codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/NFSDU 09/31/4-Add.1**
October 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Thirty first Session

Robert Shuman Hall, Museum Kunst Palast, Düsseldorf, Germany

2 – 6 November 2009

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

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

Comments from:

ARGENTINA
COSTA RICA
INDIA
PHILLIPINES
UNITED STATES OF AMERICA

IDF - International Dairy Federation

ARGENTINA

1. Scope: individuals older than 36 months of age.
2. Definitions: Argentina agrees with sections 2.1 and 2.2.
3. General Principles for Establishing Vitamin and Mineral NRVs.
A. Argentina agrees with taking into consideration the most relevant and recent data for the daily reference intake.
C. Argentina supports option 2, which considers an average value for the general population above 3 years of age.

ANNEX 2
The Reference Values are presented.
Argentina agrees with the values that are consistent with the national legislation.

The different values are:

Protein (g) 50 – Argentina: 75g of protein.
Vitamin A (µg RE) 800 550 – Argentina: 600 µg
Vitamin E (mg α-TE) 8.8 – Argentina: 10 mg
Vitamin K (µg) 60 – Argentina: 65 µg
Riboflavin (mg) 1.6 1.2 – Argentina: 1,3 mg
Niacin (mg NE) 18 - 15 – Argentina: 16 mg
Chloride (g) 2.3 – Argentina: Not considered
Magnesium (mg) 300 240 – Argentina: 260 mg

Option 3 is preferred for:
Iron (mg) 14 (14.3 ~ 43.1)
Zinc (mg) 15 (3.6 ~ 11.9)

Fluoride (mg) 3.5 – Argentina: 3 mg
Manganese (mg) 2.1 – Argentina: 2,3 mg
Selenium (µg) 30 – Argentina: 34 µg
Chromium (µg) 30 – Argentina: 35 µg

Justification:
*National legislation in force: RESOLUTION 46/03 MERCOSUR TECHNICAL REGULATION ON THE NUTRITIONAL LABELLING OF PACKAGED FOOD (*GMC/RESOLUCION Nº 46/03 REGLAMENTO TECNICO MERCOSUR SOBRE EL ROTULADO NUTRICIONAL DE ALIMENTOS ENVASADOS*).*

COSTA RICA

In Appendix 1, Costa Rica supports the phrase "older than 36 months", and would agree with deleting the corresponding square brackets. Moreover, regarding Section C. Consideration of different age-sex specific values, we support the elimination of Option 1 and the square brackets around Option 2.

Regarding Appendix 2, we support the reference to the general population, defined as individuals older than 36 months. On the other hand, when we analyse the values calculated using the reference "Vitamin and Mineral Requirements in Human Nutrition" 2nd Edition, FAO/WHO, 2004, we can confirm that many of these differ greatly from the VRNs currently established in the Guidelines for Nutritional Labelling (CAC/GL 2-1985).

With regard to vitamin A and C, we are particularly worried about the fact that the proposed values are approx. 30% below the current values cited in the Guidelines. While reviewing the FAO/OMS expert

consultation for the requirements for vitamins and minerals in human nutrition, we noticed that data used for vitamin A dated back to 1988, so that it is unclear to us why the VRN was established at 550 µg RE/day for Option 2, instead of the current value of 800 µg RE/day.

The same expert investigation mentions that there is even a high prevalence of vitamin A deficiency in the region of the Americas, which would also support the need to establish a higher VRN for this nutrient.

Similarly, for vitamin C, the consultation established a value of 45 mg/day instead of the current value of 60 mg/day, and we cannot understand the reason for this change, since literary research indicates that this value could be incremented in the near future.

We consider ourselves a developing country and should aim to adapt the new VRNs as well as possible in order to save our local industries the cost of having to use different labels to comply with the requirements of export markets. For this reason, regarding the VRN for zinc and iron, we are inclined to select Option 1, which refers to the VRN with mineral bioavailability representing the bioavailability of the mineral better in the world dietary regimen, without including regulations permitting countries to calculate their own VRN to then be able to represent the probable bioavailability in the national dietary regimen better.

INDIA

Appendix 1:

Agreeable for deleting Option 1 and the square bracket.

Age group that should reasonably represent general population:

- Considering the average mean value for chosen reference population group that reasonably represents the general population above 3 years of age, such as means of **18 -30 years** ~~adult~~ males and females values.

