



Agenda Item 5

CX/NFSDU 12/34/8

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 GUIDELINES ON NUTRITION LABELLING

(Prepared by Australia and members of an Electronic Working Group representing Bolivia, Brazil, Canada, Chile, Costa Rica, European Union, Ghana, Japan, Republic of Korea, Moldova, New Zealand, United States of America, Uruguay, FoodDrink Europe, International Alliance of Dietary /Food Supplement Associations, International Council of Beverages Associations, International Dairy Federation, International Life Sciences Institute, Institute of Food Technologists, National Health Federation)

Governments and interested international organizations are invited to submit comments on the Proposed Draft Addition or Revision, as presented in Attachment 1, at Step 3 in writing preferably by email to the Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, Fax +39-06-5705-4593, e-mail codex@fao.org with copy to Mr Georg Müller, Federal Ministry of Food, Agriculture and Consumer Protection, Rochusstraße 1, 53123 Bonn, Germany, Fax: +49 (228) 99 529 49 65, e-mail: ccnfsdu@bmelv.bund.de by **15 November 2012**.

1 BACKGROUND

1.1 Previous consideration by CCNFSDU

At its 33rd session (2011), CCNFSDU agreed to consider all nutrient reference values (NRVs) for vitamins and minerals listed in Appendix IV, ALINORM 10/33/26 at Step 3 (Appendix IV) and established an electronic Working Group (eWG), chaired by Australia and working in English, with the following Terms of Reference (TOR):

1. To consider the FAO/WHO Report *Review of existing daily vitamin and mineral intake reference values* summarized in CX/NFSDU 11/33/4 and given in full in the data compilation spreadsheet posted on the Codex website at <ftp://ftp.fao.org/codex/Meetings/CCNFSDU/ccnfsdu33/NRVreport.xls> (corrected version)
2. To recommend Nutrient Reference Values (values and footnotes) for vitamins and minerals for the general population older than 36 months.
3. To formulate these recommendations based on the [corrected] data of the FAO/WHO Report “*Review of the existing daily vitamin and mineral intake reference values*” in accordance with the Codex General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population.
4. To identify and report any issues in the application of the General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals that may arise from this work.

In 2007, the project document approved by the Commission had identified 2012 as the target year for the Commission’s final adoption of the NRVs for vitamins and minerals.

1.2 General Principles (Appendix II, REP11/NFSDU)

The *General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population* (General Principles) were adopted by the Codex Commission in 2011 in the form of a draft Annex to the Codex Guidelines on Nutrition Labelling (Appendix II, REP11/NFSDU). This Annex is further discussed in another agenda paper at this session on Proposed Draft General Principles for establishing NRV-NCD for the General Population. The General Principles that were consulted by the eWG are:

3.1.1 Relevant and recent daily nutrient intake values provided by WHO/FAO should be taken into consideration as primary sources in establishing NRVs.

3.1.2 Relevant and recent values that reflect independent review of the science, from recognized authoritative scientific bodies other than 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.

3.2.1 The NRVs should be based on Individual Nutrient Level 98 (INL₉₈). In cases where there is an absence of an established INL98 for a nutrient for a specific sub-group(s), it may be appropriate to consider the use of other reference values or ranges that have been established by recognized authoritative scientific bodies on a case-by-case basis.

3.2.2 The general population NRVs should be determined by calculating the mean values for a chosen reference population group older than 36 months. Nutrient Reference Values derived by the CCNFSDU are based on the widest applicable age range of each of adult males and females.

3.2.3 For the purpose of establishing these NRVs, the values for pregnant and lactating women should be excluded.

3.3 The establishment of general population NRVs should also take into account Upper Level of Intake established by recognized authoritative scientific bodies.

1.3 Conduct of the Electronic Working Group

In December 2011, CCNFSDU members were invited to participate in an Electronic Working Group (eWG) to further consider NRVs for vitamins and minerals.

A call for corrections to the FAO/WHO spreadsheet was made at the previous session of CCNFSDU (para 32, REP 12/NFSDU). Seven Codex members responded. A corrected spreadsheet (page 1 link) and an updated report were distributed to the eWG Chair in February 2012. The terminology was changed to “intake reference value” to describe more appropriately the values displayed, except the graph related to sodium where the term “upper intake level” was used as the sodium values are upper intake values unlike other nutrients.

The eWG considered two consultation papers prepared by the Chair that were circulated in February and July 2012 respectively. Thirteen government and 6 international non-government members responded to the first consultation paper, and 7 government and 4 international non-government members responded to the second consultation paper. All participating members are acknowledged above.

1.4 Terminology

The CCNFSDU previously referred to potential Nutrient Reference Values (pNRV) to denote draft or draft revised Nutrient Reference Values (NRV) for vitamins and minerals (para 38-39, REP 11/NFSDU). This Agenda Paper continues the use of ‘pNRV’ for the time being. The Agenda Paper on Proposed Draft General Principles for establishing NRV-NCD for the General Population at this session discusses a new name for NRVs for vitamins and minerals: NRV- R.

