TIPS & ASSOCIATES
ATTORNEYS AT LAW

807 Montgomery Street
San Francisco, CA 94133 USA
415-296-7003

138

August 22, 2002

BY E-MAIL & FAX TO (202) 720-3157
Dr. Elizabeth Yetley
U.S. Codex Office
Room 4863, South Building
Washington, D.C. 20250-3700

02-022N
02-022N-138
Scott C. Tips

#364.00

Re: Comments on CCNFSDU CL2000/22 - NFSDU

Dear Dr. Yetley:

On behalf of the National Health Federation, the nation's oldest nonprofit organization dedicated to ensuring consumers rights to freedom of choice in food, dietary-supplement and medical matters, we respectfully submit the following comments on the draft guidelines of the Codex Committee on Nutrition and Foods for Special Dietary Uses, due August 23, 2002:/[1]

1. "Positive Lists" for Vitamins & Minerals: While superficially attractive, "positive lists" of "approved" vitamins and minerals, are counterproductive, obsolete before they can even be implemented, and illegal under United States law. Therefore, you have *nu choice* but to strenuously oppose *any* and all implementation of "positive lists" within *the* Codex Committee system.

a. Counterproductive. The so-called "positive lists" are counterproductive because they will mislead consumers and governmental bodies into thinking that only those vitamins and minerals appearing on the list *are* safe and acceptable./* Eventually, if *not* more immediately, such a list will become the basis of law that only those Vitamins and minerals appearing on this list will be allowed to be lawfully sold.

---

* The draft guidelines of interest to *the* NHF are addressed by us on *the* basis *of the* proposed mechanisms *for* their implementation.

[2] Even though *such* a list may not be *intended* to be dispositive as to whether or not a vitamin or mineral is important enough to be included *in* one's diet, it will be viewed as such. Consider, *far* example, the analogous reference work published by R.R. Bowker, *Books In Print*. That work is intended to list only those books known to still be in print. If a book is not listed in *Books In Print*, it may still be in print; but consumers nevertheless consider that any books not appearing in the publication are *"out* of print."

Many vitamins and minerals, or other associated nutrients and co-factors, especially those yet *to* be fully investigated or even discovered, will not appear on this list because the committee process (particularly the *international* committee process) will be slow, arduous, and subject to arbitrary dispute by those countries with, frankly, political agendas and/or insufficient sophistication in food matters to support their inclusion. Vitamins and minerals that might otherwise help people nutritionally wilt be omitted from the list, either forever or for sufficiently long periods of time so as to negatively impact consumers' health.

b. Obsolete Before Publication. Because of the slow process mentioned above in implementing and then publicizing such a list, the current accelerating pace of advances in knowledge of clinical nutrition will make such a list obsolete before it is even fixed and published. Therefore, such a list wilt be not only counterproductive but backward. It will be the same spirit as mandating gas-lighting standards during the time that electrical lighting was being introduced. Knowledge is not static and what we know today about clinical nutrition is far beyond the knowledge *we* possessed even in 1985, slightly more than fifteen years ago. And in 15 years' time, today's knowledge on the subject will appear equally quaint.

For this reason, as both a practical matter and a philosophical approach, the free market, not agency edict, is the best mechanism here for maximizing the health of the public.

c. Illegal. The Dietary Supplement Health and Education Act of *1994* ("DSHEA") as well as the anti-harmonization provisions *of* the FDA Modernization Act of *1997* prohibit positive lists of approved vitamins and minerals. Vitamins and minerals are not "approved" as are drugs; rather, they exist and, except for newly discovered vitamins, they can be freely sold within the United States as dietary supplements provided that they are appropriately labeled and make no disease claims. The publication and use of a positive list of vitamins and minerals would be inconsistent with American law *in* this regard by its creation of a two-tier system of "approved" vitamins and minerals and "non-approved" vitamins and minerals.

Furthermore, the anti-harmonization provisions of *the* FDA Modernization Act of *1997* prohibit the Food and Drug Administration *from* engaging in any action that would subvert DSHEA and/or other existing American law. Agreeing and committing the United States government to such a list would accordingly violate U.S. law.

2. "Negative Lists" far Vitamfns & Minerals: Not even superficially attractive, the so-called "negative lists" for prohibited vitamins and minerals have all of the problems mentioned for positive lists. They *are* counterproductive, obsolete before they can even be implemented, and illegal under United States law. Moreover, negative lists would especially invite abuse, since they would proscnie certain vitamins and minerals, perhaps at certain levels, based upon data that is in dispute. Indeed, even the Food and Drug Administration has yet to define far the *Pearson v. Shalala* Court the term "substantial scientific agreement."

3. Upper & Lower Potency Limits for Vitamins & Minerals: Subsumed within the positive and negative lists are presumed upper and lower limits for vitamins and minerals. Such limits would suffer from all of the above-mentioned problems and illegalities. It would be exactly the same as bureaucratically prescribing the techniques for manufacturing early airplanes from the 1910s; knowledge advances but the rules governing such prior knowledge, being less elastic, retard the progress of knowledge and, hence, society in general.

Most importantly, United States law flatly prohibits the Secretary from imposing maximum limits on the potency *of* safe vitamins and minerals. (See the "Proxmire" Amendment of 1976, Pub. L. No. *94-278,* §501, *90* Stat. 410.) Read in juxtaposition with the FDA Modernization Act *of* 1997, this Amendment completely prevents you from agreeing *to* any maximum limits on vitamin-and-mineral potency, no matter how well meaning or based your intentions might be. You have no choice but to reject upper limits.

