[The following report was initially posted online and shared around the world in 2003. AHHA's CCNFSDU reports and the special AHHA Codex website were deactivated many years ago.]

Report from Suzan Walter, president of American Holistic Health Association, on her attendance at the November 3-7, 2003, session of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in Bonn, Germany.

A decade of polarized debate quietly came to an end on November 3, 2003. A major decision impacting international trade of nutritional supplements was made to use upper safe limits as the maximum allowed levels for vitamin and mineral food supplements. It was decided that sound scientific research using proper risk assessment protocols will establish at what point a nutrient becomes toxic or harmful. To protect the consumer, vitamin and mineral food supplement products are to be restricted to stay below this upper safe limit.

The alternative option would have set these maximum levels at a significantly lower level of 100% of the recommended daily amounts (RDA). Delegates who were against this option envisioned a future with supplement products restricted to very low levels of potency. We can breathe easier that this option was defeated.

Why should you care? Because this decision was made by the Codex Alimentarius, a body charged with drafting international trade standards for foods. These standards are used by the World Trade Organization (WTO) in settling trade disputes between countries. If a country should lose an international dispute, the WTO can use powerful economic trade sanctions to pressure a country to change its laws and actions. If you are a consumer of vitamin and mineral supplements, we encourage you to be vigilant for any potential threat from external sources that might weaken the current U.S. regulations that allow you open access to nutritional supplement products.

For now, be reassured that the decision *not* to use RDAs as the maximum upper limits removed a possible serious threat.

Since Codex is seldom mentioned in the U.S. media, those new to Codex may wish to visit ~~codexinfo.org~~ for an overview of Codex Alimentarius and an explanation of the role of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). This committee is the group responsibile for drafting the *Guidelines for Vitamin and Mineral Food Supplements.* Check out both Pro and Con viewpoints and decide for yourself if you wish to continue to track the development of the Guidelines.

Are you interested in learning more about what happened at the CCNFSDU session in Bonn, Germany, held during the first week in November, 2003? As Codex sessions do not publish detailed minutes, only very limited summary reports, I offer below my personal observations of the discussions and decisions related to the Guidelines.

My overall impression is that the 2003 CCNFSDU session was well run and productive. When compared to the session in 2002 when very little progress was made and the delegates were ready to lynch the chair for his seeming unfair and ineffective leadership, this is a significant improvement. This year the chair, Dr. Rolf Grossklaus, followed the Codex procedures for allowing comments from delegates, acknowledging written comments submitted prior to the session, summarizing general consensus, and facilitating compromises. Whereas in 2002 he allowed one agenda item to consume most of the three days allotted for discussion, this year the chair did an admirable job of allotting sufficient time for each of 13 agenda items. On several occasions this year there was applause from the 230 delegates at the completion of addressing an agenda item. This was to acknowledge that despite the divergent positions among the 48 country and 31 international non-government organization (NGO) delegations, significant progress had been made.

Not that all delegates were totally happy with the chair's actions. The Codex procedure to use consensus (as perceived by the chair) rather than voting, takes some getting used to by those of us accustomed to democratic proceedings. Consensus can be very subjective, and on occasion some delegates did voice their view that the chair was favoring the European Community (EC) delegate's positions. In defense, the chair pointed out that this one individual was representing 15 European Union countries. You can review the report below and decide for yourself.

My main interest for attending the CCNFSDU session was for Agenda Item #5, the *Guidelines for Vitamin and Mineral Food Supplements.* A copy of this document is available on-line at ~~http://ahha.org/CodexGuidelines.htm.~~ I recommend that you access the document and follow along as I move from section to section. The document shows the status of the Guidelines after the changes made at the 2003 CCNFSDU session. New words are underlined. Words removed are crossed out. Square brackets indicate that the words within the brackets are not finalized and will be debated at a future committee session.

