: when a risk assessment and cost-benefit analysis is "not practicable because of compelling circumstances," an explanation can be provided in lieu of a full analysis. *Id.* at § 2204e (b)(1). The compelling circumstances here are the imminent adoption of international standards in derogation of United States Law and practice.

III. Conclusion

Codex's restrictive vitamin and mineral guideline should be replaced by the U.S. Dietary Supplement Health Education Act (DSHEA) food-based standard as the international standard for vitamin, minerals and all other dietary supplements. The DSHEA, passed unanimously by the U.S. Congress in 1994, recognizes and protects the value of individuals making personal nutritional and health choices in a way that is rejected by the CODEX guidelines. Any attempt to restrict or limit dosages, potency, information or access to supplements denigrates their classification under DSHEA as foods and, hence, without need for access restriction.

The culmination of 50 years of U.S. legislation and litigation has refined the supplement policy of the United States ensuring that individual choice and desire play a key role in ensuring private and public health. The CODEX guideline subordinates individual choice to scientifically inaccurate and unsupported, supposed professional expertise. The DSHEA balances professionals, science and people.

Members of the public have continually warned United States policy makers that pending international regulations fail to meet both the standards of United States law and the requirements of the international law.

See for example, Public Citizen's comments regarding harmonization:

<http://www.citizen.org/trade/harmonization/comments/articles.cfm?ID=4394> and the National Health Federation, "CODEX Breaks its own Rules"

http://www.thenhf.com/codex_may_2005_nhf_press_release.htm

Also see the European Alliance for Natural Health Submission on Risk Assessment at:

http://www.alliance-natural-health.org/docs/ANHwebsiteDoc_120.pdf

The Petitioners urge the U.S. CODEX Office to adopt as the policy of the U.S. CODEX Delegation support only for international harmonization that conforms to United States law and practice, and specifically the provisions of DSHEA through 19 USC 3512, "United States law to prevail in conflict. No provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect."

Dated: June _____, 2005

Natural Solutions Foundation

Cc:

CODEX Office via facsimile and email

George W. Bush, President

Secretary HHS

Secretary of Agriculture

Secretary of Commerce

Secretary of Health and Human Services

Maj. Gen. Albert N. Stubblebine III

(US Army, Ret.)

President

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