The Summer of Our Discontent

How the Codex Commission lost its rulebook and the European Court of Justice found its own.

by Scott Tips

Board Member and Legal Counsel for NHF
September 2005

"Hell, there are no rules here—we're trying to accomplish something." - Thomas Edison.

The Codex Alimentarius Commission: By now, you will have heard the news: The Codex Alimentarius Commission, meeting in Rome, Italy on the 4th of July, approved the *Codex Guidelines on Vitamin and Mineral Food Supplements*. Among the hundreds present, only one lone voice argued against adoption—mine.

Not that there weren't sympathetic supporters present, they just could not speak out. Many others who shared my opinion had journeyed even farther than I to swelter in the unusually hot Roman sun, rub elbows with an army of anti-supplement bureaucrats, eat bland cafeteria food, and see what they could do to stop the juggernaut from crushing health freedom.

I attended this 28th session of the Codex Alimentarius Commission as the head of the National Health Federation (*www.thenhf.com*) observer delegation, as usual the only pro-health-freedom organization able to speak out at these meetings. With me were a number of marvelous health-freedom fighters such as NHF Vice Chairman Paul Anthony Taylor, who was second-in-charge of our delegation, Tamara Thérèsa Mosegaard of MayDay, Sepp Hasslberger of La Leva, and Dr. Carolyn Dean of Friends of Freedom and also an NHF Board of Governors member. In turn, we were supported by others such as Friends of Freedom International's Trueman Tuck and Peter Helgason, the Coalition for Natural Health Freedom's Diane Miller, the Dr. Rath Foundation's Kathy Perry, and Citizens for Health's Jim Turner, who were in attendance either as public observers or members of country delegations but who had no public voice at Codex. All contributed, though, and deserve recognition for their contributions.

We basically hit the ground running that first morning because we knew that the draft Guidelines for Vitamin and Mineral Food Supplements, spat out of the Bonn Committee last November, was going to be up for approval no later than the end of the first day of the meeting, July 4. Our group divided up assignments and we quickly lobbied various country delegations that we thought would be favorable to our view that the *Vitamin and Mineral Food Supplement Guidelines* should not be approved but should be sent back to the Bonn Committee for redrafting. I personally spoke with a number of country delegate heads, whom I shall not name here because this process is still ongoing, and received sympathetic responses. Others in

our group got similar responses.

Delegates to the Codex Alimentarius Commission meet in Rome, Italy in July 2005.

Australia Gets Strong-Armed First

But before we could finish, the meeting was quickly called to order by Commission Chairman Dr. Stuart Slorach and he got down to business. The first item that was of interest to the NHF was Agenda Item 4 involving a request by the delegation of Australia that certain language be left in the Codex Procedural Manual. At the last April committee meeting in Paris, the Codex Committee on General Principles, the Australians had surprisingly sought to save some language embedded in a vast amount of text that the Codex people had wanted to strike out about acceptance and rejection procedures that countries could undertake to either accept or reject Codex standards. Within that text was wording stating that, essentially, Codex standards are “not a substitute for or an alternative to national legislation.” Australia wanted to retain that language in order to protect its drug regime governing vitamins and minerals. For completely opposite reasons, the NHF strongly supported Australia’s position in order to clarify that Codex standards are not superior to national standards and thus help protect the Dietary Supplement Health and Education Act (DSHEA) in the United States.

Unfortunately, at the April committee meeting in Paris, the chairman decided that this hot potato could be passed upward for consideration at the Commission level. Well, that day arrived very quickly on Monday, July 4, and the chairman decided that the entire deletion—including the wording that Australia and the NHF had sought to save—should be approved, but then the chairman threw a scraggly bone to Australia by telling it that it could still raise that issue at next year’s Paris committee meeting. Lucky Australia.

That's how they handle opposition at Codex meetings—at least one way they handle it. It's like an egg on the floor; you push it around until it disappears. The Paris committee had pushed this issue over opposition—as approved with everything deleted—up to the Commission level. The Commission then approved all deletions (again over opposition) and pushed it back down to the committee for further discussion by Australia, *if* it chooses to do so. But if Australia does choose to tackle this issue again, then the Paris committee chairman could probably argue that the Commission has already approved the entire deletion. Health freedom loses, just as it did this July, with barely a whimper and a rollover from the Australian delegate. "*Nice boy, here's your bone*," I almost expected to hear the Chairman say.