Moreover, the practical problem with upper limits is self-evident. First of all, if they are based on common European misconceptions, then they will be far to low to be efficacious in any genuine respect. We rather suspect that that is the true intent. Assuming the best, however, that is, that the motives are sincere, then the concept of upper limits on vitamins and minerals is still greatly misguided because they will be based upon RDIs that were created to avoid *deficiencies* in those particular vitamins and minerals *in general populations*, not with *the* goal of maximizing health in individuals. Those are two very different goals.

Lower limits for vitamins 'sound" as if they might be a valid concept, but when you consider the effect, you will also realize that, however well-intentioned, the effect will be equally counterproductive. Consider multivitamincapsules or tablets that, of course, only have a finite amount of capacity available for filling. If a lower limit has been set, but inadequate space remains in which one may fill that *space* with a particular vitamin or mineral, then the manufacturer must omit that ingredient and substitute a useless filler or excipient instead. The result: the consumer will have lost out on receiving at least some of an important nutrient. Under the philosophy that something is better than nothing, the argument is made here that the consumer will have suffered a lass. It would be indefensible for you to say that you arc "protecting" the consumers' health by causing manufacturers' to omit healthful ingredients from their products. Rather, if a genuine concern exists about consumers being misled by their intake amount of a particular vitamin or mineral, then the level can be clearly and adequately disclosed on *the* product label. That is a situation that already exists and is already addressed with current label laws and regulations.

4. National Authorities Determination of Whether Vitamins & Minerals Mav be Treated as "Foods" of "Drugs" (Agenda Item 5): The proposed draft guidelines make it clear that most of the Europeans would like vitamin and mineral supplements *to* be tightly regulated and not to be sold in a free and open market. Therefore, right out of the chute, the draft guidelines are heavily biased to the restrictive European viewpoint: if a country's *laws* treat

vitamin and mineral supplements as drugs, then the Codex guidelines would not apply to those supplements since the Codex guidelines are intended only for *food.* Therefore, the precious European national laws making drugs out of natural vitamins and minerals would not be touched. The only touchable laws would be those *food and dietary supplement* laws *(such* as in the U.S.) that treat vitamins and minerals with actual concern for consumer freedom of choice. The playing field has thus been *ipso facto* unfairly defined.

5. Substances Must Prove Their Nutritive Value for Humans Before They Can Be Acceptable (Agenda Item 5): *The* National Health Federation absolutely opposes any provision that would revise the Composition section of the Proposed Draft Guidelines for Vitamin and Mineral Supplements to indicate that substances would only be acceptable *if* scientific data had proven their nutritive value for human beings and if criteria such as safety and bioavailability were considered in their selection. *Such a provision would be absolutely insane!* The National Health Federation cannot even believe that anyone would be so ignorant as to propose such a provision.

If someone must first prove the "value" *of* a substance to humans before it can even be used, then the currently feeble knowledge of humans and incomplete understanding of dietary substances will prevent many useful and important nutritional substances from being available to nourish us until human knowledge catches up with reality. And that may never *occur.* Moreover, once again we must decide upon what constitutes "value" and how *that* term is defined. This whole area *is* a veritable minefield of disasters. You not only should, but you *must,* fight against any such limiting provision. To do otherwise is to betray your duty to Americans to protect their health.

6. General Comments About Nutrient-Content Claims (Agenda Item 10): The National Health Federation's position is that all dietary supplements, including vitamins and minerals, should be permitted to have labels and labeling that advise consumers of truthful and nonmisleading information about the product.

We know that the official U.S. position has been to push for limits and lists based upon "science-based risk assessment" methods. The question, though, is upon whose "science" will this science-based risk-assessment be based? One of the risks in adopting such science-based risk assessment standards is that they will not be fair and objective, but will instead be used to create artificial barriers that will only restrict freedom of choice. *And compliance* with those standards could be equally difficult if lengthy, expensive, drug-like tests, trials, and clinical studies must first bc conducted before the standards are established and implemented. Either way, United States law will be broken if dietary supplements are required to comply with standards different than *those* already set forth in DSHEA.

While there is merit to the claim that the Europeans would be better off with vitamin-and-mineral potencies based upon a sciencebased risk assessment standard rather than their cur-

rent, completely arbitrary standard, the Food and Drug Administration's first priority is not to convert foreign agencies to American practices but rather to safeguard American health based upon American law.

7. Conclusion: These comments are relatively general in nature and intended as an overview of the Federation's positions on the subject. Nevertheless, the U.S. position absolutely must be one that stresses the importance of consumer choice and access to vitamin and mineral supplements.

Furthermore, you are bound by United States law to reject any lists or limits on vitamins and minerals or other dietary supplements. You cannot commit the United States to being a party to any agreement or protocol that would foist such dietary restrictions upon the United States. I have been disappointed that during the last Codex meeting in Berlin in Novembver 2001, none of the comments or suggestions that I made to you concerning the above were considered or implemented. Rather, the United States delegate's approach was to compromise away our rights and, in doing so, to violate American law. The United States' delegate must re-think its Codex position and follow American law.

Sincerely yours,

Scott C. Tips