

## **Introductory Discussion**

# **UNDERSTANDING CODEX ALIMENTARIUS**

**and**

# **ITS IMPACT ON HEALTH FREEDOM**

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## **Executive Summary**

**This paper is written in response to consumer questions about their access to dietary supplements; whether internationally crafted laws, policies, and standards can impact consumer access to health care products. The following is the National Health Freedom Coalition response to this question.**

**Globalization and international relations are impacting Americans** every day in the quality of the food that we eat, the air that we breath, the products that we use, and eventually the health and well-being that we so deeply desire. Americans are asking important questions, and in particular, questions regarding Codex Alimentarius, the international food standards Commission that sets food standards for international trade. Codex is important because it has to do with the food supply internationally including food quality and food trading practices. (Dietary supplements for most purposes are considered food in the United States).

**This paper creates an overview of Codex and its impact on health freedom.** International issues are complex and it is increasingly important to get basic dependable information to consumers so that they can participate in policy making in areas that impact everyday lives.

**To begin it is important to understand the types of players** that often participate in global forums. Without this knowledge consumers have no frame of reference in terms of how Codex and international laws and public policy gets made or is applied later.

**Codex is described here in the context of the global organizations** that are affiliated with it such as the United Nations (UN), the World Health Organization (WHO), and the World Food and Agriculture Organization (FAO).

**Although in the past, Codex was a voluntary Commission** spending most of its resources setting up suggested guidelines for world food trade, the signing of the World Trade Organization (WTO) agreements has changed this because of the enforceability component embodied in the WTO agreements.

**WTO is described and how it impacts Codex.** An explanation is provided as to how the WTO agreements refer to the Codex guidelines as the international food standards that member countries must abide by while trading internationally. The WTO includes a special agreement that prevents members from setting up false excuses that create trade barriers (Agreement on Technical Barriers to Trade TBT). The WTO also includes a special agreement on criteria for risk assessment when taking sanitary and phytosanitary measures (Agreement on Sanitary and Phytosanitary Measures SPS). Most importantly, the WTO has enforcement provisions by a Dispute Settlement Body to resolve complaints.

**WTO has enumerated basic principles of trade and these are described including harmonization, Most Favoured Nation policy, National Treatment policy, and preventing technical barriers to trade.** Consumer questions are addressed such as, is harmonization different than harmony? Does this mean everyone will have to do the same thing? How do we protect diversity of cultures and preferences when we are making international law? For example, what is the difference between harmonization and harmony?

**Examples of specific international conflicts are given** in order to show Americans how new global agreements can impact individual access to products and the health of nations. For example, can Codex force Japan to accept imported apples from the United States even when it is agreed that some orchards in the United States have Fire Blight and Japan has no history of Fire Blight in their apple supply?

**Basic information about US law is given including whether the WTO is a US code or a treaty.** The adoption of the WTO by the United States contributes to the complexity of United States laws. Current law is described, especially those involving dietary supplements. The definition of drug and the definition of dietary supplement are provided so that consumers understand that the dietary supplement laws in the US are very progressive as compared with other countries and that they have reason for concern.

**The role of the European Union and its new Food Supplement Directive** is discussed and its potential for impacting Codex and health freedom. The EU has a large number of votes at the global Codex table. Concerns are now raised because the European Union recently passed very restrictive laws that will literally take many products off the shelves in Europe. There is some fear that the EU Food Supplement Directive will impact the drafting of new Codex guidelines for all international trade of WTO members. For this reason, the EU Food Supplement Directive is being legally challenged in the European Court of Justice in Luxembourg (EU Supreme Court) by one consumer freedom group and 2 UK Trade Associations.

**The Dispute Settlement Body of the WTO is reviewed in the context of due process.** How can laws and trade agreements be enforced without due process? What kind of legal process is involved in the WTO dispute settlement protocols? For example, how can the parties to a complaint submit their full case when they have no power under WTO to bring their own experts and when experts are chosen by the actual WTO panel that decides the outcome of the case?

**Finally, Codex is focused on in more detail,** discussing the Eight step affirming process, and providing consumers with the actual language of the current draft guidelines for Vitamins and Minerals recently adopted by the Codex Commission July 7, 2004, at Step Five and moving on to Step Eight.

### **In Conclusion**

Principles of freedom of access to health care options are being impacted by the actual policies and laws being developed globally. A main theme negatively impacting health freedom is the fact that governments and organizations claim jurisdiction and develop enforcement mechanisms over almost all health products sometimes resulting in the potential ban on trade of many products that consumers deem to be helpful health care options. The claiming of jurisdiction over all products often proceeds without scrutinizing whether any government or international organization has the right to have jurisdiction over all products, especially since many products do not create an imminent and discernible risk of significant harm to the public even when unregulated. The establishing of enforcement mechanisms is equally onerous because concepts of due process, which Americans hold so dear to the rule of law, are not part of enforcement bodies, even though the enforcement bodies have the power to levy sanctions that can drastically affect the economy of a nation. Even when jurisdiction is created, the agreements being set up do not reflect the level of freedom and liberty that Americans are accustomed to. The concept that individuals have fundamental rights to make their own health care choices is not looked upon as taking precedent over developing trade regulations that may prohibit some health options individuals want. Individual rights to have due process are not being considered as key elements in the establishment of a global dispute settlement panel with members from multiple countries.

American values of a limited government that honors fundamental rights and liberties and Americans value their access to a full range of health care options and products. These values are not automatically part of a global agenda and this is cause for grave concern. It is extremely important that Americans get involved in learning about these issues and working to impact international conversations on behalf of their health freedoms.

**UNDERSTANDING  
CODEX ALIMENTARIUS**

**AND ITS IMPACT ON HEALTH FREEDOM**

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**Notice**

**National Health Freedom Coalition (NHFC) and National Health Freedom Action (NHFA) are sister health freedom organizations dedicated to educating consumers about key health freedom issues. NHFA also works towards legal reforms to protect health freedoms.**

**In June 2004, on behalf of NHFC and many American consumers, Diane Miller, Legal and Public Policy Director, and Linda Peterson, NHFC Board member and member of the Executive Committee, traveled to Geneva Switzerland, to attend the annual Codex Alimentarius meeting. The purpose of the trip was to gain knowledge about Codex in order to better educate Americans about how they can protect their health options.**

**In addition to attending the weeklong Codex meeting, the trip included travel to the UK to meet in London with the Alliance for Natural Health to learn of their challenge to the European Food Supplement Directive.**

**The following paper is a report back. The limited goal of this report is to educate consumers about the nature of Codex. Given that there are vast pieces of information and complex relationships that could not be included and described in this memo because of its length, I ask that it be read in the spirit of overview. In the spirit of a glimpse of global activity. In the spirit of using it to develop further questions and strategies of how to proceed to protect our access to health freedom.**

**Introduction**

United States citizens understand first-hand the need to be vigilant when it comes to government coming between themselves and what they deem to be their individual autonomy and freedoms. After all, the whole premise of their independent sovereignty and forming their own constitution was to assure that they would never again be separated from the natural state of being free. Limiting the reach of government was agreed upon in the Constitution in order to demonstrate the ability of a nation to have a useful and functioning government at the same time preserve personal independence. Freedom and independence are considered the essence and identifier of US American roots.

The question to many Americans now is whether their legacy of freedom is being preserved in their homeland as their limited government of the United States represents them in its participation in the global community? How can Americans be vigilant about a limited government when government officials are representing them at tables around the world, in many countries, on many topics, and making agreements so lengthy and complex that the average American would be overwhelmed by them? How can Americans be vigilant about a limited government when government officials are being impacted by corporate entities that are unlimited in their complexity, wealth, power, and ability to be at every negotiating table? Are government officials representing the people in a manner that would preserve the

United States foundational freedoms? These are some of the questions Americans have as they view the daily news.

The following memo is about a special global issue called CODEX. It is my hope that you will keep the above statement in mind as you read through this to help you keep in perspective and remember American roots.

The goal in these writings is to bring to the average American public an introductory insight into what is meant when they hear the word CODEX. Many Americans have this word linked with fear of losing products they currently appreciate and depend upon as informed consumers. They are asking the questions: What is CODEX? Will CODEX eliminate or change the nature of products from the marketplace that I depend on? In the health arena the question is will Codex take away my Vitamins or Food Supplements that I use for my health? Who is in charge of CODEX? How can I make sure I will maintain my access to everything I want and need? Who knows about CODEX? Who do I believe?

### **Key Parties to CODEX**

CODEX is a group of 170 country member nations, that have gotten together to set up international safety standards for the rules around the trading of food products (which they have decided includes food supplements like Vitamins and Minerals). CODEX has become a charged word in the food industry because of the differences of opinion about what type of standards should be applied to all member nations when trading food.

Key players include:

1. **Government officials:** These are generally government employees from various agencies like the FDA and the DOA representing the American people at the international Rounds on trade. These officials are certain that they are doing the right thing delivering the position statements of their governmental agencies. The question to ask in this situation is whether an “agency’s position” is really always reflective of “the people’s position”.

2. **International corporations:** These corporations finance professional staff from their for-profit corporations to travel and track the negotiations and write position papers and work to influence international governmental positions. The question here is whether the relationships between government employees and corporate employees are sufficiently independent and without conflict of interests with respect to each other’s agendas.