On Monday, November 3, the session reached Agenda Item #5. The chair announced that his main goal in this session was to address the areas in the Guidelines document that were still in square brackets and finalize as many as possible.

Even with this goal, the first item brought up was not in square brackets. It was the word "Food" in the Title: *Guidelines for Vitamin and Mineral Food Supplements*. This word had been added at the 2002 session at the request of the EC. Malaysia, South Africa, and India voiced support for removing this word. The EC supported retaining the word. South Africa suggested an alternative "Vitamin and Mineral Supplements Regulated as Foods." There was further discussion, including the chair's comment that the committee only deals with foods. Finally, the chair ended discussion on this topic, and announced that the word "Food" would not be removed. Throughout the Guidelines text, whenever the phrase, "vitamin and mineral supplements," appeared it would be changed to "vitamin and mineral food supplements"

Next, South Africa suggested revised wording for the *Preamble* to add mention of the role of vitamins and minerals in the prevention of chronic diseases. Since the Food and Agricultural Organization of the United Nation's World Health Organization (FAO/WHO) publication, "Diet, Nutrition and the Prevention of

Chronic Diseases," was being distributed at the CCNFSDU session, it was assumed this premise would be an easy sell. The National Health Federation (NHF) spoke in support of the South African suggestion. When, the EC delegate took the floor, he insisted that food and prevention did not go together. The chair commented that medicines are for prevention and treatment of diseases, whereas food supplements are to maintain health. There was continued discussion, with the key point being that Codex regulations prohibited claims that food prevents disease. The chair declared that the Preamble would not be revised.

Under the *1. Scope* section of the Guidelines, there was debate about a section dealing with jurisdictions and which countries would be under the authority of the Guidelines. The wording was ultimately condensed by deleting the first sentence and leaving the second sentence, which states that the Guidelines were limited to countries regulating vitamin and mineral supplements as foods.

Mixed in with this discussion was consideration of an EC request to expand the wording to include food supplements containing other ingredients (in addition to vitamins and minerals). This request was motivated by a concern that the addition of an extra ingredient might be a technicality to keep a product from being required to abide by the Guidelines. The EC was successful and the following was added: "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."

Under the *2. Definitions* section the focus was on deleting a sentence related to the use of supplements. The sentence in question included the text, "intake from food is insufficient or where the consumers consider their diet requires supplementation." New Zealand, Thailand, Tunisia, and Kenya supported removing the sentence. Malaysia and India voiced support for keeping the sentence. The chair declared consensus that the sentence would be removed as the content was covered in the Preamble.

The Definitions discussion continued as the EC lobbied to add the wording, "marketed in dose form" and "designed to be taken in measured small unit quantities," to ensure that supplements were not confused with conventional food. The U.S. pointed out that "dose" was related to drugs in the U.S. and that "small unit" was confusing. Many countries (including the U.S., South Africa, Nigeria, Philippines, and India) supported not adding the "small measured unit quantities" wording. It was noted that the current text, "capsules, tablets, powders, solutions, etc., not in conventional food form," was sufficient to make this point clear. The EC position was supported by Germany and France (who are members of the EC). The chair declared that the EC statement, "They are designed to be taken as measured [small unit quantities]," would be added to Guidelines. (Remember that Codex text in square brackets means that this wording is not finalized and will be debated at a future session.)

In the *3. Composition* section, there was significant support for the suggestion by the U.S. to clarify in 3.1.2 that vitamins and minerals could be from both "natural and synthetic" sources. However, this addition was put into square brackets at the request of the EC. The need to clarify the criteria for sources for purity resulted in several other additions.

The U.S. request to delete 3.1.3 was quietly declared a group consensus on the basis that the Codex risk assessment guidelines covered this safety issue.

Section *3.2 Contents of Vitamins and Minerals* contains the minimum and maximum levels - the hot topics!