The definition of NRV, adopted by the Commission in 2012, indicates that NRVs are specifically intended for labelling purposes:

2.4 **Nutrient Reference Values (NRVs)** are a set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims. NRVs are based on levels of nutrients associated with nutrient requirements, or with the reduction in the risk of diet-related noncommunicable diseases.

The Committee had previously adopted the term ‘bioavailability’ in relation to iron and zinc pNRVs derived from WHO/FAO RNIs but the term is revised to ‘% absorption’ because the definition of ‘bioavailability’ in the CCNFSU Nutritional Risk Analysis Principles and Guidelines (CAC, 2011) refers to metabolism as well as absorption. This change is consistent with the WHO/FAO (2004) explanation of bioavailability.

1.5 Scope – Sodium and Potassium

The eWG confirmed that it would not consider pNRVs for sodium and potassium based on dietary adequacy in 2012 but recognised that the Committee has so far considered only an NRV-NCD for sodium. The issue of whether multiple NRVs could be established according to both dietary adequacy and reduction of risk of noncommunicable disease is discussed in the agenda paper on Proposed Draft General Principles for establishing NRV-NCD for the General Population.

2 pNRVS IN APPENDIX IV EXCLUDING ZINC AND IRON

The eWG considered the two groups of pNRVs listed in Appendix IV:

Group 1: pNRVs derived from Recommended Nutrient Intakes (RNIs): Vitamin A to Selenium excluding Zinc and Iron (WHO/FAO, 2004).

Group 2: pNRVs for which a WHO/FAO RNI had not been established, and based on the Institute of Medicine (IOM) Dietary Reference Intakes (DRI): Phosphorus to Molybdenum (IOM, 2006).

2.1 Group 1 pNRVs (Vitamin A to Selenium, excluding Zinc and Iron)

The eWG agreed that Group 1 pNRVs derived from WHO/FAO RNIs (INL₉₈) were in accord with five of the six General Principles (GP): 3.1.1, 3.2.1, 3.2.2, 3.2.3 and 3.3.

Since the CCNFSU had expressed concern about some of these pNRVs, the eWG considered that the pNRVs should be validated by comparison with appropriate dietary intake reference values (DIRVs). However, there was a difference of view about the role of the corrected FAO/WHO spreadsheet in the comparative process.

Consistent with the eWG’s first and third TOR, the eWG Chair derived summary DIRVs for each vitamin and mineral in Group 1 from DIRVs in the FAO/WHO spreadsheet that had been populated by up to 55 countries. Three medians of averaged national adult male and female DIRVs, 19-50 years, were calculated for: INL₉₈, AI, and INL₉₈ + AI combined. The deviation of the pNRV from the median INL₉₈ + AI was determined as a percentage of that median. It is worth noting that the DIRVs for each vitamin and mineral in the FAO/WHO spreadsheet were never only INL₉₈ or only AI; the proportion of each type varied according to the vitamin or mineral concerned.

The details of the calculations and the results are given in Attachment 4.

In considering the way forward, eWG members held different views on the interpretation of the third TOR and on the role of the sixth GP – GP 3.1.2 in determining an appropriate comparator to validate pNRVs in Group 1. Despite this difference of view, there was agreement that GP 3.1.2 is relevant to:

- i) the replacement of any unsuitable pNRVs in Group 1; and
- ii) the establishment of pNRVs in Group 2.

Just over half the eWG responding to the first consultation paper (10 members) agreed that the comparator could be calculated from the FAO/WHO spreadsheet but views were divided on whether the comparator should be the median of INL₉₈ or of INL₉₈ + AI. Those who favoured INL₉₈ cited GP 3.2.1 in support of their view whereas the Chair had used INL₉₈ + AI because of advice in the

FAO/WHO Report that referred to countries' inconsistent definition of these terms and the consequent blurred distinction between INL_{98} and AI (see Attachment 4).

Comparison of each pNRV with its median $INL_{98} + AI$ indicated that the percentage deviation from the median was variable and as much as -44% (i.e. pNRV 44% lower than median $INL_{98} + AI$). Suitable pNRVs were preferred to be within $\pm 10\%$ or $\pm 15\%$ of the median which classified pNRVs that fell outside those thresholds as unsuitable. The difference between ± 10 and $\pm 15\%$ was entirely due to the calcium pNRV at 11% above the median $INL_{98} + AI$.

Just under half of the eWG responding to the first consultation paper (9 members) preferred to devise an appropriate comparator in accordance with GP 3.1.2. However, some members considered that GP 3.1.2 needed further elaboration before such a comparator could be determined. Other members could pragmatically support a list of suitable pNRVs based on comparison with their national or several national DIRVs that were sourced from organisations that, in their opinion, would qualify as recognized, authoritative scientific bodies (RASB).

