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K. Riedel
Nature's Life
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NATURE'S LIFE

7180 Lampson Avenue, Garden Grove, CA 92841-3914 USA
TEL: (714) 379-6500 • (800) 854-6837 • Fax (714) 379-6501
www.natlife.com / www.natureslife.com

October 4, 2001

TO: Dr. E. Yetley - U.S. Delegate to the CCNFSDU
FR: Karl Riedel

02-022N
02-022N-10
Karl Riedel Docket 01-025N

RE: Comments on Agenda Items for the 23rd Session of the CCNFSDU

We appreciate the opportunity to provide further comments for next week's preparatory meeting, which I will attend, although I regret that NNFA will not be directly represented at the Berlin session this year. Development of Codex Alimentarius guidelines for vitamin and mineral supplements have recently taken on a more urgent note with the recent approval by the European Parliament and the Council of Europe of a restrictive *draft* proposal for harmonized regulation of Vitamin and Mineral Supplements throughout Europe. We urge you to aggressively advocate for the open-market and consumer friendly regulations and laws of the US, as legislated through the Dietary Supplement Health and Education Act of 1994. We further pledge our support, through our international affiliate, the International Alliance of Dietary Supplement Associations (IADSA), to your efforts.

AGENDA ITEM #3 - Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B Provisions on *Dietary* Fibre)

One of the primary benefits of the Nutrition and Labeling Education Act of 1990 was the regulation on Nutrient Content claims, and its inherent adherence to the important concept of food labeling that is truthful and non-misleading. The proposed Codex conditions for making fibre claims fall woefully short of US standards, as defined in 21 CFR 101.9. The primary shortcoming of the Codex draft is not the minimum levels for claiming "source" (3 g) or "high" (6 g), but rather the reference amount of 100 g. This 100 g amount (@ 3½ ounces) is well short of the Reference Amount for 95% of the most common foods, as detailed in 21 CFR 101.12. As such, many foods that would not qualify to bear a Nutrient content claim for fibre in the US will easily qualify for such claims using the proposed Codex *standard.* Many such foods may also contain unhealthfully high levels of sodium and fat, making a fiber claim perhaps misleading from an overall nutrition benefit perspective.

We strongly recommend that the US advocate for a delay in development of this guideline, not only for the reasons discussed above, but also for the following rationale:

- the working group coordinated by the UK failed to achieve consensus on several relevant issues related to the definition and quantification of fibre.
- the committee as a whole was unable to achieve consensus on either fibre definition or the applicability of the corresponding AOAC method validated by the CCMAS.
- there is no current NRV for fiber against which to base relative claims
- the NAS fiber *study* was just recently published and many delegations have not reviewed the report, including the revised definitions, and commentary on methods of analysis

If, however, development does continue, we recommend that the US advocate for levels more in line with the 10% and 20% thresholds of the current US DRV of 25 grams:

- "source" = 6 grams of fibre for 100 grams, or 3 grams per serving
- "high" = 12 grams of fibre for 100 grams, or 6 grams per serving

AGENDA ITEM #4 - Proposed Draft Guidelines for **Vitamin** and Mineral Supplements;

We support continued development of these guidelines by ***Codex,*** although we object **strenuously** to the concept that any dietary supplement that complies with Codex Alimentarius (food) **guidelines** may **still** be considered a **drug by** any **member** of the Codex Alimentarius, or of the World Trade Organization. **In** addition, we offer the following specific comments on the individual Sections of the current draft guideline:

Preamble:

We **strongly** support the US position to delete the entire preamble **as** setting new precedent and inappropriate for a Codex Guideline. Alternatively, we recommend that the **first** statement be revised to add the word *not" prior to **"usually. Based** on the findings from the FNB/IOM/NAS, **as** reported in **their** updated DRI reports on essential **nutrients** published from **1997 > 2000.** These tomes state **that,** of the **17** essential nutrients reported **(less** Fluoride), **American** adults consume, on average, the RDA of **only 8** of them. While relatively affluent Americans **"can"** obtain **"all"** the nutrition they **need** from **a** normal diet, in fact, they do **not. In** light of **this** recently re-confirmed evidence, we **strongly** recommend that you **vigorously** advocate for inclusion of the word NOT before "usually", and challenge any delegation **that disagrees** with **this** change **to** produce **evidence** that **their** citizens **"usually** obtain **all** the nutrias **they require** from their normal *diet".*

Section **1** - Scope;

We strongly urge deletion of Section 1.2.. Codex guidelines, **by** definition are food guidelines, and once Codex determines, **by** definitions and **standards,** what food supplements **are, then** it contravenes the **General** Principles of Codex **for any** national authority to make a different unilateral determination and adapt it **as** a restrictive trade barrier. Such action **by** any national authority would **violate both** the **GATT and** the SPS **Agreements.**

We also urge retention of the brackets **around** Section 1.3, **until *such*** time **as** the balance of **this** entire elaborated guideline ***can*** be evaluated **against** the current Codes Standard **146-1985** for FSDU.

Section **2.** Definitions;

We recommend the deletion of the square brackets in **2.1 so as** to clarify **and** incorporate consumer **choice** as a primary rationale for supplementation. We **strongly** urge the deletion of the end of Section **2.2** "... and **they *are*** marketed for that particular purpose", **as** Codex **deals** with definitions **and standards** for products, packaging and labeling, and not for marketing, and also for the reason that VMS *can* serve special nutritional purposes, regardless of their marketing intent.

