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CODEX ALIMENTARIUS COMMISSION

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Agenda Item 5 **CX/NFSDU 12/34/8-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-fourth Session

Bad Soden am Taunus, Germany
3 – 7 December 2012

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

(Comments at Step 3 at the procedure)

Comments from:

CANADA

PHILIPPINES

SOUTH AFRICA

UNITED STATES OF AMERICA

URUGUAY

IADSA - International Alliance of Dietary/Food Supplement Associations

CANADA

Draft Conclusions and Recommendations	Comments from Canada
Recommendation 1 Adopt pNRVs for vitamins and minerals other than iron and zinc derived from WHO/FAO RNIs in Group 1, Table 1 as suitable to revise the respective NRVs and to establish new NRVs in the Codex Guidelines on Nutrition Labelling	Canada agrees that there is a high probability that the pNRVs for Group 1, Table 1 nutrients are suitable given that these pNRVs were found suitable using the FAO/WHO spreadsheet reference values and the Institute of Medicine reference values (the latter demonstrated by the US) as the comparators. However, Canada proposes that the committee verify suitability of these pNRVs once all RASBs are identified for determining the other NRVs.
Recommendation 2 Regard pNRVs for vitamins and minerals derived from WHO/FAO RNIs in Group 1, Table 2 and their respective NRVs in the Codex Guidelines on Nutrition Labelling as unsuitable and set them aside for further consideration.	Canada agrees that there is a high probability that the pNRVs for Group 1, Table 2 nutrients are unsuitable given that these pNRVs were found unsuitable using the FAO/WHO spreadsheet and the Institute of Medicine (demonstrated by the US) reference values as the comparators.
Recommendation 3 Regard the pNRVs for vitamins and minerals in Group 2 in Appendix IV as unsuitable and set them aside for further consideration	Canada agrees that pNRVs for nutrients in Group 2 in Appendix IV should be considered unsuitable at this time since they were derived from only one RASB (i.e., IOM). Canada proposes that these pNRVs be assessed for suitability once all RASBs are identified. For pNRVs found unsuitable, reference values from all RASBs should be considered to derive new NRVs.
Recommendation 4 Adopt the pNRV for iron of highest absorption (and lowest pNRV) and set aside the pNRVs for the other rates of iron absorption in Appendix IV and the NRV for iron in the Codex Guidelines on Nutrition Labelling for further consideration.	Canada proposes that the pNRV for iron of highest absorption should be assessed for suitability once all RASBs are identified. Only appropriate references values for highest iron absorption should be used to assess suitability. Canada recommends seeking advice from suitable RASBs (e.g., International Zinc Nutrition Consultative Group if it qualifies as a suitable RASB) to determine whether the data are strong enough to justify as many as 4 pNRVs for iron and 3 pNRVs for zinc. Given that most if not all RASBs (and all entries in the 2012 WHO/FAO Dataset) provide only one value for iron and zinc based on a single or unknown bioavailability, this suggests a lack of support for multiple pNRVs.
Recommendation 5 Set aside the pNRVs for zinc in Appendix IV and the NRV for zinc in the Codex Guidelines on Nutrition Labelling for further consideration.	See comment above

Draft Conclusions and Recommendations	Comments from Canada
Recommendation 6 Revise 'bioavailability' to 'absorption' for iron and zinc in Appendix IV	Canada agrees with replacing "bioavailability" with "absorption" in Appendix IV.
Recommendation 7 Agree in principle to include dietary descriptions corresponding to the established rates of absorption for iron and zinc**.**	Canada agrees with including dietary descriptions corresponding to the established rates of absorption for iron and zinc if it is decided to establish multiple pNRVs.
Recommendation 8 Agree that a definition of 'recognized, authoritative, scientific body' should be established and give consideration to the proposed definition	Canada agrees that a definition of a RASB should be established and the definition proposed by the US should be considered (p12, SCP). . Canada prefers [at least] to [more than] so that relevant bodies that meet the criteria for a RASB are not excluded if only one country used its advice to develop policies. The number of countries that use the advice of a RASB does not necessarily reflect the quality of the advice or its relevance to the international setting.
Recommendation 9 Consider providing indicative comment on an appropriate future stepwise decision-making process to recommend replacement and new pNRVs particularly in relation to Step 6.	Canada suggests that the committee consider clarifyingthe steps in establishing a pNRV when there are several candidate pNRVs from RASBs.
Recommendation 10 Adopt the conversion factors for niacin and folate in Appendix IV but in a re-expressed and consistent format. Revise the conversion factors for vitamin A considering WHO/FAO (2006) as a source, and consistent with the adopted format. Give consideration to including conversion factors for supplemental and/or fortificant forms for folate and vitamin A. Set aside the conversion factors for vitamin E for further consideration	Canada agrees with the conversion factors for vitamin E, niacin and folate. Canada suggests that the committee consider revising the units for vitamin A from RE to RAE as in the IOM report released in 2001, which reflects more recent scientific data. The IOM DRI report recommends that the use of alpha-tocopherol equivalents (alpha-TE) be abandoned due to lack of evidence of bioavailability of the other forms of vitamin E (besides alpha-tocopherol). The report states that the other forms of vitamin E (beta/gamma/delta tocopherols, as well as all the tocotrienols) do not contribute to meeting the vitamin E requirement because they are not converted to alpha-tocopherol in humans. We suggest that the use of alpha-TE be abandoned and that the units for vitamin E be revised to reflect only alpha-tocopherol.
Recommendation 11 Delete footnotes 3 and 5 from Appendix IV, and also delete the second sentence of footnote	Canada agrees it is not necessary to retain Footnote 3 and 5. Canada also supports deleting the second sentence in Footnote 9. We note that this footnote may not be needed if a decision is made not to establish multiple pNRVs for iron and zinc.

