

UNDERSTANDING CODEX ALIMENTARIUS and ITS IMPACT ON HEALTH FREEDOM

(A SUMMARY OF A FULL TEXT PAPER – by Diane M. Miller JD, Legal and Public Policy Director)

Why are Americans concerned about global CODEX standards? US citizens want to protect their access to all health care products including dietary supplements. They have heard that their access is being impacted by national and international commerce and trade laws. The question to many Americans is whether global trade standards such as CODEX, or world and regional trade agreements such as WTO and FTAA, are putting these freedoms at risk. Given the breadth and complexity of global and regional trade agreements and the presence of corporate entities that are unlimited in their wealth, power, and ability to be at every negotiating table, Americans are wondering whether they need to take action to protect their freedom and independent choices. The following will provide background to guide Americans as they make plans to take actions in this area of health freedom.

What is CODEX? CODEX is a group of 170 country member nations that voluntarily set up international safety standards and rules about the trading of food products (which they have decided includes food supplements like Vitamins and Minerals). CODEX originated in 1911 with no legal force as a collection of standards and product descriptions for a wide variety of foods and used as a reference to determine standards of identity for specific foods. In 1963 the World Health Assembly of WHO (of the United Nations) approved the establishment of the Joint FAO/WHO Food Standards Programme and adopted CODEX. . FAO is governed by 188 member countries and WHO has 192 countries.

What is the World Trade Organization (WTO)? WTO is the organization that implements the major global trading agreements. The main agreements are on the trading of goods (GATT 1947 and GATT 1994), on the trading of services (GATS), and on the introduction of intellectual property (TRIPS). The WTO is made up of 146 countries, many of whom are also members of the Codex Commission.

How are CODEX and WTO enforced? CODEX has always been a voluntary standard setting forum not related to WTO and with no enforcement component. WTO is not 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.

How does WTO Impact CODEX? Recently, the voluntary nature of CODEX standards has been impacted by the establishment of the World Trade Organization (WTO). The link was made when WTO referred to Codex as the international standard to be used by WTO members for trading goods. What this potentially could mean is that the WTO makes CODEX standards virtually mandatory for member countries of the WTO in some circumstances. And the enforcement arm of WTO would enforce those measures.

Special Note: Although the WTO mentions CODEX specifically, I believe that an in depth analysis of all of the documents of the WTO in their entirety is needed to explore the possibility of whether there may be a substantive argument, asserting that the CODEX standard should not be exclusively applicable and that other standard with proper assessment may be used by traders. To my knowledge there has not been an opinion rendered on this specific question.

What Parts of WTO are especially important to health freedom? WTO is very large and is made up of many special agreements, three of which are especially important to health freedom. They are: The Sanitary and Phytosanitary Measures Agreement (SPS); The Technical Barriers to Trade Agreement (TBT); and The Understanding of Dispute Settlement Body (DSB).

How does the WTO-SPS agreement Impact CODEX? The language of the Sanitary and Phytosanitary Measures (SPS) agreement has potential for impacting health care products trade for many reasons including: It's very broad definition of "sanitary and phytosanitary measures" which notably includes methods of risk assessment; its' definition of "harmonization" which includes the establishment of common measures; its' reference directly to CODEX in its' International Standards, Guidelines and Recommendations; and its' definition of "risk assessments" which includes evaluations according to the sanitary or phytosanitary measures.

Enforcement of SPS Agreement. Trade concerns are regularly raised in SPS Committee meetings. Since 1995, 27% of the concerns are related to food. Since 2003, eight food safety issues were raised for the first time. As of 2003, four SPS-related issues have been considered by dispute resolution panels. One SPS case concerned food safety regulations – the EC ban on imports of meat treated with growth-promoting hormones, challenged and won by both the United States and Canada (Hormones).

How does the Agreement on Technical Barriers to Trade (TBT) impact CODEX? 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. 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.

Fundamental WTO Policies of MFN and National Treatment may impact trade: Above and beyond the language of the individual SPS and the TBT agreements, the two principles set forthright from the start in the GATT, GATS, and TRIPS trade agreements are: the policy on "Most favored nation treatment"(MFN); and the policy on "national treatment".

General Most Favoured Nation Treatment (MFN). Under all of the WTO agreements, countries cannot normally discriminate between their trading partners. If you grant someone a special favour you have to do the same for others. The basic MFN is found in Article I of GATT National Treatment (Treating foreigners and locals equally) 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. The basic national treatment language is found in GATT 1947, Article 3.

What impact do WTO fundamental policies have on American products? It is unknown whether the principle of national treatment or MFN or harmonization language will impact United States products sold internally. However it would impact imported and exported products. It is unclear how it will impact internal products because in certain places in the agreement language 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 is whether nations can have more liberal standards 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.

What is the difference between Harmonization and Harmony? To a health freedom advocate, "harmonization" does not equal "harmony". Harmonization has vast implications of homogeneity, and the loss of diversity, and potentially the loss of freedoms, in this case freedom of access to desired products. 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. In a free society the burden of proof of intervention is always on the government.

Does the WTO provide adequate Due Process to protect product access? 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 that is 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. 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. 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.

How will the fact that the US adopted WTO into US law impact trade? US law now states that WTO will not impact US law unless "specifically provided for" in the new trade law Act. This makes it very important to read and understand the new US trade law! Even if the United States law states in part that WTO impact would not be inconsistent with United States law, the reality and long term dependability of this will be a political question as well as a legal question because the lack of abiding by WTO could result in the imposition of trade sanctions on a nation. To avoid trade sanctions the United States will most reasonably work to make United States laws conform to WTO agreement language whenever possible. As new laws are introduced in the US attempting to conform to WTO this will be a political discussion and a deciding factor as to votes.

