June 14, 2005

To: Dr. Edward Scarbrough
U.S. CODEX Manager
U.S. CODEX Office
United States Department of Agriculture
South Building, Room 4861
1400 Independence Ave, SW
Washington, DC 20250

Dear Dr. Scarbrough:

I am writing to you as you as a concerned American, a physician and scientist practicing medicine for 35 years, a parent, a wife and a citizen of the planet. My concerns are specific and global. No regulatory structure in history has the potential to do as much harm in as short a time as the CODEX ALIMENTARIUS as currently constructed. While I am not particularly concerned by the existence of, say, a standard for sweet cassava or gouda cheese, CODEX is preparing to create guidelines with massive negative impact on the population of the earth.

I have no doubt that, as CODEX Manager for the US, your focus has been on regulation and structural matters. However, taking a slightly wider view of CODEX yields a picture that may not emerge at the level of detail and diligent administration which your job requires. Please take these questions very seriously. They represent careful and detailed study of the CODEX ALIMENTARIUS literature as well as the scientific and clinical data which makes it clear that the pro-illness aspects of CODEX must not be supported by the United States, a country perceived world-wide as a leader in thought and science.

This letter is submitted pursuant to your requests for written questions and comments at the US CODEX Office Public Hearing on June 9, 2005; please provide written answers to each of the following questions prior to the 28th CODEX ALIMENTARIUS Commission Meeting in Rome. If you are unable to answer these questions in conformity with United States Law, and specifically 19 USC 3512 and DSHEA, these questions should be put to the Commission Meeting and its adoption of the Vitamin and Mineral Guidelines should be delayed until they can be answered in conformity with United States Law.

1. What is the potential liability of the Secretaries of the Departments of Agriculture, Commerce, Health and Human Services, Transportation, Commissioners of the EPA and FDA, the US CODEX Manager, Delegates to the 28th CODEX ALIMENTARIUS Commission meeting, the President of the United States and other Americans involved in the process of setting policy favorable towards and actually ratifying the Vitamin and Mineral Guidelines at that meeting under International Criminal and Civil Law who would face charges of Crimes Against Humanity given

a. The Vitamin and Mineral Guidelines 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;

b. Risk Assessment analysis, by its very nature, cannot not take benefits derived when a substance is ingested into account. Enhanced functioning, health, well-being and emotional states, and decreased ill health, pain and suffering cannot be accounted for or included in the evaluation of nutrients since Risk Assessment methodology does not allow for benefit analysis. Risk Assessment thus precludes the finding that nutrients are useful in human health and in reducing morbidity and mortality due to procedural and structural flaws in the analysis process itself;

c. The United States Codex Office is well aware that countries of the developing world are likely to, and in fact, urged to, adopt the CODEX Vitamin and Mineral Guidelines as their own national guidelines and laws making supplemental feeding of nutrients to prevent, treat or cure any condition or disease illegal in those countries, even with a prescription, if those guidelines are enacted;

d. International aid and relief organizations will be prevented from selling, shipping and supplying high potency supplemental nutrients to disaster, famine and refugee areas resulting in massive starvation and death from chronic under-nutrition in areas where nutritional supplementation is illegal because of the adoption of the CODEX guideline on vitamin and mineral nutritional levels;

e. The World Health Organization (WHO) and Food and Agriculture Organization (FAO) have produced a joint publication[1] which was made available to delegates to the November, 2004 Bonn meeting of the CODEX Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) documenting the importance of enhanced strategies in preventing, treating and curing the chronic diseases of under-nutrition which the available diet is incapable of alleviating and documenting the "non-contagious epidemic of chronic under-nutrition" currently responsible for at least 89% of all deaths in the developing world. The enactment of the Vitamin and Mineral Guidelines will make this situation vastly worse;

f. UNESCO, WHO and FAO, among hundreds of others, have documented the impact of vitamin and mineral deficiency or chronic under-nutrition on fertility, morbidity, mortality, IQ, stress hardiness, immune status and a host of other parameters. The unanimous conclusion of every evaluation

