CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 5 **CX/NFSDU 12/34/8-Add.2**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-fourth Session

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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 of the procedure)

Comments from:

BRAZIL

CHILE

COSTA RICA

EUROPEAN UNION

NEW ZEALAND

ICGMA - International Council of Grocery Manufacturers' Association

IDF - International Dairy Federation

BRAZIL

GENERAL COMMENTS

Brazil would like to express its appreciation for the document "Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling" prepared by Australia, based on the discussion of the Electronic Working Group (eWG), in which Brazil participated.

Moreover, Brazil thanks for the opportunity to present comments on the CX/NFSDU 12/34/8.

We decided to comment only the Conclusions (A to I) and the Recommendations of the eWG pointed out in the document.

SPECIFIC COMMENTS

Conclusion A

Based on the eWG's consideration, pNRVs for vitamins and minerals derived from WHO/FAO RNIs in Table 1 are suitable for the purpose of Codex nutrition labelling. pNRVs for vitamins and minerals derived from WHO/FAO RNIs in Table 2 are considered to be unsuitable for use in Codex nutrition labelling.

Comments:

Brazil agrees with this conclusion. So, we understand that is possible to approve de pNRV for Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Falate, Vitamin B12, Pantothenate, Biotin, Calcium and Iodine. On the other hand, based on the rationale used by the eWG, Brazil understands that it is not possible to approve the pNRV for Vitamin A, Vitamin D, Vitamin E, Vitamin C, Magnesium and Selenium.

Conclusion B

The suitability of the pNRV for iron of highest absorption was found to be acceptable. Based on the eWG's consideration, the suitability of the pNRVs for zinc and higher rates of iron absorption, or the number of pNRVs, could not be concluded. Once pNRVs are established, short dietary descriptions to describe the diets associated with the % absorption figures would be useful to include.

Comments:

Brazil agrees with this conclusion. We understand that it is possible to approve the pNRV for iron of the highest absorption. We also agree to better discuss the suitability of the pNRVs for zinc and higher rates of iron absorption.

Conclusion C

Based on the eWG's consideration, pNRVs for vitamins and minerals in Group 2 are considered to be unsuitable for use in Codex nutrition labelling because they were not determined in accordance with the General Principles.

Comments:

Brazil agrees with this conclusion.

Conclusion D

Based on the eWG's consideration, a definition of recognized, authoritative, scientific body should be established and the Committee is requested to give consideration to the proposed definition. No conclusion was reached in relation to the suitability of AIs based on national nutrient intake data as the basis of pNRVs.

Comments:

Brazil agrees that is important to establish a definition recognized, authoritative, scientific body. We suggest deleting the square brackets from the following definition:

"For the purposes of establishing Codex Nutrient Reference Values, an organization supported by a government(s) to provide independent, authoritative scientific advice on dietary intake reference values, and for which such advice is recognised through its use in the development of policies in ~~[~~at least~~]~~~~[~~more than one~~]~~ country."

Brazil believes that pNRVs based on AIs from national nutrient intake are not appropriate.

Conclusion F

Based on the eWG's considerations, conversion factors are provided as information in support of pNRVs. The conversion factors for niacin and folate in Appendix IV were considered suitable but these should be re-expressed to a consistent format. The conversion factors for vitamin A should be updated and factors available in WHO/FAO (2006) could be used. Consideration should be given to including conversion factors for supplemental and/or fortificant forms for folate and vitamin A. The conversion factors for vitamin E could not be concluded.

Conclusion G

Based on eWG consideration, footnotes 3 and 5 should be deleted, and the second sentence of footnote 9 should also be deleted.

Comments:

Brazil agrees with this conclusion.

Conclusion H

The Committee is requested to give consideration to the placement of any guidance material produced to implement the General Principles. It is also requested to 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.

Comments:

Brazil suggests including the guidance material in conjunction with the General Principles in the Codex Nutrition Labelling Guidelines. We also suggest recording decision making into an Appendix to a Report of a future CCNFDSU session after the work is completed.