3. **International non-profit corporations:** These groups, (non-governmental organizations – NGOs) are nonprofit corporations taking a stand one way or the other on global issues in order to impact international policy and laws. They can be special interest corporations that have an invested interest in a product area such as the International Dairy Association, or they can be consumer-based groups such as Consumers International. Although consumer-based NGOs and other corporate NGOs are very different in focus and nature, they are all considered NGOs. NGOs have to raise donations from, often times, corporate sources. The questions here are whether the NGO is representing their members properly and whether they have been influenced by their funding sources or markets that they have an interest in. For consumers, it is especially important to ask whether a consumer-based NGO is reflecting consumer wishes.

4. **Local and national activist groups:** Local groups in each country generally do not have an international membership so they communicate with the international groups to glean information to tell the local people. Most of their staffs are volunteers. The question here is whether they are getting accurate and unbiased information.

5. **Trusting Americans:** Trusting Americans often are comfortable in their job, home, and priorities, and busy with their lives, and have no intention of learning or acting on global issues because

of their complexity. Therefore, they trust their elected officials and the people who really care about specific issues to do the right thing. The question here is whether the American people can trust the global process like they trust their own local processes.

6. And finally, **vigilant Americans:** Vigilant Americans are interested in being enlightened citizens on many issues and would do the right thing if they just knew what to do. The question for them is also one of trust. It is “who to believe?”.

As Legal Director for two local sister organizations, national nonprofits, called National Health Freedom Coalition and National Health Freedom Action, and with support of independent donors, I have traveled to Geneva Switzerland to first-hand observe a Codex meeting. I have also returned and taken time to study documents relating to Codex and international trade, in order to make a good faith effort to learn about this issue. This issue is complex and would take years of study to understand the depth of it entirely. But I have been in the shoes of a vigilant American as I study. And I have drafted this document as an overview to help educate we Americans on this very important issue. This is what I have found.

### **Codex Alimentarius**

CODEX: The present-day Codex Alimentarius draws its name from the Austrian code. In the Austro-Hungarian Empire, between 1897 and 1911, a collection of standards and product descriptions for a wide variety of foods was developed as the *Codex Alimentarius Austriacus*. Although lacking legal force, it was used as a reference by the courts to determine standards of identity for specific foods.<sup>1</sup>

In 1961, the current Codex Alimentarius Commission, (CODEX), was born. An FAO (Food and Agriculture Organization) Conference passed a resolution to create an international food standards program. The following year they requested WHO (World Health Organization) to endorse a joint FAO/WHO food standards program. In 1963 the World Health Assembly of WHO approved the establishment of the Joint FAO/WHO Food Standards Programme and adopted CODEX.<sup>2</sup>

FAO, a specialized agency of the United Nations, was founded in 1945, with responsibilities covering food and agriculture. “*Achieving food security for all is at the heart of FAO's efforts - to make sure people have regular access to enough high-quality food to lead active, healthy lives. FAO's mandate is to raise levels of nutrition, improve agricultural productivity, better the lives of rural populations and contribute to the growth of the world economy.*”<sup>3</sup> FAO meets every two years and is governed by 188 member countries.

WHO was founded in 1948, with responsibilities covering human health. This included “*the attainment by all peoples of the highest possible level of health. Health is defined in WHO's Constitution as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*”<sup>4</sup> WHO is also a United Nations specialized agency, independent and linked to the UN through cooperative agreements. WHO is governed by 192 Member States through the World Health Assembly (WHA). WHA is the supreme decision-making body for WHO. It meets annually in Geneva and has 192 countries in attendance and makes policy decisions for WHO.

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<sup>1</sup> Understanding the Codex Alimentarius origins of the Codex Alimentarius  
<http://www.fao.org/docrep/w9114e/W9114e03.htm>

<sup>2</sup> Id.

<sup>3</sup> [http://www.fao.org/UNFAO/about/mandate\\_en.html](http://www.fao.org/UNFAO/about/mandate_en.html)

<sup>4</sup> World Health Organization: About WHO. <http://www.who.int/about/en/>

The United Nations was established in 1945 by 51 countries and currently has 191 countries as members. Member countries agree to accept the UN Charter, an international treaty that sets out basic principles of international relations. According to the Charter, the UN has four purposes; to maintain international peace and security, to develop friendly relations among countries; to cooperate in solving international problems and in promoting respect for human rights; and to be a center for harmonizing the actions of nations.<sup>5</sup> Although it is often stated by the UN that “The United Nations is not a World government and does not make laws.”<sup>6</sup> the UN is situated in a complex web of interlocking global relationships with the power to lay sanctions and drastically impact the economies of nations. Thus, in some way it has the power of governance that many governments have. It describes itself as providing the means to resolving international conflicts and, in some cases, makes decisions, which can be enforced in ways such as economic sanctions or trade embargoes or encouragement of members to use the means they need to resolve the conflict.<sup>7</sup>

CODEX is a joint venture of FAO and WHO with historically FAO providing the majority of funding. Most recently, in response to World Health Assembly Resolution 53.15, WHO is stepping up its participation “...to give greater emphasis to food safety, in view of WHO’s global leadership in public health, and in collaboration and coordination with other international organizations, notably the Food and Agriculture Organization of the United Nations (FAO), and within the Codex Alimentarius Commission, and to work towards integrating food safety as one of WHO’s essential public health functions, with the goal of developing sustainable, integrated food safety systems for the reduction of health risk along the entire food chain, from the primary producer to the consumer”.<sup>8</sup> WHA Resolution 53.15, 2000.

CODEX has always been a voluntary standard setting forum with no enforcement component to it. Members have participated in discussing, researching, establishing and publishing standards that countries could then voluntarily use to enhance the safety of their food products and the predictability in their food quality for purposes of food safety and trading with other trading partners. The official purposes of CODEX in its Statutes is:

“Article 1....

- (a) protecting the health of consumers and ensuring fair practices in the food trade;
- (b) promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations;
- (c) determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;
- (d) finalizing standards elaborated under (c) above and, after acceptance by governments, publishing them in a Codex Alimentarius either as regional or world-wide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable;
- (e) amending published standards, after appropriate survey in the light of developments.”

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<sup>5</sup> How the UN Works, <http://www.un.org/Overview/brief1.html>

<sup>6</sup> Id.

<sup>7</sup> Id.

<sup>8</sup> Weekly Epidemiological Record, 2004, 79, 173-180, No. 18, April 30. <http://www.who.int/wer>.

Of course, when international standards are set they create public policy and also reference points to turn to when countries are deciding what standards to use or in the case of conflicts, what standards countries “should have used”. For this reason, many groups begin to use international standards on their own accord, or at least pieces of the standards that make sense for their culture.

### **World Trade Organization (WTO)**

However recently, the voluntary nature of CODEX standards has been impacted by the establishment of a new organization, namely the World Trade Organization (WTO). The WTO, made up of 146 countries, many of whom are also members of the Codex Commission, basically took the long standing trade agreements originating out of the General Agreement on Tariffs and Trade (GATT ) (1947 and 1994), the results of past trade liberalization efforts, and all of the results of the Uruguay Round of Multilateral Trade Negotiations, and established an institutional framework for the conduct of all international trade relations.<sup>9</sup> The WTO is currently the host to new trade negotiations, under the “Doha Development Agenda” launched in 2001.<sup>10</sup>

**Re GATT, GATS, and TRIPS:** WTO is a massive organization, holding over 30,000 relevant documents alone. Suffice to say that this overview will not attempt to give a complete overview of WTO. However, it is important to note that the WTO is implementing the major global trading agreements and these agreements are not confined to the trading of goods alone. The main agreements of the WTO on the trading of goods are GATT 1947 and GATT 1994.

**Re GATS:** In addition to GATT and the trading of goods, the WTO also includes agreements on the trading of services (GATS). At the Uruguay Rounds in 1994, the General Agreement on Trade in Services (GATS) was established. This is the first and only set of multilateral rules governing international trade in “services”.<sup>11</sup> The significance of GATS to a democracy such as the United States is that generally speaking, services are regulated by state governments in that state governments regulate standards of qualifications for professions to practice within their state borders. The “trading” of services internationally is now concerned with qualifications and standards. This discussion will be complex, and because of the state’s rights to regulate the practice of trades and professions, these discussions should be closely monitored.

**Re TRIPS:** The third arena of WTO jurisdiction since the Uruguay Rounds in 1994 is the introduction of intellectual property rules into the multilateral trading system for the first time.<sup>12</sup> *“Ideas and knowledge are an increasingly important part of trade. Most of the value of new medicines and other high technology products lies in the amount of invention, innovation, research, design and testing involved.... It {WTO TRIPS} establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members.”*<sup>13</sup> There is a World Intellectual Property organization (WIPO), a specialized agency under the United Nations, that already existed before WTO. WTO holds that *“In some cases, the standards of protection prescribed were thought inadequate. So, the TRIPS agreement adds a significant number of new or higher standards.”*<sup>14</sup>

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<sup>9</sup> Agreement establishing the World Trade Organization, preamble clause four.

<sup>10</sup> World Trade Organization, *Understanding the WTO*, 3<sup>rd</sup> Edition, previously published as “Trading into the Future”, September 2003. Pg 10.

<sup>11</sup> Id. at 39.

<sup>12</sup> Id at 45

<sup>13</sup> Id at 46

<sup>14</sup> Id. at 46

**Re Dispute Resolution:** Most importantly, and impacting Codex Alimentarius significantly in the long run, is the fact that the WTO is not merely a voluntary standard setting body like Codex, but rather it includes an enforcement component, requiring member countries to abide by the trade agreements and to cooperate with its Understanding on Rules and Procedures Governing the Settlement of Disputes<sup>15</sup>.

