codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 7 **CX/NFSDU 08/30/7-Add.1**
October 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
30th Session

Cape Town, South Africa, 3 - 7 November 2008

PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING AT STEP 4

- ***Comments at Step 3 of the Procedure*** -

Comments from:

SOUTH AFRICA
UNITED STATES OF AMERICA

SOUTH AFRICA

Comments at step 4-

A. Selection of appropriate basis

South Africa supports option 2: "Individual level (INL_x), the estimated nutrient intake values that meet the requirements of (98percent) of an apparent healthy specific sub-group of the population (e.g. considering the subgroup's sex and lifestage such as age and pregnancy/lactation). In cases where there is an absence of established INL_x for a nutrient for a specific sub-group, it may be appropriate to consider the use of acceptable nutrient intake values or ranges that have been established by authoritative scientific bodies. It is necessary to review how these values were derived on a case-by-case basis."

Motivation: Considering the nutrient deficiencies and malnutrition in South Africa, the use of INL_x is more appropriate as it meets the requirements of most of the population in order to protect public health and safety. South Africa further recommends the use of the latest scientific evidence and expert consultations during this process.

B. Consideration of different age-sex specific values

South Africa supports option 1: "considering the highest values from the different age-sex groups" on condition that INL_x for pregnant and lactating women are not included for this purpose. If the values for pregnant and lactating women would be included, the values would exceed the recommended maximum intake for most individuals specially children.

Motivation: The use of the highest age-sex INL_x will ensure that the daily intakes of most age-sex specific groups of the whole population are met.

C. Consideration of upper levels of intake

South is of the notion that the establishment of general population NRVs may also take into account upper levels of intake.

D. Selection of a suitable data source to extract NRVs

South Africa supports the use of the most up to date scientific evidence from credible data sources with consideration of the current health threats.

UNITED STATES OF AMERICA

GENERAL COMMENTS

The United States expresses its appreciation to the Delegation of the Republic of Korea for their leadership in chairing an electronic working group to facilitate progress on this very challenging agenda item, and for preparing CX/NFSDU 08/30/7 (hereafter referred to as "the document") for the Committee's consideration.

Below are general comments on this document that mainly focus on paragraph 7 (and Recommendation #2). The United States anticipates it will have additional comments at the upcoming meeting.

Paragraph 7 in the document states:

> "Prior to starting this proposed work, the Committee needs to determine if it may be appropriate to update and extend the current NRVs in these guidelines as opposed to identifying only general principles for governments to derive their own set of food labeling values, considering the increased complexity in establishing the specific international food labeling values since the Helsinki consultation."

I. Increased Complexity of Establishing International Food Label Reference Values

The United States agrees that it is important for the Committee to consider the increased complexity of this proposed work compared to that previously undertaken by this Committee when it considered the

recommendations of the 1988 Helsinki FAO/WHO Expert Consultation in establishing the existing NRVs[1].

Number of Nutrients. For example, NRVs are currently provided for *only 14 vitamins and minerals* in these Codex guidelines. In contrast, the U.S. Institute of Medicine (IOM) has established recommended intakes for *more than two dozen* vitamins and minerals. (These include "Recommended Dietary Allowances" for nutrients with an "Estimated Average Requirement" (EAR) or "Adequate Intakes" for those for which an EAR could not be determined.)

Number of Recommendations. Moreover, paragraph 10 of the document states that "many member nations and authoritative bodies have established multiple categories of nutrient intake values." As noted in a recent article in the Food and Nutrition Bulletin (United Nations University)[2]:

> "The amounts of nutrient intakes recommended vary considerably from country to country. Also the terms used to describe the intake values differ. For example, some countries recommend a single value that serves as a recommended intake for all members of a population subgroup, whereas other countries recommend four different values: a lower reference intake, an average requirement, a recommended intake for nearly all members of a population group, and an upper tolerable level or limit. Furthermore, there is no standard method or approach for deriving these different nutrient intake values."

Insufficient Scientific Basis for Some Recommendations. In addition, other categories of nutrient reference values (e.g., the IOM "Adequate Intake" values) may be established when there are insufficient data to determine a statistical distribution of requirements (including EAR and RDA). These may be expressed either as a single value or range and are derived in different ways.

Special Considerations for Certain Nutrients. Moreover, if this new work were to encompass establishing an NRV for a mineral such as "sodium" (for which the Helsinki Consultation did not propose an NRV), the Committee might need to consider additional quantitative intake recommendations provided in dietary guidance at the national, regional and/or international levels, and perhaps separate general principles for nutrients associated with risk of noncommunicable diseases. Alternatively, the Committee may wish to consider an NRV for sodium with separate work under consideration by CCNFSDU to expand the NRVs to nutrients associated with noncommunicable diseases that is related to the Global Strategy.

Additional Considerations in the Absence of Input by an Expert Consultation. Finally, the U.S. notes the increase in amount of work by CCNFSDU if it is to be done *de novo* as opposed to this Committee's previous role in consideration of recommendations for NRVs proposed by a Joint FAO/WHO Expert Consultation. However, regardless of who would propose revised and additional international food label reference values for vitamins and minerals (i.e., CCNFSDU or expert consultation), it is still unclear how a single food label reference value for each nutrient for global application would be derived.