Conclusion I

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

Comments:

Brazil agrees with this conclusion.

RECOMMENDATIONS

These recommendations fulfil the eWG's TOR 2 and are based on the conclusions of the eWG's consideration of pNRVs and further consideration by the Chair.

Noting that that the work is at Step 3, it is recommended that the CCNFSDU at this session:

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

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

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

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

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

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

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

8. Agree that a definition of 'recognized, authoritative, scientific body' should be established and give consideration to the proposed definition

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

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

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

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.

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

Comments:

Brazil supports the recommendations above. With regard to the recommendation 10, Brazil is still discussing internally.

CHILE

2 PNRVs INCLUDED IN APPENDIX IV, EXCLUDING ZINC AND IRON

2.1 Group 1 pNRVs (from vitamin A to selenium, excluding zinc and iron)

Comment: In this point it is stated that there is a mean between INL98 + AI, and so the members of this committee suggest that it should be possible to explain the reason for said mean to enable us to better understand what is expressed in the document.

3 ESTABLISHMENT OF SUBSTITUTE AND NEW pNRVs

- *"For the purposes of establishing Nutrient Reference Values of the Codex, an organisation support by a government(s) to enable independent consulting and with scientific validity in relation to dietary intake reference values and, thanks to said consulting, it is recognised through its use in the development of policies in [at least][more than one] country."*

Comment: Following review, we think the existence of more than one representative in the opinion on this point is necessary and adequate.

- *"On GP3.3 some members of eWG think it is important that the pNVRs based on adults be compared with UL in children, suggest that in this way the ULs be considered the worst case and that the pNVRs will not have adverse effects on the health of almost all the population."*

Comment: We think it is adequate to consider the most sensitive individual but, in turn, this person ought to be correct by calorie intake, considered as nutrient density.

5 RECOMMENDATIONS

"4. Adopt the pNVRs for iron with the maximum absorption percentage (and the minimum pNVRs) and remove the pNVRs for the other iron absorption percentages from Appendix IV and the NRVs for iron from the Directives of the Codex so that they may be examined later."

Comment: This measure may be complicated and adopting the highest absorption level may not be very true to reality and, moreover, it would be important to verify whether any safety consideration exists in this respect.

Chile does not present any more observations or comments on the document and we thank you for the opportunity to express these comments.

COSTA RICA

Costa Rica agradece al Grupo de trabajo electrónico coordinado por Australia por la preparación del documento de la referencia. A continuación detallamos nuestra posición con respecto a las recomendaciones planteadas en el punto 5 del documento y los aspectos que deberían discutirse en el Comité:

1 Adoptar pVRN de vitaminas y minerales del cuadro 1 del grupo 1 distintos del hierro y el zinc que se deriven de las RNI de la OMS/FAO, según proceda para revisar los VRN respectivos y para establecer nuevos VRN en las Directrices del Codex sobre etiquetado nutricional.

Costa Rica está de acuerdo con la propuesta.

2 Considerar inadecuados los pVRN de vitaminas y minerales derivados de las RNI de la OMS/FAO e incluidos en el cuadro 2 del grupo 1 y sus respectivos VRN de las Directrices del Codex sobre etiquetado nutricional, y dejarlos de lado para su examen posterior.

Costa Rica está de acuerdo con el planteamiento.

3 Considerar inadecuados los pVRN de las vitaminas y los minerales del grupo 2 del apéndice IV y apartarlos para su examen posterior

Costa Rica está de acuerdo con lo recomendado.

4 Adoptar los pVRN para el hierro con el máximo porcentaje de absorción (y los pVRN mínimos) y apartar los pVRN para los demás porcentajes de absorción del hierro del apéndice IV y los VRN para el hierro de las Directrices del Codex sobre etiquetado nutricional, a fin de examinarlos más adelante Me inclino por dejar el hierro para examen posterior.

Costa Rica está de acuerdo, incluso si se acordara dejar el pVRN para el hierro para un examen posterior.