For example, this is an explanation by the WTO dispute settlement component off their website:

#### **“1. A unique contribution**

Dispute settlement is the central pillar of the multilateral trading system, and the WTO’s unique contribution to the stability of the global economy. Without a means of settling disputes, the rules-based system would be less effective because the rules could not be enforced. The WTO’s procedure underscores the rule of law, and it makes the trading system more secure and predictable. The system is based on clearly-defined rules, with timetables for completing a case. First rulings are made by a panel and endorsed (or rejected) by the WTO’s full membership. Appeals based on points of law are possible.

However, the point is not to pass judgment. The priority is to settle disputes, through consultations if possible. By May 2003, only about one third of the nearly 300 cases had reached the full panel process. Most of the rest have either been notified as settled “out of court” or remain in a prolonged consultation phase — some since 1995.<sup>16</sup>

See below for a more detailed review of the Understanding on the Dispute Settlement Body.

### **WTO Impacts Codex**

How does the formation of WTO impact CODEX directly?

WTO is made up a group of special agreements, all of which are very important to the implementation of WTO. However, I believe that the three most important agreements for purposes of protecting health freedom directly and immediately in the context of Codex are:

- 1.) The Sanitary and Phytosanitary Measures Agreement (SPS); and
- 2.) The Technical Barriers to Trade Agreement (TBT).
- 3.) The Understanding of Dispute Settlement Body (DSB);

#### **WTO - Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)**

The link is made between CODEX and WTO when WTO refers to Codex as the international standard to be used by WTO members for trading goods.

CODEX is specifically referred to in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). CODEX is named as the international standard to be used by trading members of WTO when applying sanitary measures.

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<sup>15</sup> Agreement establishing the WTO, Annex 2, Understanding on Rules and Procedures Governing the Settlement of Disputes.

<sup>16</sup> World Trade Organization, Understanding the WTO, 3<sup>rd</sup> Edition, previously published as “Trading into the Future”, September 2003. Pg 64

What this potentially could mean in a legal context is that the WTO makes CODEX standards virtually mandatory for member countries of the WTO in the context of sanitary issues in some circumstances. And the enforcement arm of WTO would enforce those measures. Thus, the WTO SPS agreement and the WTO Dispute Settlement Body agreement are important agreements impacting substances covered under the Codex standards.

It important to note that WTO has its own criteria and public policy agendas for Sanitary and Phytosanitary Measures above and beyond Codex (See Below). However, the majority of its members are members of CODEX. When members are participating in CODEX meetings to develop new standards they will be developing the new standards in the midst of economic scrutiny and political agendas because of the enforceability of their trade agreements in the WTO including the SPS agreement.

It is informative to look at the base language of the SPS Agreement to understand the relationship between WTO's attempt to promote international safety standards which would prevent nations from discriminating with each other in the marketplace. The Preamble of the SPS agreement reads:

*“Reaffirming* that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

....

*Desiring* 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 ...”<sup>17</sup>

And for example, referring to international standards, Article 3 of the SPS agreement on Harmonization reads:

“1. 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, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.”<sup>18</sup>

And for example, the definitions describing what is meant by sanitary and phytosanitary measures is very broad in Annex A, Definitions, of the SPS agreement which reads:

“1. *Sanitary or phytosanitary measure* - Any measure applied:

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<sup>17</sup> Agreement establishing the WTO, Annex 1A: Multilateral Agreements on Trade in Goods, Agreement on the Application of Sanitary and Phytosanitary Measures.

<sup>18</sup> Id at SPS, Article 3, Harmonization.

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.<sup>19</sup>

The actual word “harmonization” is defined in the context of this agreement as follows:

“2. *Harmonization* - The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

And the SPS agreements actually lists its enforceable guidelines of choice as follows:

- 3. *International standards, guidelines and recommendations*
  - (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
  - (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
  - (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
  - (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international

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<sup>19</sup> Id at SPS, Annex A, Definitions

organizations open for membership to all Members, as identified by the Committee.<sup>20</sup>

And the application of these guidelines is spelled out in the risk assessment language, laying out just what members must take into consideration when regulating trade.

4. *Risk assessment* - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.<sup>21</sup>

### **Enforcement of SPS Agreement.**

Here is a quote from a document written by the WTO Secretariat, June 2004, regarding disputes that have arisen under the SPS agreement.

“21. As of 2003, four SPS-related issues have been considered by panels. One SPS case concerned food safety regulations – the EC ban on imports of meat treated with growth-promoting hormones, challenged by both the United States and Canada (*Hormones*). Two SPS cases dealt with plant pests and quarantine requirements: a US complaint about Japan’s requirement for testing each variety of fruit for efficacy of treatment against codling moth (*Variety Testing*); and a US complaint about Japan’s set of requirements on apples imported from the United States relating to fire blight (*Fire blight*). One dispute case dealt with diseases of fish, brought by Canada against Australia’s import restriction on fresh, chilled or frozen salmon (*Salmon*).”<sup>22</sup>

Trade concerns are regularly raised in SPS Committee meetings. Since 1995, 27% of the concerns are related to food.<sup>23</sup> Since 2003, eight food safety issues were raised for the first time in the SPS Committee.

They are:

- US concerns on EC restrictions on honey imports due to the non-submission of a residue surveillance plan by the US;
- US concerns on EC food and feed control measures;
- US concerns on Korea’s guidelines for maximum residue level (MRL) testing;
- Argentina’s concerns on EC maximum levels for aflatoxins in corn and sampling of contaminants in food;

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<sup>20</sup> Id at SPS, Annex A, Definitions

<sup>21</sup> Id at SPS, Annex A, Definitions

<sup>22</sup> Codex Alimentarius Commission/27 INF 8, June 2004, Joint FAO/WHO Food Standards Programme, 27<sup>th</sup> Session, International Conference Centre, Geneva (Switzerland), 28 June – 3 July 2004, “Activities of the SPS Committee and Other WTO Activities relevant to Food Safety in 2003 to the Present”, Report by the WTO Secretariat, page 5. Referring to (*Hormones*) footnote 10– The report of the Panels is contained in documents WT/DS26/R/USA/ and WT/DS48/R/CAN. The Appellate Body report is in document WT/DS26/AB/R and WT/DS48/AB/R. and (*Variety Testing*) footnote 11– The report of the Panel is contained in document WT/DS76/R. The Appellate Body report is contained in document WT/DS76/AB/R. and (*Fire blight*) footnote 12 – The report of the Panel is contained in document WT/DS245/R. The Appellate Body report is contained in document WT/DS254/AB/R. and (*Salmon*) footnote 13– The report of the Panels is contained in documents WT/DS18/RW. The Appellate Body report is in document WT/DS18/AB/R.

<sup>23</sup> Id CAC/27/INF 8, page 2.

- China's concerns on EC maximum residue levels in plant and animal products;
- China's concerns on Japan's maximum residue levels (MRLs) for several pesticides;
- Colombia and Papua new Guinea's concerns on Germany's maximum tolerance levels for ocratoxin A in coffee; and
- EC concerns on certain Members' measures on aromatic polycyclic hydrocarbures in pamace olive oil

Issues that were previously raised were discussed again and they include:

- Bolivia's concerns over EC aflatoxin limits for Brazil nuts;
- EC concerns on China's import ban on products of Butch origin;
- US concerns on the EC regulations on genetically modified food and feed;
- US, Canada and Argentina's concerns on EC measures on traceability and label ling of genetically modified organisms and food and feed;
- Argentina, Australia, Bolivia, Brazil, The Gambia, India, Indonesian, Malaysia, Philippines, Senegal, and Thailnad's concerns on EC maximum levels for certain contaminants (aflatoxins) in foodstuffs;
- Brazil's concerns on EC restrictions on the importation of fruit and fruit juices; and
- Canada's concerns on the Philippines' certification n of meat and dairy products<sup>24</sup>

It is apparent from the issues coming up in the SPS agreement that countries are expecting each other to abide by standards that are mutually agreeable to both parties and that the WTO SPS forum provides a place where they can air their concerns. If the concerns are not dealt with in a manner satisfactorily with the parties then they know that they have the Dispute Settlement Body to assist in the matter.

### **WTO - The Agreement on Technical Barriers to Trade (TBT).<sup>25</sup>**

Although the SPS agreement relates to Phytosanity measures and refers to Codex specifically, it is part of a much broader and foundational principle of free trade which is embodied in the TBT agreements.

The TBT, like the SPS, is one of the 13 Multilateral Agreements on Trade in Goods attached in Annex 1A to the establishment of the WTO. TBT tries to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade.<sup>26</sup> The agreement recognizes countries' rights to adopt the standards they consider appropriate and members are not prevented from taking measures necessary to ensure their standards are met. But the WTO publication on Understanding the WTO says, "to prevent too much diversity, the agreement encourages countries to use international standards where these are appropriate, but it does not require them to change their levels of protection as a result." However, on the other hand it also states; "The agreement says the procedures used to decide whether a product conforms with national standards have to be fair and equitable. It discourages any methods that would give domestically produced goods an unfair advantage." What this means will play out as particular cases go to the dispute settlement body.

It appears that TBT embodies principles that prevent nations from unjustifiably creating trade barriers. As you can see, the above statement seems to indicate that "too much diversity" can be a bad thing for trade. Freedom advocates would pose the question, "Can too much diversity be a bad thing?" "What would that look like?" and "Who decides whether a nation is acting out of national pride and protection of

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<sup>24</sup> Id. CAC/27/IN 8, page 2

<sup>25</sup> Agreement establishing the WTO, Annex 1A: Multilateral Agreements on Trade in Goods, Agreement on Technical Barriers to Trade

<sup>26</sup> Id. Understanding the WTO, page 35.

their cultural values as opposed to blocking trade based on their diverse nature?" Once again, we are pointed to the Dispute Settlement Body for resolution as a powerful decision maker in these matters.

