

# Codex Commission Adopts Vitamin and Mineral Guidelines

## *Discordant Reactions Greet Harmonization Efforts*

Rima E. Laibow, M.D., and Karen L. Dean

The Codex Alimentarius Commission's (CAC's) July 4, 2005 ratification of the Vitamin and Mineral Guideline (VMG) developed by the Codex Nutrition Committee (CCNFSDU) over the past 10 years triggered a predictable round of calls to action and calls for celebration from various U.S. industry and consumer stakeholders. The VMG offers a "blank check" to be filled in with exact values in November 2005 by the CCNFSDU.

Codex and the CCNFSDU classify nutrients as *toxins* from which consumers must be protected, and use inappropriate science to bolster this unscientific position. This violates U.S. law and custom, in that the 1994 Dietary Supplement Health and Education Act (DSHEA), passed unanimously by Congress, classifies nutrients as *foods* for which no upper limits can be set. Because of the significant conflict between these two positions, and the unclear legal weight of CODEX standards on domestic law, the full impact of the VMG on the U.S. vitamin, mineral, and supplement (VMS) markets, and on American health consumers, is not likely to be a positive one.

Treating nutrients as toxins, the CCNFSDU takes the position that consumers must be protected from nutritional supplements, lest supplements have any significant impact on the body. The CCNFSDU employs "junk science" to provide the methodology to eliminate therapeutic potencies of vitamins and minerals.

Risk Assessment (RA) is a discipline of toxicology that determines the maximum dose of a toxin that will have no discernible impact on a human who has been exposed to it. This exposure dose, the Maximum Permissible Upper Limit, is then divided by 100 to provide a "safety margin," and the result is the Maximum Upper Limit. The theoretical contribution of an imaginary "expectable global daily diet" is then subtracted from the Maximum Upper Limit and a final, ultra-low dose is derived.

Using RA instead of nutrition science, the CCNFSDU will insert subtherapeutic dosage levels for the small number of permitted nutrients into slots on a "Positive List" this coming November. Positive Lists, part of the Napoleonic Code, *forbid* everything that is *not* on a list, while Common Law *permits* anything that is *not listed*. VMG ratification has ignited powerful concerns in American

consumers and health freedom advocates who fear negative repercussions on their supplement choice freedom if U.S. regulators succumb to pressure to bring U.S. laws into conformity with the VMG, which will permit sale of only a limited number of ultra-low potency nutrients. For example, Rep. Susan Davis (D-CA) has already introduced H.R. 3156, which excludes vitamins and minerals, and is designed to end American supplement access.

At the same time, the supplement industry welcomes the VMG because it offers the promise of consistent regulatory principles and forced access to markets in countries that were previously closed to international trade in high-potency VMS. In the June 2004 issue of *Alternative & Complementary Therapies*, attorney Alan Dumoff reviewed concerns about the potential impact of Codex on the U.S. VMS industry, observing that:

Codex, a 42-year old commission setting world food trade policy enforceable under World Trade Organization (WTO) agreements, has the potential to seriously restrict U.S. citizens' access to vitamins, minerals, botanicals and other products. The Codex process is part of a far-reaching effort to assure abundant food and harmonize world trade policy in order to make the global movement of foods easier. Trade has been burdened by wide differences in national regulations regarding permissible products for sale, including health claims and nutritional labeling.<sup>1</sup>

Most WTO member nations regulate dietary supplements as foods, so the CCNFSDU addressed issues surrounding international VMS commerce. International stakeholders have been following the CCNFSDU's deliberations closely, with varying degrees of enthusiasm and trepidation.

Initial reactions to the Codex ratification fall into predictable camps. "The Industry Boosters"—VMS industry trade associations, such as the National Nutritional Foods Association (Washington, D.C.), the Council for Responsible Nutrition (Washington, D.C.), and the International Food/Dietary Supplements Alliances (Brussels, Belgium)—view Codex optimistically.

Many consumer health freedom groups, "The Loyal Opposition," regard Codex, and international harmonization with it, as a draconian threat to the American way of health. Analysts who contribute to websites covering Codex tend to project "worst-case" scenario futures in which restrictive Codex stan-

## The Industry Boosters

### Council for Responsible Nutrition

1828 L Street, NW, Suite 900  
Washington, DC, 20036-5114  
Phone: (202) 776-7929  
Fax: (202) 204-7980  
Website: [www.crnusa.org](http://www.crnusa.org)

Founded in 1973, the Council is a Washington-based trade association representing ingredient suppliers and manufacturers in the dietary supplement industry.

