



Briefing: April, 2009

## **CODEX ALIMENTARIUS**

### **Clarification of Codex and its predicted influence and impact on the natural health industry in non-European Union countries**

#### **Part One: A storm is brewing...**

The future of each nation's natural health industry, nutritional innovation and each individual's personal freedom of choice regarding access to a wide range of vitamin supplements, amino acids, herbs and ancient and modern traditional medicines, appears with little doubt to be at genuine risk in the not-too-distant future. One can later speculate and even try to reason the intentions and motivations that have brought about this situation; however, it is certain that the situation exists and is no accident of circumstances.

This article will attempt to explain, document, and clarify the actual situation by separating the facts from numerous assertions, biased interpretations, and short-sighted solutions being attempted.

The situation we face is primarily the result of a series of apparently unrelated, but in fact, well-coordinated and complex events; executed slowly over time in incremental steps. It is a situation driven by vested interests, implemented by cooperating foreign and national governmental representatives, agencies, and legislative bodies, and fully upheld by a number of international trade agreements signed by heads of state.

While much confusion, conflicting opinion, and even heated argument exist as to the legal relevance and potential influence of "[Codex Alimentarius](#)" (Codex) to the future of vitamin supplements, herbs, amino acids, and many widely accepted forms of traditional medicines, the story does not begin in the Americas.

#### **It began in the European Union**

In Europe, the [European Food Supplement's Directive](#) was legislated and brought into law in 2002. The EU Food Supplements Directive was then upheld in the European Court of Justice despite fierce legal challenges by watchdog organizations within the natural health community in 2005.

These unnecessary and severely restrictive pieces of European legislation are now in various stages of clarification, finalization, and implementation throughout the European Union.

In summary, the EU Food Supplements Directive will:

- (a) Eliminate (completely ban) almost two-in-every-three currently available vitamin substances, amino acids, herbs; and traditional medicines;
- (b) Dramatically reduce dosage levels to newly established Maximum Permitted Levels (MPLs), based on a severely flawed procedure for assessing risk (no consideration is even given to existing benefits) and directly influenced by pharmaceutical industry participants;
- (c) Reclassify the remaining “allowable” vitamin substances as medicine;
- (d) Severely censor what the industry itself or any practitioner can promote, publish, or say about their mental or physiological influence.

Amino acids, herbs, Ayurvedic and other long-accepted, traditional health remedies are also under the EU Food Supplements Directive’s legislative control.

Natural products and vitamin substances that have not been approved, or those of manufacturers who fail to provide adequate and fully documented dossiers to the authorized governing bodies, will begin to be removed from the shelves in shops and websites throughout Europe in the months to come.

It is important to note that we are not reporting on a few “snake oil” or “miracle water” bottles. This is really not a massive attempt to protect consumers against the few undesirable “con artists” in this industry. No, we’re actually reporting on the fact that nearly 2/3rds of currently available and perfectly valid natural products have been unequivocally banned by the EU Food Supplements Directive and will soon be pulled from the shelves throughout Europe.

Products like:

- Nearly the entire spectrum of natural vitamin E, including gamma tocopherols and tocotrienols
- Mixed, natural spectrum of carotenoids
- All forms of Boron
- 14 different forms of Selenium, including selenium yeast products
- 23 different food forms of Calcium
- Colloidal or ionic trace elements derived from natural sources
- 21 food forms of Iron including iron-based yeast
- 30 different forms of Magnesium
- 21 different forms of Potassium
- Molybdenum – 15 forms of amino acid chelate

**... and many other natural substances already proven to be effective.**

**In fact, a detailed list of the remaining** allowable vitamin substances, known as the [“Approved List”](#) should leave many food supplement manufacturers, health practitioners and consumers quite distressed over the obvious and severe limitations and impact it will have on viable and beneficial existing products – let alone its impact on continued research and innovation.

## **High Dose Supplements**

While food-based (normally low-dose) products *appear* to have been spared from outright banning by the EU Food Supplements Directive, there are three important points to think about;

1. The EU Food Supplements Directive will eliminate High-dose supplements through the establishment of (upper safe) Maximum Permitted Levels (MPLs). Based on faulty risk-assessment evaluation, the “MPLs” will dramatically reduce legal dosage levels to nearly placebo levels.
2. Even the low-dose, food-based supplementation, herbs, and other (natural) nutritional substances are targeted to be re-classified as medicine by the EU FOOD SUPPLEMENTS DIRECTIVE’s Human Medicinal Products Directive.