Do Americans have recourse under the WTO? 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. 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.

Will other trade agreements such as FTAA impact health care product trade? There are many who say that in concept similar restrictions on trade will arise out of FTAA as have arisen out of WTO. Also, that the making of multiple smaller trade agreements may be even more onerous than the WTO because of less visibility and less public scrutiny in the making. These trade agreements should be carefully reviewed for any negative impact they might pose on access to health care products.

How have Americans experienced trade law impacting health freedom in the past? Americans have first hand experience at health freedom impacts. 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. 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. 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.

What do Health Freedom Advocates expect from the US government? 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 engineered food additives, or genetic modification, do not get on the market that by their nature 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 and food supplements. They also do not expect Safety concerns to be equated with efficacy. Efficacy is up to the consumer when it comes to food.

Why is the new European Union Food Supplements Directive FSD a threat to health freedom? Last year the EU passed a law, the Food Supplements 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 1st, 2005. 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.

Under the new law 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).

Most notably, the government will be the final authority on deciding what is acceptable science. 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 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.

Why are their mixed opinions about the threat of the EU FSD? The new 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. The reason for this in theory is that some manufacturers are large enough to prepare complex dossiers and be active in the larger economic business of the approval process eventually giving them a predictable market even if with less variety of product. 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 EU 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. What impact could the EU FSD have on future CODEX? There is some fear that in global arenas such as CODEX there is a desire to shift 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.

Can the EU Food Supplements Directive be successfully challenged? Specifically in the EU, two organizations are going forward to challenge the Food Supplements Directive with very good initial responses from the courts: 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. The challenge being mounted by the Alliance for Natural

Health is considered by many to be 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 and health freedom advocates from around the world are supporting 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.) NHFA has encouraged 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.)

CODEX has a process and it is moving forward: The Codex Alimentarius Commission works through individual Committees hosted by member countries. 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. The Committee works to draft international standards and get their approval by the full annual Codex Commission. There are Eight Steps a Committee must go through in order to get final approval of a standard. Many of the steps require 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.

CODEX Committees affecting health freedom are: The Committee on Food Labeling hosted by Canada; the Committee on Nutrition and Foods for Special Dietary Uses hosted by Germany; the Committee on General Principles, The Committee on Food Additives and Contaminants, and many others. Most recently a new Task Force on Foods derived from Biotechnology has been formed hosted by Japan. 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. Health freedom advocates have especially been watching the work of the Committee on Food Supplements for Dietary Use as they are drafting trade standards for Food Supplements and are in the final steps of attempting to get standards approved for Dietary Use products. In June 2004, their draft standards were approved at Step 5 by the full Codex Commission. They are now proceeding to work on further steps and hope to achieve Step 8 agreement at their next Committee meeting in Bohn Germany on November 3, 2004, and then take it to the full Commission for final approval next Spring 2005.

Health freedom advocates oppose the current CODEX language: Health freedom advocates oppose the language of the standards being promoted in the CODEX committees on Foods for special Dietary Uses and the for Labeling because they do not reflect the legal concepts of the US DSHEA. Advocates are requesting and demanding that in the case of the current CODEX standards for vitamins and minerals, a third option of no mandatory upper limits should be discussed above and beyond the concepts of RDAs and risk assessments by manufacturers. Especially for GRAS substances and ingredients where there is truthful labeling and no adulteration CODEX governments should be adopting DSHEA type burden of proof regulations.

Some Corporations and NGO's need to reconsider their understanding: Some NGO's observing at the Codex meetings in Geneva in June 2004 came away from the 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". Of course the US would not ever agree to mandated RDA maximum levels. But "mandated risk assessments" also do not reflect DSHEA. There are more options than the "RDA" and "mandatory risk assessment".

The quick response to supporting mandatory risk assessment indicates a dangerous trend of understanding in the supplement industry. It shows that some manufacturers have already given up the fundamental principles of DSHEA and have arrived at thinking that it is a given that the government has a right to have jurisdiction over all products and the right to make regulations about what products go on the market including establishing maximum upper limits based on risk assessment and putting the burden of proving no harm on the manufacturers. Corporations, manufacturers and organizations should be reminded that the burden of proof should be on the government whenever reasonably possible and that natural food 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.

November 2004 CODEX Committee in Bohn: Draft Guidelines from the Committee on Nutrition and Food Used for Dietary Use will proceed to committee meetings in Bohn Germany in November 2004 and the Committee wishes to move the standards to Step Eight. Health freedom advocates are demanding that these guidelines be sent back to Step 3 and be required to consider US concepts of DSHEA.

International Relationships with other nations are very important to health freedom: CODEX Committees and the full Commission are made up of member nations. These member nations often have never been introduced to the concept of regulations similar to DSHEA. Often they tend to regulate healthful products as drugs. In order for global awareness to increase, these nations must be introduced and educated about American concepts of health freedom and DSHEA This knowledge will provide them the opportunity to join the US in their concerns about the restrictive CODEX language. And it will provide all nations the opportunity to adopt policies and regulations that allow for the maximum access to health care products thus preserving a free society and good global health policy.

US health freedom workers are now beginning to send their letters to all international member nation CODEX delegates.

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 global 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. Commerce seems to be taking precedence over human rights.

Americans value 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.