Draft Conclusions and Recommendations	Comments from Canada
Recommendation 12 Give consideration to the placement of any guidance material produced to implement the General Principles and consider whether the decision making process for the revision and further development of NRVs for vitamins and minerals should be recorded and if so, where in Codex document(s) the information would be best recorded.	Canada supports the documentation of the decision making process for the revision and further development of NRVs for vitamins and minerals. We support the approach of consolidating this information into an Appendix to a Report of a future CCNFDSU session.
Recommendation 13 Request WHO and FAO representatives to report details about the progress, concrete plans and timeframe for re-establishing JEMNU.	Canada supports this request to the WHO and FAO representatives.

PHILIPPINES

POSITION

The Philippines appreciates the work of Australia and the electronic working group for the improvements made in the proposed draft.

The Philippines supports the proposed Suitable Nutrient Reference Values (Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenate, Biotin, Calcium and Iodine in Table 1 since the values of these nutrients are similar, if not closely similar with the values of the Philippine Recommended Energy and Nutrient Intake (RENI) for these nutrients.

In our view, the inclusion of footnote 8 indicating that countries should determine the appropriate NRV that best represents the bioavailability of iron and zinc in national diets is acceptable.

We are of the opinion that the recommended nutrient intakes based on large databases and Upper Level of Intake based on current scientific data could be considered to replace unsuitable NRVs.

RATIONALE

The argument of global harmonization of nutrient-based dietary guidelines is based on the premise that the physiologic requirements are expected to be similar across healthy population groups. However, nutrient requirements are known to be affected by other factors such as genetic heterogeneity, usual diet composition, lifestyle, etc. (WHO/FAO Vitamin and Mineral Requirements in Human Nutrition, 2004). Our support for the proposed values of Vitamin K, Thiamin, Riboflavin, Vitamin B6, Folate and Vitamin B12 stems from the fact that these values are similar if not closely similar with the Philippine recommended nutrient intakes for these nutrients. These recommended intakes which on the basis of current scientific knowledge are considered adequate for the maintenance of health and well-being of nearly all healthy persons in the population (Nutrition Review 50 (3:89, 1992).

Although the Philippines uses recommended energy and nutrient intakes (RENI) for specific age groups, we are of the opinion that the proposed Nutrient Reference Values maybe considered as useful reference values for nutrients without established RENI. These nutrients include Panthothenic acid and Biotin. We prefer establishment of NRVs for Chloride, Copper, Manganese, Chromium and Molybdenum since these nutrients have no RENI.

Inclusion of Footnote 8 will give flexibility to national governments to establish NRVs that will best correspond to the % absorption of iron and zinc in the country's diet considering the variations in the typical composition and food sources of these minerals in the local diets. Hence, in our view, 14.4 mg NRV for Iron and 6 mg NRV for Zinc are acceptable since these values are closest to the national recommended intakes.

For other vitamins (vitamins A, D, E, C) and minerals (magnesium and selenium) in Table 2 found unsuitable by the EWG, it is reiterated that the three General Principles (3.1.2, 3.2.1 and 3.3) should be consistently applied in establishing new proposed NRVs. We believe that the proposed stepwise decision making process to be used to derive NRVs for vitamins and minerals would be useful. Pending a concrete definition of "recognized authoritative scientific body" and results of joint FAO/WHO committee (JEMNU), we are of the opinion that recommended intakes based on large databases and Upper Level of Intake established based on based on current scientific data be reviewed to determine if these could also be considered to derive NRVs. After all, determining nutrient requirements and recommended intakes can be largely based on expert interpretation and consensus on the best available scientific information.

SOUTH AFRICA

For Attachment 1

South Africa welcomes the addition of more nutrients to the list of nutrient reference values for labeling purposes in the Codex Guidelines on Nutrition labeling. General principles for developing NRVs of vitamins and minerals for the general population were finalized 32nd CCNFSDU meetings and were acceptable to South Africa. However, as a developing country, food and nutrition security remains a challenge and national studies indicate wide-spread micronutrient deficiencies in both children and adults. On this premise, South Africa is concerned about the low values obtained for nutrients in Group 2 (vitamins A, D, E and C and minerals magnesium and selenium) and agrees that these values are "unsuitable" and that they should be further considered. South Africa is also concerned about the lower values recommended for some nutrients in Group 1 (thiamin, riboflavin, niacin and vitamin B6) and pleads for flexibility to allow National Governments to set higher NRVs which will not exceed the upper levels of intake.

South Africa supports the adoption of the term % absorption for zinc and iron to a minimum of two values i.e. highest and lowest % absorption value. This allows national governments flexibility to establish NRVs that best correspond to their national diets.

South Africa agrees that a definition of a "recognized authoritative, scientific body" should be discussed and defined (also in context of the developing world in countries with limited resources).

South Africa further supports the proposed new text for the conversion factors for vitamins equivalents to enable the national authorities to determine the application of NRVs at national level.