5 Apartar los pVRN para el zinc del apéndice IV y los VRN para el zinc de las Directrices del Codex sobre etiquetado nutricional para su examen posterior

Costa Rica está de acuerdo con esta propuesta.

6 Cambiar "biodisponibilidad" por "absorción" en el apéndice IV en relación con el hierro y el zinc

Costa Rica está de acuerdo con el cambio, nos parece que queda más claro el uso del término absorción.

7 Acordar en principio incluir descripciones dietéticas relativas a los porcentajes de absorción del hierro y el zinc establecidos

Costa Rica está de acuerdo con esta propuesta.

8 Acordar que debería establecerse una definición para "organismo científico competente reconocido" y examinar la definición propuesta:

Organismo científico competente reconocido

Se entiende, a los efectos de establecer valores de referencia de nutrientes del Codex, toda organización apoyada por uno o varios Gobiernos para ofrecer asesoramiento científico independiente y competente sobre los valores de referencia de la ingesta dietética, y cuyo asesoramiento está reconocido al usarse en la elaboración de políticas en [al menos][más de un] país.

Costa Rica está de acuerdo y apoya la definición propuesta. Consideramos que debería quedar el texto entre corchetes que dice "más de un" país, de manera que sea un organismo cuyas recomendaciones no solo se conozcan en el país en el que se ubica tal organismo, sino que otros países lo utilicen para el establecimiento de sus propios valores de referencia.

9 Considerar la posibilidad de realizar observaciones indicativas sobre un futuro proceso adecuado por trámites para la toma de decisiones con el objetivo de recomendar pVRN de sustitución y nuevos, en especial en relación con el trámite 6

Costa Rica está de acuerdo con respecto a las notas del procedimiento por trámites.

10 Adoptar los factores de conversión para la niacina y el folato del apéndice IV, pero expresados en un formato coherente; revisar los factores de conversión para la vitamina A utilizando como fuente los documentos de la OMS/FAO (2006), y de forma coherente con el formato adoptado; examinar la posibilidad de incluir factores de conversión para el folato y la vitamina A en forma de complementos alimentarios y productos para enriquecimiento; y apartar los factores de conversión para la vitamina E para su examen posterior

Costa Rica está de acuerdo con esta propuesta de avance para la adopción de los factores de conversión.

11 Suprimir las notas 3 y 5 a pie de página del apéndice IV, así como la segunda oración de la nota 9 a pie de página

Costa Rica está de acuerdo con la recomendación. Además sugiere que en la nota 9 a pie de página también se sustituya biodisponibilidad por absorción, tal como se planteó para el Apéndice IV.

12 Estudiar la ubicación del material orientativo elaborado para implantar los Principios generales y si debería mantenerse un registro del proceso de toma de decisiones para la revisión y el desarrollo posterior de los VRN de las vitaminas y los minerales, y, en caso afirmativo, decidir en qué parte de los documentos del Codex debería registrarse la información

Costa Rica considera de utilidad tanto el material orientativo como el registro del proceso de toma de decisiones. Sin embargo, dado que son orientaciones para futuras revisiones de los Valores de Referencia de Nutrientes, podrían referenciarse en los principios generales de las Directrices del Codex sobre etiquetado nutricional, pero colocarse en un informe de una futura reunión del CCNFSDU.

13 Solicitar a los representantes de la OMS y la FAO que informen sobre el progreso de las consultas, así como sobre los planes concretos y los plazos para volver a organizar JEMNU.

EUROPEAN UNION

The European Union (EU) has the following comments on the Proposed Draft Additional or revised Nutrient Reference Values for labelling purposes in the Codex Guidelines on Nutrition Labelling (CX/NFSDU 12/34/8).

With respect to minerals for which pNRVs should be established, the EU would like to stress that the exclusion of potassium at this stage from the consideration of pNRVs based on nutrient requirements should not be seen as a decision on the basis of the pNRV. There is still a need to discuss in a future session of the Committee whether potassium should be included in the work for revised nutrient reference values for vitamins and minerals for labelling purposes or in the work for reference values for labelling purposes related to noncommunicable diseases .