[1] Diet, Nutrition and the Prevention of Chronic Disease, http://www.who.int/hpr/NPH/docs/who_fao_expert_report.pdf

is that for the vast majority of humanity, for a wide variety of reasons, diet alone is insufficient to supply essential nutrients at the varying levels required to support each human in the face of biochemical individuality, varying states of underlying ill health, toxic load (which enhances requirements for nutrients), acute disease and other stressors and the quality of the diet available to the individual;

g. Each of these individuals has reason, by virtue of his or her education, professional specialization and position of responsibility of the dangers of this standard to the well being and survival of large numbers of humans and can, as experts in related fields, be expected to know the dangers and consequences of the enactment of the restrictive Vitamin and Mineral Guidelines which are based on toxicology rather than nutritional science;

h. General consensual understanding, as well as an immense body of scientific data, confirms the importance of preventing and eliminating malnutrition in reducing the morbidity and mortality among affected populations;

i. Developing countries which are being urged to adopt CODEX standards, including the Vitamin and Mineral Guidelines, as their national laws will be lured into making inexpensive, effective and urgently needed health promotion and disease prevention measures illegal under the deceptive and deadly Vitamin and Mineral Guidelines;

j. US representatives at all levels complicit in these decisions and actions will be knowingly acting in such a way as to bring about the preventable deaths and needless suffering of billions of people;

k. Please provide a legal opinion on this issue.

2. What is the authority by which the US Government, the US CODEX Office and all other involved agencies has set a Policy for the United States Government, and its Delegates to the 28th CAC meeting next month 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?

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

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

c. Please provide a legal opinion on this issue.

3. Why has the United States accepted the use of Risk Assessment procedures for nutrients when Risk Assessment is a methodology relevant to toxicology and irrelevant 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 clear in order to prevent the restrictive, and, because of US law (see 2 a above), we believe, illegal Vitamin and Mineral Guidelines from moving forward via consensus to Step 8 in preparation for ratification?

4. The Technical Report discussing Risk Assessment for nutrients makes it clear that this procedure does not properly apply to nutrients because, unlike drugs, they have minimum intake limits which are required for life. Risk Assessment procedures were modified for this purpose 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 indefensible policy?

5. Why has the United States not expressed its opposition to the setting of any upper limits of any type on nutrients given that the United States law, DSHEA, specifically forbids the restriction of nutrient intake levels since nutrients are treated as food?

6. Why has the United States not chosen to act as the standard bearer for the community of belief and thought represented by its citizens, well over 200 million of whom make use of nutrients for the prevention, treatment and cure of diseases and conditions as allowed by US law making DSHEA the international standard?

7. Has the US CODEX Office, the Department of Agriculture, the Department of Health and Human Sciences, the Departments of Commerce, Transportation, The FDA, the EPA, the Surgeon General's Office, the National Science Academy, the US Congress or any other agency of the United States Government not held public fact finding hearings to establish the appropriateness or lack thereof of supporting a standard which assesses nutrients, which have virtually no toxicity[2], as dangerous substances whose permissible intake levels must be set so low that they lead to no discernable change in physiology or function, thus inevitably leading to malnutrition and chronic, degenerative consequences of that malnutrition in any population affected by such standards? Has the United States held a public fact finding hearing on this issue? If not, why has the US adopted this scientifically and epidemiologically unsound policy?

8. I was pleased to learn that CODEX will have no significant impact on nutrients in the United States and would appreciate clarification. What is the legal basis for

[2] Nutrients have an enviable safety profile. See References below in No. 18

your emphatic statement at the June 9, 2005 Public Hearing on CODEX that under no circumstances would the Vitamin and Mineral Guidelines, the ratification of which we believe is illegally supported by the US Office at the upcoming CODEX ALIMENTARIUS Commission meeting in Rome, have an impact on the United States? Please provide a legal opinion with citations of the operant legal statutes, rulings and case law on the question of whether the Sanitary and Phytosanitary Agreement, Article 3 or any part of that or any other agreement, regulation, code, guideline, standard or similar language or agreement of the CODEX ALIMENTARIUS Commission or the World Trade Organization could force a change in US law, availability of nutrients or supplements, levels or legality of access.