UNITED STATES OF AMERICA

B. CX/NFSDU 12/34/8 on Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling: Agenda #8

The United States thanks Australia for chairing the eWG on this agenda item. We offer the following comments on the recommendations on p.13 in CX/NFSDU 12/34/8. These recommendations address the eWG's second term of reference which is to recommend vitamin and mineral NRVs and footnotes for the general population older than 36 months.

Group 1, Table 1 Nutrients: Identification of pNRVs derived from WHO/FAO Values that are *Suitable*

Recommendation 1

Adopt pNRVs for vitamins and minerals other than iron and zinc derived from WHO/FAO RNIs in Group 1, Table 1 as suitable to revise the respective NRVs and to establish new NRVs in the Codex Guidelines on Nutrition Labelling.

Note: Group 1, Table 1 nutrients on p. 4 in CX/NFSDU 12/34/8 includes vitamin K, thiamin, riboflavin, niacin, vitamin B_6, folate, vitamin B_{12}, pantothenate, biotin, calcium and iodine.

U.S. Comments:

The U.S. agrees that the pNRVs for vitamins and minerals derived from WHO/FAO RNIs in Group 1, Table 1 are suitable. Accordingly, we support revising Section 3.4.4 in the Guidelines on Nutrition Labelling to reflect these values. Our rationale is below.

Approach for Assessing Suitability

The U.S. supports the determination of suitable and unsuitable pNRVs derived from the WHO/FAO RNIs in accordance with the adopted general principles (GP) for establishing vitamin and mineral NRVs for the general population (CAC/GL 2-1985, Annex). This includes GP 3.1.2 which indicates that in addition to FAO/WHO values as primary sources for establishing NRVs, relevant and recent values that reflect *independent review* of the science from *recognized authoritative scientific bodies* other than FAO/WHO could also be considered. Accordingly, the U.S. considers that only values that are in accordance with GP 3.1.2 are appropriate as comparators to assess the suitability/unsuitability of pNRVs derived from the FAO/WHO values.

The Committee may wish to consider the compilation of daily intake reference values used by the subset of Codex member countries in the FAO/WHO spreadsheet as background or supplementary information. However, the U.S. does not consider the use of a median pNRV derived these values appropriate as the main basis for assessing suitability/unsuitability because of the spreadsheet limitations in implementing GP 3.1.2. Specifically, the spreadsheet cannot be used to identify daily intake reference values from recognized authoritative scientific bodies *only* or to assess which values are based on an independent review of the science. In addition, another limitation is the lack of common terminology, with countries and scientific bodies using the same term to describe different concepts (CX/NFSDU 11/33/4 p.8 and CX/NFSDU 12/34/8 Attachment 4).

Need for Working Definition of a "Recognized Authoritative Scientific Body" ("RASB") to implement GP 3.1.2

As addressed in later recommendations, in order to implement GP 3.1.2 for all NRVs, the U.S. supports the Committee's development of a working definition of a "recognized authoritative scientific body". The U.S. proposes the following definition:

> Recognized Authoritative Scientific Body ("RASB")
>
> "For the purposes of establishing Codex Nutrient Reference Values, an organization supported by a government(s) to provide independent and transparent* authoritative scientific advice on daily intake reference values upon request, and for which such advice is recognized through its use in the development of policies in more than one country."
>
> * In providing *transparent* scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value to understand the derivation of the value.

At a minimum, the U.S. considers that the Institute of Medicine of the National Academies of sciences (IOM) in the U.S. would meet the above definition for a RASB. As identified on its web site,[1] the IOM is

[1] About IOM page. Institute of Medicine Web Site. http://iom.edu/About-IOM.aspx . Accessed April 4, 2012.
IOM Study Process page. Institute of Medicine Web Site. http://www.iom.edu/About-IOM/Study-Process.aspx . Accessed April 4, 2012.

an independent, nonprofit organization established in 1970 that works outside of government to provide unbiased and authoritative advice to decision makers and the public on questions about health and health care. The IOM applies a rigorous research process in which committee members are carefully selected to ensure an appropriate range of expertise for a task with a balance of perspectives, and provisional committee members are screened to avoid conflicts of interest. The IOM study process involves checks and balances at every step to protect the integrity of its reports. In 1995, the Food and Nutrition Board of the IOM, with support from the governments of Canada and the U.S., established the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes (DRIs) to oversee the development of DRIs for nutrients. This comprehensive effort has resulted in a series of DRI reports published between 1997 and 2010 which expands on and replaces previous Canadian and U.S. reference intakes.

Group 1, Table 1 Nutrients: Comparison of pNRVs Derived from WHO/FAO with IOM Recommended Intakes

Attachment A compares pNRVs calculated from the WHO/FAO recommended intakes with those from IOM. Based on this comparison, all pNRVs derived from WHO/FAO RNIs in Table 1, Group 1 appear suitable. Specifically, there are no differences between the pNRVs derived from the FAO/WHO and IOM values for the following vitamins and minerals: thiamin, riboflavin, niacin, vitamin B6, Vitamin B12, folate, pantothenate, biotin, calcium and iodine. For vitamin K, the pNRV derived from the FAO/WHO values (i.e, 60 mg) differed considerably from the pNRV derived from the IOM values (i.e., 105 mg). However, given that the former is an INL_{98} value and the latter is an Adequate Intake value based on median Vitamin K intakes in the U.S., we consider that the vitamin K pNRV derived from the FAO/WHO values is suitable, in the absence of compelling recent scientific evidence from FAO/WHO or another recognized authoritative scientific body to reconsider this pNRV.