Appendix 2:

Protein (g) 50 **(consider expressing it as per kg body weight).**

Vitamin A (µg RE) 550 (**acceptable except for the conversion factor of 1 µg retinol = 6 µg β-carotene. This conversion factor is applicable only when fat intake is adequate.)**

Vitamin D (µg) 5 (**in tropical country like India, local conditions are adequate for meeting the requirements and therefore no RDA has been fixed).**

Vitamin E (mg ∝-TE) 8.8 **(Acceptable)**
Vitamin K (µg) 60 **(Acceptable)**
Vitamin C (mg) 45 **(Acceptable)**
Thiamine (mg) 1.2 (**Acceptable)**
Riboflavin (mg) 1.2 **(Acceptable)**
Niacin (mg NE) 15 (**Acceptable)**
Vitamin B6 (mg)1.3 **(Acceptable)**
Folate (µg DFE) 400 **(Need to define DFE in the footnote)**
Vitamin B12 (µg) 2.4 (A**greeable for a range since Indian RDA is only 1µg/day**)
Pantothenate (mg) (**No comments as there is no Indian RDA)**
Biotin (µg) 30 ((**No comments as there is no Indian RDA).**
Calcium (mg) 1000 (**Acceptable for range since India RDA for calcium requirement is fixed at 600 mg)**
Phosphorus (mg) 700 (**Adjusted in tune with calcium requirement)**
Chloride (g) 2.3 (**No comments as there is no Indian RDA)**

Magnesium (mg) 240 **(Acceptable)**

Option 1 or Option 2
Iron (mg) 14.3, 18.0, 21.6 or 43.1 **(Acceptable for Option 2)**
Zinc (mg) 3.6, 6.0 or 11.9 **(Acceptable for Option 2 only)**

Option 3

Iron (mg) 14.3 – 43.1 (Acceptable for Option 2 only)
Zinc (mg) 3.6 – 11.9 ((Acceptable for Option 2 only)
(*Option 2***:** Select the NRV for which the bioavailability of the mineral best represents the bioavailability of the mineral in the global diet (and include a footnote that describes quantitatively or qualitatively the assumption regarding bioavailability), and **DO** include provisions to permit countries to determine their own NRVs based on alternative assumptions).
Copper (µg) 900 **(Acceptable)**
Fluoride (mg)3.5 **(No comments as there is no Indian RDA)**
Maganese (mg) 2.1 **(Acceptable)**
Iodine (µg) 150 **(Acceptable)**
Selenium (µg) 30 **(Acceptable)**
Chromium (µg) 30 **(Acceptable)**
Molybdenum (µg) 45 **(No comments as there is no Indian RDA)**

PHILLIPINES

Reference: Alinorm 093226.pdf

In Section 3 Development of General Principles for Establishing Vitamin and Mineral NRVs for the General Population, the Philippines proposes the following:

A. Selection of the appropriate basis

> The Philippines supports the use of Option 2 as the appropriate basis for NRVs: *Individual Nutrient Level (INLx), the estimated nutrient intake value that meets the requirements of most (98 percent) of an apparently 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 INLx 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.*
>
> Rationale: The use of INLx will ensure that the daily intakes of most individuals of the whole healthy population are met. NRVs should protect the average population from lack of nutrients and only INLx meets the requirements of 98% of the population. Where an INLx cannot be determined then the use of an acceptable nutrient intake values such as Adequate Intake (AI) would be appropriate. This position also supports the computation approach used for Philippines Recommended Energy and Nutrient Intakes for Filipinos (RENI).

B. Consideration of different age-sex specific values

> The Philippines supports the use of Option 1 "considering the highest values from the different age-sex groups" on condition that INLx for **pregnant and lactating women are not included for this purpose**. Further attention should be considered for nutrients where the difference between requirements and excess are small.

Rationale: The use of the highest age-sex INLx will ensure that the daily intakes or requirements of the highest proportion of the population are covered. The values for pregnant and lactating women are excluded so as not to exceed the recommended maximum intake for most individuals. The Philippines acknowledges that this option also presents the risk that label values could cause an individual to exceed the nutrient upper level (UL) for some age-sex specific groups, but over consumption of vitamins and minerals does not typically occur through conventional eating patterns, but rather from additional supplementation, nevertheless, due consideration should still be given as well as to nutrients where the difference between requirements and excess are small to ensure values are closer to the actual needs of each individual. Other options particularly census and population–weighted means are too complex as values need to be revised regularly to account changes in population age and gender distributions over time.

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

Relationship of this Agenda Item to Potential Work on Nutrient Reference Values for Labeling Purposes (NRVs) for Nutrients Associated with Risk of Noncommunicable Diseases.

At the last meeting, the Committee agreed to convene a physical working group at the next session to develop principles and criteria for the development of NRVs (for labeling purposes) for nutrients associated with risk of noncommunicable diseases (ALINORM 09/32/26, para 153).