9. Is it still the policy of the FDA, as stated in the United States Federal Register, October 11, 1995, FDA Policy on Standards, "where a relevant international standard exists, or completion is imminent, it will generally be used in preference to a domestic standard...."?

    a. If this is still the FDA policy, once the Codex Vitamin and Mineral Guidelines are finalized this summer, will the FDA create new regulations in order to nullify, undermine or gut DSHEA in order to comply with CODEX guidelines and standards such as the Vitamin and Mineral Guidelines?

    b. Since, as of 1997, the United States is forbidden to harmonize with international standards which conflict with US law (as we believe the Vitamin and Mineral Guidelines could be interpreted to conflict with DSHEA) how will the CODEX standards, guidelines and similar items affect US law and DSHEA?

    c. How do the FDA Policy of October 11, 1995 and the 1997 Title 19, Section 3512 impact each other?

    d. Please provide a legal opinion on these issue.

10. Please provide a legal opinion with citations of the operant legal statutes, rulings and case law on the question of why you believe that the CODEX Vitamin and Mineral Guidelines will have no direct or indirect impact through economic pressure, trade sanctions or other means on DESHEA, which regulates vitamins and minerals in the United States?

11. Why has the United States not firmly opposed the development of a Vitamin and Mineral Guideline through vigorous opposition in the CCNFSDU since DSHEA was passed by unanimous consent of the US Congress in 1994 and the will of the American People, as well as the law of the land, supports unrestricted access to high potency nutrients as food, putting the CODEX Vitamin and Mineral

Guidelines in direct defiance of American law? Please provide a legal opinion on this issue.

12. Has the United States carried out responsible due diligence in order to ascertain the truth, or lack thereof, in the possibility that the risk assessment procedures that we believe are inappropriately being applied to supplements are undermined not only by scientific inapplicability but by financial conflict of interest as well, based on the partnership, ownership or other close financial ties to BfR (German Risk Assessment Institute) imputed to Dr. Rolf Grossklaus, the Chairman of the CCNFSDU? I would be pleased to learn that this conflict of interest does not exist. Please provide the basis upon which the US has concluded that this conflict of interest does not exist. Please also provide the standards which govern conflict of interest as it applies to the participants of CODEX in general and what conflict of interest rules govern the participation of Americans in the CODEX process.

13. During the meeting you repeated several times, as did your associate, that the US would not be bound by upper limits of any type because of the Vitamin and Mineral Guidelines or any other CODEX guideline or standard. When asked why Article 3 of the Sanitary and Phytosanitary Agreement did not apply to compelling the US to bring their laws into conformity with the ratified CODEX standards, you said you would, if asked in writing, provide the relevant legal substantiation. Please provide a legal opinion on this vitally important matter.

14. Please provide a legal opinion on why the World Trade Organization Agreements, and the standards which the WTO accepts, including CODEX ALIMENTARIUS, do not supersede US law pursuant to the US Constitution, Article VI, Clause 2.

15. Given that the Vitamin and Mineral Guidelines can be expected to sharply reduce the number and dosage of vitamins and minerals in many parts of the world, has the United States carried out a cost projection on the financial impact of making nutrients to prevent, treat and cure diseases unavailable on the world economy and the developing world in terms of loss of manpower, economic growth and markets into which we can sell our products secondary to the loss of life and increased consumption of resources in those markets by illness, disease and death? Has the United States conducted studies or held a fact finding hearing to determine the impact of the Vitamin and Mineral Guidelines on these areas? If not, why has the US adopted this scientifically indefensible policy?

16. Are you, as the US CODEX Manager , the US CODEX Office, or any other person or agency involved with CODEX in the United States, either directly or indirectly, aware of any plans or intents to bring US law, including DSHEA, into conformity with CODEX regulations, guidelines or standards either through legislation or regulation? If so, what are those plans or intents?

17. Please provide a legal opinion on the relationship of the Common Law practices and legal traditions which guide US law in relationship to the Napoleonic Code

practices and traditions which guide CODEX. For example, the Napoleonic Positive List principle, under which everything not permitted is prohibited, is in direct opposition to the Common Law concept that everything not prohibited is permitted. Yet a Positive List is highly likely in the Vitamin and Mineral Guidelines. Would that mean that our permissive tradition and legal intent is voided by CODEX? A detailed legal analysis and opinion is sought in order to clarify this vitally important issue.