*This Directive asserts that any product, even a food or food supplement, which has a physiological effect on the body, can be classified as a drug by the regulators.*

3. The [Nutrition and Health Claims Regulation](#), an integral part of the EU Food Supplement’s Directive, will severely censor what can actually be said, promoted or advertised about mental or physiological benefits of nutritional supplements.

## **What about “Sovereign” nations?**

The EU FOOD SUPPLEMENTS DIRECTIVE may very well be the law now, but it certainly will *only* affect Europe. And while other countries might sympathize with the fate of the European natural health industry, it doesn’t really have anything to do with the U.S. or other countries outside of Europe.

**...or does it?**

## **Part Two: The *current* U.S. consensus**

In the United States, the European Food Supplements Directive and Codex would appear to be completely irrelevant largely due to massive efforts that lead to the passage of the [Dietary Supplements Health and Education Act](#) (DSHEA) of 1994.

In fact, Codex is barely even on the radar as a real threat to the natural health industry in the U.S. DSHEA is perceived to be an unbreakable steel barrier to Codex or Europe's legislative influence or any other "foreign" attempt to breach America's "safe haven" status for the natural health and nutritional innovative industries.

The consensus within the U.S. natural health industry is that it will continue to enjoy unfettered access to the full array of innovative products and high-dose supplementation. This view continues to be promoted by the very associations that are actually paid by its members to protect industry, practitioner, and consumer interests.

There is no argument that the passage of the Dietary Supplement Health and Education Act in the United States was perhaps the single most important legislative development in the history of health freedom. Since 1994, interest in supplements, traditional medicines, alternative therapies and the natural health industry as a whole has grown dramatically in the United States. So much so that it is now estimated that more than 40 percent of the entire U.S. population take dietary supplements on a regular basis and as much as 70 percent use them periodically.

So, are the United States and other non-European nations sufficiently protected against the already approved European anti-vitamin legislation and Codex's mandate to fully incorporate them as international "Standards?" A number of the unbiased experts and Health Freedom Campaign organizations wholeheartedly agree – they are NOT!

### **What is the truth?**

Unfortunately, sorting out the true relevance and potential threat can be a somewhat daunting and complicated process. Some definite effort on the reader's part is required in order to bring together, review, and personally inspect the truly relevant information.

To separate these out from the tiring and relentless "alarm bells, conflicting media coverage, well funded public relations efforts, and misleading and sometimes completely false opinions and interpretations, let's review some key elements.

First of all, one of the main reasons confusion continues to exist is that Codex's *actual* relevance to the United States stems not from Codex's own documents, which in the main appear simply to promote health and nutritional "guidelines and standards" that each nation should aspire to, but from actual and legal obligations contained within a number of international trade agreements already signed by the governments of numerous countries outside of Europe, including the U.S.

These include the [General Agreement on Tariffs and Trade](#)(GATT), which was signed in 1947, and more recently, the [World Trade Organization](#) (WTO) agreement signed during President Clinton's administration in 1995, updating and virtually replacing the original GATT agreement.

In fact, it appears the legal basis for enforcement of the various "Guidelines" and "Standards" created by Codex will come from the '[Agreement on the Application of Sanitary and Phytosanitary Measures](#),' known as the "SPS Agreement" and the '[Agreement on Technical Barriers to Trade](#)' known as the "TBT" Agreement.

Both the SPS and TBT agreements were included among the [Multilateral Agreements on Trade in Goods](#), which was annexed to the agreement that originally established the WTO.

A lot of legal gibberish? We couldn't agree more, but unfortunately, quite dangerous to the natural health industry, as the following pages may make clear.

## Part Three: European Influence on Codex

The European Union is without doubt the single most powerful influence on international Codex conferences and discussions. European Council documents acknowledge the *increasing legal relevance* that the various Codex Alimentarius guidelines and standards have acquired:

*“... by virtue of the reference made to the Codex Alimentarius in the WTO Agreements and the presumption of conformity which is conferred on relevant national measures when they are based on such standards, guidelines or recommendations adopted by the Codex Alimentarius Commission.*

*Likewise, we also acknowledge that one of the objects of the Codex Alimentarius Commission is to harmonise worldwide health standards.”*

It now appears quite likely that European health and nutritional policy will gradually become the blueprint for a new *global* nutrition and health policy. The growing similarities between the text of the EU Food Supplements Directive and that of the Codex Draft Guidelines for Vitamin and Mineral Supplements are no coincidence.