TBT has strong harmonization language, mandating the use of international standards, that reads in part as follows:

F. Where international standards exist or their completion is imminent, the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate, for instance, because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems.

G. With a view to harmonizing standards on as wide a basis as possible, the standardizing body shall, in an appropriate way, play a full part, within the limits of its resources, in the preparation by relevant international standardizing bodies of international standards regarding subject matter for which it either has adopted, or expects to adopt, standards. For standardizing bodies within the territory of a Member, participation in a particular international standardization activity shall, whenever possible, take place through one delegation representing all standardizing bodies in the territory that have adopted, or expect to adopt, standards for the subject matter to which the international standardization activity relates." (TBT Annex 3. Code of Good Practice for the Preparation, Adoption and Application of Standards).

The goal of CODEX to encourage the voluntary use of international standards has now come to fruition by the WTO enforcement bodies. Harmonization and preventing technical trade barriers appear to be the language used to accomplish the goal and enforce the provisions.

## **WTO Fundamental Principles**

### **General Most-Favoured-Nation Treatment (MFN)**

#### **National Treatment**

There is the theory that globalization and harmonizing trade standards and rules will strengthen economies and increase trade and make trade patterns more predictable. This premise is widely debated between various economist and trading groups and there are strong camps that believe that this is not true and would eventually destroy the global economy.

Given that the WTO has been adopted, it important to understand its two overarching fundamental principles that describe its way of proceeding in a global economy. Above and beyond the language of the individual SPS and the TBT agreements, these two principles were set forthright from the start in the GATT, GATS, and TRIPS trade agreements. They are: the policy on "Most favored nation treatment" (MFN); and the policy on "national treatment".

### **General Most Favoured Nation Treatment<sup>27</sup> (MFN)**

MFN is the founding principle of the GATT 1947 trade agreement implemented now by the WTO. It also appears in the GATS and the TRIPS agreements. Under all of the WTO agreements, countries cannot normally discriminate between their trading partners.<sup>28</sup> If you grant someone a special favour you have to do the same for others. *“Some exceptions are allowed. For example, countries can set up a free trade agreement that applies only to goods traded within the group —discriminating against goods from outside. Or they can give developing countries special access to their markets. Or a country can raise barriers against products that are considered to be traded unfairly from specific countries. And in services, countries are allowed, in limited circumstances, to discriminate. But the agreements only permit these exceptions under strict conditions. In general, MFN means that every time a country lowers a trade barrier or opens up a market, it has to do so for the same goods or services from all its trading partners — whether rich or poor, weak or strong.”*<sup>29</sup>

The basic MFN is found in Article I of GATT and reads in part as follows:

“...1. With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation, and with respect to all matters referred to in paragraphs 2 and 4 of Article III,\* any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties....”<sup>30</sup>

There are multiple exceptions to this premise listed in the Agreements however this is the basic foundational principle. How this plays out in the context of freedom and diversity once again requires vigilance.

### **National Treatment (Treating foreigners and locals equally)<sup>31</sup>**

The principle of National Treatment has to do with the premise that after an item enters the international market, that imported and locally produced goods should be treated equally.<sup>32</sup>

The basic national treatment language is found in GATT 1947, Article 3 and reads in part as follows:

“...4. The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product.”<sup>33</sup>

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<sup>27</sup> Id. Understanding the WTO, page 12

<sup>28</sup> Id at 12.

<sup>29</sup> Id at 12

<sup>30</sup> GATT 1947, Part I, Article I, 1.

<sup>31</sup> Understanding the WTO, page 12

<sup>32</sup> Id. at 12

<sup>33</sup> GATT 1947, Part I, Article III, 4.

There are multiple exceptions and parameters to follow regarding this principle spelled out in the agreement due to the existence of multiple already existing domestic regulations within countries.

If the United States FDA “harmonized” to use global standards for imports and exports the question still remains, how would United States policy impact Americans?

It is unknown whether the principle of national treatment or MFN or harmonization language will impact United States products made internally. However, it certainly would impact products from other nations. It is unclear how it will impact internal products because in certain places in the agreements it states that nations should use international standards when available. In other parts it says that nothing should stop a nation from using its own standards to regulate as long as they abide by the agreements. In other places it says to treat all nations alike. The questions that will eventually arise as to whether a nation can have a more liberal standard than Codex. Theoretically speaking, harmonization could increase the power of product-based corporations inside and outside of nations in general and could impact world public policy because conventional science and scientific experts at the base of the technology of the products, will be able to count on enforcement of their science, via a global body without due process, and via international standards set by their own parameters. This will most undoubtedly dictate the economics of nations’ trading opportunities on the whole.

### **Harmonization vs. Harmony**

To a health freedom advocate, “harmonization” does not equal “harmony”. From a freedom point of view, harmonization has vast implications of homogeneity, and the loss of diversity, and potentially the loss of freedoms. One of the founding premises of individual freedom and individual autonomy is to use the rule of law and due process to protect diversity as much as possible. The goal in a freedom premise is to create harmony at the same time preserve diversity. The goal of a freedom premise is to leave all in the public domain, free to manifest as they will, allowing individual, groups, individual cultures, and sovereign nations, to flourish in their own way, and to utilize government to step in when government has shown in a particular instance that the lack of government would create an imminent and discernable risk of significant harm to the public. In a free society the burden of proof of intervention is always on the government.

It appears that the international trade agreements take a sweeping stroke and create jurisdiction over all things and then allow particular exemptions. This is exactly the opposite of how the concept of limited government would work to create harmony and preserve diversity.

Because of this sweeping stroke and shifting the burden of proof of harm to the individual, or to individual countries, individual countries are being asked to harmonize first, and act in accord with their own diversity second if the rules allow them to do so.

It is apparent that in the context of trade it appears the general sentiment of the WTO and Codex is that it is good to have rules and order mandating everyone who is trading on the market follow the same standards of trade when possible. However, in the process of creating order it appears that the trade agreements have massively claimed jurisdiction over everything.

The agreements create exemptions to their jurisdictional reach and mandates. However, there is a marked lack of a strong and underlying principle of preserving diversity. There is a strong lack of leaving everything in the public domain, free to trade, as it will, for those products that do not pose an imminent risk of harm to the public.

The trade agreements do not ask what products do we have jurisdiction over? Rather they assume jurisdiction over all products on the market. Although there are sections that allow member nations to have their own national laws that are not to be overturned, the cases of dispute resolution tell another story.

## **WTO Dispute Settlement Body**

### **Due Process**

The Understanding of Dispute Settlement Body (DSB), like the SPS and the TBT, is one of the 13 Multilateral Agreements on Trade in Goods attached in Annex 1A to the establishment of the WTO. A big concern about the WTO agreements in general is the fact that member countries of the agreements have agreed to participate in a legally binding dispute settlement process under the WTO Understanding of Dispute Settlement. Unlike a court of law in the United States where individual parties must be able to have access to a detailed process to protect their individual liberties, the Dispute Settlement Body appears to have a more relaxed set of rules which is more geared towards resolving disputes generally. On a close look the Body wields a mighty power in the process.

For example: The Dispute Settlement Body “shall have the authority to establish panels, adopt panel and Appellate Body reports, maintain surveillance of implementation of rulings and recommendations, and authorize suspension of concessions and other obligations under the covered agreements.”<sup>34</sup>

Most notably, the Body has the power to set up panels to examine the matter referred to the Body, and to make findings of fact that will assist the Dispute Settlement Body in making the recommendations or in giving the rulings about the dispute.<sup>35</sup>

Unlike in the United State judicial system where experts are brought forward by each party of the dispute party’s choice, the DSB relies on experts chosen by the DSB itself from a supposedly dependable lists of experts. Here are some of the parameters that the DSB abides by in selecting a panel to help them decide the case:

“1. Panels shall be composed of well-qualified governmental and/or non-governmental individuals, including persons who have served on or presented a case to a panel, served as a representative of a Member or of a contracting party to GATT 1947 or as a representative to the Council or Committee of any covered agreement or its predecessor agreement, or in the Secretariat, taught or published on international trade law or policy, or served as a senior trade policy official of a Member.

....

3. Citizens of Members whose governments are parties to the dispute or third parties as defined in paragraph 2 Article 10 shall not serve on a panel concerned with the dispute, unless the parties to the dispute agree otherwise

....

4. To assist in the selection of panelists, the Secretariat shall maintain an indicative list of governmental and non-governmental individuals possessing the qualifications outlined in paragraph 1, from which panelists may be drawn as appropriate. That list shall include the roster of non-governmental panelists established on 30 November 1984 (BISD 31S/9), and other rosters and indicative lists established under any of the covered agreements, and shall retain the names of

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<sup>34</sup> Agreement establishing the WTO, Annex 2, Understanding on Rules and Procedures Governing the Settlement of Disputes, Article 2. 1.

<sup>35</sup> Id. at Annex 2, Article 7 1.

persons on those rosters and indicative lists at the time of entry into force of the WTO Agreement. Members may periodically suggest names of governmental and non-governmental individuals for inclusion on the indicative list, providing relevant information on their knowledge of international trade and of the sectors or subject matter of the covered agreements, and those names shall be added to the list upon approval by the DSB. For each of the individuals on the list, the list shall indicate specific areas of experience or expertise of the individuals in the sectors or subject matter of the covered agreements.

...

6. The Secretariat shall propose nominations for the panel to the parties to the dispute. The parties to the dispute shall not oppose nominations except for compelling reasons.