### International Food/Dietary Supplements Alliances (IADSA)

50 Rue de l'Association  
B-1000 Brussels  
Belgium  
Phone: +32 (0)2 209 1155  
Fax: +32 (0)2 223 3064  
Website: [www.iadsa.org](http://www.iadsa.org)

The IADSA is the leading voice of the worldwide supplement manufacturing industry and is an accredited international nongovernmental organization with a seat at the table of the main international regulatory bodies. It represents 45 national trade associations and more than 8500 member companies.

### National Nutritional Foods Association

1220 19th Street, NW  
Washington, DC 20036  
Phone: (202) 223-0101  
Fax: (202) 223-0250  
Website: [www.nnfa.org](http://www.nnfa.org)

The National Nutritional Foods Association, founded in 1936, represents the interests of manufacturers and retailers of a wide variety of natural products including organic and health foods, natural ingredient cosmetics, sports nutrition products, and vitamins, herbs, and other dietary supplements.

dards have supplanted hard-won health freedoms assured by the 1994 U.S. Dietary Supplement Health and Education Act (DSHEA).

These groups also point out that such harmonization violates U.S. law, which prohibits the United States from harmonizing with international standards that violate U.S. laws<sup>2</sup>: the VMG violates both DSHEA and the FDA Modernization Act. These groups are the most ubiquitous and visible on the Internet, and include the Natural Solutions Foundation (Croton-on-Hudson, New York), The American Holistic Health Association (Anaheim, California), the National Health Federation (Monrovia, California), the Health Freedom Coalition (St. Paul, Minnesota), Citizens for Health (Washington, D.C.), the Dr. Rath Health Foundation (Plantation, Florida), The Law Loft (Liberty, Missouri), and the Alliance for Natural Health (Albans, Hertfordshire, United Kingdom).

A third group of commentators, "The Reassuring Rationalists," has also emerged, projecting optimistic future scenarios and citing governmental and regulatory policies that will surely protect the VMS market and American health freedom advocates from the dire fates predicted by The Loyal Opposition. This Rationalist group—the American Herbal Products Association (Silver Spring, Maryland), the Center for Food Safety and Applied Nutrition (College Park, Maryland), and Andrew

Weil, M.D. (University of Arizona, Tucson)—includes organizations concerned with basic food and supplement research and safety. Foods and herbal supplements are not yet affected by the VMG (although they will be in the future), and this may account for the more sanguine reactions of these commentators. Commentaries posted on the commercial websites of VMS manufacturers and distributors are beyond the scope of this preliminary review. Most consumer sites reiterate a common core of articles and information similar to those posted on the Rationalist websites. The sections below describe how the three groups see the VMG.

## The Industry Boosters

The July 5, 2005, press release issued by the Council for Responsible Nutrition (CRN)<sup>3</sup> announced:

The Codex Alimentarius Commission (CAC) yesterday declared vitamin independence worldwide from arbitrarily set standards for supplement upper levels by approving and adopting the Vitamin and Mineral Food Supplement Guideline during the meeting of the CAC in Rome. . . .

CRN's analysis is that the guideline should improve the international market for U.S.-made products, and contrary to the notions of some alarmists, the guideline cannot override DSHEA for U.S. domestic policy.

The International Food/Dietary Supplements Alliances (IADSA) executive director Simon Pettman was quoted in an online publication<sup>4</sup> describing the great significance of Codex to the emerging world market for vitamin and mineral supplements. The same online article featured comments by John Hathcock, vice president of scientific and international affairs at CRN, forecasting the benefits of Codex's future setting of maximum safe levels of vitamin and mineral supplements, based on risk assessment rather than on the recommended daily allowances set by many WTO member countries at the present.

## The Loyal Opposition

Without effective opposition, illegal harmonization with VMG can be expected to erode U.S. protection of supplements as foods that, therefore, have no upper limits. The Food and Drug Administration has stated that harmonization is official U.S. policy.<sup>5</sup> The organizations identified here as The Loyal Opposition explore many different "worst-case" scenarios on their websites. Some projections are more drastic than others, and different groups propose different strategies and tactics for managing the risk that the VMG carries. Readers are urged to visit the websites listed below and make their own evaluations.