18. At the June 9, 2005 Public Hearing on CODEX, I understood you to state that there is no literature showing that nutrients are safe. If you recall, I challenged that statement from the floor and we had a discussion about it at that point. Based on that understanding, I asked if US policy would change if the literature were presented which dissipated this incorrect notion. You stated that there was a possibility of making that policy change although you clarified that it was "only a theoretical possibility". If I misunderstood you, please clarify what you meant in this exchange. In order to deal with the possibility that I understood you correctly and your position is, in fact, that there is no significant literature supporting the safety of dietary supplements, I have compiled a bibliography of data bases and studies documenting the appropriate examination of supplement use and safety as I indicated to you during the hearing and after it that I would do:

    This introductory bibliography focusing on the science of nutrition as it applies to fertility, development, immunology, endocrinology, psychiatry biochemistry, epidemiology, pediatrics, oncology, premature aging, otorhinolaryngology, allergy, obstetrics, gerontology, surgery, cardiology, internal medicine and preventive medicine as well as other specialties, the use of risk assessment in nutritional science and the safety of nutrients. The total literature is vast. I am sure that your support personnel will be able to use this material to take your office much more deeply into the literature of biochemistry and nutritional science. If looking for this information in the literature of toxicology, one would not find it since toxicology and therefore, risk assessment, had no interest in any benefit which a substance, in this case, vitamins and minerals, might provide. Toxicology, of course, does not deal with items for which there is no safe upper limit because they provide no toxicity and are eliminated or used without negative impact of they type that industrial poisons and pesticides, etc, are responsible for.

    Even a brief perusal of this material, with special reference to the first 8 references makes it clear that the type of toxicity associated with poisons and drugs does not apply to nutrients such as vitamins and minerals as used by humans. Even the fat soluble vitamins, ADEK, have limited capacity to do harm in the doses that people select for themselves and nutritional practitioners give them.

The undernourished body, the ill body, the toxic body and the marginally nourished body all require much higher doses of vitamins and minerals, rather than ultra low, ineffective doses of them in order to reach optimal levels and achieve and maintain a state of health and biological homeostatis.

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 testimony before the Canadian Parliament, "*Where Are The Bodies*?", http://www.doctoryourself.com/testimony.htm.

Following are scientific documents submitted by the Alliance for Natural Health (an advocacy group in the United Kingdom) to various European official bodies.

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

http://www.alliance-natural-health.org/_docs/ANHwebsiteDoc_11.pdf

http://www.alliance-natural-health.org/_docs/ANHwebsiteDoc_147.ppt

The United States government also provides access to many thousands of peer reviewed articles regarding Dietary Supplement safety and efficacy.

http://dietary-supplements.info.nih.gov/Health_Information/IBIDS.aspx

NIH Office of Dietary Supplements IBIDS Data Base

http://dietary-supplements.info.nih.gov/Research/CARDS_Database.aspx

http://ods.od.nih.gov/Research/CARDS_Database.aspx
CARDS - the Computer Access to Research on Dietary Supplements - an ODS database of federally funded research projects pertaining to dietary supplements.

19. I am perplexed by the apparent internal contradiction stemming from item Number 18. If US policy is indeed based on faulty logic and inaccurate information (i.e., that supplements have only risks, not benefits), why was a change in that policy, following the presentation of accurate information and sound logic, only a "theoretical possibility"? Please clarify the decision making process which goes into developing US Policy. I am having difficulty understanding why United States policy would not be changed by the weight of scientific and clinical evidence. Please explain in detail why, in the face of this

huge body of scientific and clinical evidence, delegates to CODEX would, at the very least, are not being instructed to exert pressure to table the Vitamin and Mineral Guidelines until further study of the matter could be carried out and a policy in line with global human experience, clinical evidence and scientific literature available to the US policy makers could be further evaluated.

The following questions were not directly addressed at the US CODEX Office Public Hearing on CODEX but are relevant and pertain to active CODEX issues. I would appreciate written replies to these questions as well.