9. Panelists shall serve in their individual capacities and not as government representatives, nor as representatives of any organization. Members shall therefore not give them instructions nor seek to influence them as individuals with regard to matters before a panel....<sup>36</sup>

“The function of panels is to assist the DSB in discharging its responsibilities under this Understanding and the covered agreements. Accordingly, a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements, and make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements. Panels should consult regularly with the parties to the dispute and give them adequate opportunity to develop a mutually satisfactory solution.”<sup>37</sup>

Given that the member nations to the agreement have all agreed to participate in dispute settlement process, Americans would wonder what recourse they would have if they wanted to challenge anything about the agreement themselves? To answer this question it appears that the US Code law that has been adopted to ratify these trade agreements, makes it very clear that no person other than the United States itself can bring a cause of action or defense under any of the trade agreements.<sup>38</sup> It also prohibits persons other than the United States from challenging in any action brought under any provision of law, any action or inaction by any department, agency, or other instrumentality of the United States, any State, or any political subdivision of a State on the ground that such action or inaction is inconsistent with the trade agreements.<sup>39</sup> The law follows up to make a statement about the intent of Congress in passing the trade laws:

It is the intention of the Congress...to occupy the field with respect to any cause of action or defense under or in connection with any of the Uruguay Round Agreements, including by precluding any person other than the United States from bringing any action against any State or political subdivision thereof or raising any defense to the application of State law under or in connection with any of the Uruguay Round Agreements - ...<sup>40</sup>

So, what would happen if a trade dispute actually impacted the liberty interests of the people of the United States. At this point it appears that we would have to rely on the United States government to represent our interests. Given that sometimes the government is not representing all of the views of the people but are representing their governmental public policy agenda, this could lead to a situation of abuse of power in regards to liberty and freedom interests.

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<sup>36</sup> Id. at Annex 2, Article 8, 1-9.

<sup>37</sup> Id at Annex 2, Article 11.

<sup>38</sup> US Code Title 19, Chapter 22, Subchapter I Part A, Section 3512. (c) (1) and (2).

<sup>39</sup> Id at (c) (1) (B).

<sup>40</sup> Id at (c) (2)

### **Specific Case Outcomes**

Although there are thousands of documents to consider when trying to get our minds around the WTO principles, I think it is helpful to review particular dispute resolution outcomes, trusting that the member nations had proper legal counsel to defend the particular issues and explore all of the rules and regulations that might help them in their defense. Here are examples of some of these principles applied and questions to ask for the future.

#### **Case #1: Sea Turtles and Shrimp Imports**

This case is central to the MFN (Most Favoured Nation) principle. Under the US Endangered Species Act of 1973 listed the five species of sea turtles that occur in US waters.<sup>41</sup> Under the act, the US required US shrimp trawlers to use “turtle excluder devices” (TEDS) in their nets. Section 609 of US Public Law 101-102, enacted in 1989, dealing with imports said, among other things, that shrimp harvested with technology that may adversely affect certain sea turtles may not be imported into the US – unless the harvesting nation was certified to have a regulatory programme and an incidental take-rate comparable to that of the US or that the particular fishing environment of the harvesting nation did not pose a threat to sea turtles.<sup>42</sup>

The ruling of the Appellate Dispute Settlement Body made clear that under WTO rules, countries have the right to take trade action to protect the environment. The WTO does not have to “allow” them this right. It also said measures to protect sea turtles would be legitimate under GATT provided certain criteria such as non-discrimination were met.

The U.S. lost the case, not because it sought to protect the environment but because it discriminated between WTO members. It provided countries in the Western hemisphere – mainly the Caribbean- technical and financial assistance and longer transition periods for their fishermen to start using turtle-excluder devices. It did not give the same advantages to the four Asian countries (India, Malaysia, Pakistan and Thailand) that filed the complaint with the WTO.

The good news about this case is that there was much discussion by the panel as to the United State’s right to have environmental laws. The bad news is that we lost the case. It is sad that we could not provide aid to our neighbors to help them comply with our laws without giving aid to everyone of the WTO countries importing shrimp. This put us in a position of not being able to have preferences about how to allocate our resources in this matter.

#### **Case #2: Beef with Hormones**

“22. This was the first formal food safety dispute alleging violation of the SPS Agreement. The United States and Canada brought separate complaints against the EC’s ban on imports of beef from cows treated with hormones for growth-promotion purposes. They claimed that there was no evidence of adverse effects on human health.

23. The panel and Appellate Body ruled that the EC was in violation of the SPS Agreement as its measure was not based on international (Codex) standards and was not justified by a risk

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<sup>41</sup> Understanding the WTO, page 77

<sup>42</sup> Id at 77

assessment. The Appellate Body made it clear that a risk assessment need not be quantitative, and that it could take into account alternative scientific views....”<sup>43</sup>

This case was extremely sad in the sense that it is apparent that the EC had a preference of banning beef containing hormones. Who is to say whether they were worried about the health risks or whether it was a disguised barrier to trade and competition. This is an example of how much effort it will take for countries to state their preferences. And even if they spend their resources to create a lengthy risk assessment, the SDB panel might not agree with their scientific outcome.

The power of the scientific community making a statement that “there was not evidence of adverse effects on human health” reminds me acutely of consumer battles waging in the United States. For example, when the tobacco industry claimed no adverse affects from cigarettes. And most recently the government saying that thimerisol in vaccines does not cause autism in children. If it were not for the power of the court system through legal challenges and class actions, where would we be? The question that has to be asked in this beef hormone case is “what experts were used by the panel in this case and why was not the EC allowed to use the precautionary principle of better safe than sorry.”

### **Case #3: Fire Blight in Apples**

“29. The most recently concluded case was the dispute regarding *Fire blight*. The panel and Appellate body reports in that case were issued during 2003. There was no disagreement between the United States and Japan that fire blight was not currently found in Japan, that the disease did occur in some US apple orchards, and that the disease could cause serious phytosanitary damage. The panel considered Japan’s set of requirements as a whole (which included that the fruit come from disease-free orchards in designated states, inspection of orchards at least three times per year, a 500-meter buffer zone around the orchards, chlorine-treatment of harvested apples, containers and packing facilities, etc.) to be the measure at issue. To determine whether there was sufficient scientific evidence supporting Japan’s measure, the panel considered the evidence both with regard to mature, symptom less apples, which the United States claimed was the product it exported, and with regard to immature or damaged fruit which might inadvertently enter Japan. The panel noted that this was a well-studied plant disease, yet there was not sufficient evidence that fresh apple fruit could serve as a pathway for the spread of fire blight, nor was there convincing evidence that the disease has ever been spread through trade in apples. The Appellate Body upheld the pane’s findings that Japan was maintaining its measure without sufficient scientific evidence. The panel and Appellate Body also relied that Japan could not defend its measure as a provision measure in the context of Article 5.7, because this was not a situation in which the scientific evidence was insufficient.

30. In the *Fire blight* case, the Untied States also challenged the risk assessment provided by Japan. The panel and Appellate Body ruled that Japan had not met the obligations under Article 5.1 to ensure that its measure was based on an appropriate risk assessment, because it had failed to evaluate the likelihood of entry, establishment and spread of the disease from imported apple fruit per se. Furthermore, Japan had not evaluated this likelihood according to the SPS measures which might be applied, but had only considered the risk in light of the measures which is was

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<sup>43</sup> Codex Alimentarius Commission/27 INF 8, June 2004, Joint FAO/WHO Food Standards Programme, 27<sup>th</sup> Session, International Conference Centre, Geneva (Switzerland), 28 June – 3 July 2004, “Activities of the SPS Committee and Other WTO Activities relevant to Food Safety in 2003 to the Present”, Report by the WTO Secretariat. Page 5.

currently applying. The risk assessment standards of the IPPC were taken into consideration in his case.”<sup>44</sup>

In this case to an average person it seems very reasonable, since Japan had no Fire Blight, that they would want to hold the bar really high for anyone coming into the country to preserve its purity. If money were not involved this value of protectionism would have been respected. It is only common sense. In this case the high bar was considered a barrier to trade.

### **New Complaints alleging Violation of the SPS Agreement**

“...31. In 2003, three new dispute settlement panels were established to consider complaints alleging violation of the SPS Agreement. On 29 August 2003, two new panels were established on SPS-related issues. One will examine the complaints by the United States, Canada and Argentina regarding the European Communities measures affecting the approval and marketing of biotech products.”<sup>45</sup>

“...32. Another panel was established to examine complaints by the Philippines against the procedures applied by Australia on imports of fresh fruit and vegetables, including fresh bananas, papaya, and plantains. The Philippines alleges that Australia’s import requirements violate the SPS Agreement because they are not based on an appropriate risk assessment; are not based on scientific principles; are not the least trade restrictive available; do not take into account pest- or disease-free areas; are not based on international standards; discriminate between Members where similar conditions prevail and are applied in a manner which constitutes a disguised restriction on international trade; and result in arbitrary and unjustifiable distinctions in levels of phytosanitary protection...”<sup>46</sup>

“...33. On 7 November 2003, another panel was established at the request of the European Communities to examine Australia’s quarantine regime for imports, including tomatoes, fresh citrus fruit, apples, peaches, nectarines, cucumber, lettuce, carrots, apricots, edible eggs and egg products, uncooked pigment, pig semen, uncooked poultry meat, calf- milk replacer, and organic fertilizer based on chicken manure. According to the European Communities, the requirements on these products are unduly restrictive and breach Australia’s obligations to ensure that its measures are not maintained without sufficient scientific evidence, and are based on appropriate risk assessments...”<sup>47</sup>

### **WTO: A Treaty or a Federal Statute?**

Many persons ask the question: Is the WTO a treaty or is it a United States regular law. The reason they ask this question is that a treaty requires a two-third vote of the Senate, whereas a regular Congressional law requires a majority vote of each House and Senate. At this point, my understanding is that the WTO is not a treaty but rather it is an international agreement that the President submitted to Congress for ratification as a regular federal trade law.