The establishment of vitamin and mineral NRVs and potential new work to establish additional NRVs that are related to the Global Strategy on Diet, Physical Activity and Health both involve the development of general principles and the revision of the list of NRVs in Section 3.4.4 in the Codex *Guidelines on Nutrition Labelling.* While we believe it is appropriate for work on these two agenda items to progress in separate tracks and with different time frames, we believe it also important to keep the work on these two agenda items closely coordinated, and for those general principles that are the same, to strive for consistency in their wording. Accordingly, in the background paper prepared by the U.S. and Thailand for the physical working group meeting, the April 2009 draft principles for vitamin and mineral NRVs were used as a starting point to consider general principles for the establishment of NRVs for nutrients associated with risk of noncommunicable disease. With this approach and provided that new work on the additional NRVs is approved, the Committee can decide at a later stage whether it would be appropriate to merge certain text relating to the general principles and how best to present the NRVs in Section 3.4.4.

II. SPECIFIC COMMENTS

The United States of America is pleased to offer the following preliminary comments on the proposals in Appendix 1 and 2 and related text in the discussion paper. (Note: For any proposed edits to the appendices, we use bolded text to indicate proposed text to be added and strikeout for proposed deletions).

Appendix 1 Comments

Title of Appendix 1

Editorial Comment: The United States of America notes that the clarification that Nutrient Reference Values are for labelling purposes is in the preamble but not in the title of Appendix 1. The Committee may wish to consider whether this clarification should also be reflected in the title of Appendix since only the latter part of the title would be retained in a new Annex to the *Guidelines.* A slightly revised title with this addition for the new Annex would read:

"General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals **for Labelling Purposes** for the General Population"

The Committee may also consider the need for this added text in the title of the draft Annex on general principles for NRVs for nutrients associated with increased risk of noncommunicable disease.

2. DEFINITIONS

2.2. "Upper Nutrient Level (UNL) is the highest level of daily intake that is likely to pose no risk of adverse health effects for almost all individuals in a specific lifestage and sex group."

Comment: The United States of America supports the use of a consistent term and definition for upper levels of intake of nutrients in Codex texts. At the 32nd (2009) session of the Codex Alimentarius Commission, the Commission adopted the *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the (CCNFSDU)* which included the following definition:

> "Upper level of intake –The maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans."

The term and definition in the nutritional risk analysis principles are also consistent with those in the 2006 report of a joint FAO/WHO technical workshop entitled, "A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances." In the above report, "upper level of intake" is abbreviated as "UL".

Accordingly, the United States of America proposes to use the above term and definition in the current draft and consider using abbreviation "UL". The U.S. believes it is important to revise the definition in Appendix 1 to be consistent with that used in the Nutritional Risk Analysis principles, including the clarification that the maximum level refers to nutrient intake from *all* sources.

In addition in second sentence, we propose deleting"nutrient" from "Tolerable Upper ~~Nutrient~~ Intake Level" to be consistent with the term used in the U.S. and in some other countries.

3. GENERAL PRINCIPLES FOR ESTABLISHING VITAMIN AND MINERAL NRVS

A. Selection of a suitable data sources to establish NRVs

Editorial comment: Suggest delete "a" from above heading.

B. Selection of the appropriate basis

Editorial comment: In the second sentence, suggest change "sub-group" to "sub-group**(s)**".

C. Consideration of different age-sex specific values

Comment:
The United States of America notes that the majority of comments submitted by the electronic working group favored Option 2 (para 14, CX/NFSDU 09/31/4), and that the Delegation of Korea posed a question to the Committee on whether Option 1 should be deleted. The United States of America supports consideration of all comments from Codex members and observers to this document in response to this question.

The United States of America proposes the following edits to the description of Option 2:

The general population NRVs shall be determined by:

Option 2: Considering the ~~average~~ mean **of the** value**s** for **a** chosen reference population group ~~that reasonably represents the general population above 3 years of age, such as~~ **(specifically,** ~~means of~~ adult males and females **aged 19 to 50 years** ~~values~~).

Rationale:
The United States of America proposes the above revision which we believe is clear and specific about the source of the values used to determine the NRVs.
While it may be appropriate to refer to a "chosen reference population" in describing Option 2 (and we support identifying the chosen reference population), we have concerns in further characterizing this reference population as "reasonably representing the general population above 3 years of age." Such a characterization could be misinterpreted as representing the specific requirements of each age-sex group over 36 months of age, which can vary, especially for certain nutrients such as iron and vitamin D. In addition, it is likely that the proportion of adults aged 19 to 50 years varies among Codex member countries.

D. Consideration of upper levels of intake

The United States of America suggests the following edits to the first sentence to refer to "Upper Levels of Intake" and to add "recognized" for consistency with other parts of Appendix 1.

"The establishment of general population NRVs should also take into account Upper ~~Nutrient~~ Levels ~~(UNLs)~~ of **I**ntake **(UL)** established by **recognized** authoritative scientific bodies.