The considerable influence of various activists is evident in the defensive tone of press releases and postings on the Industry Booster and Reassuring Rationalist sites. The Loyal Opposition spokespeople provide an invaluable, critical service in successfully alerting and informing the public and proposing ways for people who are concerned with health freedom to express their views. Fears about the Central American Free Trade Act (CAFTA)

and Free Trade Act of the Americas (FTAA) loom large on Loyal Opposition websites despite the fact that the WTO agreements CAFTA/FTAA are derivative and merely implement whatever CODEX/VMG contain but have no impact on CODEX or VMG.

The good news/bad news is that implementation of Codex, domestically and internationally, is likely to be a slow process. Since CODEX defines itself as “science based,” irrational and unscientific provisions based on poor science (e.g., VMG, which rests on the premise that nutrients, essential for life, are toxic substances that must be guarded against through toxicology methodology) can be challenged and revised if one or more nations move to have it

reopened. This creates an opportunity for health freedom proponents to work within, as well as outside of, the system while multiple unresolved issues create opportunities for strategists. These opportunities are already being explored by members of The Loyal Opposition, and their suggestions deserve serious consideration.

## The Reassuring Rationalists

The websites maintained by these organizations tend to focus on Codex, ignoring possible future threats to the U.S. VMS industry. They quote soothing, and often misleading, statements

## The Loyal Oppositionists

### Natural Solutions Foundation

88 Batten Road  
Croton-on-Hudson, NY 10520  
Phone: (914) 271-6792  
Fax: (914) 730-9805  
Website: [www.HealthFreedomUSA.org](http://www.HealthFreedomUSA.org)

Established in 2004, the Natural Solutions Foundation is dedicated to promoting, protecting, and defending America's health and health freedom by every means available under the U.S. Constitution. The Foundation is deeply involved in domestic and international activities to promote health and health freedom.

### American Holistic Health Association

P.O. Box 17400  
Anaheim, CA 92817-7400  
Phone: (714) 779-6152  
Website: [www.ahha.org](http://www.ahha.org)

Established in 1989, the American Holistic Health Association is dedicated to promoting holistic principles, which include honoring the whole person (mind, body, and spirit) and encouraging people to participate actively in their own health and health care.

### National Health Federation

P.O. Box 688  
Monrovia, CA 91017  
Phone: (626) 357-2181  
Fax: (626) 303-0642  
Website: [www.thenhf.com](http://www.thenhf.com)

Established in 1955, the not-for-profit National Health Federation is a consumer-education, health-freedom organization working to protect individuals' rights to choose to consume healthy food, take supplements, and use alternative therapies without government restrictions.

### Health Freedom Coalition

P.M.B. 218  
2136 Ford Parkway  
St. Paul, MN 55116-1863  
Phone: (651) 690-0732  
Fax: (651) 699-8306  
Website: [www.nationalhealthfreedom.org](http://www.nationalhealthfreedom.org)

This organization promotes access to all health care information, services, treatments, and products that people deem beneficial for their own health and survival; aims to promote an understanding of the laws and factors that make an impact on the right to access to these items; and works to promote the health of the people in the United States.

### Citizens for Health

Health Action Center  
5 Thomas Circle NW, Suite 500  
Washington, DC 20005  
Phone: (202) 483-4344  
Fax: (202) 462-6534  
E-mail: [info@healthactioncenter.org](mailto:info@healthactioncenter.org)

Citizens for Health works to improve access to health choices because the organization believes that people have a right to choose their practitioners and treatments, including vitamin supplements, herbs, homeopathy, and other nonconventional modalities as well as being able to purchase vitamins, herbs, and other supplements easily and in the dosages required.

### Dr. Rath Health Foundation

950 South Pine Island Road, Suite A-150  
Plantation, FL 33324  
Phone: (800) 381-4185  
Fax: (954) 452-5104  
Website: [www4.dr-rath-foundation.org](http://www4.dr-rath-foundation.org)

The primary goal of the Foundation is to establish a new global health care system that can be implemented in any country, at the local level, and right up to the level of national public health policy. The Foundation is also actively engaged in worldwide initiatives that promote the right to natural health freedom, particularly in Europe and the United States, where the activities of the Codex Alimentarius Commission and the European Commission threaten that basic human right most.