When I was finally recognized to speak at the end (by mistake I later learned), I raised some delegates' eyebrows when I supported the original Australian delegation position but said that I was disappointed that Australia had chosen to "cave in" on this issue. Evidently, non-governmental observer delegations, such as the NHF, are supposed to show "proper respect" for government employees. Funny, I always thought they worked for us and should show *us* respect. The Commission broke for lunch as I mulled this over.

The FAO Headquarters in Rome, Italy where the Codex meeting was held.

Then Consumers Get Bludgeoned

With the delegates sleepy from their nutrient-poor, pasta-rich meals, the Chairman began with Agenda Item 5, which was to consider a long list of many Codex guidelines up for approval by the Commission. It was obvious to all that the Chairman was hell-bent for leather to get every single one of those guidelines approved by the Commission, and in record time. He *very*

quickly ran down the list, just as if he were literally going through a grocery list—a quick look at the item, an equally quick mention of it, and then a quick look up-and-around to make sure no one dared slow him down before he announced "approved!" A staccato rhythm of approval was quickly set.

When the Chairman reached the draft *Guidelines for Vitamin and Mineral Food Supplements*, the momentum slowed for just a moment as he dealt with some last-minute wording revisions sought by Australia, Venezuela, and China. The first two countries' revisions were ruled technical, while China's was determined by the Chairman to be substantive. The last ruling was important because under Codex procedural rules if a change sought by a country is substantive, then the guideline cannot be approved and *must* be sent back to its committee for re-review.

But sitting in the German delegation to this meeting was Dr. Rolf Grossklaus, the chairman of the Bonn Codex committee, who reminded the Swedish Chairman of how wonderful these *Guidelines* were. He spoke at length and directly to the Chairman, as if they had discussed this all before and he, unworried, were merely going through the motions.

Then, the Colombian delegate tried to speak and, after a technical problem with his microphone was resolved, was able to blurt out his message: vitamins are dangerous and should be stopped! Obviously he had never read Mark Twain's admonishment, "*It is better to keep your mouth shut and appear stupid than open it and remove all doubt*."

After these countries were heard, the Chairman recognized me to speak out on the issue. Unfortunately, I was the sole voice *against* adoption of the draft *Guidelines* by the Commission. Arguing that they were defective and must be sent back to Committee, I gave three main reasons: (1) According to Codex's own Procedural Manual, guidelines must state a purpose for those guidelines in the Preface and the draft *Guidelines for Vitamin-and-Mineral Food Supplements* do not contain a purpose; (2) The *Guidelines* fail to define what vitamins and minerals are covered by the *Guidelines* since they refer to a nonexistent FAO/WHO list of approved vitamins and minerals and therefore it is unclear as to what would actually be covered by the *Guidelines*; and (3) The comments made by China, and the changes sought by China to the *Guidelines*, were substantive and according to the Codex Rules of Procedure as stated on page 27 of the Manual of Procedure, any substantive amendment *must* be sent back to the Committee and dealt with at the committee level.

After I spoke, during which time the Chairman never even once looked at me, none of the countries that we had expected to support our position did so, and there was nothing but silence from the floor. Then, the International Alliance of Dietary/Food Supplement Assocations (IADSA) observer delegate was recognized to speak. He argued in favor of the adoption of the *Guidelines* because, believe it or not, the committee had spent 10 "long" years working on them; so—in his view—they had to be approved no

matter how defective they were. Had he been alive when the debate was ongoing about whether to end torture and the Spanish Inquisition in 1834, I suppose he would have argued against its abolition because of the 350 *long* years it had been operating.

Well, regardless, he got his wish because the Chairman ignored the blatant procedural defects, and with all of the countries silent on this issue, the Chairman simply acted in a very arbitrary manner. He brushed aside the substantive nature of the Chinese-requested changes, completely failed to address the issue of those defects, and decided on his own and by fiat that the *Guidelines* were adopted.