Group 1, Table 2 Nutrients: Identification of pNRVs derived from WHO/FAO Values that are *Unsuitable*

Recommendation 2

Regard pNRVs for vitamins and minerals derived from WHO/FAO RNIs in Group 1, Table 2 and their respective NRVs in the Codex Guidelines on Nutrition Labelling as unsuitable and set them aside for further consideration

Note: The Group 1, Table 2 nutrients on p. 5 in CX/NFSDU 12/34/8 include vitamin A, Vitamin D, Vitamin E, Vitamin C, magnesium and selenium.

U.S. Comments:

The U.S. agrees that the pNRVs for vitamins and minerals derived from WHO/FAO RNIs in Group 1, Table 2 may be unsuitable. Accordingly, we support considering additional scientific advice in accordance with the GP. Our rationale is provided below.

Group 1, Table 2 Nutrients: Comparison of pNRVs Derived from WHO/FAO with IOM Recommended Intakes

With regard to identifying a subset of the WHO/FAO pNRVs to consider additional scientific advice, we note from Attachment A that the difference the WHO/FAO pNRVs and IOM pNRVs (calculated from INL_{98} values only except for vitamin E) is $\geq$ a minimal "threshold" difference of 10 percent[2] for the following nutrients:

vitamin A (-31%)

[2] The U.S. considers that a minimal threshold difference of 10% may be useful as one criterion to identify pNRVs derived from RNIs that may be unsuitable. Given that a 10% Coefficient of Variation was generally assumed for IOM estimated average requirements, the U.S. supports the use of a 10% difference in initial screening for suitability when quantitative percentage differences can be determined (e.g,, the values compared are all INL_{98} values and in the same units).

vitamin D (-67%)

vitamin E (-41%)

vitamin C (-54%)

magnesium (-34%)

selenium (-45%)

For vitamin A, quantitative differences between WHO/FAO pNRVs and IOM pNRVs are identified in Attachment A even though there are different units (with the former being in Retinol Equivalents (RE) and the latter in Retinol Activity Equivalents (RAE)).[3] [4] Based on reviewing reports for these values, the U.S. supports considering additional scientific advice for vitamin A in accordance with the GP, including the IOM values. Specifically, we consider two limitations of the WHO/FAO pNRVs for Vitamin A are that they are not based on INL_{98} values and the units are in RE rather than RAE.[5]

The 2001 IOM report that provides INL_{98} values for vitamin A in RAE addressed these limitations.[6] It concluded that 50 percent less bioconversion of carotenoids to vitamin A in food occurs than was previously thought when vitamin A was expressed in REs. Thus, vitamin A is an example where recent and relevant values from a recognized authoritative scientific body (in this case the IOM) provide INL_{98} values that update "recommended safe intakes" from the 1998 Joint FAO/WHO Expert Consultation and address the limitations of the FAO/WHO values identified in the 2004 report.

Group 2 Nutrients: pNRVs for Other Nutrients that Do Not Have WHO/FAO Values

Recommendation 3

Regard the pNRVs for vitamins and minerals in Group 2 in Appendix IV as unsuitable and set them aside for further consideration.

Note: The Group 2 nutrients in ALINORM 10/33/26, Appendix IV include phosphorus, chloride, copper, fluoride, manganese, chromium, and molybdenum.

U.S. Comments:

The U.S. does not consider that *all* pNRVs in Appendix IV, which were derived from IOM values, are necessarily unsuitable. Rather, the wording in the eWG report on p.7 indicates that certain GP had not been *fully* considered, including 3.2.1 which addresses the preferred use of INL_{98} values. It may be noted that the IOM established INL_{98} values for three of the seven nutrients—phosphorus, copper and molybdenum.

With regard to further consideration of the Group 2 nutrients, the U.S. suggests that the Committee first discuss the global public health significance of these nutrients, their relevance to all Committee members, and the need for NRVs for one or more of these nutrients (as opposed to food label reference values established by governments.

[3] Conversion factors for RAE are identified in Attachment A.

[4] The units RE and RAE are assigned for the purpose of determining the vitamin A activity of a food for meeting the daily requirement (µg/day).

[5] These limitations are identified on p. xvi of the 2004 WHO/FAO report as follows:

> "Conversion factors for carotenoids are under review, with the pending conclusion that servings of green leafy vegetables needed to meet vitamin A requirements probably need to be at least doubled. In view of this uncertainty, only "recommended safe intakes" rather than RNIs are provided for this vitamin."

[6] Institute of Medicine. *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc.* Washington DC:National Academies Press, 2001.

Iron and Zinc: Identification of pNRVs derived from WHO/FAO Values that are Suitable/Unsuitable

Recommendation 4

Adopt the pNRV for iron of highest absorption (and lowest pNRV) and set aside the pNRVs for the other rates of iron absorption in Appendix IV and the NRV for iron in the Codex Guidelines on Nutrition Labelling for further consideration.

U.S. Comments

At this time, the U.S. considers that all four pNRVs for iron derived from the FAO/WHO values appear to be suitable. However, in light of the eWG's support for footnote 9 and Preamble which provide governments flexibility to establish NRVs that best correspond to national diets, the Committee could consider the suitability of using two NRVs for iron (specifying an upper and lower range for bioavailability) for labelling purposes.

