# CODEX: Myth and Fact

# **HEALTH FREEDOM FACTS**

### A Joint Response to CRN's Myth and Fact by

## Friends of Freedom International and National Health Freedom Action

Friends of Freedom International (FOFI) and National Health Freedom Action (NHFA) recently received an email that was circulated which set forth a sequence of Codex: MYTHS AND FACTS produced by the Council for Responsible Nutrition (CRN).

FOFI and NHFA now provide these responses on behalf of health freedom advocates.

#### CRN:

#### On Codex and WTO

After the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) promoted at its November 2004 meeting the "Vitamin and Mineral Supplement Guideline" to Step 8, ready for Commission approval at its July 2005 meeting, the internet and emails have been flooded with allegations that the World Trade Organization (WTO) is going to "take away your vitamins." The Council for Responsible Nutrition (CRN) believes that these claims are nonsense and offers the following explanation in a "Myth and Fact" format.

MYTH: Your right to choose your vitamin, mineral and other supplements may end in June of this year (2005).

FACT: Whatever the impact of Codex, the Codex Alimentarius Commission meets in July, not June. CRN will work to assure that the national representatives present at the Codex Alimentarius Commission (CAC) meeting in Rome, July 2005, approve the Vitamin and Mineral Supplement Guideline, as promoted to Step 8 in Bonn, Germany in November 2004.

#### FOFI/NHFA HEALTH FREEDOM FACTS:

The MYTH is off by two months if you live in Europe because August 1st 2005 marks the date that the new European Union Food Supplements Directive goes into effect literally forcing thousands of dietary supplement products off the shelves for not being on the pre-approved government controlled "list".

HEALTH FREEDOM FACTS PLUS: Supporting the final approval of the Codex guidelines for Vitamins and Minerals in Italy in July 2005 would be to ignore the foundational freedom concept of our own US – DSHEA where we demand that the burden of proof of harm remains with the government before it sets any upper limits on amounts of food in dietary supplements. Instead of supporting this basic freedom of access to mother earth concept, large companies and organizations are supporting the shifting of the burden of proof and making the assumptions that all Vitamins and Minerals are suspect and that they have to go through a risk assessment process and require setting of safe upper limits. We passed DSHEA because we hold that dietary supplements are food and as such should be regulated as food and as such no upper limits should be set unless the government meets their burden to show harm on one specific product. Supporting the Codex guidelines would be rejecting the will of the American people resulting in loss of basic freedom.

#### CRN:

MYTH: After that [June 2005] U.S. supplements will be defined and controlled by the World Trade Organization (WTO) and the World Health Organization (WHO).

FACT: This is sheer nonsense. Codex guidelines will be recognized by the WTO as an international trade standard. The actual maximums will not be set by Codex until it gets the report from FAO/WHO nutrient risk assessment project—and that current project will only identify a method, and test that method with a very few examples. It will be years before the maximum contents are set. When established, the maximum contents will serve as a protection for exports by not allowing an importing country to set a maximum below the Codex maximum. An importing country could accept any level of potency it chose and a producer was willing to make. Codex and WTO do NOT set domestic standards for any country unless that country chooses to model its laws/regulations on the Codex document. (Some small countries without the critical mass of resources and scientists sometimes to utilize Codex documents as their national! regulations, but they are not required to do so.)

#### FOFI/NHFA HEALTH FREEDOM FACTS:

HEALTH FREEDOM FACTS: Not nonsense. Yes, World Health Organization is one of the two UN bodies that make up Codex. It is a joint program of the WHO and the FAO (Food and Agricultural Organization). Codex Vitamin and Mineral guideline drafts define Vitamin and Minerals and if you are a country that treats vitamins and minerals as food (the US does this) then these guidelines can apply to you for trading between international countries. Even though compliance with Codex guidelines are voluntary, if you are a country member of the WTO then you will be expected to comply with Codex guidelines when you internationally trade food. WTO has an enforcement body that can levy trade sanctions for non-compliance of WTO agreements. Trade sanctions can be significant in motivating lawmakers to revise internal country laws.