Curiously enough, throughout the rest of the week, neither the Chairman nor the FAO Secretariat later showed the least bit of inhibition in quoting from the Procedural Manual when it was in *their* interests to do so. The Chairman, who has since been replaced by a new person elected during this meeting, and the Secretariat must have lost their copies of the Manual and with it, their sense of justice. In 1943, U.S. Supreme Court Justice Felix Frankfurter noted in a court decision that the "*history of liberty has largely been the history of observance of procedural safeguards*." When the Chairman and the Secretariat lost their rulebook that afternoon, they let procedural safeguards slip away and with it freedom. The next time an issue like this arises, it will be even easier for them to forget procedural safeguards because habits will have been built upon habits. And, accustomed to that, no country delegate will object—just as none did here.

So, what is next? Come this Thanksgiving week, the *Guidelines* will be back before the Codex Committee in Bonn, Germany so that some of the blank spaces in it can start to be filled in—particularly applying the nutrient risk-assessment analysis that was agreed to two years ago to establish the maximum upper limits for vitamins and minerals. The NHF will be there again, this time with scientific advisers, to influence the debate.

As Sepp Hasslberger, a long-time Codex observer, has recently noted, "there is talk about 'risk assessment' but the name of the game is to *not* allow any supplements that would be useful over and above the 'food-physiological' handling of deficiencies." The Germans will dig in and seek to restrict vitamin-and-mineral potencies to no more than three times the RDA, if even that.

The challenge here will be to apply the more libertarian American model of risk assessment rather than the restrictive European model that is stridently anti-supplement. In that way, hope still exists for sanity. But the European stranglehold upon Codex is viciously tight. That must and will be changed.

"*Show me a thoroughly satisfied man and I will show you a failure*." – Thomas Edison

The European Court of Justice: The European Union's food-and-drug bureaucrats have consistently striven, and so far successfully, to make the

Codex Guidelines for Vitamin and Mineral Food Supplements match—virtually word for word—their own Food Supplements Directive.

In other words, Europe will soon be locked down tight with the Food Supplements Directive so that almost nothing that is useful in the form of vitamins or minerals will be legally sold within Europe. (Of course, a huge black market, unstoppable by the EU bureaucrats, will arise almost immediately.) Then, with the Codex *Guidelines* matching closely the Food Supplements Directive, they will prevent any lawful sales *into* Europe of the high-value, low-cost, usually superior American dietary supplements because that international trade, at the very least, will be prevented by the Codex *Guidelines* and its enforcement mechanism, the World Trade Organization.

The only thing that was standing in the European regulators' domestic path was the pan-European Alliance for Natural Health's excellently-managed lawsuit that was launched a few years ago against the Directive, with the aim of taking the case to the European equivalent of the Supreme Court, the European Court of Justice. The ANH, and its fellow litigants, were successful in January 2004 in getting the London court to refer the case to the higher court - the European Court of Justice (ECJ) in Luxembourg.

I attended the hearing before the ECJ on the ANH's court case, which was held on January 26, 2005. (See "My Luxembourg Morning," **WholeFoods** Magazine, June 2005, Page 46.) At that hearing, the EU and certain supporting countries' legal counsel were a sad lot presenting even sadder arguments. Perhaps I am biased, but, in contrast, the ANH's attorney, Paul Lasok QC, did an outstanding job with his arguments. The ECJ even seemed somewhat sympathetic to ANH's case, as revealed by its hard questions asked of ANH's opponents. This view was supported by the Advocate General's preliminary and non-binding opinion, handed down last April 5, wherein he found the Directive invalid.

Then, with the Codex Commission showdown over the *Codex Guidelines* looming large on the horizon, most of us were expecting the ECJ decision to conform, as it usually does, to the Advocate General's preliminary opinion. Expectations were high for a favorable decision, set to be announced just after the Codex Commission finished its early July meeting in Rome.

On July 12, the ECJ finally handed down its written decision and everyone, myself included, rushed to read the bottom line. Initially disappointing, the Court's decision failed to adopt the Advocate General's preliminary opinion and instead upheld the validity of the Directive. Years of hard work went seemingly unrewarded, except for one small comment made by the Court, almost offhandedly and in passing, earlier in the text. And then another … and then yet another.