20. Why does the United States continue to pursue a policy of unlabeled Genetically Modified Organism use and growth when the health hazards of GMOs are of serious concern to independent scientists world wide and 43 other countries objected strenuously to the unlabeled use of GMOs at the last Biotechnology Committee meeting? Has the United States CODEX Office or any other relevant agency such as the FDA conducted or reviewed research on the short, intermediate or long term impact of single GMO item ingestion or multiple GMO item intake on humans during all phases of the life and illness/wellness continuum? Has a public fact finding hearing been held to determine whether the use of GMOs is safe despite a lack of clinical testing and in the face of the serious hazards of both long-term consumption of GMOs and occupational exposure? If not, why has the US adopted this scientifically indefensible policy?

21. Given the US's willingness to "go it very nearly alone" on the issue of GMO non-labeled use, your comment to me following the June 9 public hearing that the US must agree to the Vitamin and Mineral Guidelines "because we cannot afford to be the only country opposing it" makes even less sense. Please explain why the United States can pursue a lonely policy on GMO unlabeled use without public consensus in the US, but not on the Vitamin and Mineral Guidelines, where US Policy, as enacted by Congress in DSHEA, is clear?

22. Why does the United States support the use of Bovine Growth Hormone world wide when the research on the health hazards of hormone stimulated milk is strong and ominous? Has the US held a public fact finding hearing to determine whether there are serious health risks associated with the use of this hormone in dairy cattle? If not, why has the US adopted this scientifically indefensible policy?

23. Why does the US support the use of exogenous estrogen as a growth stimulant in food animals when the biochemical, oncological, eondocrinological and pathophysiological consequences of this practice are well known and very negative? Has a public fact finding hearing been held to determine the safety of this practice and the prevalence of such side effects as premature puberty and premature closure of the epiphysial plates? If not, why has the US adopted this scientifically indefensible policy?

24. Why does the US support CODEX standards which allow and require sub clinical antibiotic feeding of food animals when the hazards of chronic antibiotic administration are well recognized as a major threat to world health? Has a public fact finding hearing taken place to determine that this is a safe and appropriate way to rear food animals taking into account the issues of toxic antibiotic metabolite residues and antibiotic resistance locally and globally? If not, why has the US adopted this scientifically indefensible policy?

25. Why does the US support CODEX standards which allow and require irradiation of food when the hazards to the public in ingesting the extremely high populations of free radicals produced by exposing food to high intensity gamma rays are well known to biochemists and nutritional scientists? Has the US held a public fact finding hearing to determine that food irradiation, in which components of foods can be irradiated over and over again as they are combined and the product is re-irradiated, is safe for food consumed by all types of humans, from infants to the elderly, regardless of their health status and biochemical individuality? If not, why has the US adopted this scientifically indefensible policy?

26. Has a valid scientifically based study been carried out to determine if antioxidant restriction (e.g., Vitamin C) is safe in the face of the huge free radical population induced by the process of food irradiation? Has a public fact finding hearing been held on this issue? If not, why has the US adopted this scientifically indefensible policy?

27. Why is the US acquiescing to the use of, and levels of, pesticides, herbicides and other toxins in the CODEX permitted substances and residue levels which are scientifically understood to increase the incidence of cancer, infertility, autoimmune disease, neurodegenerative disease, life threatening allergic reactions, genetic damage, organ disease and failure, teratogenicity, brain damage and a host of other environmentally induced illnesses? Have public fact finding hearing been held to determine the safety of these compounds and the levels at which they are permitted? If not, why has the US adopted this scientifically indefensible policy?

28. What is the United States doing to protect the biological diversity and integrity of the biosphere from the spread of foreign genetic material through the widespread and, if the US has its way, unlabeled use of GMOs? How are organic crops and farms being protected? If they are not being protected, why has the US adopted this scientifically indefensible policy?

29. Has the United States conducted public fact finding hearings on the impact of the loss of organic farming on the economy and the health status of consumers of organic produce secondary to genetic drift and contamination of organic farms by GMOs? If not, why has the US adopted this scientifically indefensible policy?

Thank you for your immediate attention to these urgent issues. I look forward to your prompt response to these questions. I am deeply concerned by the current US CODEX policy and look forward to learning that you have brought it into conformity with US law prior to the 28th CODEX ALIMENTARIUS Commission meeting in Rome July 4-9, 2005.

Yours in health and freedom,

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