With regard to Recommendation 6 the EU does not support to revise 'bioavailablility' to 'absorption' for iron and zinc in Appendix IV as this change would modify the meaning of the value in the document. Therefore, the EU proposes that the current wording of 'bioavailability' should be maintained.

Concerning Recommendation 9, the EU would like to ask for clarification about its meaning and what this recommendation implies regarding the procedures as established by the Procedural Manual of Codex.

With regard to Recommendation 10 the EU has not established in its nutrition labelling legislation conversion factors for vitamins and minerals. An understanding of the basis of the pNRVs with respect to conversion factors for certain nutrients can help the national authorities in their consideration of the CODEX values and their application at national levels. However, the EU believes that if the conversion factors are included in the guidelines the purpose of their inclusion should be clear and an explanation given that their inclusion is not intended as a harmonisation of the conversion factors per se. Although the EU prefers the conversion factors to be included as footnotes, however, if they were to be presented in tabular form the EU would propose the title of the table should be change to "Conversion factors for vitamin equivalents used to derive the NRVs".

NEW ZEALAND

New Zealand appreciates the opportunity to have participated in the electronic working group chaired by Australia and to provide comments at Step 3 on the draft Proposed Draft Additional or Revised Nutrient

Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling. New Zealand is supportive of all recommendations put to the committee and has the following comments to make on specific issues.

Group 1 pNRVs

New Zealand supports conclusion A, that the Group 1 pNRVs listed in Table 1 are considered suitable. The pNRVs listed in Table 1 satisfy all General Principles and there was general consensus within the electronic working group to accept these pNRVs.

New Zealand agrees that further work is required to establish suitable pNRVs for those micronutrients listed in Table 2. The pNRVs listed in Table 2 should be considered as potentially unsuitable. A method has not yet been established to review those pNRVs found to be potentially unsuitable, and it is possible that when compared to RASBs the WHO/FAO value may be considered to be the most up-to-date, scientifically sound, and globally relevant.

For those Group 1 pNRVs considered unsuitable listed in Table 2 it is considered that they should be compared to NRVs derived by scientific bodies which qualify as a recognised authoritative scientific bodies (RASBs). In comparing WHO/FAO values to RASB values the derivation of the NRVs must be considered in order to determine suitability. Internationally work is being conducted to harmonise dietary requirements. In doing so it is recognised that methodological differences must be harmonised to establish basal requirements. These basal requirements may be adjusted, where necessary, to address environmental, dietary or host factors which influence specific country's nutrient requirements.

Iron and Zinc

Iron and zinc are nutrients for which basal requirements must be adjusted for various country specific dietary patterns which will influence the absorption of these nutrients, and hence their requirement. It is considered that multiple pNRVs should be established for iron and zinc based on three levels of percentage absorption. As highlighted in the Preamble to the General Principles Annex, this allows for national authorities to consider which level of bioavailability is most suited to their national diet, also but provides guidance on which pNRVs are suitable.

Levels of percentage absorption must be accompanied by dietary descriptors to ensure they are used appropriately and to guide national authorities to select the pNRV which best suits their national diet. These dietary descriptors could either be presented as part of a footnote or accompanying table as has been done for the conversion factors.

Iron

The Australian and NZ Nutrient reference values are based on the assumption that 18% of dietary iron is absorbed, citing the IOM report (2002) as the basis for this. According to the WHO/FAO vitamin and mineral requirements in human nutrition text (2004), a level of absorption of dietary iron of 18% may be suitable in countries with a very high intake of meat, but for typical Western style diets a 15% or 12% level of absorption is considered appropriate.

A simplified list of iron dietary descriptors could be presented in accordance with the WHO/FAO Guidelines on fortification with micronutrients (2006) the three levels of bioavailability would be:

- 5% Low absorption. Diets low in vitamin C and animal protein
- 10% Moderate absorption. Diets rich in cereals but including sources of vitamin C.
- 15% High absorption. Diets rich in vitamin C and animal protein.