### Who is really who at Codex?

The Codex Alimentarius Commission was created in 1963 by the Food and Agricultural Organization (FAO) and the World Health Organization (WHO).

There are 181 members of the Codex Alimentarius Commission, (180 member countries and one member organisation); however, [Mr. Basil Mathioudakis](#), who was originally responsible for drafting the actual text of the EU Food Supplements Directive, is also head of the European Commission delegation at Codex, and represents numerous European countries at Codex meetings.

Additionally, the European Union has full membership status at Codex. Mr. Mathioudakis, on behalf of the EU Commission, will certainly be entitled to exercise a significant number of votes equal to the number of its Member States present at the time votes are taken.

Furthermore, whenever Mr. Mathioudakis exercises his right to vote, the Member States will *not* be entitled to individually exercise their own votes. As such, the European Union Member States are in a weak position to oppose the EU Commission at Codex; especially given the fact that the majority of the guidelines being drawn up are either already law, or in various states of clarification and implementation in their own countries.

### So, what is Codex, exactly?

## Part Four: What is Codex, exactly?

Originally designed by military and business leaders from the pharmaceutical industry in Germany shortly after World War II, historically, Codex was evolved from a collection of standards and product descriptions for a wide variety of foods developed in the Austro-Hungarian Empire between 1897 and 1911. Austria subsequently pursued the creation of a regional food code, the “Codex Alimentarius Europaeus” between 1954 and 1958.

In 1961 the Council of Codex Alimentarius Europaeus adopted a resolution proposing that its work on food standards be taken over by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

Today’s “Codex Alimentarius” was formed by the FAO of the United Nations World Health Assembly in 1963.

In the mid-1990s Codex Alimentarius signed agreements with the World Trade Organization (WTO), enabling Codex to establish trade standards that the WTO would use to resolve international trade disputes.

To explain, perhaps some Trade Agreement background is in order:

- Since 1947 the General Agreement on Tariffs and Trade (GATT) oversaw the multilateral trading system and the otherwise sovereign governments that signed GATT were known as “GATT Contracting Parties.”
- On January 1, 1995 the [World Trade Organization](#) (WTO) replaced the General Agreement on Tariffs and Trade (GATT).
- Upon signing the new WTO agreements, including the updated GATT agreements the “GATT Contracting Parties” now became officially known as “WTO Members” which was actually based on some of the principles that actually underline the current European Union.

As of July 23, 2008, the WTO has a total membership of 153 countries including the United States who signed on as a member in 1995.

As already pointed out, in the mid-1990s, Codex Alimentarius signed agreements with the WTO, which enabled Codex to establish trade standards that the WTO would use to resolve international trade disputes.

In summary then we have (1) the EU Food Supplements Directive, now law throughout Europe and in various stages of clarification, finalization and implementation; (2) Codex Alimentarius adopting these laws as “guidelines and standards” that each nation should aspire to, but are actually supported by legal obligations contained within a number of international trade agreements signed by the governments of numerous countries outside of Europe, including the U.S.

## Part Five: Are all WTO member countries *obligated* to follow Codex “Standards and Guidelines”?

A great deal of discussion is taking place within the natural products industry on this subject. Arguably, there appears to be no single and *categorical* obligation for governments to adopt Codex standards and guidelines.

However, the preamble to the [SPS Agreement](#) (to which all WTO Members are signatories) specifically mentions Codex and states that WTO Members (and hence all SPS signatories) desire:

*“To further the use of harmonized sanitary and phytosanitary measures between Members on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission.”*

In fact, Article 3.1 of the [Agreement](#) goes even further than this to state:

*“To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist.”*

The key word here, from a legal point of view, would appear to be the word, “shall,” which could perhaps be said to make the Guidelines for Vitamin and Mineral Food Supplements mandatory for all WTO member countries.

This is where possible future legal battles may arise on the international trade level in order to sort out “voluntary” from “mandatory” legal interpretation. On one side the natural health industries, practitioners and consumers and on the other side Codex, the WTO and our own government who’s main interests may or may not be influenced more by international relations and trade pressure.

### What about Countries that choose to continue to ignore Codex?

Even if a country decided *not* to follow Codex guidelines and standards, the standards that the refraining country *does* employ in place of Codex standards remains subject to a wide range of conditions as set out in detail in Article 5 of the [Sanitary and Phytosanitary Measures \(SPS Agreement\)](#).