Section 3: COMPOSITION:

Section 3.1 - Composition **Of** Vitamins and Minerals;

We recommend that you review the context of the currently bracketed "or" and "and" in Section **3.1.2.** to ensure that the **final** adopted text does not provide opportunity for national authorities to define a list of nutrients that would be a restrictive barrier to trade. We recommend use of specific punctuation and adjectives as follows: "The selection of admissible ingredient **sources** or compounds should be based **on** criteria ***such*** **as** safety and bioavailability of the FAO/WHO or authoritative Pharmacopoeias." This will ensure national authorities use the FAO/WHO criteria primarily, but can add additional essential nutrients based **on** authoritative criteria (much **as** the US recently added Choline **as a** DRI nutrient). While **we realize** that **this** addition will likely retard progress of the guideline, we feels its inclusion is critical for **future** development of a comprehensive framework for international trade in dietary supplements

We **strongly** recommend, to preclude functional use of the Precautionary Principle or other restrictive policy based criteria **by** national authorities, to delete **this** entire Section **3.1.3.** Alternatively, **place** in square brackets the last part of **this** sentence, or preferably, replace it **with:** "based **on** science based risk assessment principles", to ensure that appropriate criteria are used for **any** limitations

To ensure that these guidelines clarify that inclusion of ingredients other **than** essential vitamins and minerals is allowed, we recommend that you propose to add, at the end of the unbracketed Section **3.1.4, this new** text: "**...** and **may also** contain other dietary ingredients, and excipients approved **by** the CCFAC".

Section **3: COMPOSITION:** (con't)

Section **3.1** - Composition Of Vitamins and Minerals: (con't)

We urgently request that your advocate strongly for deletion of the entire alternate bracketed Section 3.1.4 as, again, elaborating guidelines for marketing intent, as opposed to standards for products, packaging and labeling. Delegates concerns are better addressed by subsequent guidelines that will be promulgated by the CCFL. We recommend deletion of the entire Section as redundant and having the potential for engendering dissension within the committee.

Section 3.2 - Contents of Vitamins and Minerals

We recommend that the brackets be removed from Section 3.2.1, and the *text* retained unchanged.

We strongly recommend that Section 3.2.2. be deleted, in favor of Section 3.2.3., which should be retained unchanged and the brackets removed.

We urgently request that your advocate *strongly* that Section 3.2.4. be deleted, as it is an open invitation for invocation of the Precautionary Principle and the precedence of national standards over Codex *standards*. This Section offers restrictive national authorities facile means to establish unreasonable and unjustified technical barriers to trade, and is, further, violative of Codex General Principles.

Section 4: PACKAGING

While the intent of Section 4.3 is admirable, its current form leaves it too open to interpretation, and could, conceivably, be used by a particular national authority to mandate CRCs for *ALL* vitamin and mineral supplements. We *strongly recommend* that this section be deleted, and the point added to Section 4.1, as follows: "The products shall be packed in containers which will safeguard the hygienic and other qualities of the supplement, and also reduce the risk of unsupervised consumption by children''.

Section 5: LABELLING

We recommend that Section 5.2, as mandated by the Codex General Standard for the Labelling of Prepackaged Food, be simplified to read: "The name of the product shall "Dietary Supplement"."

We recommend removal of the brackets around Section 5.3, and retention of the text as is, with the following addition at the end of the second sentence: "... or compendial Units of Activity for the fat-soluble nutrients Vitamin A, Vitamin E and Vitamin D." to *enhance* consumer understanding of product content.

We strongly request that you advocate vigorously that Section 5.7 be revised as follows: "The label must contain a consumer caution or warning statement if the suggested dose of the product contains a nutrient or nutrient amount that has been shown, through nument-specific scientific risk assessment, to create an adverse effect in a specific population or population sub-group. Such statement must clearly communicate the specific at-risk population or population sub-group, the nature of the risk, and the germane nutrient or nutrients." We firmly believe that this text will satisfy the most rigorous risk manager, and also be beneficial to informed choice by health-conscious consumers.

We strongly recommend that Section 5.8 be deleted as unnecessary and redundant, but, alternatively, we recommend that it be revised to read: "This supplement is not a meal replacement".

We strongly request that you advocate deletion of Section 5.9 as outside the purview of the CCNFSDU. Vitamin and Mineral Supplements are FOODS, and, as herein defined and constrained by these guidelines do *NOT* necessitate the recommendations, advice, prescription or intervention of *ANY* person other than the purchasing consumer. Such proposed statement is egregious governmental zealotry, and must be vigorously opposed as contradictory to the spirit and the letter of DSHEA.

AGENDA ITEM #8 - Discussion Paper on Review of Provisions for Vitamins and Minerals in Codex Standards: Vitamins and Minerals in Foods for Special Dietary Purposes:

We agree with the US position, stated during the 22nd CCNFSDU session, that elaboration of this guideline is unnecessary, and we further recommend that you propose that this work be discontinued by the committee. If, however, the committee decides to proceed, we recommend that *only* general principles, and not specific product standards be developed, because these FSDU vary widely based on the specific use for which they are intended.

AGENDA ITEM #9 - Discussion Paper on Energy Conversion Factors;

We agree with the US statements, made during the 22nd CCNFSDU session, supporting development of a Codex guideline on this issue, and recommending *a priori* establishment of scientific criteria. As the US *currently* lacks such regulatory criteria for all carbohydrates, and specifically no regulatory

standards for physical analysis of carbohydrates, we recommend observation, as opposed to direct. generation and submission of comments. We anticipate offering constructive comments when proposed *draft* text is published for comment by the committee.

We again would like to express our appreciation for the opportunity to offer comments, and express my personal *regrets* for not being able to participate at the Berlin session. We antiupate a lively, and hopefully productive, preparatoxy meeting on October 12.

Cc: FDA/CFSAN Dr. Christine Lewis, US CODEX Dr. F. Edward Scarbrough, DOC Marnie Morrion
NNFA Executive Director, Counsel & International Committee, IADSA Secretariat

(nets/codex/ccnfsdu/comments.Oct.2001)