New Zealand considers the pNRV for iron at %15 absorption to be acceptable and agrees that further work is required on the lower levels of absorption in addition to suitable dietary descriptors for all levels of bioavailability.

Zinc

There is considerable discrepancy between the FAO/WHO values and those of other scientific bodies that NZ considers could be recognised as RASBs. The FAO/WHO values are substantially lower than most other countries recommendations whose diet would meet the criteria for high absorption. This has also been noted in a review of the NRVs published in the EU in a paper by Doets et al (2011). In this paper many of the EU

countries assumed that 30% of dietary zinc was absorbed, this corresponded to INL_{98} values ranging between 9-10 mg/day and 7-9 mg/day for men and women, respectively.

		INL_{98} (mg/day)		
RASB	% Absorption	Adult males	Adult female	pNRV
IOM	M - 41%, F – 48%	11	8	9.8
NHMRC	M – 24%, F – 31%	14	8	11.6
FAO/WHO	High 50%	4.2	3.0	3.6
	Moderate 30%	7.0	4.9	9.45
	Low 15%	14.0	9.8	11.9
IZiNCG	Mixed diet 31%	13	8	10.5
	Cereal-based diet 23%	19	9	14

Variability in INL_{98} values derived internationally arise from differences in types of studies included, percentage absorption applied, and the coefficient of variation used to convert the ANR to INL_{98} (Doets 2011, IZiNCG 2004). In the IZiNCG technical report recommendations are made for the methodology that should be used to derive INL_{98} values based on a review of both the IOM report (2002) and WHO report (2004). In their assessment of these reports the IZiNCG recommend: using only total diet studies and excluding single meal studies; using a CV of 12.5%; and to exclude semi-purified formula diets from deriving levels of percentage absorption. Generally the IZiNCG assessment accepted the methodology used by the IOM.

Percentage absorption of dietary zinc is variable across countries with what would seem to be similar dietary patterns of refined diets with high intakes of animal protein. The FAO/WHO sets their % absorption rating as 50% for high bioavailability diets, yet Australia and NZ and many EU countries take a more conservative approach and have based their country specific nutrient reference values on an absorption level of ~30%. Although some countries have not specified different levels of bioavailability, in the IOM and NHMRC reports recommendations are made for vegetarians. These reports state that due to lower absorption in a vegetarian diet, particularly strict vegetarians, vegetarians will need intakes about 50% higher than those set.

It is noteworthy that collaboration between IZiNCG and the IOM is planned to update zinc dietary reference intake values.

New Zealand considers that once the criteria for RASBs have been decided and the process for dealing with potentially unsuitable pNRVs the committee should consider information on % absorption used to derive NRVs for all identified RASBs for both iron and zinc.

Group 2 pNRVs

New Zealand agrees that the suitability of the Group 2 pNRVs has not yet been determined and should be set aside for further consideration.

RASBs

New Zealand agrees that a definition of a recognised authoritative scientific body should be established in accordance with GP 3.1.2. New Zealand prefers an approach in which NRVs can be established that are internationally relevant and based on recent data, which have been evaluated in a transparent unbiased manner, preferably through the use of a systematic review.

GP 3.1.2

Relevant and recent values that reflect independent review of the science, from recognised authoritative scientific bodies other than the WHO/FAO could be taken into consideration. Higher priority should be given, as appropriate, to values in which the evidence has been evaluated through a systematic review.

Proposed working definition from CX/NFSDU 12/34/8:

For the purposes of establishing Codex Nutrient Reference Values, an organization supported by a government(s) to provide independent, authoritative scientific advice on dietary intake reference values, and for which such advise is recognised through its use in the development of policies in [at least] [more than one] country.

New US proposed definition:

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, and for which such advise is recognised through its use in the development of policies in ~~[at least]~~ [more than one] country.