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<sup>44</sup> Id CAC/27/INF 8, at Page 6

<sup>45</sup> Id. CAC/27/INF 8, pg 6, referring to footnote 14 – The requests for the establishment of a panel by the US, Canada and Argentina are found in the documents WT/DS291/23, WT/DS292/17, and WT/DS293/17.

<sup>46</sup> Id CAC/27/INF 8, pg 7, referring to footnote 15 – The request by the Philippines for the establishment of a panel is found in document WT/DS270/5/Rev.1.

<sup>47</sup> Id CAC/27/INF 8, pg 7, referring to footnote 16 – The request by the European Communities for the establishment of a panel is found in document WT/DS287/7.

The United States Constitution gives the President of the United States the power “to make treaties”<sup>48</sup>. However, it is conditional “provided two thirds of the Senators present concur:...”<sup>49</sup> In the history of the United States the majority of treaties were with Native Americans. The treaties were only presented to the Senate for ratification. Once ratified, treaties became the “supreme law of the land” just as federal law passed by both House and Senate became the supreme law of the land. In the mid 1800s the House of Representative members were angry about this practice of only having the Senate make treaties because they had no say in the negotiations of the treaties but after the treaty was ratified by the Senate, the House was expected to pass legislation financing the treaty obligations. Eventually “...the House balked altogether: it refused to appropriate funds to meet new treaty obligations until it was given an equal voice in Indian affairs.”<sup>50</sup> The United States then past a law that stopped the United States from making any more treaties with the Native Americans.<sup>51</sup>

This history gives us some view of public policy regarding treaties and why the WTO agreements were ratified by the United States Congress as trade agreements and encoded into federal law as opposed to being set forth as a treaty, ratified by two-thirds vote of the Senate.

An important note: the word treaty is used internationally in a different manner and is used to describe international agreements.

#### **Adoption of the WTO Agreement in US Code of Law:**

The new trade law begins right up front by commenting on the relationship between the international agreement and existing United States law. Here is how it begins:

“...(a) Relationship of agreements to Unites 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.*** (bold italics added)

\*\*\*So of course, it is imperative for Americans to know what is “**specifically provided for in this Act.**”!

Even if the United States law states that their WTO impact would not be inconsistent with United States law, the reality of this will be a political question because lack of abiding by WTO will impose sanctions on a nation. And the United States will most reasonably work to make United States laws conform to WTO agreement language whenever possible. As new laws are introduced to attempt to conform to WTO this will be a deciding factor.

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<sup>48</sup> United States Constitution, Article II, Section 2., 2004.

<sup>49</sup> Id.

<sup>50</sup> Federal and Indian Law: Cases and Materials, Second Edition, David H. Getches and Charles F. Wilkinson 1986, page 110.

<sup>51</sup> Id. at 110.

The cases that I have described above give some show of how a country's existing laws can be impacted by a trade agreement. The detailed criteria set forth in all of the agreement documents come to bear on how a country's laws will be impacted by a trade agreement.

### **Health Freedom and Trade**

Americans have first hand experience at how trade laws impact their health freedoms. After drug regulation laws within the United States were passed under the FDA, Americans lived under a broad definition of the word "drug" which covered any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and substance intended to affect the structure or any function of the body of man or animal.<sup>52</sup> Drug manufacturers were mandated to fill out an Application for New Drug and prove to the Federal Drug Administration (FDA) that the drug was safe and effective, which generally costs upwards of 2 million dollars. Consumers worked hard for decades to protect access to supplements by introducing various forms of legislation. In 1993, DSHEA was passed, with the understanding that vitamins, minerals, herbs, and many other dietary supplements would not automatically be considered a drug in our country but would rather (for purposes of substances intended to affect the structure or function of the body) be considered food. The attempt with DSHEA was to pull out some products from the definition of a drug. DSHEA could have gone much farther in its approach but it was a beginning in the process of shifting the burden of proof to the government and limiting its authority to take jurisdiction over all substances. The current definition of drug we now have is as follows:

"...(g)(1) The term "Drug" means

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) of this title or sections 403(r)(1)(B) and 403(r)(5)(D) of this title, is made in accordance with the requirements of section 403(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement."<sup>53</sup>

NOTE: In US Code "The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.<sup>54</sup> A key element in the definition of drug, and often times litigated, is paragraph (B) above, whether a substance has an intended use. The statutory definition indicates

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<sup>52</sup> 21 U.S.C. Sec. 321 (g). (before DSHEA)

<sup>53</sup> 21 U.S.C. Sec. 321 (g) 2002

<sup>54</sup> 21 U.S.C. Sec 321 (f) 2002

that “whether a product is a drug depends on its intended application.”<sup>55</sup> It is my hope that this paragraph can also be altered to protect food substances from being categorized as a drug when their intended use is for cure.

An important element of DSHEA is that it embodied the American freedom principle that food substances are “innocent until proven guilty” and it left the burden of proof of showing significant harm to the public on the government before the government could ban any type of substance from the market just because it has health benefits. It also provided an avenue of being able to make health claims in certain circumstances.

DSHEA could go farther by exempting food out of the definition of drug entirely. It is no secret that many food substances are used in the diagnosis, cure, mitigation, treatment, or prevention of disease, for example “grandmother’s chicken soup”, and yet the definition of drug has not been modified in this area. Mostly because of the political and economic forces behind the industry that manufacture and sell products used for treatment of disease. Many health freedom advocates hold that their access to health-related options is a fundamental right under the constitution and that the government should have the burden of proof to show harm before blocking access. Also, that if a regulation is developed, that it be the least restrictive means possible because of the nature of fundamental rights.

Americans cherish their access to substances from nature such as herbs and vitamins and minerals and hold it as our natural right as human beings on the planet. Americans hold that governments cannot block our access to natural substances unless they have a legitimate reason. Trade agreements, and interstate commerce previously were considered good enough reasons to enforce the definition of a drug and the definition was not overturned on constitutional grounds. So, the people of the United States mobilized to make a law to demand that the government take back the burden of proof on dietary supplements and let the access flow. Although DSHEA is a political product, it accomplished an important step in health freedom concepts.

Recently there is a bill in the US Congress trying to shift the burden back on the manufacturers and this bill House bill 722 is being strongly opposed by health freedom advocates.

Health freedom advocates appreciate the government helping to assure that products are what they say they are and that toxic drugs and substances like food contaminants or additives, or genetic modification, do not get on the market that pose a significant risk of harm to the public. But they don’t want the government to be in charge of regulating clean natural food substances, i.e. how much to take, or which ones to eat, or whether some kinds of food supplements are helpful to cure or prevent disease. Efficacy is up to the consumer when it comes to food. Safety concerns should not be equated with efficacy. That, they believe, is the responsibility and the right of the consumer.

## **European Union Food Supplements Directive FSD**

### **An example of burden of proof misplaced**

Last year the EU passed a law<sup>56</sup> that many freedom advocates believe flies in the face of health freedom concepts of limited government jurisdiction. They passed the Food Supplements

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<sup>55</sup> U.S. v. Drugs for Veterinary Use, 50 F. 3d 497 (8<sup>th</sup> Circuit) 1995.

Directive, allegedly to enhance trade between their countries. It mandates that all member countries must allow trading of food supplements (ie. dietary supplements) which consist of prescribed vitamin and mineral nutrients (on a so-called “positive list”) between countries. However, and regrettably, the Directive will also ban all mineral nutrients not on the positive list. Such products will be prohibited from manufacture, marketing and sale in the EU from August 1<sup>st</sup>, 2005.

In other words, an individual country would not be able to ban a product from coming into its country if the product met the new standard. However, it allows countries to ban the rest of all of the food supplements to be traded between countries unless the manufacturers have proven through a government approved dossier that they are safe and effective, similar to the requirement for a dossier that drug manufacturers have to fill out to get approve. These dossiers cost the manufacturer’s large sums of money (estimated at anywhere between £80,000-£250,000 per dossier where significant safety data is not available).

This essentially puts the burden of proof on the manufacturers to prove the safety of age-old nutrients before they are allowed to go to market. This is different than the United State’s approach to dietary supplements where the burden of proof of harm is on the government before a product can be blocked from the marketplace.

The EU FSD also gives the government the role of reviewing the science and deciding what food will be available to consumers based on the science they reference. This dynamic puts the government in charge of what is “good science” and what is “bad science”. For scientists on the cutting edge or with integrative or holistic approaches or with new methodologies not yet considered standard in the industry, this could block these new and innovative products from the market in the name of conventional science, even when the products are from natural sources and labeled truthfully.

This can work the other way as well where holistic health care community and literature may believe that a product produced from a source or in a particular form is not the best choice for human health, however the product is made in the form on the positive list based on modern science and conventional science refuses to acknowledge that there may be a negative impact on health and states that there ‘is no evidence to indicate a negative impact on human health”. In this case, if a consumer wants to avoid such a product based on their own research and information and find another product that is made from a different source such as hickory root source, the consumer cannot because the natural source product will not be on the positive list and will thus not be on the market.