Appendix 2 Comments

The United States of America notes that Appendix 2 is a new proposal from the Delegation of the Republic of Korea. We offer the following preliminary comments and anticipate offering additional comments at the meeting.

3.4.4 (Third paragraph)

The United States of America suggests the following edits to the proposed text in the third paragraph of Sec. 3.4.4.

"The following Nutrient Reference Values **for labelling purposes (NRVs)** are for the general population identified as individuals older than 36 months. ~~and should be used for labelling purposes in the interest of international standardization and harmonization.~~"

Rationale: The reference to "in the interest of international standardization and harmonization" does not appear necessary, for we believe the role of Codex provisions in facilitating fair international trade is well understood in Codex texts.
In addition, the statement that NRVs *should* be used for labelling purposes appears inconsistent with the following text in the preamble of the general principles: "A government may select to use NRVs, or alternatively, consider the suitability of the general principles below and additional factors specific to a country or region in establishing their own reference values for labelling purposes."

Scope of Vitamin and Mineral NRVs

The United States of America supports, at a minimum, the establishment of new or updated NRVs for the six minerals and 13 vitamins for which Recommended Nutrient Intakes (RNI) are provided in the 2004 FAO/WHO data source. We further note that the FAO/WHO data source provides RNIs for one mineral and three vitamins which currently do not have an NRV in 3.4.4 (i.e., selenium, biotin, vitamin E, and vitamin K.)

With regard to proposing additional NRVs that go beyond the nutrients in the FAO/WHO data source, the U.S. recommends placing these nutrients in brackets in Appendix 2, pending the review of how these values were derived. For example, the U.S. notes applicable guidance in the general principles in Appendix 1 Sec. 3 B. that "In cases where there is an absence of an established INL_{98} for a nutrient for a specific subgroup, it may be appropriate to consider the use of other reference values or ranges that have been established by recognized authoritative scientific bodies. (*but that*) It is necessary to review how these values were derived on a case-by-case basis." In this regard, the Committee may wish to consider the appropriateness of setting additional NRVs based on any such values that have been derived solely or primarily from nutrient intake data that can vary among countries.

The United States of America also proposes that the Committee consider establishing an NRV for potassium. We believe that it may be more appropriate to consider an NRV with the new potential work on NRVs for nutrients associated with decreased or increased risk of non-communicable disease.

Options for Iron and Zinc Values

With regard to the three options for identifying iron and zinc NRVs, the United States of America tentatively supports the third option which would identify NRVs corresponding with three levels of bioavailability based on the 2004 FAO/WHO reference, with countries determining the NRV that best represents bioavailability of these two nutrients in their national diets. The United States of America notes that Option 1 and 2 would require that the Committee decide on a single NRV that best represents the bioavailability of the mineral in "the global diet," and that such a determination may be difficult.

Footnotes

Option 3, footnote 6 and 7, editorial comment: Propose delete "recommended".

IDF - International Dairy Federation

Table 1: The potential Nutrient Reference Values (pNRVs) derived according to Options 1 and 2, and ULs for 4-8 year age group.

IDF would like to ask the eWG to consider a more in depth opinion on the Nutrient Reference Values (NRV) of Vitamin K, based on the differences between K1 and K2.

According to Schurgers et al. (2007) Vitamin K is a cofactor in the production of blood coagulation factor (in the liver) and matrix-Gla protein (cartilage and vessel wall). Accumulating evidence suggests that for optimal bone and cardio health relative high intakes of vitamin K are required. In food, the most important K vitamins are K1 notably found in green vegetables and some plant oils, and K2 composed of several longer chains of Menaquinones (MK)- MK-7 , M-8, MK-9- notably found in fermented foods such as cheese and natto.

A major difference between the 2 vitamin K species is the very long half-life of MK-7 resulting in a much more stable serum level and higher accumulation during prolonged intake.

In addition, according to Hojo et al. (2007), the analysis of the different forms of Vitamin K in different cheese shows a noticeable difference between the types of cheese and one could observe in certain cheese variety a amount of K2 ten times higher than K1 -as an example the Jarlsberg cheese contains 653ng/g of K2 and only 60ng/g of K1.

References

Schurgers LJ, Teunissen KJF, Hamulyak K, Knapen, MHJ, Vik, H. and C Vermeer. Vitamin K-containing dietary supplements: comparison of synthetic vitamin K1 and natto-derived menaquinone-7. Blood, 2007, 109(8), 3279-3283.

Hojo K, Watanabe R, Mori T and N Taketomo. Quantitive measurement of tetrahydromenaquinone-9 in cheese fermented by Propionibacteria. J. Dairy Sc., 2007, 90, 4078-4083.