The eligibility of milk to carry calcium content claims if the calcium NRV was set at 1,000 mg was assessed by one member. Although milk is regarded as one of the best sources of dietary calcium, (120 mg calcium/100 mL; 70 kcal/100 mL), a serving of milk <250 mL would not qualify for a 'high' source calcium claim for liquids according to two Codex content claim conditions: $\geq 15\%$ NRV/100 mL; $\geq 30\%$ NRV/serving; however it would qualify according to $\geq 10\%$ NRV/100 kcal.

In the interests of progressing the Committee's consideration of pNRVs, and after considering the impact of applying a comparator from summary DIRVs from the FAO/WHO spreadsheet or national (or several national) DIRVs, a large majority of the eWG came to the view that the following pNRVs based on WHO/FAO RNIs could be classified as suitable (Table 1) or unsuitable (Table 2).

Table 1: Suitable pNRVs, Group 1

Vitamins and Minerals	pNRVs
Vitamins	
Vitamin K (μg)	60
Thiamin (mg)	1.2
Riboflavin (mg)	1.2
Niacin (mg NE)	15
Vitamin B6 (mg)	1.3
Folate (μg DFE)	400
Vitamin B12 (μg)	2.4
Pantothenate (mg)	5
Biotin (μg)	30
Minerals	
Calcium (mg)	1,000
Iodine (μg)	150

Table 2: Unsuitable pNRVs, Group 1

Vitamins	pNRVs
Vitamins	
Vitamin A (µg RE)	550
Vitamin D (µg)	5
Vitamin E (mg α-TE)	8.8
Vitamin C (mg)	45
Minerals	
Magnesium (mg)	240
Selenium (mg)	30

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.

2.2 Iron and Zinc

Table 3: Iron and zinc pNRVs, Appendix IV

Minerals	pNRVs
Iron (mg) (% bioavailability)	14.3* (15%); 18.0 (12%); 21.6 (10%); 43.1 (5%)
Zinc (mg) (% bioavailability)	3.6 (high); 6.0 (moderate); 11.9 (low)

* Rounding error, hereafter corrected to 14.4

Although the pNRVs for iron and zinc are derived from WHO/FAO RNIs and therefore in Group 1, the eWG considered these pNRVs separately because of their multiple values based on varying % absorption from national diets. The FAO/WHO spreadsheet provided very little information on the % absorption underpinning national DIRVs therefore it was not possible to directly compare the multiple pNRVs for iron and zinc with the FAO/WHO spreadsheet. Nevertheless, the eWG noted that the pNRV of highest absorption for iron was comparable with the median INL₉₈ and median INL₉₈ + AI (see Attachment 4). The dietary description for that pNRV also corresponded to the diet in many western countries.

The eWG held divergent views on the number of pNRVs that should be established for iron and for zinc. Several members found the current number of pNRVs for each mineral to be acceptable whereas others preferred fewer pNRVs or only one pNRV per mineral. Some members who preferred fewer pNRVs drew attention to footnote 9 and also the preamble to the General Principles that gave additional flexibility for governments to establish NRVs that would best correspond to the % absorption of iron and zinc in national diets.

Some members considered that the differentiation of multiple pNRVs should include dietary descriptions to complement % absorption data and linked this suggestion with edits to footnote 9; another member suggested that the % absorption could be expressed as a range; whereas others were concerned about the paucity of data underpinning the multiple pNRVs.

2.2.1 Zinc

One member of the eWG drew attention to the recommendations of the International Zinc Nutrition Consultative Group (IZNCG) because it had conducted a systematic review of the literature (IZNCG, 2004) as an update to both the WHO/FAO RNIs and IOM DRIs for zinc. The IZNCG's mean adult (≥19 yrs) male and female Recommended Dietary Allowances (RDA) (INL₉₈) relating to two dietary descriptions are shown in Table 4.

Table 4: Dietary descriptions, % absorption and mean adult RDAs for zinc (IZNCG, 2004)

Dietary descriptions	% absorption	Mean adult RDA (mg)
Refined diets low in cereal fibre, and where animal foods provide the principal protein source. Includes semi-purified formula diets	NR	NR
Mixed diets, and lacto-ovo vegetarian diets that are not based on unrefined cereal grains or high extraction rate (>90%) flours	31%	10.5
Cereal-based diets, with >50% energy intake from cereal grains or legumes and negligible intake of animal protein	23%	14

NR Not Reported

Table 5 provides the dietary descriptions of the WHO/FAO RNIs used as the basis for the multiple pNRVs and the related % absorption for zinc.