In relation to dietary supplements, one of the most important of these conditions would appear to be a requirement to take into account risk-assessment techniques developed by “*the relevant international organizations.*”

And you should also note that [guidelines on risk analysis](#) are already under discussion at meetings of the Codex Committee on Nutrition and Foods for Special Dietary Uses. Unfortunately, the committee has already indicated that this work will be concentrating upon “the development of methodological aspects for over dosage of nutrients.”

Other conditions that would blunt deviating “standards” utilized by non-conforming countries in place of Codex standards include;

- A requirement to take into account economic factors as well as the relative cost-effectiveness of alternative approaches to limiting risks
- A requirement to take into account the objective of minimizing negative trade effects
- A requirement to avoid arbitrary or unjustifiable distinctions in the levels of risk protection that it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade

Again, the resultant impact of signing onto earlier trade agreements is that, even if a country decided not to follow a Codex standard within its own borders, they would remain subject to a wide range of conditions set out in detail in Article 5 of the Sanitary and Phytosanitary Measures (SPS Agreement) and thereby made to comply.

Therefore, countries that are members of the WTO are effectively required to implement all Codex standards by virtue of the fact that they have signed the SPS Agreement.

It may not be entirely coincidental that many countries have already begun taking steps to implement stringent restrictions upon the dosage levels and availability of a number of vitamins and minerals, including the United States and Canada, in preparation for the finalization of the Codex Guidelines for Vitamin and Mineral Supplements.

Additionally, what can be said, promoted or advertised as mental or physiological benefit from such substances are already being restricted within the borders of the United States by the FDA who issued “cease and desist” letters to more than 40 supplement manufacturers and distributors last January.

Indeed, the significance of Codex was underscored in 1985 by United Nations Resolution 39/85, whereby guidelines were adopted on consumer protection policies.

One could also argue that countries were already expected to adopt Codex guidelines and standards before either the WTO or the SPS Agreement came into existence on the grounds that a United Nations General Assembly resolution in 1985 gave rise to the United Nations “[Guidelines for Consumer Protection](#).” These guidelines stated that

*"Governments should take into account the need of all consumers for food security and should support and, as far as possible, adopt standards from ...Codex Alimentarius."*

Although it could also be said that the use of the word “should” in this text, as opposed to the word “shall,” could arguably be said to amount to something less than a mandatory requirement; nevertheless, the United Nations Guidelines for Consumer Protection were later expanded in 1999 and [the reference to Codex was retained](#).

More recent developments might make the issue of “adoption” somewhat academic however, as the Codex Alimentarius Commission has recently deleted the notification and acceptance procedures from the [Codex Procedural Manual](#). Prior to this, there had been three levels of acceptance procedures for [Codex texts](#), and countries were, theoretically, supposed to inform the Codex Alimentarius Commission of which level of acceptance they would be applying to each individual Codex standard within its territorial jurisdiction. This is no longer an option.

Consequently, while these notification and acceptance procedures had effectively been ignored already by governments for many years, the fact that they have now been abolished provides further substantiation that in light of the SPS Agreement, compliance with Codex standards and guidelines is [effectively assumed to be mandatory](#).

Finally, it should be noted that the text of the Codex Guidelines for Vitamin and Mineral Food Supplements specifically states in paragraph 1.2 that

"These Guidelines *do apply* in those jurisdictions where products defined in 2.1 [i.e. vitamin and mineral food supplements] are regulated as foods."

As such, given that the United States regulates dietary supplements as foods, notwithstanding the popularity and apparent protections under DSHEA, it seems quite clear that the guidelines will indeed apply in the U.S.

## Part Six: Final Summary

Europe is effectively the most influential entity at Codex and the EU Food Supplements Directive is essentially the de facto blueprint for the Codex Guidelines for vitamin and mineral supplements.

As a result of international trade agreements such as the Sanitary and Phytosanitary Measures (SPS Agreement), Codex texts, guidelines and standards are effectively mandatory for all WTO Members.

Additionally, as the WTO does not distinguish between guidelines and standards, and utilizes Codex texts to resolve international trade disputes, a finalised Codex text would likely have the ability to countermand the dietary supplement laws of all WTO member countries – overriding even the United States and its hard-fought victory in its passage of the Dietary Supplement Health and Education Act (DSHEA).

