Codex Gets One Step Closer To Control

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Category: Codex
Published: January 2002

For us Southerners, Berlin in November 2001 was dark and cold. The bitterly cold wind off the Spree River blew through the city and sent leaves and pedestrians alike scattering across the pavement for cover. And at this time of year, and at this high a latitude, the sun sets early. By 4:00 p.m., the sun has disappeared over the horizon and the big department stores are lit up like traffic accidents. But the coldest and darkest place of all was in the meeting hall of the German Federal Institute for Health Protection of Consumers and Veterinary Medicine building where the Codex Alimentarius Commission was holding its week-long session.

As I arrived on the drab-gray morning of the first day of the Twenty-Third Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, I was confronted by virtually the same anti-Codex demonstrators as had been outside the building during last year's meeting. With festive blue-and-white party balloons adorning the nearby tree and the demonstrators' huge banner blowing in the wind like a sail, anti-Codex media crews shoved cameras in my face seeking any words of wisdom that I might have about Codex. One member of the group filled my arms with a huge spiral-bound anti-Codex petition. I decided to get even with him, so I gave him a copy of my previous Whole Foods article on last year's Codex meeting. He smiled bravely, poor thing, clutching my article as I left him to walk past the guards and enter the building.

The Issues At Stake.

Thanks once again to the National Health Federation, which paid my expenses, I was there as a second-time member of the U.S. delegation to Codex. The issues are important: International vitamin-and-mineral regulations are being slowly but surely established that will determine not only what vitamins and minerals you can take but in what amounts and at what levels as well. A rapidly shrinking number of our own industry members are still pretending that U.S. domestic legislation will protect us from these harsh international standards; but, as I (and others) have pointed out before, the danger is a gradually encroaching one if not an immediate one that will eventually overwhelm American protections against such madness. If you boil frogs, you gradually turn up the heat so that they do not sense the danger and try to escape. In this case, we are the frogs and the heat is being gradually increased every year.

The Codex Meeting.

Once inside the building, I scooped up the Codex meeting documents that had been placed on the tables near the entrance, grabbed a quick bite to eat from the free-food counter, and moved on into the meeting hall where the other delegation members were taking their seats. There were a few new faces, but it was a meeting much like the

previous one in June 2000.
The important discussions picked up where they had last left off and focused on the international "guidelines" that were to be established for vitamin-and-mineral dietary supplements. The Codex chairman, a German named Dr. Rolf Grossklaus, kept insisting that these standards under discussion were only "guidelines" and "not standards," implying if not actually stating that no one need therefore be overly concerned. Guidelines are of course voluntary, but because of World Trade Organization ("WTO") membership obligations prohibiting its members from engaging in unfair trade practices, member countries may be sued and heavily fined if their trade practices do not conform to adopted international standards. We have already witnessed at least one instance where the United States Congress was forced to rescind domestic American law governing international business corporations because of a WTO dictate. So, far from being "guidelines" as we might think of them, once adopted, these guidelines will have a very real bite and they will restrict vitamin and mineral potencies at ridiculously low levels.

The irony is that these rules will only have a bite on those countries where citizens already have the relative freedom to buy and consume those vitamins and minerals they want and at effective levels. Countries that have already classified vitamins and minerals as drugs, such as Germany, are exempt from these Codex rules. They do not have to change a single law, rule, or regulation. Only those countries that classify their vitamins and minerals as foods will be affected. It is a rigged game, from the outset. And it stinks.

Minimum Levels For Vitamins and Minerals.

As I sat there in my fold-down seat in the meeting hall and read the Codex guidelines and heard the various government delegates speak, I was struck by the incredible ignorance on parade. Many of the countries such as Canada and Australia had sensibly enough written in their discussion papers that there should be no lower limits on vitamins and minerals unless claims of potency were being made, but when it came time to speak up against lower limits, no one really did. Dr. Elizabeth Yetley, the U.S. delegate, was especially passive and quiet, even though I had just given her arguments against lower limits in our pre-meeting before the general session.