Piecing them together, it became increasingly clear that the Court had *not* handed the regulators and their fellow travelers the victory that they were

trumpeting. While the ECJ did not, in my opinion, make new law, it did state more clearly and precisely existing law. And that existing law is *not* favorable to the EU regulators, who have been misapplying the law for years. That is about to end for the following reasons:

The Directive distinguishes between vitamins and minerals used in food supplements that are manufactured from "chemical substances" and all other ingredients in food supplements that come from natural sources in foods. In making that distinction, the Court clearly states that those vitamins and minerals normally found in foods are not covered by the Directive or its ban. (Decision ¶ 63)

- In those instances where it is necessary to apply to be on the positive list of permitted vitamins and minerals, the process will now be a much simpler, less time-consuming, and less-expensive undertaking than before. (Decision ¶¶ 72-91)

- The burden of proof (and hence the greater part of the expense) for showing a food-supplement ingredient to be unsafe lies with the regulator and not the manufacturer. That ingredient cannot be refused unless and until the regulator proves it unsafe by undertaking a full risk/safety assessment based upon "the most reliable scientific data available and the most recent results of international research." (Decision ¶ 73, cited cases)

- All of which in turn means that most vitamin-and-mineral food supplements on the markets in the EU will not have been banned come August 1, especially if they are outside the purview of the Directive because of being "naturally sourced."

Because, prior to this decision, the Directive has been vague and thus subject to bureaucratic interpretive whim, supplement manufacturers followed the *regulators'* view of how supplements should gain access to the positive list of vitamins and minerals that may be lawfully sold in Europe. That meant that both parties assumed that the manufacturer had to shoulder the burden of proof of safety and would have to spend, in many cases, more than £250,000 per supplement ingredient on a complex dossier submission to the food authorities. For natural, unpatented food products, such costs would be prohibitively expensive, especially for those companies with 30 or more ingredients to list.

Thanks now to the Alliance for Natural Health and its fellow plaintiffs, and thanks to a Court that follows procedure, that appears to no longer be necessary. Since the Court has ruled technically that the Directive only applies to those supplements manufactured from chemically derived substances and since the burden of proving safety has been clearly placed upon the regulators' shoulders within a system that must be more transparent, the dreaded death-grip of the Directive has been greatly reduced. That, then, would constitute a victory for ANH and the rest of us, even if the Directive was not struck down in its entirety.

However, it remains to be seen if the European Commission and some of

the European governments will choose to interpret the ECJ's ruling accurately. They may decide to play by their own rules, in the hope that neither the ANH nor any other party will risk going back to court for a further challenge. One of the ironies in this is that it is quite likely that different countries will choose to make different interpretations of the ruling, thus upsetting the ideal of a level playing field that this harmonizing Directive was promising to offer.

In fact, as Dr. Robert Verkerk, Executive Director of the ANH, has commented, we should also be consoled in some ways that the Directive was *not* invalidated by the Court, probably largely as a result of a face-saving exercise on the part of the Court, that is, as a means of protecting the European institutions such as the European Commission and the European Food Safety Authority. Had the Directive been invalidated, then the ANH and a rash of competing interests would have had to lobby the European Commission and the Council of Ministers, made up of Health Ministers from the 25 European governments, and an amended proposal would then eventually be agreed upon. This would then be put before the European Parliament. If whatever emerged from the end of this complicated European law-making sausage machine had an effect that was similar to the ruling given now by the ECJ, then the ANH and many pro-health-freedom interests would have been quite happy. This ruling has avoided the need for this—the process has been fast-tracked, and the European Commission has not been embarrassed. Some would call this a win-win.

Dr. Verkerk has also noticed that the Court's placement of the burden of proving safety upon the regulators, and not manufacturers, suggests a similarity between the European Directive and America's DSHEA. This is an interesting concept and one to be explored further.

In the meantime, even with the Court's clarification of the Food Supplements Directive, many questions remain—such as, determining exactly the composition of the simplified procedures for getting ingredients onto the "positive list" and whether different European countries will accept those derogations that have been applied for in a different country than their own. So, too, those regulators who wish to preserve their view of the Directive will challenge the plaintiffs' interpretation of the Court ruling, almost certainly insisting that they may proceed as they planned. There will be further fights as the Directive's limits are defined and the regulators attempt to impose their interpretations instead.

But, rather than be unhappy that the structure of the Directive was not brought down by this decision, we should be satisfied—but not thoroughly satisfied—that the Court had the wisdom to rein in the regulators. Those who hate and fear food supplements are rejoicing, seeing only the edifice of the Directive, which the Court has left standing. Overlooked, though, in their blind joy, is the bomb that the Court has exploded inside the structure, gutting it, and taking away half its backside. The dust is still settling.