New Zealand considers that the working definition should be broadened to ensure that international collaborative groups focussed on harmonizing Nutrient Intake Values (NIVs) across regions are considered as well as those developed by well renowned expert groups (King 2007).

Expert groups such as the IZiNCG committee have not been supported by a government to provide advice; however their advice has been recognised through its use in development of NRVs in Australia and New Zealand and is recognised by the WHO/FAO. The IZiNCG group have provided high quality, systematic reviews of the evidence used to derive NRVs and have considered these in an international context. Groups such as these are very applicable to the work of CCNFSDU as they are able to derive NRVs applicable to numerous countries which is not often the focus of organizations sponsored by government to derive population specific NRVs. In addition to this, groups aiming to harmonise NIVs across regions such as the ILSI-South East Asian Region group which published recommended dietary allowances in 2005 would also fall under this category and should also be considered.

New Zealand does not consider that an organisation must be supported by a government to provide recent, robust, internationally relevant authoritative advice. It is more important that the RASB is providing independent, transparent, authoritative scientific advice on dietary intake reference values, which are adopted in at least one country or recognised by the WHO/FAO/UNICEF/UNU. This was demonstrated in the case of Vitamin A conversion factors in which more recent publications by WHO/FAO/UNICEF recognised groups such as the IOM as providing more up-date guidance on issues, and updated their values accordingly in newer publications.

Inclusion of the need for transparency in deriving NRVs by RASBs is fundamental to evaluating the suitability of their consideration by CCNFSDU and establishing the suitability of the NRVs that they have derived. It is considered that by including principles around independence, transparency, and preference for a systematic review, many organizations that have not reviewed the evidence and adopted values from other sources without consideration of their applicability would not be included. Furthermore these principles would also exclude those organizations that might have self-interests in establishing NRVs from being recognised as transparent, independent, and authoritative.

New Zealand also proposes that text throughout the NRVs for labelling refer to 'Nutrient Intake Values' (NIV) rather than 'Dietary intake reference values' in accordance with the recently established WHO/FAO/UNU harmonised approach (King 2007).

New Zealand considers that the text around development of policies should be amended to state development of NIVs. The establishment of a NIV by a RASB is not a policy in itself and should not be considered as such. New Zealand prefers amending the statement to refer to a government or UN agency adopting the NIV as means of establishing that the source is authoritative.

New Zealand proposed working definition:

For the purposes of establishing Codex Nutrient Reference Values, a **scientific body** ~~an organization supported by a government(s)~~ which provides independent, **transparent**, authoritative scientific advice on ~~dietary~~ **nutrient** intake ~~reference~~ values, **preferably through the use of a systematic review,** and for which such advice is recognised through its use in the development of **nutrient intake values** ~~policies~~ **by at least one government** ~~in at least one country~~ **or UN agency**.

Stepwise Process

New Zealand supports discussions to progress a stepwise process on how unsuitable pNRVs are to be dealt with. New Zealand is supportive of Steps 1-5 as they outline the steps taken in the identification of pNRVs in determining the suitability of the Group 1 nutrients in the eWG.

At Step 6 New Zealand does not consider that a method of calculation can be determined to create a representative pNRV. New Zealand strongly supports reviewing unsuitable pNRVs on a case by case basis.

As identified in reviews of NRVs internationally, differences can exist due to either differences in methodology or country-specific factors which influence requirements. Differences in methodology can arise

from differences in types of studies included, differences in criteria for establishing a NRV, differences in the CV applied to the average nutrient requirement (ANR) to derive the individual nutrient requirement level (INL_x).

Vitamin A, a pNRV found unsuitable in the working group, is a good example of differences in methodology resulting in substantially different NRVs. It has been observed that Vitamin A NRVs have either been derived to maintain adequacy or for the prevention of a clinical signs of deficiency. Countries which have adopted an approach to maintain stores of vitamin A in the liver in healthy subjects have derived much higher INL_{98} than the WHO/FAO who based their values on extrapolation of data from infants for the prevention of vitamin A deficiency.