The U.S. supports the recommendation to adopt the pNRV for iron of 14.4 mg (15% absorption) that was derived from the FAO/WHO values, and which differs little from the current iron NRV of 14 mg. However, we do not support the use of the FAO/WHO spreadsheet as the main basis for this recommendation. In addition, the U.S. supports consideration of one or more of the higher pNRVs for iron derived from FAO/WHO based on lower absorption, depending on countries' interest in these values.

Recommendation 5

Set aside the pNRVs for zinc in Appendix IV and the NRV for zinc in the Codex Guidelines on Nutrition Labelling for further consideration.

U.S. Comments:

At this time, the U.S. considers that all pNRVs for zinc derived from the FAO/WHO values may be suitable. We look forward to further discussion of these values at the Committee meeting. As with iron, the Committee could consider the suitability of using two NRVs for zinc (specifying an upper and lower range for bioavailability) for labelling purposes.

Recommendation 6

Revise 'bioavailability' to 'absorption' for iron and zinc in Appendix IV.

U.S. Comments:

We agree with referring to iron and zinc "absorption" rather than "bioavailability" given that the definition of "bioavailability" in the Codex Nutritional Risk Analysis Principles (CAC, 2011) refers to metabolism as well as absorption.

Recommendation 7:

Agree in principle to include dietary descriptions corresponding to the established rates of absorption for iron and zinc.

U.S. Comments:

We agree in principle to include these dietary descriptions.

Definition of "Recognized Authoritative Scientific Body"

Recommendation 8

Agree that a definition of 'recognized, authoritative, scientific body' should be established and

give consideration to the proposed definition.

U.S. Comments:

As earlier noted, the U.S. agrees that a working definition of "recognized authoritative scientific body" should be established for use by the Committee in implementing GP 3.1.2 for all NRVs. The U.S. suggests the following edits to the draft definition of "recognized authoritative scientific body" identified on p.8 of the eWG report for consideration:

> Recognized Authoritative Scientific Body ("RASB"
>
> "For the purposes of establishing Codex Nutrient Reference Values, an organization supported by a government(s) to provide independent and transparent* authoritative scientific advice on [dietary intake reference values] [daily intake reference values] upon request, and for which such advice is recognized through its use in the development of policies in ~~[at least]~~ ~~[~~more than one~~]~~ country."
>
> * In providing *transparent* scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value.
>
> Rationale for suggested edits:

- We suggest adding "transparency" with an explanatory footnote. In addition, we consider that appropriate websites and references of potential RASBs could be provided to assist in assessing which nominated RASBs meet the definition.
- We suggest placing "*dietary* intake reference values" in brackets. We do not object to this term, but are wondering whether "*daily* intake reference values should be used here to be consistent with terminology in the general principles.
- We propose that the scientific advice be recognized by more than one country because we consider that these recommendations would have more international relevance.

Step Decision-Making Process to Recommend Replacement and New pNRVs

Recommendation 9

Consider providing indicative comment on an appropriate future stepwise decision-making process to recommend replacement and new pNRVs particularly in relation to Step 6.

U.S. Comments:

We have several questions and comments about the Chair's new proposal of the seven step process identified on p. 9 of the eWG report. First, we request confirmation that this process is proposed only for NRVs based on requirements. This appears to be the case with the reference in Steps 3 and 4 to vitamins and minerals. Second, we believe discussion is needed on which proposed steps (and decision-making) would be most appropriately done by the full Committee and which could be delegated to a eWG. Based on this discussion, certain steps might be clarified. For example, the Committee could *select* which additional vitamins and minerals should be considered for an NRV beyond the values agreed upon at the upcoming session and decide on a preliminary working definition for a RASB, whereas an eWG could *recommend* which nominated organizations meet this working definition, with a final determination made by the Committee after possible adjustment of the definition after its

application. We likewise consider that the last step (#7) of deciding whether advice should be requested from WHO/FAO and provisional NRV(s) established if consensus can't be reached would be most appropriately made by the Committee.

In addition, with regard to Steps 6a and 6b and consistent with our view that the scientific basis of daily intake reference values from RASB be transparent, we consider that the Committee (and eWG) should have access to how values from RASB were derived.

Conversion Factors for Vitamin Equivalents that are Relevant to NRVs

Recommendation 10

Adopt the conversion factors for niacin and folate in Appendix IV but in a re-expressed and consistent format. Revise the conversion factors for vitamin A considering WHO/FAO (2006) as a source, and consistent with the adopted format. Give consideration to including conversion factors for supplemental and/or fortificant forms for folate and vitamin A. Set aside the conversion factors for vitamin E for further consideration.

U.S. Comments:

The U.S. supports continuing to include conversion factors for vitamin equivalents that are relevant to NRVs in Section 3.4.4 of the Guidelines because they provide important context for using and interpreting NRVs.

We support the adoption of the conversion factors for niacin and folate in the suggested format in Table 7 on p. 10 of the eWG report, except we suggest that the conversion factors for folate be slightly revised as follows based on consideration of the 1998 IOM report on folate intake recommendations:

Vitamin	Dietary Equivalents	
Folate	1 µg dietary folate equivalents (DFE)=	1 µg food folate 0.6 µg folic acid as fortificant or as supplement consumed with food 0.5 µg folic acid as supplement taken on an empty stomach

With regard to vitamin A, we propose the following edits to the expression of the conversion factors on p. 16 of the eWG report which are intended for clarification. In addition, although the eWG report suggests the term "Retinol Equivalent (RE)" be retained for consistency with terminology in two recent FAO/WHO reports despite the doubling of the conversion factors for carotenoids since the 2004 report, we propose that "Retinol Activity Equivalents (RAE)" be used instead to avoid confusion, because RE represents a different meaning of the vitamin A activity in fruits and vegetables (i.e., provitamin A carotenoids).