The discussions very quickly degenerated into simply a question of establishing the minimum levels for vitamins and minerals, not considering whether they should be set at all. Not a single one of the government delegates had the moral fiber to argue strongly against the imposition of a minimum level, even those who had opposed them in writing. So, the Codex rule is being established that no vitamin or mineral supplement may contain less than 15% of the Reference Daily Intake (RDI). Countries such as India want the minimum level to be 33%, while others such as Norway and Cuba want the minimum to be 25%.

Besides the obvious moral problem of prohibiting people from freely and voluntarily contracting with one another as they wish, the practical problem with minimum levels is that they foreclose manufacturers from adding something useful

(such as a vitamin or mineral) in a capsule or tablet instead of something worthless, like a filler or excipient. In my view, it would be better for a person to get some additional nutritive value from a capsule or tablet, than nothing at all. I pointed this out to Dr. Yetley, while another U.S. delegate thoughtfully added the argument that special formulations exist that would in the future be prohibited because they could no longer include sub-minimum levels of vitamins and minerals. To my mind, the higher those levels are set (e.g., at 33% as India wants), then the more the consumer will be hurt. If countries are concerned about wild health claims being made for low potency vitamin supplements, then there are other ways to address that concern. As the Canadian delegate argued on paper (but not in the discussions unfortunately), you can simply restrict wild claims from being made. In fact, establishing minimum levels comes from the same mind set that would prohibit everyone from driving on public roads in order to stop accidents and save lives. The intention might be laudable, but the implementation of that goal is irrational, if not outright stupid.

Maximum Levels For Vitamins and Minerals.

In setting maximum levels for vitamins and minerals, the Codex meeting saw the real "fight." But, again, it was never a fight between those forces arguing against implementing maximum levels and those forces arguing in favor of such limits. Once more, it was the typical control-oriented, bureaucratic mind set that saw the two sides only arguing over how the maximum levels would be set. Like Hitler and Stalin battling it out with each other, the issue of freedom of choice never was even considered; it is simply a question of which dictatorial rules you will be forced to live under.

The debate, then, was between the RDI (or RDA)-based group and the "nutrient appropriate risk assessment" group. The RDA-group (primarily Third World countries) wants upper (and lower) permissible levels set at a percent of the RDA, while the second group (such as the U.S.) wants the upper limit to be based upon "science-based risk assessment considerations, as determined by appropriate risk analysis methodology."

The Council for Responsible Nutrition ("CRN") was in attendance as a non-governmental organization and argued both in a written position paper and at the meeting itself against the RDA-group's position. As CRN correctly pointed out, if safety is the issue, then the RDA is the wrong standard to apply because the RDA was never defined to address safety and none of the data that was used to establish RDAs is even pertinent to safety issues. CRN's position paper zeroed in on the defects in the RDA-group's position when it said, "RDA-based limits are arbitrary and not related to safety, and thus carry the potential to be harmfully restrictive. With the progress in nutrition research, any assumption that the RDA represents safety is, in effect, imposing limits based on current knowledge of the benefits related to higher intakes nutrients [sic]. Calcium, folic acid, and vitamins C and E are examples of nutrients with higher needs recently recognized by increased RDA from the U.S. National Academy of Sciences."

However, despite its insightful skewering of the RDA approach, CRN is a grand cheerleader for the second, alternative approach that would set upper-potency limits

based upon scientific analysis. While this approach based upon "science-based, risk assessment" methods is more rational and is certainly preferable to the simplistic RDA-based approach, it is still fatally flawed because (once again leaving the moral and ethical considerations to one side) any upper limits would be set in stone, or at least hard-to-change clay, that could never keep up with the rapidly accumulating knowledge on nutrition. By their very nature, government rules and regulations can never change quickly enough to keep up with advances in human knowledge. In the meantime, countless thousands of people will suffer, even die, because they cannot have access to those health products that the latest advances could bring them.