Table 2: Methodology used to derive Vitamin A INL98 values in a selection of countries from the FAO/WHO dataset

		INL_{98} (µg/day)		
RASB	Methodology	Adult males	Adult female	pNRV
IOM	Body stores Vitamin A	900	700	820
NHMRC	Body stores Vitamin A	900	700	820
FAO/WHO	Prevention of deficiency in infants, extrapolated	500	600	550
DACH (2004)*[†]	Body stores Vitamin A	1000	800	900
Nordic countries (2004)*[‡]	Body stores Vitamin A	900	700	800
South Korea	Body stores Vitamin A	725	650	700

*Grouped based on country alliances outlined in Doets *et al* 2008
[†]DACH: Germany, Austria, Switzerland

[‡]Nordic countries: Norway, Sweden, Finland, Denmark, Iceland

After establishing which organisations qualify as a RASB, the RASBs should be evaluated as to their suitability in deriving Codex pNRVs. Consideration should be given to several factors:

- Date of last review of evidence
- Criteria to establish recommendation (adequacy vs prevention of clinical signs of deficiency)
- Type of evidence used (systematic review vs experts' opinion)
- Assumptions made

New Zealand supports a step wise process which evaluates the suitability of RASBs and determination of suitable pNRVs is conducted on a case-by-case basis. New Zealand supports requesting expert advice or scientific advice from WHO/FAO when consensus cannot be reached in CCNFSDU.

Conversion Factors

New Zealand is supportive of the recommendation to adopt the conversion factors for niacin and folate in Appendix IV but in a re-expressed and consistent format, and to revise the conversion factors for vitamin A considering the WHO/FAO (2006) as a source in line with current scientific evidence.

In principle New Zealand supports the inclusion of conversion factors for supplemental forms of nutrients as it provides guidance on conversion factors suitable for supplements which are covered by Codex Guideline for vitamin and mineral food supplements. The Guideline document refers to the Codex Guidelines on Nutrition Labelling so it is considered suitable to include. New Zealand is supportive of the conversion factor for folic acid but is uncertain of the basis for deriving β-carotene and all-rac-α-tocopherol supplemental conversion factors.

As noted in the 2006 FAO/WHO Guidelines on food fortification with micronutrients conversion factors for synthetic β-carotene are still uncertain so it may not be appropriate to include the value of 2 µg supplemental all trans β-carotene and should not be recommended until more evidence is presented.

Table: Conversion factors for vitamin equivalents relevant to NRVs

Vitamin	Dietary equivalents	
Vitamin A	1 µg retinol equivalents (RE) =	[1 µg retinol 12 µg β-carotene 24 µg other provitamin A carotenoids [2 µg all-*trans*-β-carotene (as supplement)]]
[Vitamin E]	[tbd]	[tbd]
Niacin	1 mg niacin equivalents (NE) =	1 mg niacin 60 mg tryptophan
Folate	1 µg dietary folate equivalents (DFE) =	1 µg food folate 0.6 µg folic acid [(as fortificant)] [0.5 µg folic acid (as supplement)]

[tbd] to be determined

Footnotes

New Zealand supports the deletion of both footnotes 3 and 5 but is only supportive of deletion of the second sentence of footnote 9 when replaced with dietary descriptors of percentage absorption. If an NRV is adopted for iron it must be accompanied by a statement on what the % absorption level is based on.

References

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ICGMA - International Council of Grocery Manufacturers' Association

(From CX/NFSDU 12/34/8, Page 13)

5. Recommendations

These recommendations fulfill the eWG's TOR 2 and are based on the conclusions of the eWG's consideration of pNRVs and further consideration by the Chair

Noting that the work is at Step 3, it is recommended that the CCNFSDU at this session:

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

ICGMA POSITION: SUPPORT

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

ICGMA POSITION: SUPPORT

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

ICGMA POSITION: SUPPORT

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

ICGMA POSITION: SUPPORTS DEVELOPMENT OF ONLY TWO pNRVs for iron, most obvious being a high absorption as already spelled out and a low absortion