It is interesting to note in the FSD the motivations of the EU for such a law:

(2) Those products are regulated in Member States by differing national rules that may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community

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<sup>56</sup> Official Journal of the European Communities, 12.7.2002, L 183/51, Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

rules on those products marketed as foodstuffs.<sup>57</sup>

However, the anti-competition language is followed by additional reasons, one of which is geared towards consumers:

“(5) In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labeling.”<sup>58</sup>

Consumers are not the ones beating the drums to be protected in their health care choices. Consumers want maximum access to products. Yes, consumers want truth in labeling and they want to know that their supplements are not contaminated and that they are what they say they are. But in terms of which ones are available to them, consumers do not believe that limiting choices is a way to protect them.

It is important to note that the current FSD is just the beginning and that it is set up in two stages. The first stage dealing with regulations for specific vitamins and minerals is spelled out in the FSD. But the current FSD has language in it setting the stage for the future. A second stage is described for dealing with vitamins and minerals, or other substances with a “nutritional or physiological effect” used as ingredients of food supplements as long as adequate and appropriate scientific data about them becomes available.<sup>59</sup> This second stage is going to be even more of a concern for consumers because all consumers know that supplements have a “nutritional and physiological effect”.

Regarding the rationale stated for making a proactive list and having the government add to the list through the dossier process has to do with identifying substances that have not been evaluated by the scientific community and making sure that they are not allowed unless evaluated. As follows:

“(9) Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore, it is appropriate to establish a positive list of those vitamins and minerals.

(10) There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Food and consequently are not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested parties.”

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<sup>57</sup> Id EU FSD, Recital (2).

<sup>58</sup> Id EU FSD, Recital (5).

<sup>59</sup> Id EU FSD, Recitals (7) and (8).

It is important to note that in the EU, food supplements are not drugs. The FSD applies only to food supplements marketed as foodstuffs and presented as such and does not apply to medicinal products as defined by EU law for medicinal products for human use.<sup>60</sup>

In the United States dietary supplements are also considered food. The definition of dietary supplement under the food-labeling act is broader than the EU Food Supplement Directive definition. For example, the United States definition of a “dietary supplement” is in part:

- ...” (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); ....<sup>61</sup>

The EU - FSD definition of “food supplement” is much narrower and only includes the following:

- (a) ‘food supplements’ means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;
- (b) ‘nutrients’ means the following substances:
  - (i) vitamins,
  - (ii) minerals.

The issue of upper safe levels in the EU - FSD is also addressed. It makes a finding that excessive intake of vitamins and minerals may result in adverse effects and therefore necessitates the setting of maximum safe levels for them in food supplements.<sup>62</sup> This is ironic because in the United States, before the Dietary Supplement Act passed, there was much political battling for decades over the setting of maximum levels of supplements. DSHEA has attempted to put a stop to that conversation and has put the burden of proof on the government before mandating maximum levels of food products.

Given that EU manufacturers will be confined eventually to regulations on upper safe levels, the FSD will be setting its safe levels by taking into account “the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those nutrients from the normal diet. Due account should also be taken of reference intake amounts when

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<sup>60</sup> Id EU FSD Article 1, (1). and 2.

<sup>61</sup> 21 U.S.C. Sec. 321 (e) 2002

<sup>62</sup> Id. EU FSD Recital (13)

setting maximum levels.”<sup>63</sup> Once again, the government is the final authority on deciding what is acceptable science.

#### Rules regarding trade in the FSD

The FSD says that member states must ensure that food supplements may be marketed within the EU only if they comply with the rules of the FSD.<sup>64</sup> It deciphers between the actual food supplements themselves and the forms that the products are manufactured in. It clearly states that only vitamins and minerals listed in what is called “Annex I” may be used for the manufacture of food supplements, and only vitamins and minerals manufactured in the forms listed in what is called “Annex II” may be used by manufacturers.<sup>65</sup> The EU FSD makes a finding that the chemical substances that are used for sources of vitamins and minerals should also be pre-approved as safe.<sup>66</sup> It encourages the revision of the list promptly when revising the list.<sup>67</sup>

There is an exception to this for food supplements already on the market:

“6. By way of derogation from paragraph 1 and until 31 December 2009, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:

(a) the substance in question is used in one or more food supplements marketed in the Community on the date of entry into force of this Directive,

(b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 12 July 2005.”

The FSD allows countries that already have bans in place to continue to ban products that are not on these lists or within these exceptions.<sup>68</sup>

The labeling of the new FSD food supplements must not attribute to food supplements the property of preventing, treating, or curing a human disease, or refer to such properties.<sup>69</sup> Nor shall it include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrient in general.<sup>70</sup>

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<sup>63</sup> Id. EU FSD Recital (14)

<sup>64</sup> Id. EU FSD Article 3

<sup>65</sup> Id. EU FSD Article 4.

<sup>66</sup> Id. EU FSD Recital (11)

<sup>67</sup> Id. EU FSD Recital (12)

<sup>68</sup> Id. EU FSD Article 4 (7).

<sup>69</sup> Id. EU FSD Article 6 (2).

<sup>70</sup> Id. EU FSD Article 7.

Members countries will not be allowed for reasons related to their composition, manufacturing specifications, presentation or labeling, prohibit or restrict trade in products that comply with the FSD.<sup>71</sup>

In summary, as it stands today, the European Union FSD is in effect and the dates of going into effect are: they will “permit” trade starting August 1, 2003. they will “prohibit trade” in product which do not comply with the FSD by August 1, 2005.

### **EU FSD Impact on Health Freedom**

This law passed in the EU amidst millions of signatures of consumers opposing it.

However, manufacturing associations and companies are split in terms of their thinking about the EU Directive. Some sources say not to worry, all is well. Some manufacturers are not worried because they are large enough to prepare complex dossiers and be in the larger economic business of the approval process. Other manufacturers are smaller and although they are committed to having good manufacturing standards and truthful labeling, the economics of submitting dossiers will force them to eliminate products. Some consumer activists are of the thinking that the manufacturers that have products on the positive list of substances, have a financial interest in having the list as it stands, while smaller companies who have smaller markets and more innovative products but with less overhead for developing dossiers and also less funds to lobby have lost out.

Of course, the final loss is on the doorstep of consumers who have just lost access to hundreds of products that have not had acceptable dossiers presented to the government. Products that have truthful labeling. Natural products that consumers believe they should have the right to be able to evaluate regarding health risk and efficacy as long as there is no fraud and there is truthful labeling. Products that are generally considered safe and that they already love and depend on in Europe.<sup>72</sup>

The following (see Figure 1 below) is an example of some of nutrients in popular food supplements that David Hinde, attorney from the Alliance for Natural Health in the United Kingdom, believes will be legal under the new FSD and some of the nutrients that might well be illegal in Europe in response to the Food Supplements Directive. This is spelled out in an Alliance for Natural Health power point presentation:<sup>73</sup>.

These examples are based on the lists set forth in the EU directive.<sup>74</sup> As you can see, there are forms in the legal list that many holistic consumers avoid because of health concerns.

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<sup>71</sup> Id EU FSD Article 11.

<sup>72</sup> See for example the Alliance for Natural Health website at [www.alliance-natural-health.org](http://www.alliance-natural-health.org).

<sup>73</sup> Alliance for Natural Health, *Safeguarding the Leading Edge*, 2004, by David Hinde, Solicitor, and Robert Verkerk, PhD. 2004. Slide information used with permission.

<sup>74</sup> Id. at slide 34.

LEGAL	ILLEGAL
<p><u>Minerals:</u> Calcium 175 mg, phosphorus 125 mg, iodine 0.15 mg, iron 10 mg, magnesium 100 mg, copper 2 mg.</p> <p><u>Nonmedicinal ingredients:</u> Ascorbyl palmitate, BHT, crospovidone, FD&amp;C Yellow #6, gelatin, hydrolyzed protein, lactose, magnesium stearate, mineral oil, peanut oil, polysorbate 80, silicon dioxide, sodium aluminum silicate, sodium ascorbate, sodium benzoate, sodium citrate, sodium lauryl sulfate, sorbic acid, stearic acid, sucrose, titanium dioxide and triethyl citrate.</p>	<p>Calcium mg 500,* Magnesium mg 250,* Potassium mg 99,* Iron mg 9,* Zinc mg 20,* Manganese mg 6,* Chromium mcg 120,* Selenium mcg 50,* Molybdenum mcg 100*</p> <p>* These minerals are all in the following form: Phytavail complex – proprietary mixture of soluble minerals of vegetable origin, aminoates, aspartates, citrates, ascorbates, lysinates, methioniates, trace minerals and fructooligosaccharides (extracted from Dahlia inula tuber and Chicory root)</p>

**Figure 1.**

Moving on to the larger global conversations, including the discussions at WTO and Codex. There is some fear that the political arenas in other global arenas such as CODEX are supporting the shifting of the burden of proof onto manufacturers of natural products similar to the EU. To health freedom activists, this means that companies with the most money in combination with governmental politics will be dictating what consumers have access to. This has caused a ground swell of consumer activists to begin studying the situation and preparing to challenge this trend.

Specifically, in the EU, two organizations are going forward to challenge the Food Supplements Directive: 1.) The Alliance for Natural Health’s challenge to the FSD, and 2.) the challenge to the FSD by the National Association of Health Stores (NAHS) in combination with the Health Food Manufacturer’s Association (HFMA).

NHFC has reviewed the grounds for the ANH challenge and will be reviewing the grounds for the NAHF/HFMA challenge in the near future.