The other fatal flaw in the "science-based, risk assessment" method is that it is probable that the upper limits would be based upon faulty data. I have heard that the director of one of the major scientific institutions processing this type of data has admitted that her facility did not have enough funds to collect and process the data correctly. So, the old expression, "garbage in, garbage out" still applies. As we should all know by now, just because something is dressed up in fancy and impressive scientific clothes does not make it so. Scientific data, like anything else, can be manipulated, ignored, suppressed, or even out-and-out wrong.

Moreover, the "science-based, risk assessment" method addresses the wrong question anyway. With almost all vitamins and most minerals there is no toxicity issue at even the high doses many Americans consume. In court, I would have no problem defending vitamins and minerals by comparing their death toll to that caused by prescription and OTC drugs. As even CRN admitted, "Many vitamins and some minerals are so nontoxic that setting safety limits would be an idle gesture." So, why with the impressive safety record of dietary supplements must we spend so much time, money, and effort establishing "safety" limits? I guess these countries just have money to burn, or certain other industries want to restrict the competition.

In this sense, the "science-based, risk assessment" method, once implemented, could greatly increase the cost of your vitamins and minerals because they will essentially have to be safety-tested. I myself have made it through those thirty-plus years of my life that I have taken vitamins without having been poisoned by them and I am willing to take that chance for another thirty or more years. But under this scheme, I would be protected from myself by the Codex dictates; but at a cost that would come at a steep price. If new drug approval expenses are any indication, the costs for this unnecessary increase in safety would be enormous. And only large companies could afford to compete.

Approved Vitamins and Minerals Only.

One of the more insidious Codex provisions states that "Vitamin and mineral supplements shall contain vitamins/provitamins and minerals in conjunction with the relevant Codex standards whose nutritional value for human beings has been proven by scientific data." All of my previous points concerning the flaws of upper and lower potency limits for vitamins and minerals apply equally to this attempt to restrict the sale of vitamins and minerals to only those approved by Codex. There is no need to repeat

those points here. Just bear in mind the disgusting fact that there was no opposition to this provision. Even though such a provision clearly violates American dietary-supplement law, the U.S. delegate sat through this provision's discussion and approval as if she were listening to last year's farming statistics. I have seen more excitement out of comatose patients.

Final Analysis.

At last year's meeting, there was at least an argument that Codex might be salvageable in some way. Unfortunately, this year's meeting was the definitive nail in the coffin. Upper and lower limits have been approved, it is just a question as to where to set those limits. The "approved" vitamins-and-minerals concept is solidly in place. It is all downhill from here because no one ever takes a firm position in favor of freedom of choice. Everyone, including Dr. Yetley, is content to not rock the boat and let matters take their natural course. Despite my flurry of protest notes and suggestions to Dr. Yetley throughout the course of the Codex meeting, unlike last year, nothing positive resulted from my efforts.

I think that Dr. Yetley and the FDA truly believe that it is worth sacrificing freedom of choice so long as the "science-based, risk assessment" method is implemented. But as Robert De Niro quipped to Dustin Hoffman in the movie "Wag The Dog" after he had convinced the CIA agents to free and not kill him, "they are nice enough people, they just hadn't thought it through." They do not see that they are giving up everything in exchange for nothing, a chimera that will disappear and leave us all with nothing but chains.

So what to do? For those various countries that are already predisposed to freedom of choice, strong delegates must be put in place who will dig in their heels and reverse the erosion. Your voices must be directed to your representatives and the government, as well as the FDA, expressing your disgust with the FDA delegate's approach and telling them, in no uncertain terms, that if the United States (or your other country's) position in Codex does not change immediately, then the United States (or other country) should withdraw from the process and those ties that bind us to the process. "Harmonization" is no more worth the heavy price that will be exacted in this decade than appeasement was worth the cost in the 1930s. The sooner we realize that, the better off we will be.