HEALTH FREEDOM FACTS PLUS: The fact that "upper limits" will take years to implement does not make them acceptable! The tragedy today is that freedom foundational principles could be given the death sentence and the sentence would be carried out slowly, year by year. Today is the day that counts because today is the day that players are attempting to shift the burden of proof about natural food products to the citizenry and in this case namely manufacturers. When the burden of proof is misplaced and governments no longer serve the people many suffer. In this case not only will the shift rob consumers of access to the products they need but it will also place a disproportionate burden on small and middle-sized manufacturers who do not have the same wherewithal to meet these costly requirements and this same shift of burden would provide large and global corporations a major advantage to qualify and re-tool products for trade. The rational for supporting the setting of upper limits appears to be to "protect exports". Rather than offering a health freedom option above and beyond RDAs or risk assessment, American participants remained silent and did not promote the "no upper limit" freedom concepts of DSHEA. One might ask why not? Maybe they wanted risk assessment all along. Maybe risk assessment not only protects exports but also establishes predictable markets for large companies whose own marketing goals are volume of sales and not uniqueness of product. CRN:

MYTH: CODEX drastically restricts vitamins, minerals, herbs and other supplements.

FACT: Germany, France, most other European countries, and indeed most countries in the world currently (and have for a long time) restrict vitamin and mineral supplements to low multiples of the RDA. This is the reason these countries so strongly fought against the Codex guideline including maximums that are based on risk assessment.

#### FOFI/NHFA HEALTH FREEDOM FACTS:

HEALTH FREEDOM FACTS: The Codex guidelines draft only includes Vitamins and Minerals. And the Codex guidelines draft does not recommend the use a low RDA limit like some countries use today. However, fear of RDA is not a rational for taking away freedom and placing upper limits on safe food products. Who fought for "no upper limits"? What is the police power and commerce power rational for risk assessment setting of upper limits on safe foods? By whose authority can an international body recommend and enforce upper limits on foods generally regarded as safe?

"3.1.3 Science-based risk assessment cannot be justified for a large number of nutrient forms where; a) nutrients are known to be safe even when consumed in high dosages, and; b) there is no evidence that the nutrient form has caused any significant adverse effects in a population despite the fact that they are consumed by hundreds of millions of people around the world on a daily basis...."FAO/WHO nutrient risk assessment project. ANH submission. December 2004

#### Notes from CRN on this point:

(1) Sure, risk assessment can be done badly, but when done appropriately it gives good answers. With it, you can get the right answer. With RDA-based limits you automatically get the wrong answer. Most of the world currently imposed RDA-based maximums.

(2) Hypothetically, a country could still restrict domestic production to

RDA-based maximums after Codex maximums based on risk assessment are implemented, but they could not afford to do so because imports would have to be permitted to the Codex maximum, and foreign competition would kill the domestic industry.

(3) We must now guard against arbitrarily restrictive risk assessment that amounts to nothing more than a "back door" to RDA-based limits. But even under a worst-case scenario it is no worse than the current system of RDA-based limits.

#### FOFI/NHFA HEALTH FREEDOM FACTS:

HEALTH FREEDOM FACTS PLUS: Whether risk assessment is done properly or badly there is no authority to mandate risk assessment at all and avoiding discussing the role of government in society is irresponsible and misleading. RDA and risk assessment are not the only two options. No upper limits for food generally regarded as safe is a freedom option which currently exists in America. Consumers want unadulterated products, pure quality, and truthful labeling of food. But setting "upper limits" on consumption without a rational is completely unwarranted and is a direct infringement on our right of access to food products.

#### CRN:

MYTH: CODEX now applies to Norway and Germany, among others.

FACT: Codex guidelines on supplements have not been approved. When approved, implementation is likely to take a couple of years or more. Norway and Germany, among many others, have long had very restrictive supplement regulations. Codex did not create this situation, but should help liberalize it. The price differential is great between "food" and "drug" supplements, but this is not the work of Codex. WTO may be a useful forum to resist the unilateral declaration by some countries, such as Denmark, that supplements are drugs, not foods, and thus exempt from Codex guidelines.

#### FOFI/NHFA HEALTH FREEDOM FACTS:

HEALTH FREEDOM FACTS: Many people are understandably confused between the European Union Food Supplements Directive and Codex. International legal issues can be complex. The EU FSD is a new European Union law taking affect in August 2005. Codex is an international trade standard setting body and they are considering approval of Vitamin and Mineral guidelines July 2005.