Table 5: Dietary descriptions (WHO/FAO, 2004); % absorption and pNRVs for zinc

Dietary descriptions	% absorption (rating)	pNRV (mg)
Refined diets low in cereal fibre, low in phytic acid content, and with phytate-zinc molar ratio <5; adequate protein content principally from non-vegetable sources, such as meats and fish. Includes semi-synthetic formula diets based on animal protein.	50% (high)	3.6
Mixed diets containing animal and fish protein. Lacto-ovo vegetarian, or vegan diets not based primarily on unrefined cereal grains or high extraction rate flours. Phytate-zinc molar ratio of total diet within the range 5-15, or not exceeding 10 if more than 50% of the energy intake is accounted for by unfermented, unrefined cereal grains and flours and the diet is fortified with inorganic calcium salts (>1 g Ca ²⁺ /day).	30% (moderate)	6.0
Diets in which, singly or collectively, approximately 50% of the energy intake is accounted for by the following high-phytate foods: high-extraction-rate (>90%) wheat, rice, maize, grains and flours, oatmeal, and millet; chapatti flours and <i>tanok</i> ; and sorghum, cowpeas, pigeon peas, grams, kidney beans, black-eyed beans, and groundnut flours. High intakes of inorganic calcium salts (>1 g Ca ²⁺ /day), either as supplements or as adventitious contaminants (e.g. from calcareous geophagia), potentiate the inhibitory effects and low intakes of animal protein exacerbates these effects.	15% (low)	11.9

2.2.2 Iron

Short dietary descriptions for three of the four levels of iron bioavailability (not 12% bioavailability) WHO/FAO (2004) are reported in WHO/FAO (2006) as shown in Table 6. (The four levels of % iron absorption were originally established because of the very skewed requirements of menstruating women). It was suggested that the number of iron pNRVs could be reduced to correspond to the number of dietary descriptions.

Table 6: Dietary descriptions (WHO, 2006); % absorption and pNRVs for iron

Dietary description	% absorption (rating)	pNRV (mg)
Diets rich in vitamin C and animal protein	15% (high)	14.4
Diets rich in cereals but including sources of vitamin C	10% (moderate)	21.6
Diets low in vitamin C and animal protein	5% (low)	43.1

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.

2.3 Group 2 pNRVs (Phosphorus to Molybdenum, Appendix IV)

The CCNFSDU requested that all NRVs identified in Appendix IV (para 37, REP 12/NFSDU) be considered. The eWG confirmed that pNRVs could be established for all seven vitamins and minerals in Group 2 since they could be used in the nutrition labelling of foods and food supplements.

In the absence of WHO/FAO RNIs, new pNRVs for Group 2 were initially derived from IOM Recommended Dietary Allowances (INL₉₈) or Adequate Intakes (CX/NFSDU 09/31/4). The eWG considered that these pNRVs were in accord with GPs 3.2.2 and 3.2.3 and that other GPs were either not relevant (GP 3.1.1) or not yet fully considered (GPs 3.1.2, 3.2.1 and 3.3). The current Group 2 pNRVs should therefore be set aside in order to give full consideration to the application of the relevant GPs, particularly GP 3.1.2, 3.2.1 and 3.3, to the determination of Group 2 pNRVs.

The eWG also considered that a pNRV for chloride, if established, should be based on satisfying nutritional requirements for chloride and not be derived from sodium intake recommendations based on reduction of noncommunicable disease risk. This was because the sodium recommendations could exceed nutritional requirements and also that chloride could be present in a food without any link to dietary sodium. Some concern was also expressed about the exceedance of the pNRV for fluoride above the UL for young children (see Attachment 4).

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.

3 ESTABLISHMENT OF REPLACEMENT AND NEW pNRVs

'Replacement' pNRVs are those intended to replace unsuitable pNRVs in Group 1 (no matter how determined) and 'new' pNRVs are those NRVs in Group 2 that will be established for the first time.

3.1 Application of the General Principles

The eWG sought to apply the *General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population* to its work however it became apparent that several approaches could be taken. Further consideration was needed to ensure that GPs 3.1.2, 3.2.1 and 3.3 could be consistently and unambiguously applied. The GPs are individually discussed as follows.

3.1.1 General Principle 3.1.2

3.1.2 Relevant and recent values that reflect independent review of the science, from recognized authoritative scientific bodies other than 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.

As previously mentioned, GP 3.1.2 is relevant to both replacement and new pNRVs. The following key terms in GP 3.1.2 were identified as possibly having various interpretations among Codex members:

- relevant values
- recent values
- independent review of the science
- recognized, authoritative, scientific body (RASB)
- systematic review.

The eWG supported the development of a definition of *Recognized, authoritative, scientific body* since that term appeared in GPs 3.1.2, 3.2.1 and 3.3. A working definition was proposed but eWG comments were not specifically sought on it. Differing views were held about the need for other terms in GP 3.1.2 to be defined. Therefore, only the proposed working definition for RASB is presented.

Recognized, authoritative, scientific body

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.

In deciding the construct of a definition, key points for consideration relate to the:

- RASB's advice;
- support for the RASB;
- recognition given to RASB DIRVs.

3.1.2 General Principle 3.2.1

3.2.1 The NRVs should be based on Individual Nutrient Level 98 (INL₉₈). In cases where there is an absence of an established INL₉₈ for a nutrient for a specific sub-group(s), it may be appropriate to consider the use of other reference values or ranges that have been established by recognized authoritative scientific bodies on a case-by-case basis.

The eWG considered that AIs were the most likely 'other reference values' to be used as alternatives to INL₉₈. AIs are based on limited scientific evidence that is judged to be insufficient to serve as the basis for INL₉₈, or on national dietary intakes of apparently healthy populations.