II. Appropriateness of International versus Country- or Region- Specific Food Label Reference Values

Recommended intakes (and consequently food label reference intakes) may take into account factors specific to a country or region--such as the bioavailability of food sources for a nutrient such as iron. For example, the 1998 joint FAO/WHO expert consultation held in Bangkok proposed Recommended Nutrient Intakes for iron for four different levels of bioavailability (ranging from 5 to 15 percent). There is also increased recognition of the wide range of country/region specific factors that can influence nutrient absorption and utilization.[3] Moreover, at the national level, population-weighted

---

[1] Throughout our comments, we use the term "NRV" to refer only to Nutrient Reference Values for food labeling purposes that have been established by the Codex Alimentarius, and not to other label reference values that may be established by governments.

[2] King JC, Vorster HH, and Tome DG. Nutrient intake values (NIVs): A recommended terminology and framework for the derivation of values. Food and Nutrition Bulletin, vol. 28, no. 1 (supplement). 2007. S16-S26.

[3] Gibson, Rosalind. The role of diet- and host-related factors in nutrient bioavailability and thus in nutrient-based dietary requirement estimates. *Food and Nutrition Bulletin*, vol. 28, no. 1 (supplement). 2007. The United Nations University. http://www.unu.edu/unupress/food/FNBv28n1_Suppl1_final.pdf

values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group.

Consequently, if the Committee decides to continue work to revise and expand the vitamin and mineral NRVs, the U.S. recommends: 1) retaining the language proposed in the preamble of the Annex in the document to clarify that it may be appropriate and desirable for a government to establish its own food label reference values, and 2) revising the introductory text to Sec. 3.4.4 in the Guidelines so as not to imply that all food label reference values should be the same. For example, the Committee may wish to consider the following edits:

> "The following Nutrient Reference Values **may** ~~should~~ be used for labeling purposes ~~in the interests of international standardization and harmonization~~."

III. Use of International versus Country- or Region- Specific Food Label Reference Values

Recommendation 2 in the document proposes that in considering whether to include specific international food labeling values in the Guidelines, the Committee may wish to consider the extent to which NRVs are used by member countries. The U.S. agrees that this input would be useful. In addition, the Committee may wish to consider whether to inquire about the extent to which: 1) food label reference values *have been developed* at the national level and regional level, and 2) interest among Codex members in guidance or principles for developing food label reference values at the national or regional level.

IV. Possible Options for CCNFSDU to Consider for General Population Reference Values

The Committee may wish to further consider the desirability and feasibility of the following options with respect to food label reference values for vitamins and minerals for the general population:

1) CCNFSDU Development of Both Principles and Specific NRVs
2) CCNFSDU Development of Principles and Request for FAO/WHO Expert Consultation to Propose Specific NRVs
3) CCNFSDU Development of Principles to Guide the Development of Country or Regional Food Label Reference Values[4]

V. Time Frame for Completing Work

If the Committee decides to proceed with option 1, the United States seeks clarification about the timeframe for completing this work as identified on p. 2 of the document. Specifically, the United States asks about the intended meaning of the third bullet (i.e., Is it intended to refer to the adoption of vitamin and mineral NRVs *for the general population* by 2012)?

SPECIFIC COMMENTS

While our specific comments are focused on the draft Annex, we would like to clarify that the first table on p.6 of the background paper that may have been provided by an electronic working group member is *an adaptation* of a table identified in the U.S. Federal Register source. For example, in this Federal Register notice, the numbers in the table referred to the U.S. Institute of Medicine Dietary Reference Intakes (i.e., "highest RDA", "weighted RDA", "highest EAR", "weighted EAR", "UL 4-8 years"), whereas the adapted version used proposed generic terminology for these concepts.

If the Committee decides to proceed with option 1, the United States has the following comments on the draft Annex in CX 08/30/7. Some of these edits may also apply to Options 2 and 3.

[4] Presumedly, this option would then necessitate changing the connotation of an NRV in these guidelines and other Codex texts to refer to food labeling values established by governments as opposed to the Codex Alimentarius Commission.

PREAMBLE

1st para, 2nd sentence.

"These values may be used for helping consumers 1) estimate the relative contribution of individual products to ~~the~~ overall **healthful** dietary intake and 2) as one way to compare the nutrient content between products."

Comment: The above edits are suggested for clarification.

2nd para

Comment: The United States believes the second paragraph is necessary to acknowledge that it is appropriate and sometimes preferable for governments to develop their own food label reference values to take into account, among other things, country or region specific factors that affect nutrient absorption or utilization. (See related comments on proposed revisions to the introductory text in Section 3.4.4)

Moreover, the second paragraph in the preamble provides appropriate context that governments may also consider whether to establish separate food label reference values for specific segments of the general population such as pregnant and lactating women.

GENERAL PRINCIPLES FOR ESTABLISHING VITAMIN AND MINERAL NRVs

B. Consideration of different age-sex specific values

"The general population NRVs shall be determined by:

Option 4. Considering the specific sub-group population weighted means, such as means of adult male and female values."

Comment: The United States is unclear as to the meaning of Option 4 given its current wording, including what is meant by a sub-population ***weighted*** mean in the context of this option. We further note that this current wording appears to suggest *multiple* options (e.g., with the use of the phrase "such as"….).

The Committee may wish to consider whether it would be desirable to identify one or more *specific* options related to Option 4 instead—with example(s) provided if needed for clarification.

For example, would the following wording reflect an option as illustrated in the table on p. 6 of CX/NFSDU 08/30/7 (without presupposing the Committee's decision on whether "INLx" or "ANR" type values would be used)?

"The general population NRVs shall be determined by:

"Option #. Considering averages of the highest value from males and the highest value from females from the different age groups."

Are there other *specific* options related to Option 4 that Codex members believe should be considered?