The numerous coercions in place for governments to adopt Codex guidelines and standards texts appear to be such that they leave little option but to comply.

In fact, as already noted, the Codex Alimentarius Commission itself has no uncertainty of their own as to whether WTO Member nations have to comply with the guidelines and standards they set. According to published documents from their [Twenty-Seventh Session in Genève Switzerland](#), 28 June – 3 July 2004:

“Members of the World Trade Organisation (WTO) are required to base their domestic technical regulations or standards on standards developed by international organisations. These organisations include the Joint FAO/WHO Codex Alimentarius Commission for food safety; the Office International des Epizooties (OIE) for animal health; and the International Plant Protection Convention (IPPC) for plant health.”

It appears that pursuing policies of appeasement or attempting to work within the restrictive parameters set by the European Food Supplements Directive by the natural health industry would only serve to soften the blow, but only temporarily.

Unless the innovative side of the natural health industry sufficiently coheres to effectively place this issue back “on the radar” in Congress and other legislative bodies and fight back, it is difficult to see how it can continue to effectively serve its adherents and the consumers it serves in the not too distant future.

Until serious changes are made to the manner in which Codex currently operates, it would not be unreasonable to expect that other European health-related legislation, such as their very restrictive regulations on nutrition and health claims, will also become the blueprints for further standards to be enacted on a globally harmonised basis.

The planetary effects upon natural health, and by implication public health, would be both profound and disastrous.

## APPENDIX

**Food and Agriculture Organization (FAO)**  
[United Nations Food and Agriculture Organization \(FAO\).](#)

### **Codex Alimentarius:**

["Understanding Codex Alimentarius the Food and Agriculture Organisation of the United Nations World Health Organization."](#)

[General Principles of the Codex Alimentarius. 4.A.i/ii/iii.](#)

[Codex Committee on Nutrition and Foods for Special Dietary Uses. Agenda for Twenty-fifth Session, held at "Brückenforum Bonn", Friedrich-Breuer-Strasse 17, Bonn, Germany, on 3 – 7 November 2003.](#)

[Report of the Thirteenth Session of the Codex Committee on General Principles, held in Paris from 7 to 11 September 1998. Item 6.2; paragraph 43. Revision of the Acceptance Procedure \(CX/GP 98/8\).](#)

[COUNCIL DECISION of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission \(2003/822/EC\). \(Preamble; paragraph 2\)](#)

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l\\_183/l\\_18320020712en00510057.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_183/l_18320020712en00510057.pdf)

[Codex Committee on Nutrition and Foods for Special Dietary Uses. 25<sup>th</sup> Session. Brückenforum, Bonn, Germany 3-7 November 2003. ALINORM04/26.](#)

[COUNCIL DECISION of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission \(2003/822/EC\).](#)

[Codex Alimentarius Commission. Procedural Manual. Thirteenth Edition. Rules of Procedure of the Codex Alimentarius Commission. Rule II \(3\) - Member Organizations. p. 6.](#)

[European Community Comments on the Joint FAO/WHO Evaluation of Codex Alimentarius and other FAO and WHO work on Food Standards. \(Codex Circular Letter CL 2003/8-CAC\). p. 9.](#)

[ftp://ftp.fao.org/codex/alinorm04/al04\\_26e.pdf](ftp://ftp.fao.org/codex/alinorm04/al04_26e.pdf)

[European Community Comments on the Joint FAO/WHO Evaluation of Codex Alimentarius and other FAO and WHO work on Food Standards. \(Codex Circular Letter CL 2003/8-CAC\). p. 1.](#)

[Codex Alimentarius Commission. Procedural Manual. Thirteenth Edition. Part 2: Uniform Accelerated Procedure for the Elaboration of Codex Standards and Related Texts. pp. 22-23.](#)

### **World Trade Organization:**

[World Trade Organization Membership](#)

[The man who built the WTO: an interview with Peter Sutherland.](#)

[World Trade Organization: Dispute Settlement.](#)

[World Trade Organization: Settlements and Appeals.](#)

## **Other International Trade Agreements**

**[SPS Agreement. World Trade Organization. URUGUAY ROUND AGREEMENT: Agreement on the Application of Sanitary and Phytosanitary Measure.](#)**

**[TBT Agreement. World Trade Organization. URUGUAY ROUND AGREEMENT: Agreement on Technical Barriers to Trade.](#)**