It is the opinion of NHFC that the challenge being mounted by the Alliance for Natural Health is one of the most effective things happening on the globe regarding health freedom, consumer access, and personal liberties. ANH has been successful in obtaining a reference to the European Court of Justice in Brussels<sup>75</sup> and health freedom advocates from around the world are supporting

<sup>75</sup> [www.alliance-natural-health.org](http://www.alliance-natural-health.org)

them and watching their websites for outcomes. (ANH has now filed its European Court legal brief and this can be found on the *Documents* section of their website.)<sup>76</sup>

We believe that ANH truly understands the deep injustice and negative impact on health freedom that has been created in forming an exclusive positive list in the FSD. ANH displays strong consumer advocacy, understanding that we are all naturally human and have a right to the earth and all of its natural substances and nutrients. And that governments should have the burden of proof of showing danger before it steps into the arena of blocking access to Mother Nature and products that individuals deem beneficial for existence.

NHFC is encouraging everyone to support these efforts and hope that the higher court in the EU returns food supplements back into the public domain. (See Alliance for Natural Health at: [www.alliance-natural-health.org](http://www.alliance-natural-health.org).)<sup>77</sup>

### **CODEX and Health Freedom**

Finally, we arrive at Codex. The reason for this memorandum.

Remember that Codex international trade standards will provide the standards for member nations of the WTO agreements.

The work of Codex is done by consensus whenever possible although it is possible to call for a vote if efforts to reach consensus have failed.<sup>78</sup> The Codex Alimentarius Commission works through individual Committees hosted by member countries. The Committee works to draft international standards and get their approval by the full Codex Commission. There are Eight Steps a Committee must go through in order to get final approval of a standard. Many of the steps requiring coming back to the full Commission to get approval and adoption of the draft standards before moving to the next step. The final approval will be given when the full Commission by consensus, approves the Step Eight draft. It is important to note that in certain circumstances there is an expedited Five Step process available as well.

There are many committees in Codex that affect health freedom on many levels: The Committee on Food Labeling hosted by Canada covers among other things topics such as Nutrition and Health Claims; the Committee on Nutrition and Foods for Special Dietary Uses hosted by Germany covers among other things draft guidelines for Vitamin and Mineral Supplements and draft guidelines for Infant formula; the Committee on General Principles, The Committee on Food Additives and Contaminants, and many others cover a broad range of topics.

Most recently a new Task Force on Foods derived from Biotechnology has been formed and Japan will be the host country. It will be called the Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology and the final report should be submitted to the Codex Commission in 2009.<sup>79</sup>

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<sup>76</sup> [www.alliance-natural-health.org](http://www.alliance-natural-health.org)

<sup>77</sup> [www.alliance-natural-health.org](http://www.alliance-natural-health.org).

<sup>78</sup> Codex Alimentarius Commission, Procedural manual, Thirteenth edition, ISSN 1020-8070, 2003, Page 16.

<sup>79</sup> ALINORN 04/27/41, June 2004, Draft Report of the 27<sup>th</sup> Session of the Codex Alimentarius Commission, Geneva, Switzerland, paragraph 83. and 84.

Health freedom advocates have most especially been watching the work of the Committee on Food Supplements for Dietary Use. It is currently drafting trade standards for Food Supplements. That Committee is in the final steps of attempting to get standards approved for Dietary Use products. Just recently, in June 2004, their draft standards were approved at Step 5 by the Codex Commission.<sup>80</sup> They will now proceed to work on the steps towards final approval.

Some NGO's observing at the Codex meetings recently came away from the June 2004 meeting and the adoption of the Step 5 Standards for Vitamins and Mineral Supplements as "claiming a victory for health freedom." They explained that the draft standards had rejected the idea of using RDA levels for maximum levels of nutrients in supplements and rather the Codex Commission adopted the more progressive and liberal draft standards that would allow setting maximum levels of nutrients in supplements based on "risk assessment". (Here you can refer back to the SPS agreement on risk assessment issues and issues relating to expert scientific experts in dispute settlements)

Have we already arrived at many organizations seeing as a given the right of governments to have jurisdiction over all products and the right of the government to make regulations about what products go on the market and putting the burden of proving no harm on the manufacturers? Do organizations ever consider that the burden of proof should be on the government and that products that are not contaminated or adulterated should be allowed on the market and that governments should be responsible for doing "risk assessments" on those products they believe pose a risk to society.

The very sad thing about this is that seldom in trade meetings is there a discussion about the loss experienced by the consumers of health care products and the violation of freedoms in a society that was deprived of the concept of free peoples with limited government in matters of health.

In the case of the current standards for vitamins and minerals, the third option should have been discussed above and beyond RDAs and risk assessments by manufacturers. It would look something like this: no maximum limits for any natural products that say truthfully what they are, and where they are from, and contain what they say they contain, and not considered by evidence from the government to pose an imminent risk of harm to society.

There is a clear difference between a consumer advocacy organization and an organization that leans towards representing the interests of regulators and large manufacturers. There are many corporations that believe that deleting trade barriers and having the government being in charge of screening natural products for the consumer are honorable motives. But consumers are wanting to take back responsibility for what they purchase and use the government to assure truthful labeling and recourse for fraud and contaminants.

Many committees have drafts in progress that are impacting health freedom and it would be too consuming to go through them all in this memo. So, I will focus on one set of standards. The Draft Guidelines from the Committee on Nutrition and Food Used for Dietary Use were adopted by the Codex meeting in June 2004 in Geneva Switzerland and will proceed to committee

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<sup>80</sup> ALINORM 04/27/41, June 2004, Draft Report of the 27<sup>th</sup> Session of the Codex Alimentarius Commission, Geneva, Switzerland.

meetings in Bohn Germany in November 2004 to work towards final Step Eight adoption. The draft guidelines are below as follows:<sup>81</sup>

*ALINORM 04/27/26 page 44*

**APPENDIX IV  
PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL FOOD  
SUPPLEMENTS**

**(Adopted at Step 5 of the Procedure)**

**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 supplements serve to supplement the daily diet.**

**1. SCOPE**

**1.1 These guidelines apply to vitamin and mineral supplements intended for use in supplementing the daily diet with vitamins and/or minerals. Food supplements containing vitamins and/or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in these Guidelines.**

**1.2. These Guidelines do apply in those jurisdictions where products defined in 2.1 are regulated as foods.**

**1.3 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 these Guidelines.**

**2. DEFINITIONS**

**2.1 Vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet [They are designed to be taken as measured small unit quantities].**

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<sup>81</sup> ALINORM 04/27/26 page 44, 27<sup>th</sup> Commission, Geneva 2004.

### **3. COMPOSITION**

#### **3.1 Selection of vitamins and minerals**

**3.1.1 Vitamin and mineral supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognized by FAO and WHO.**

**3.1.2 The sources of vitamins and minerals may be from either [natural or synthetic sources] and should be based on consideration such as safety 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, and national legislation may be used.**

**3.1.3 Vitamin and mineral supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1, a single vitamin and/or mineral 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 supplement per daily portion of consumption as suggested by the manufacturer should be 15% of the recommended daily intake as determined by FAO/WHO.**

**3.2.2 Maximum amounts of vitamins and minerals in vitamin and mineral 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 minerals 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 should be taken to the reference intake values of vitamins and minerals for the population.]**

### **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 such substance used as packaging material, that standard shall apply.**

## **5. LABELLING**

**5.1 Vitamin and mineral supplements are labeled according to the Codex Standard for the Labelling of Prepackaged Foods (Codex-Stan 1-1985, Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979). 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.**

**5.4 The amounts of the vitamin and minerals declared should be those per portion of the product as recommended for daily consumption on the labeling [and if different, the amount per single use].**

**5.5 Information on vitamins and minerals should also be expressed as a percentage of the nutrient reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labeling.]**

**5.6 The label must indicate the recommendations on how to take the product (quantity, frequency, special conditions).**

**5.7 The label shall contain advice to the consumer 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 reach of young children.**

## CONCLUSION

When peoples make laws for their own people that are within their own community, there is a better sense as to what principles to apply that will benefit the community because the discussion can take place on a local level.

As laws are made globally which affect our daily lives in direct ways, specifically affecting our food sources, our nutrient access, and our idea of what we need for our own health care, peoples of all nations are called to rise to the occasion of becoming educated and forming educated opinions on how their country or nation should proceed, for the good of their own country, for the good of the world neighbors, and for the longevity of the global community.

Trade negotiations are affecting our fundamental right to manage our own health care in the way that we see fit.

United States people have enjoyed access to natural substances without a list of maximum limits. United States people use dietary supplements for their health. It is not a secret. It is not a secret in the United States that the people use food and dietary supplements for cure and detoxification purposes. That is why they know that DSHEA has to be improved and expanded for them. Our markets are flourishing and consumers are very active participants in their health care choices. People in the United States are protective of our laws which protect their access to these products.

It is possible that United States agency policy is not as happy about the Dietary Supplement Act in the US as the people are, and that they are not promoting the limited government concept of health freedom in the global arena. This is always a potential problem as the government represents the American people at trade negotiation tables. For that reason, the people have to also show up at global forums and hold the government accountable for policies, which they are promoting on their behalf.

NHFC does not support the prohibition of trade of any natural health care product that has not been shown to pose a risk of significant harm to the public. Of course, we support clean water, food, air, product trade that is not contaminated or adulterated, truth in labeling (we would not support regulations that would infringe freedom of speech on labeling or inhibit the right to say what is truthful.). NHFC does not support government dictating which natural substances and in what quantities they can be accessible to consumers as set forth in the EU Food Supplements Directive and we want to help our European colleagues in their campaign to prevent its negative aspects from taking effect.

Regarding Codex, the draft standards of Vitamins and Minerals for Dietary Use that Codex Alimentarius has promoted thus far have not been written with a view to limited government jurisdiction over food products that are generally regarded as safe and that are used for health reasons. For this reason, we believe there is a need to work to stop the Codex standards, until they are revised and reflect health freedom for consumers and a freer market.