The eWG gave consideration to the factors that might be involved in deciding 'case by case'. The eWG agreed that AIs based on scientific data should be considered but views were evenly divided on whether AIs based on national nutrient intake data should be regarded as suitable. Some members who supported AIs based on nutrient intake considered that these AIs could be cautiously used where a large database of intake data existed. Other members not in favour indicated that it was not appropriate to derive a Codex pNRV on the basis of national intake data because of the potential inapplicability to global nutrient requirements.

3.1.3 General Principle 3.3

3.3 The establishment of general population NRVs should also take into account Upper Level of Intake established by recognized authoritative scientific bodies

Some eWG members considered it important to explain why general population NRVs based on adult RNIs are compared against ULs for young children. They suggested that this approach avoids misunderstanding and clarifies that the use of such ULs considers the worst case; also that suitable NRVs pose no risk of adverse health effects for almost all individuals in the population.

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.

3.2 Stepwise Process

Although the eWG was guided by the General Principles, the guidance was general in nature and some interpretation was necessary which often resulted in differing views. To enable decisions about the full set of recommendations to be as efficient as possible, it would be useful for the Committee to give consideration to more detailed guidance to be applied to future work on pNRVs.

In this regard, the eWG considered a proposed 3-step process that could implement GP 3.1.2 for all pNRVs in Group 1 but this was not pursued because the eWG was able to support a set of suitable pNRVs from Group 1. The following 7-step process was not discussed by the eWG but, based on the past year's experience, it is put forward as one option to guide future decision making about replacement and new pNRVs. The choice of DIRVs from only one or a combination of RASBs, and the approach when consensus cannot be reached were adapted from the proposed 3-step process.

Step 1	Select the vitamins and minerals requiring a pNRV
Step 2	Select appropriate RASBs in accordance with an agreed definition
Step 3	Identify DIRVs produced by selected RASBs for the selected vitamins and minerals according to GP 3.1.2 (prioritise by how recent and systematic review)
Step 4	For each identified vitamin and mineral, calculate candidate pNRVs from DIRVs of each selected RASB in accordance with GPs 3.2.1, 3.2.2, 3.2.3 (INL ₉₈ or AI, mean adult 19-50 years, non pregnant/lactating) to produce candidate pNRVs
Step 5	Compare each candidate pNRV with GP 3.3 (UL young children from RASB) and remove unsuitable candidate pNRVs
Step 6a	From consideration of the nature and magnitude of the differences between acceptable candidate pNRVs, select the most appropriate pNRV
	OR
Step 6b	From consideration of the nature and magnitude of the differences between acceptable candidate pNRVs, select those that qualify and determine a representative value by an agreed method
Step 7	Decide whether advice should be requested from WHO/FAO if consensus cannot be reached in CCNFSDU on the outcomes of Step 6. Decide if a provisional NRV should be established in the interim.

3.2.1 Notes on Stepwise process

These notes in the box below are not comprehensive but were put forward during the eWG deliberations and are included for the Committee's information to indicate the level of detail that is needed in decision making.

Step	Notes
1	The choice of suitable pNRVs could be made by CCNFSDU in this session based on the eWG's recommendation.
2	The meaning of relevant terms in GP 3.1.2 discussed above may need to be determined. Appropriate websites and references of potential RASBs could be provided to assist determination of which nominated RASBs meet the definition
3	In addition to identifying the year of publication for recent reports from RASBs, the year of the latest literature cited in the scientific review could be identified because the time between a scientific review and its publication can vary
4 & 5	Calculations would be expected to be similar to those already carried out in 2012 for comparators
6a	The criteria relating to the nature and magnitude of the differences between acceptable candidate pNRVs may need further consideration to enable selection of the most appropriate pNRV
6b	As for Step 6a plus method of calculation to determine a representative pNRV
7	CCNFSDU may consider requesting joint WHO/FAO scientific advice to resolve a difference of view. However the Committee should have regard to a 2012 Commission paper on financial and budgetary matters which acknowledged that "several Codex committees face limitations on the provision of scientific advice from WHO and FAO, and if these limitations are not addressed, the development of Codex standards and related texts is likely to be delayed" (para 18, CX/CAC 12/35/15-Add 1).

Table 7: Conversion factors for niacin and folate equivalents

Vitamin	Dietary equivalents	
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)

3.3.1.1 VITAMIN A

Most eWG members supported revision of the currently listed conversion factors for vitamin A. The eWG's attention was drawn to the comments of WHO/FAO (2004) "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.". It was further pointed out that WHO/FAO (2006) and WHO (2009) have cited the IOM conversion factors but retained the term Retinol Equivalents.