Vitamin	Dietary Equivalents	
Vitamin A	1 µg Retinol Activity Equivalent (RAE)=	~~[~~1 µg all-*trans*-retinol 12 µg dietary all-*trans*-β-carotene 24 µg dietary α-carotene or β-cryptoxanthin ~~other provitamin A carotenoids~~ ~~[~~2 µg all-*trans*-*β*-carotene (as supplement)~~]~~

Footnotes

Recommendation 11

Delete footnotes 3 and 5 from Appendix IV, and also delete the second sentence of footnote 9.

U.S. Comments:

The U.S. agrees with the above recommendation. Specifically, we agree that footnote 3 (which indicates that the NRVs should be kept under review) is unnecessary because it is always possible to update Codex texts in light of new developments. We further agree that footnote 5 (which clarifies that NRVs for certain nutrients may not be applicable to certain countries) is not needed because this is acknowledged in the Preamble. In addition, we agree with removing the second earlier proposed sentence in footnote 9 which refers to guidance in a 2004 WHO publication because over time guidance documents may become outdated and superseded by more recent evidence.

Guidance to Implement the General Principles

Recommendation 12

Give consideration to the placement of any guidance material produced to implement the General Principles and consider whether the decision making process for the revision and further development of NRVs for vitamins and minerals should be recorded and if so, where in Codex document(s) the information would be best recorded.

U.S. Comments:

We do not consider that there is a need to revise the Annex (es) on general principles to include any additional guidance on implementing these general principles. Whereas the U.S. supports the Committee's development of a working definition of a "recognized authoritative scientific body", a record of decision making on a preliminary definition can be recorded in the 34th CCNSFDU session report, and any needed revisions recorded in a subsequent report(s). At this time, we consider it premature to comment on possible placement of potential additional guidance to implement the GP until the nature of such guidance can be clarified and discussed.

Mechanism for Providing FAO/WHO Joint Scientific Advice on Nutrition

Recommendation 13

Request WHO and FAO representatives to report details about the progress, concrete plans and timeframe for re-establishing JEMNU.

U.S. Comments:

We agree with this recommendation. As noted in the eWG report, the CCNFSDU currently does not have a mechanism for obtaining joint FAO/WHO scientific advice on review of NRVs and other nutrition topics. Although the WHO representative indicated at the last CCNFSDU session that "consultations were ongoing with FAO" regarding the establishment of a joint FAO/WHO committee (JEMNU), no additional details were provided to assess whether any progress has resulted from these consultations (REP 12/NFSDU, para 25).

In a related issue, we are pleased that JEMNU is included in the draft Codex Strategic Plan for 2014-2019 among the FAO/WHO expert bodies identified relative to Objective 2.2- Achieve sustainable access to scientific advice (REP12/EXEC 2, June 2012).

Attachment A

Comparison of FAO/WHO[1] and Institute of Medicine (IOM) pNRVs for Vitamins and Minerals

Vitamins and Minerals	1) pNRVs Appendix IV (Based on WHO/FAO 1998 consultation[1])	WHO/FAO RNI M 19-50 y / F 19-50 y	2) pNRVs Calculated[2] from IOM Recommended Intakes[3 4]	IOM Recommended Intakes M 19-50 y / F 19-50 y	Year of IOM Report / Latest Literature Cited	pNRVs : % Difference of 1) from 2) w/ IOM values as the Base (≥ 10% in Bold)
Vitamins						
Vitamin A	**550[5] (µg RE)**	600/500 (µg /RE)	**800 (µg RAE[6])**	900/700 (µg RAE)	2001/2000	**-31%**
Vitamin D (µg)	**5**	5/5	**15**	15/15	2011/2010	**-67%**
Vitamin E (mg α-TE)	**8.8[7]**	10/7.5	**15**	15/15	2000/2000	**-41%**
Vitamin K (mg)	**60**	65/55	**105***	120*/90*	2001/1999	**Apparent considerable difference; Not quantified because IOM values are based on U.S. median intakes.**
Vitamin C (mg)	**45**	45/45	**83**	90/75	2000/2000	**-54%**
Thiamin (mg)	**1.2**	1.2/1.1	**1.2**	1.2/1.1	1998/1997	0
Riboflavin (mg)	**1.2**	1.3/1.1	**1.2**	1.3/1.1	1998/1997	0
Niacin (mg NE)	**15**	16/14	**15**	16/14	1998/1997	0
Vitamin B_6 (mg)	**1.3**	1.3/1.3	**1.3**	1.3/1.3	1998/1998	0
Folate (µg DFE)	**400**	400/400	**400**	400/400	1998/1998	0
Vitamin B_{12} (µg)	**2.4**	2.4/2.4	**2.4**	2.4/2.4	1998/1998	0
Pantothenate (mg)	**5.0**	5/5	**5**	5*/5*	1998/1996	0
Biotin (µg)	**30**	30/30	**30**	30*/30*	1998/1997	0 (IOM values are based on limited U.S. intake data and extrapolations from infant data)
Minerals						
Calcium (mg)	**1000**	1000/1000	**1000**	1000/1000	2011/2010	0
Magnesium (mg)	**240**	260/220	**365[8]**	M 400 (19-30) 420 (31-50)/ F 310 (19-30) 320 (31-50)	1997/1997	**-34%**
Iodine (µg)	**150**	150/150	**150**	150/150	2001/2000	0