### The Law Loft

310 South La Frenz  
Liberty, MO 64068  
Website: [www.thelawloft.com](http://www.thelawloft.com)  
Radio program: KCXL 1140 AM

Founded in 1992, the Law Loft functions as a “think tank” that does analyses, projections, and strategic planning for ordinary Americans by tracking information located in the cracks between disciplines and in odd mixtures of disciplines such as food science, international comparative analysis, and legislative analysis. (For The Law Loft's statement on Codex and the European Union, visit: [http://thelawloft.com/050405\\_eu\\_court.htm](http://thelawloft.com/050405_eu_court.htm))

### Alliance for Natural Health

Unit 5, Forge End  
St Albans, Hertfordshire AL2 3EQ  
United Kingdom  
Phone/fax: +44 (0) 1252-371-275  
Website: [www.alliance-natural-health.org](http://www.alliance-natural-health.org)

The Alliance for Natural Health (formerly Free Choice for Supplements Alliance) was formed in February 2002 as a nonpartisan, not-for-profit Europe-wide association of consumers, complementary practitioners, distributors, retailers, and leading-edge manufacturers who have an interest in food supplements and natural health.

## The Reassuring Rationalists

### American Herbal Products Association

8484 Georgia Avenue, Suite 370

Silver Spring, MD 20910

Phone: (301) 588-1171

Fax: (301) 588-1174

Website: [www.ahpa.org](http://www.ahpa.org)

The American Herbal Products Association exists to promote the responsible commerce of herbal products.

### Center for Food Safety and Applied Nutrition (CFSAN)

51 Paint Branch Parkway

College Park, MD 20740-3835

Phone: (888) 723-3366

Website: [www.vm.cfsan.fda.gov](http://www.vm.cfsan.fda.gov)

CFSAN is one of six product-oriented centers that carry out the mission of the Food and Drug Administration (FDA). CFSAN, in conjunction with the FDA's field staff, is responsible for promoting and protecting the public's health by ensuring that the U.S. food supply is safe, sanitary, wholesome, and honestly labeled.

### Andrew Weil, M.D.

Program in Integrative Medicine

University of Arizona

P.O. Box 245153

Tucson, AZ 85724-5153

Website: [www.drweil.com](http://www.drweil.com)

Dr. Weil is the founder and director of the Program in Integrative Medicine at the University of Arizona, Tucson. He is also a clinical professor of internal medicine and public health; a regular contributor to yearly botanical seminars held each year in New York City; and a well-known and respected expert in the field of alternative medicine.

(For Dr. Weil's comment on the Codex, visit: [www.drweil.com/u/QA/QA356136/](http://www.drweil.com/u/QA/QA356136/))

ures will occasion. Countries, like the United States, with their own standards are permitted to retain them but, if they do, will be assumed to be out of compliance with the WTO standard and CODEX, and will therefore automatically lose any trade dispute involving CODEX.

The health choice freedom that is so dear to the American consumer rests on twin pillars:

- Nutrients are food and, as such, they can have no upper limit
- Access to the widest possible array of nutritional options.

By using phony toxicology science to construct an illusion that nutrients are dangerous and using Positive Lists to restrict them, CODEX presents an external threat to U.S. and global health freedom.

By serving pharmaceutical interests, compliant congresspeople are standing by to introduce yet more legislation to gut the DSHEA and remove its protective shield.

Consumers and sellers of dietary supplements anticipated a total collapse of the supplement industry in the year or so before the DSHEA was enacted. Public outcry forced the DSHEA to be passed by unanimous Congressional assent: no one dared to oppose this Act! Since then, it has been under continuing domestic attack. This time, the attack is both domestic and international.

*Note: Dr. Laibow plans to explore the ramifications of the VMG further in the October issue of the Journal.* □

from U.S. government websites that domestic trade in vitamins and minerals will be regulated by the DSHEA, not by Codex, ignoring the well-orchestrated legislative assaults on the DSHEA. Some of these sites object to the calls to action by Loyal Oppositionists and advise people to remain alert to Codex and not to fear it, although this provides little real direction or substance.

## Looking Ahead

When the CCNFSDU convenes in Bonn in November 2005, it will decide:

- Which vitamins and minerals are on the Positive List (all others will be forbidden substances), and their
- Permitted sources
- Permitted dosages.

Countries in the developing world are being urged to enact VMG and other CODEX standards as their domestic laws despite the well-documented epidemiologic and public health forecasts regarding the unparalleled disease and death that these mea-

## References

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5. US Federal Register, October 11, 1995, page 53080.

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