Table 8: Conversion factors for Vitamin A

Appendix IV (reformatted)	1 µg Retinol Equivalents =	1 µg retinol 6 µg β-carotene 12 µg other provitamin A carotenoids
IOM (2006)	1 µg Retinol Activity Equivalent (RAE)=	1 µg all-trans-retinol 12 µg dietary all-trans-β-carotene 24 µg α-carotene or β-cryptoxanthin 2 µg all-trans-β-carotene (as supplement)
WHO/FAO (2006)	1 µg Retinol Equivalents =	1 µg retinol 12 µg β-carotene 24 µg other provitamin A carotenoids

3.3.1.2 VITAMIN E

The eWG held divergent views on whether Vitamin E should be expressed as equivalents to recognise different vitamin isomers in food or whether only the α-tocopherol form was biologically active in humans. Tabulated recommendations for vitamin E in WHO/FAO (2004) refer to α-tocopherol but the text lists several conversion factors. WHO/FAO (2006) refers only to α-tocopherol. The activity of the commonly used fortificant all-rac-α-tocopherol acetate (dl-α-tocopherol acetate) was suggested for inclusion (=1.49?).

Table 9: Conversion factors for Vitamin E

Appendix IV (reformatted)	1 mg α-tocopherol equivalents (α-TE) =	1 mg RRR-α-tocopherol (d-α-tocopherol) 2 mg β-tocopherol 10 mg γ-tocopherol 3.3 mg α-tocotrienol 1.35 mg all-rac-α-tocopherol (dl-α-tocopherol) (as supplement)
WHO/FAO (2004)	1 mg α-tocopherol equivalents (α-TE) =	1 mg RRR-α-tocopherol (d-α-tocopherol) 2 mg β-tocopherol 10 mg γ-tocopherol 3.3 mg α-tocotrienol

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.

3.4 Footnotes

The eWG considered the wording of three footnotes 3, 5 and 9 in Appendix IV. Other footnotes numbered between 3 and 9 refer to conversion factors as discussed above.

3.4.1 Footnote 3

3 In order to take into account future scientific developments, future FAO/WHO and other expert recommendations and other relevant information, the list of nutrients and the list of nutrient reference values should be kept under review.

The eWG considered footnote 3 to be unnecessary because it was always possible to update Codex texts in view of new developments. Deleting this footnote is similar action to that taken recently by the Codex Committee on Food Labelling in deleting Section 5, Periodic Review of Nutrition Labelling, from the Codex Nutrition Labelling Guidelines.

3.4.2 Footnote 5

5 Nutrient Reference Values for Vitamin D, Niacin and Iodine may not be applicable for countries where national nutrition policies or local conditions provide sufficient allowance to ensure that individual requirements are satisfied. See also section 3.2.4.1 of the Codex Guidelines on Nutrition Labelling.

The eWG considered footnote 5 to be unnecessary in view of the preamble of the General Principles which mentions that governments can consider the suitability of the General Principles and additional factors in establishing their own NRVs.

3.4.3 Footnote 9

9 Countries should determine the appropriate NRV that best represents the bioavailability of iron and of zinc in national diets. Guidance on determining the iron and zinc bioavailability of national diets can be found in the publication: WHO/FAO (2004) Vitamin and mineral requirements in human nutrition. 2nd Ed. World Health Organization, Geneva.

The eWG considered footnote 9 to be necessary but the second sentence referring to the WHO (2004) should be deleted because, over time, documents can become outdated or superseded by more recent evidence-based recommendations.

Conclusion G

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

3.5 Documentation of guidance material and record of approach

Development of any definitions or criteria to guide the implementation of the General Principles will raise the associated issue of whether the guidance should be documented and if so, whether in conjunction with the General Principles. Also, a record of the decision-making process used to derive NRVs for vitamins and minerals would be useful to assist future understanding of the current revision.

If the Committee agrees to develop further guidance material, options to capture the information could be:

- For guidance material
 - in conjunction with the General Principles in the Codex Nutrition Labelling Guidelines (see Attachment C to the *Proposed Draft General Principles for Establishing Nutrient Reference Value for Nutrient Associated with Risk of Diet-Related Noncommunicable Diseases for the General Population*)
 - consolidated into an Appendix to a Report of a future CCNFDSU session
- For record of decision making
 - consolidated into an Appendix to a Report of a future CCNFDSU session after the work is completed
 - within the series of relevant Codex agenda papers.

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.

4 ADDITIONAL ISSUES

This section is included in accordance with the eWG's TOR 4.

The eWG has identified as a significant issue that the CCNFSDU currently does not have a mechanism for obtaining joint FAO/WHO scientific advice on nutrition for review of NRVs. 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 (para 25, REP 12/NFSDU). Thus, the eWG requests WHO and FAO representatives to report details about the progress, concrete plans and timeframe for re-establishing JEMNU.

In a related issue, the eWG is pleased to see 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).

Conclusion I

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

5 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.

6 ATTACHMENTS

ATTACHMENT 1 provides a revision to Appendix IV, ALINORM 10/33/26 by updating the Committee's previous pNRVs with the eWG's recommendations on pNRVs and includes proposed new text and table for conversion factors. Please note that most footnotes are omitted here for clarity of text but are addressed in Attachment 3. Footnote number 9 incorrectly appears as footnote 8.