Vitamins and Minerals	1) pNRVs Appendix IV (Based on WHO/FAO 1998 consultation[1])	WHO/FAO RNI M 19-50 y / F 19-50 y	2) pNRVs Calculated[2] from IOM Recommended Intakes[3 4]	IOM Recommended Intakes M 19-50 y / F 19-50 y	Year of IOM Report / Latest Literature Cited	pNRVs : % Difference of 1) from 2) w/ IOM values as the Base (≥ 10% in Bold)
Iron (mg) (% bioavailability)						
15%	**14.35 (14.4 if round up)**	9.1/19.6	**13 (18% bioavailability)**	8/18 (18% bioavailability)	2001/2000	Apparent minimal difference based on similar bioavailability.
12%	**18.0**	11.4/24.5	--	--	--	N/A[9]
10%	**21.6**	13.7/29.4	--	--	--	N/A
5%	**43.1**	27.4/58.8	--	--	--	N/A
Zinc (mg) (% bioavailability)						
(bioavailability unspecified)	--	--	**9.5**	11/8	2001/2000	Difference can't be quantified
(high)	**3.6**	4.2/3.0	--	--	--	*(see above)*
(moderate)	**6.0**	7.0/4.9	--	--	--	*(see above)*
(low)	**11.9**	14.0/9.8	--	--	--	*(see above)*
Selenium (µg)	**30**	34/26	**55**	55/55	2000/1999	**-45%**

[1]World Health Organization (WHO) . *Vitamin and Mineral Requirements in Human Nutrition*. 2nd Ed. Geneva:WHO; 2004.
[2]These pNRVs are rounded up in the same manner as the pNRVs in Appendix IV. For example, the pNRV for vitamin C is 83 mg based on rounding up the value of 82.5 mg,
[3]Attachment B identifies citations for the IOM reports for these recommended intakes and web links to access the full reports.
[4]Note: An asterisk (*) identifies IOM "Adequate Intake" (AI) values; all other IOM recommended intakes are INL_{98} values. The AI is believed to cover the needs of all healthy adults, but data were insufficient to establish an estimated average requirement and INL_{98}.
[5]This value is identified as a "recommended safe intake" rather than a Recommended Nutrient Intake (or INL_{98} value). The 2004 report noted that RNIs for vitamin A could not be calculated because of inadequate data to derive mean requirements.
[6]As retinol activity equivalents (RAEs). 1 RAE= 1 µg retinol, 12 µg ß-carotene, or 24 µg α-carotene, or 24 µg ß-cryptoxanthin. The RAE for dietary provitamin A carotenoids is two-fold greater than retinol equivalents (RE), whereas the RAE for preformed vitamin A is the same as RE.
[7]Data were insufficient to establish an estimated average requirement and Recommended Nutrient Intake (INL_{98}). As noted on p.341 of the 2004 WHO report, *Vitamin and mineral Requirements in Human Nutrition*, the values for Vitamin E "represent the best estimate of requirements".
[8]For this calculation, the daily intake reference values were weighted according to the relative proportion of years in each age group within the relevant age range.
[9]N/A = Not Applicable.

Attachment B

Below are citations for the Institute of Medicine reports on recommended intakes in Attachment A for comparison with the FAO/WHO values. Underlined text identifies the relevant nutrients in each report.

IOM (Institute of Medicine). 2011. *Dietary Reference Intakes for Calcium and Vitamin D.* Washington, DC: The National Academies Press.

Note: This report updates the Calcium and Vitamin D Dietary Reference Intakes (DRIs) published in 1997.

1. IOM. 2001. *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc.* Washington, DC: National Academy Press.
2. IOM. 2000. Dietary *Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids.* Washington, DC: National Academy Press.
3. IOM. 1998. *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline*. Washington, DC: National Academy Press.
4. IOM. 1997. *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride*. Washington, DC: National Academy Press.

Note: For 1-4 above, a PDF file of the reports can be downloaded from the following website:

About Reports page. Institute of Medicine of the National Academies Web site.

http://www.iom.edu/Reports.aspx?page=1&Series={508F5CFF-EE88-4FF6-92BF-8D6CAB46F52E} Accessed September 5, 2012.

For the 1997 DRI report identified in 5 above, the report can be accessed at:

http://www.nap.edu/openbook.php?record_id=5776 . Accessed September 5, 2012.

URUGUAY

Uruguay thanks Australia for the opportunity to present the following comments

1) Uruguay agrees with the proposal for of 20 g a day to saturated fatty acids and 2000 mg to sodium
2) After carefully reading the final document prepared by the coordination of electronic working group, Uruguay has no further comments to add.