HEALTH FREEDOM FACTS PLUS: Although the role of WTO has been played down by many supporters of Codex it is apparent from this MYTH FACT pattern that the power of WTO will be looked to and utilized to attain preferred outcomes by exporters.

#### CRN:

MYTH: No supplement can be sold for preventive or therapeutic use.

FACT: This falsely implies that such sale is currently permitted and Codex will prohibit it. This is simply false. All or nearly all countries in the world currently prohibit "therapeutic" claims for supplements. Note that "preventive" claims will be permitted by Codex under its "health claims" guideline, which includes both NLEA- and DSHEA-type claims. CRN is working to make sure that the science standards are reasonable for these decisions. (Yes, this is a tough fight, but better than the current prohibitions.)

HEALTH FREEDOM FACTS: Consumers and freedom activists in the U.S. want to expand DSHEA to allow even greater freedom of speech regarding health claims on products used for prevention or therapeutic use. Since Codex does not recognize DSHEA's core principle of freedom of access, Codex will be implementing a global standard with more restrictions than DSHEA. Health claims is one aspect of labeling and it will be impacted if risk assessment goes forward.

#### CRN:

MYTH: Any potency higher than RDA is a "drug" under Codex guidelines.

FACT: This is a great "shell game" being played by some internet activists. The statement implies that current limits are very generous and Codex seeks to restrict them. The facts are the exact opposite. Many countries currently impose RDA-based maximums, and they resisted (for nearly 10 years!!!) the international movement toward risk assessment-based limits. Risk assessment is not a guarantee of appropriate maximums but will allow them. On the other hand, the RDA-baseis is a guarantee of inappropriate maximums (the current situation in most countries.

#### FOFI/NHFA HEALTH FREEDOM FACTS:

HEALTH FREEDOM FACTS: Codex guidelines do not indicate that any potency higher than RDA is a drug, however the guidelines are misleading on this issue because they are treating Vitamins and Minerals like drugs in the sense that they are giving the impression that they are dangerous, guilty until proven innocent, similar to how we treat toxic substances and drugs in the U.S., and imposing upon them a mandatory risk assessment and compliance to safe upper limits....yet Codex needs to call Vitamins and Minerals "food" in order to maintain jurisdiction over them because Codex only has to do with food safety standards. If Codex is claiming jurisdiction over Vitamins and Minerals as food, then it should be treating them with food thresholds regarding upper limits.

#### CRN:

MYTH: "Codex regulations become binding internationally."

FACT: This false by omission of material fact. Yes, Codex regulations are recognized by the WTO as the basis of trade standards. This Myth falsely implies that Codex and WTO will impose domestic regulations for all countries. WTO cannot impose sanctions for failure of a country to adopt Codex guidelines as its domestic regulations. WTO sanctions relate only to failure of a country to allow imports that meet Codex guidelines. For more information, contact CRN (202-776-7929). John Hathcock, jhathcock@crnusa.org

HEALTH FREEDOM FACTS: Yes, "Codex regulations become binding internationally" could become a true statement if you are a member of a trade agreement that requires them such as WTO. Regarding domestic regulations inside each individual country these MYTHS AND FACTS have given two examples of how the implementation of WTO might impact internal policies in individual countries and there are many more. For example, the author shows the muscle of the WTO contracts when coupled with Vitamin and Mineral guideline when they intimate that "WTO may be a useful forum to resist the unilateral declaration by some countries, such as Denmark, that supplements are drugs,..." and "WTO sanctions relate only to failure of a country to allow imports that meet Codex guidelines." These views lead to further questions by health freedom advocates. Is "risk assessment" a tool to force exports onto unwilling countries? We not only lose our freedom concepts at home but we are free to force our exports into other countries that really don't want them. This smacks of harmonization and the weakening of the diversity, which we thrive on. Harmonization is not harmony. Harmony only comes through tolerance of diversity.

For information on HEALTH FREEDOM FACTS, Please call 651-699-8300 and speak with attorney Diane M. Miller with questions or 718-885-1126 and speak with Dr. Carolyn Dean, MD, ND.