The Attachment shows the original NRV for iodine and pNRVs for all other vitamins and minerals in Appendix IV either as:

- Unchanged: these pNRVs are recommended for adoption; or
- With strike out accompanied by [tbd]: these pNRVs are recommended to be set aside for further consideration.

ATTACHMENT 2 provides a clean list of the vitamins and minerals and their present NRVs, pNRVs in Appendix IV and the eWG's recommended changes to the pNRVs.

ATTACHMENT 3 provides a list of present footnotes, revisions and additional to footnotes in Appendix IV and the eWG's recommended changes to the footnotes. Information for each footnote consists of the text to which the footnote is anchored, the footnote number and footnote text.

ATTACHMENT 4 provides an extract from the eWG's first consultation paper presenting the data calculations and associated issues involved in deriving a comparator from the FAO/WHO corrected spreadsheet.

7 REFERENCES

Codex Alimentarius Commission (2011) Procedural Manual, 20th edition. Food and Agricultural Organization and World Health Organization, Rome

Institute of Medicine (2006) Dietary reference intakes (DRI): The essential guide to nutrient requirements. Otten JJ, Hellwig JP, Meyers LD (eds). National Academies Press, Washington D.C.

International Zinc Nutrition Consultative Group (2004) Assessment of the risk of zinc deficiency in populations and options for its control. Food and Nutrition Bulletin 25(1):S99-129 (Supplement 2)

World Health Organization and Food and Agricultural Organization (2004) Vitamin and Mineral Requirements in Human Nutrition, 2nd edition. WHO, Geneva

World Health Organization and Food and Agricultural Organization (2006) Guidelines on food fortification with micronutrients. WHO/FAO, Geneva

World Health Organization (2009) Global prevalence of vitamin A deficiency in populations at risk 1995-2005. WHO Global Database on Vitamin A Deficiency http://www.who.int/nutrition/publications/micronutrients/vitamin_a_deficiency/9789241598019/en/index.html Accessed 17 October 2012.

ATTACHMENT 1

Proposed Draft Additional or Revised NRVs for the General Population – Amendments to Appendix IV based on eWG Recommendations

3.4 Presentation of nutrient content

3.4.4 [TEXT: refer to Agenda paper on Proposed Draft General Principles for establishing NRV-NCD for the General Population]

3.4.4.1 NRVs-R

Protein (g) 50

Vitamins**NRV-R**Vitamin A (µg **RE**) 800 ~~550~~ [tbd]

Vitamin D (µg) 5 [tbd]

Vitamin E (mg [α -TE]) **8.8** [tbd]**Vitamin K (µg)** **60**Vitamin C (mg) 60 ~~45~~ [tbd]Thiamin (mg) 1.4 ~~1.2~~Riboflavin (mg) 1.6 ~~1.2~~Niacin (mg **NE**) 18 ~~15~~Vitamin B₆ (mg) 2 ~~1.3~~Folic acid (µg) 200 **Folate (µg DFE) 400**Vitamin B₁₂ (µg) 1 ~~2.4~~**Pantothenate (mg)** **5.0****Biotin (µg)** **30****Minerals** **NRV-R**Calcium (mg) 800 ~~1,000~~Magnesium (mg) 300 ~~240~~ [tbd]

Iodine (µg) 150

Iron (mg) (% bioavailability-absorption)⁸ 14 ~~14.4 (15%)~~ ~~18.0 (12%)~~ ~~21.6 (10%)~~ ~~43.1 (5%)~~ [tbd] [tbd]Zinc (mg) (% bioavailability-absorption)⁸ 15 ~~3.6 (high)~~ ~~6.0 (moderate)~~ ~~11.9 (high)~~ [tbd] [tbd] [tbd]Selenium Value to be established **(µg) 30** [tbd]Phosphorus (mg) ~~700*~~ [tbd]Chloride (mg) ~~2,300*~~ [tbd]Copper Value to be established **(µg) 900*** [tbd]Fluoride (mg) ~~3.5*~~ [tbd]Manganese (mg) ~~2.1*~~ [tbd]Chromium (µg) ~~30*~~ [tbd]Molybdenum (mg) ~~45*~~ [tbd]

[tbd] to be determined

* Value is based on the Institute of Medicine of the National Academies of Science in the United States

⁸ Countries should determine the appropriate NRV that best represents the bioavailability of iron and of zinc in national diets. Guidance on determining the iron and zinc bioavailability of national diets can be found in the publication: FAO/WHO (2004) Vitamin and mineral requirements in human nutrition

PROPOSED NEW TEXT

The conversion factors for vitamin equivalents in the Table provide supporting information to enable national authorities to determine the application of NRVs at national level.