IADSA - International Alliance of Dietary/Food Supplement Associations

IADSA welcomes the opportunity to comment on the Report of the Electronic Working Group on the Proposed Draft Additional or Revised Nutrient Reference Values (NRVs) for Labelling Purposes in the Codex Guidelines on Nutrition Labelling (CX/NFSDU 12/34/8). IADSA general comments are as follows:

1. IADSA would like to reiterate its previous comments about the difficulties of comparing the pNRVs with the upper levels of intake (ULs) for young children and the need for caution so as not to raise unnecessary concerns about exceeding these ULs. This approach is included as Step 5 in the proposed **Stepwise Procedure on page 9, Section 3.2**. The significant uncertainties surrounding the derivation of the children's ULs make it unlikely that intakes that exceed the UL by small amounts are the problem, but rather that application of a UL on the basis of inadequate data is. For some nutrients, the narrow range between an RDA or pNRV and the UL is unjustified, and caution is needed not be overly restrictive in establishing NRVs that are too low, e.g. vitamins A, C, D and E and the minerals zinc, magnesium and selenium (Zlotkin S, (2006) A critical assessment of the upper intake levels for infants and children *J Nutr* **136**: 502S–506S).

Additional points:

- Children generally have a higher intake of food and nutrients expressed per kilogram of bodyweight compared with adults and are potentially the most vulnerable group to exceed the UL.

- Each nutrient should be considered separately based on the available (usually limited) intake data from conventional foods, foods with added nutrients and food supplements.

- All three groups of scientific risk assessors, US IOM, EFSA and the UK EVM, address the setting of ULs for children, and the accepted method is, where appropriate, to extrapolate the UL from adult data, usually made on the basis of bodyweights by means of reference bodyweights. The large differences in bodyweights between younger and older children can markedly influence the magnitude of the UL. To illustrate the point, in the extrapolation of data from adults to children based on bodyweights the following equation is often used:

$$\textbf{UL children} = \textbf{UL for adults} \times \frac{\textbf{weight of child}}{\textbf{weight of adult}}$$

Based on a reference bodyweight for adults of 70 kg and a child weighing 20 kg, the child's UL for a 4–6 year old would be estimated to be 29% of the adult value, whereas for a 7–10 year old weighing 28.5 kg, the UL would be 41% of the adult UL.

- Clearly, the use of the lower UL for 4–6 year old children introduces a very substantial precautionary measure. The children's ULs are taken from adult risk assessments where they are set, and these ULs already have built-in precautions for chronic exposure.

2. Conceptually, it is necessary to consider the amounts of vitamins and minerals that maximise a healthy lifespan that are higher than the amounts needed to prevent acute deficiency diseases on which RDAs are based. The setting of requirements of key micronutrient compounds need a greater emphasis on development, degenerative diseases and ageing itself to prevent damage to DNA as well as focusing on avoidance of micronutrient deficiencies (Hanekamp JC and Bast A (2007) A critique and implications for nutritional, toxicological and regulatory consistency. *Critical Reviews in Food Science and Nutrition* **47**: 267–285).

3. IADSA supports the use of median INL_{98} values where they are available and pragmatic approaches where the data sets for AIs are substantial and supportive **(see section 3.1.2 General Principle 3.2.1)**.

4. Regarding **section 2.1 Group 1 pNRVs (Vitamin A to Selenium, excluding zinc and iron),** and particularly **Table 1: Suitable pNRVs Group 1 (page 4):** IADSA supports the pNRVs for vitamins and minerals in Table 1 except for biotin, which is considered too low at 30 µg. An pNRV of 50 µg/day would

be considered appropriate. The decisions about the pNRV for biotin could be deferred, but as there are no major safety issues, IADSA recommends that the level for biotin could be resolved speedily.

5. Regarding **section 2.2 Iron and Zinc**, and particularly **Table 3: Iron and zinc pNRVs, Appendix IV (pages 5-7),** IADSA considers that there is a paucity of data underpinning the percentage absorption assumptions for iron and zinc, and recommends the pragmatic use of single values of 14 mg and 10 mg for iron and zinc, respectively, for labelling purposes. IADSA supports a single value for an NRV. However, countries should be free to determine the percentage absorption if based on evidence by RASBs and knowledge of the effects of national diets.

6. **Scope:** IADSA supports the exclusion of sodium and fluoride. A key objective of the review is to include additional essential micronutrients. In the UK, the Expert Vitamins and Minerals Group concluded that it was more appropriate to consider sodium chloride as a salt rather than the separate elements. IADSA supports the argument that the consideration of salt intakes and reduction of chronic disease is a separate exercise. In the case of fluoride, this element is considered to be essential, although this is difficult to demonstrate experimentally. IADSA would argue that fluoride is not a priority for use in fortified foods or food supplements, and that the two major sources of exposure are drinking water and dental products. Determining the risks and benefits of fluoride should be considered as a separate exercise.

7. IADSA considers that the US 4-step proposal made to the EWG generally implements GP 3.1.2, as these steps provide a pragmatic framework for the progression of the work programme.

8. IADSA supports the US proposal made to the EWG for the definition of a Recognised Authoritative Scientific Body (RASB) and the New Zealand proposal made to the EWG for the concept of a systematic review. IADSA supports the proposals for nominated RASBs. There are national authoritative scientific bodies that could be considered, e.g. the UK Scientific Advisory Committee on Nutrition (SACN). The list of RASBs should be flexible and non-exhaustive, and additional RASBs could be included on a case-by-case basis.

9. IADSA agrees that it is more pragmatic to have a tabulation entitled “CONVERSION FACTORS”.

10. IADSA supports the proposal that there should be a mechanism for obtaining FAO/WHO scientific advice on nutrition within defined timescales as appropriate. However, national and international RASBs can also be used as sources of information and the provision of advice by FAO/WHO should not delay the progress of work.

11.IADSA supports the stepwise approach outlined in **Section 3.2**, but advises caution on the application of Step 5 in terms of the interpretation of the General Principle 3.3.