Section 3.2.1 sets the minimum level of each vitamin and/or mineral contained in a supplement product. Up to now, the amounts 15% and 33% were in square brackets, meaning that the committee needed to pick. My notes show that the U.S., Malaysia, South Africa, and the NHF spoke out to support 15%. Japan, India, Thailand, and Switzerland felt this was too low. The chair declared that the 15% had the majority and that 15% corresponded to the value for "source" in the Guidelines for Use of Nutrition Claims and a higher value might create practical difficulties for certain nutrients.

Next we arrived at Section 3.2.2, dealing with maximum levels. For years this has been the most dramatically debated section of the Guidelines. The two widely divergent options are about what will be the criteria for setting maximum levels.

> *For maximum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer*
>
> *• (Option #1) should not exceed [100%] of the recommended daily intake as determined by FAO/WHO.*
>
> *OR*
>
> *• (Option #2) shall be set taking the following criteria into account:*
>
> *(a) upper safe levels of vitamins and mineral 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.*

My notes show that this year Norway, Malaysia, and Thailand spoke in support of the first option. The EC, South Africa, Japan, the U.S., and Switzerland spoke in support of the second option. The chair declared consensus in support of the second option, with the final report to record that Norway, Malaysia, and Thailand did not agree. (Later, Brazil requested to go on record that its written comments supported the first option.) Thus, after years and years of heated debate, this important issue was quietly decided and the session moved on. Amazing.

Next, the discussion was on the final sentence under Option #2, " When the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population." The U.S., Tunisia, the International Alliance of Dietary/Food Supplement Association (IADSA), New Zealand, Philippines, South Africa, the Council for Responsible Nutrition (CRN), and the National Health Federation (NHF) spoke in support of deleting this sentence. The EC, Norway, and Italy spoke in support of retaining this sentence. The chair decided to keep this sentence, but retain it in square brackets for further discussion at a future session.

On Tuesday, November 4, the session continued with Agenda Item #5. Section *4. Packaging*, was skipped over, as it did not have any text in square brackets. The final section *5. Labeling*, which included square brackets in 5.2 - 5.5 and 5.8 - 5.9, received considerable attention.

Under 5.2, the need for the "name of the product" was hotly debated. The IADSA and South Africa noted that any product label will indicate the contents and adding "vitamin and mineral supplement" was not needed. The chair quoted from *Codex Procedural Manual*, page 95, that the label must have the "name of the food." After much discussion, the compromise was to change the wording to "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 was finalized (removed from square brackets) with some minor revisions.

The discussion on 5.4 was most interesting. Although the EC was open to removing the "dose" reference, the various ways amounts of a nutrient could be presented on a label immediately came into contention. There could be the amount per portion of the product recommended for daily consumption (such as three units of the product provide the recommended daily intake of nutrient listed on the label). There could also be the amount per single unit of the product (such as amount of nutrient per tablet or capsule in the container). Do consumers need to be able to determine how many units are needed to reach the amount they wish to take, or will they be forced to do the math? Consensus could not be reached. One option was finalized and the second placed within square brackets. Again, the EC and the U.S. were on opposing sides of the debate, with the U.S. and NHF supporting the single-use information that makes it easier for consumers to calculate the amount they desire.

In this discussion, the U.S. succeeded in changing "shall" to "should" throughout the document, as appropriate, to be in keeping with the intent that this is to be suggested *guidelines*. (Note: This ignores the fact that WTO does not differentiate between standards and guidelines and uses both as standards.)

Section 5.5 includes text stating that labeling is to be in terms of "reference values." Some delegates pointed out that current Nutrient Reference Values (NRVs) are based on a 1988 Helsinki Consultation and are thus incomplete and outdated. The ideal would be to have FAO/WHO fund an expert consultation for these updates. However, current FAO/WHO budgeting problems would prevent this from happening for quite some time. The committee decided to do what was within their jurisdiction: establish an electronic working group made up of members of CCNFSDU delegations. Leadership of this working group needs to be a country. The U.S., Germany and the EC were invited, but each felt it was unable to accept. Non-government organizations NHF and CRN were willing to assist, once a lead country was established. No country stepped forward. Later in the session, however, South Africa accepted the leadership of this important assignment. All delegations were invited to submit proposals for inclusion in this project. While the current NRVs are based on statistics combining men and women, the committee voiced the opinion that separate values needed to be established by gender, age (children and seniors), and special needs groups (pregnant women and nursing mothers). The working group is to compile all into a document of revised NRVs for consideration at the 2004 CCNFSDU session.