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

ICGMA POSITION: SUPPORT

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

ICGMA POSITION: SUPPORT

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

ICGMA POSITION: SUPPORT

8 Agree that a definition of 'recognized, authoritative, scientific body' (RASB) should be established and give consideration to the proposed definition

ICGMA POSITION: SUPPORT that a definition for RASB be established and that the following definition be advanced based on suggestion presented on page 8 of CX/NFSDU 12/34/8

For the purpose of establishing Codex Nutrient Reference Values an organization supported by a government(s) to provide independent, authoritative, scientific advice on dietary intake reference values and for which such advice is recognized through its use in the development of policies in [at least] [more than one] country

ICGMA SUPPORTS THE OPTION [at least]

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

NO ICGMA POSITION AT THIS POINT

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

ICGMA POSITION: SUPPORT

11 Delete footnotes 3 and 5 (Appendix IV), and also delete the second sentence of footnote 9 (Details can be found on page 11 & 12 of CX/NFSDU 12/34/8)

ICGMA POSITION: SUPPORT

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.

ICGMA POSITION: SUPPORT RETAINING THIS INFORMATION to the benefit of future work, and

Suggest that it be maintained in *General Principles on Nutrient Reference Values.*

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

ICGMA POSITION: SUPPORT

IDF - International Dairy Federation

The International Dairy Federation (IDF) appreciates the opportunity to submit comments to on proposed draft additional or revised nutrient reference values for labeling purposes in the codex guidelines on nutrition labelling

IDF would like to take the opportunity to point out potential considerations in relation to Calcium and vitamin K.

Calcium

IDF has a specific concern regarding the unintended consequences of the NRV for calcium which is proposed at 1000 mg. According to the Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Calcium (EFSA, 2012) "Foods vary widely in calcium content and bioavailability. The best sources are milk (120 mg/100 g) and milk products (up to 1100 mg/100 g), from which about 32% is absorbable, which is higher than most other natural food sources of calcium. In European diets about 45 to 70% of the dietary calcium intake is provided by dairy products." In Japan, where dairy consumption is less than in Western countries, about 30% of the calcium intake is from milk and milk products according to the 2002 National Nutrition Survey by the Ministry of Health Labor and Welfare. Therefore, milk and milk products are a major calcium source in several parts of the world.

According to the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997), "source of calcium" may be used for solids which contain the vitamin or mineral in amounts that are at least 15% of the NRV and for liquids which contain the vitamin or mineral in amounts that are at least 7.5% of the NRV. The conditions required to claim "high in calcium" are 2 times the level required to claim "source of calcium". Taking milk as a reference (120 mg calcium/100 ml), the proposed value of 1000 mg would allow to make a nutrition claim on milk as 'source of calcium' but not "high in" or "rich in" Calcium. As a consequence it is feared that consumers will no longer recognize the true value of milk as an excellent source of calcium which would not be in line with the purposes of the guidelines on nutrition labelling as it could be misleading for the consumer.

Reference:

EFSA. 2012 Scientific Opinion on the Tolerable Upper Intake Level of calcium by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) Available at http://www.efsa.europa.eu/fr/efsajournal/doc/2814.pdf (access date 21 August 2012)

Vitamin K

IDF would like to ask CCNFSDU to consider a more in depth opinion on the Nutrient Reference Values (NRV) of Vitamin K, based on the differences between K1 and K2. New scientific data suggest that effects attributable to vitamin K may in fact be linked to vitamin K1, vitamin K2 or both. Recently, the European Food Safety Authority (2009) expressed an opinion on three health claims related to vitamin K and clearly differentiated between vitamin K1 and K2, and assessed their respective effects as well. In order to anticipate the future evolution of the research, IDF proposes to add "vitamin K1 + vitamin K2" in parenthesis besides the mention of "vitamin K".

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 certain fermented foods, one example being cheese.

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 varieties show noticeable differences between the types contained in them, for instance one could observe in a certain cheese variety the amount of K2 ten times higher than K1.

References

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