The discussion on 5.7 was whether or not a warning statement is needed on supplement labels. Arguments to delete this requirement were based on the fact that products would be safe because of the 3.2.2 upper safe limits criteria. Another argument noted that too much data on a label might dilute its impact. The U.S., CRN, and NHF supported deleting 5.7. The EC did not. A compromise was reached that instead of a warning there would be a recommendation not to exceed the maximum one-day amount.

Under 5.8. there were strong feelings about wording on a label about supplements might be used in place of a meal. The EC supported a mandatory statement that food supplements should not be used as a substitute for a varied diet. The U.S. supported the position that no statement on the label should imply that supplements be used to replace a meal or a varied diet. This would remove an additional required statement on the label. China supported deleting 5.8 entirely. A compromise statement similar to what the U.S. proposed received consensus.

The 5.9 text that the label must include a statement that supplements should be taken on the advice of a nutritionist, dietitian, or medical doctor has generated heated debate in past years. This year, after very little discussion, the chair declared general consensus to delete 5.9. It was noted that Philippines and Malaysia did not support this consensus.

At this point in the session, all square brackets for Agenda Item #5 had been addressed. Now the chair allowed delegates to bring up issues regarding other sections of the Guidelines.

The EC brought up 4.3 in the Packaging section. This text required child-resistant packaging. They recommended deleting 4.3 and substituting a statement that the label must contain a statement that product should be stored out of the reach of young children. Many countries supported the EC. One of the arguments pointed out the difficulty senior citizens have in opening the child-resistant packaging. The chair declared consensus, 4.3 was deleted, and the new statement added as a new 5.9 under Labeling.

Next, South Africa brought up 3.2.3 and suggested additional wording to stop regulatory authorities from making unscientific barriers to trade. The chair felt this was redundant. Then the EC questioned the levels referenced and recommended deleting 3.2.3. The chair declared that 3.2.3 would be deleted. (Note: Prior written comments by the U.S. supported deleting 3.2.3 as no longer necessary with the approval of 3.2.2.)

This concluded committee revisions of the Guidelines at this session. The chair declared that significant progress had been made and the document was to move from Step 3 to Step 5 (Note: There are eight steps before final approval of a standard by the Codex Alimentarius Commission (CAC) and availability for official use. Once a text is close to its final form, it is set at Step 5 and submitted to the CAC for initial feedback.).

The chair moved on to the next agenda item. The CCNFSDU session continued.

The significant progress made this year was in sharp contrast to the ineffective 35 minutes of debate in 2002. Delegates could feel very proud of what they accomplished in 2003.

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The American Holistic Health Association (AHHA) is a 501(3)(c) educational nonprofit organization, not a lobbying group. AHHA president, Suzan Walter, researched and compiled information on Codex and the WTO in order to explain these matters to the U.S. public through the web site ~~codexinfo.org~~. AHHA is careful to only share facts, encouraging you to review the various positions and make up your own mind about which positions to support.

Suzan researched Codex procedural manuals and other documents, then compared them with what Codex delegates and the nutritional supplement industry reported. It became apparent that there are a number of areas with conflicting interpretations. This has motivated Suzan to continue to research the agreements between Codex and WTO and how Codex standards and guidelines are used. Feeling a responsibility to bring these facts to the attention of CCNFSDU delegates, Suzan attended the CCNFSDU sessions as an observer in 2002 and 2003.