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- <i>trans</i> -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

ATTACHMENT 2

NRVs, pNRVs in Appendix IV and eWG's Recommendations for pNRVs

	NRV (CAC-GL 2-1985)	Previous pNRVs (Appendix IV)	eWG Recommendations for pNRVs
Vitamins			
Vitamin A	800 µg	550 µg RE	[tbd] RE
Vitamin D	5 µg	5 µg	[tbd] µg
Vitamin E	-	8.8 mg α-TE	[tbd] [α-TE]
Vitamin K	-	60 µg	60 µg
Vitamin C	60 mg	45 mg	[tbd] mg
Thiamin	1.4 mg	1.2 mg	1.2 mg
Riboflavin	1.6 mg	1.2 mg	1.2 mg
Niacin	18 mg	15 mg NE	15 mg NE
Vitamin B ₆	2 mg	1.3 mg	1.3 mg
Folic acid	200 µg	400 µg DFE	400 µg DFE
Vitamin B ₁₂	1 µg	2.4 µg	2.4 µg
Pantothenate	-	5.0 mg	5 mg
Biotin	-	30 µg -	30 µg -
Minerals			
Calcium	800 mg	1000 mg	1,000 mg
Magnesium	300 mg	240 mg	[tbd] mg
Iodine	150 µg	150 µg	150 µg
Iron	14 mg		
Iron (%bioavailability)	-	14.4 mg (15%) 18.0 (12%) 21.6 (10%) 43.1 (5%)	
Iron (%absorption)	-	-	[tbd] mg (%) [tbd] mg (%) [tbd] mg (%)
Zinc	15 mg		
Zinc (%bioavailability)	-	3.6 mg (high) 6.0mg (moderate) 11.9mg (low)	
Zinc (%absorption)	-	-	[tbd] mg (%) [tbd] mg (%) [tbd] mg (%)
Selenium	Value to be established	30 µg	[tbd] µg
Phosphorus	-	700 mg	[tbd] mg
Chloride	-	2, 300 mg	[tbd] mg
Copper	Value to be established	900 µg	[tbd] µg
Fluoride	-	3.5 mg	[tbd] mg
Manganese	-	2.1 mg	[tbd] mg
Chromium	-	30 µg	[tbd] µg
Molybdenum	-	45 µg	[tbd] µg

ATTACHMENT 3

Present Footnotes, Footnotes in Appendix IV and eWG's Recommendations

The following Table provides the text to which the footnote is anchored, footnote numbers and footnote text for each of the Nutrition Labelling Guidelines, Appendix IV, and the eWG Recommendations. The notation of (delete) is used to show a deletion of a footnote number in case it is not clear. The eWG recommended changes are applied to Appendix IV rather than to the Nutrition Labelling Guidelines.

Footnote number		Codex Nutrition Labelling Guidelines	Appendix IV	eWG Recommendations
3	Anchor text, no.	In addition, information on protein may also be expressed as percentages of the Nutrient Reference Value ³	In addition, information on protein may also be expressed as percentages of the Nutrient Reference Value ³	In addition, information on protein may also be expressed as percentages of the Nutrient Reference Value ^{3(delete)}
	Number and text	3) In order to take into account future scientific developments, future FAO/WHO and other expert recommendations and other relevant information, the list of nutrients and the list of NRVs should be kept under review.	3) In order to take into account future scientific developments, future FAO/WHO and other expert recommendations and other relevant information, the list of nutrients and the list of NRVs should be kept under review.	3) In order to take into account future scientific developments, future FAO/WHO and other expert recommendations and other relevant information, the list of nutrients and the list of NRVs should be kept under review.
4	Anchor text, no.	Vitamin A (µg) 800 ⁴	Vitamin A (µg RE) 550 ⁴	Vitamin A (µg [RE]) 550 ^{4(delete)} [tbd]
	Number and text	4) Proposed addition to Section 3.2.7 (Calculation of Nutrients) of the Codex Guidelines on Nutrition Labelling : "For the declaration of β-Carotene (provitamin A) the following conversion factor should be used: 1 µg retinol = 6 µg β-carotene.	4) Proposed addition to Section 3.2.7 (Calculation of Nutrients) of the Codex Guidelines on Nutrition Labelling : "For the declaration of β-Carotene (provitamin A) the following conversion factor should be used: 1 µg retinol = 6 µg β-carotene. RE=retinol equivalents: 1 µg retinol = 1 µg RE; 1 µg β-carotene = 0.167 µg RE; 1 µg other provitamin A carotenoids = 0.084 µg RE	4) Proposed addition to Section 3.2.7 (Calculation of Nutrients) of the Codex Guidelines on Nutrition Labelling : "For the declaration of β-Carotene (provitamin A) the following conversion factor should be used: 1 µg retinol = 6 µg β-carotene. RE=retinol equivalents: 1 µg retinol = 1 µg RE; 1 µg β-carotene = 0.167 µg RE; 1 µg other provitamin A carotenoids = 0.084 µg RE.
5	Anchor text, no.	Vitamin D (µg) 5 ⁵ ; Niacin (mg) 18 ⁵ ; Iodine (µg) 150 ⁵	Vitamin D (µg) 5 ⁵ ; Niacin (mg NE) 48 ⁵ 15 ⁷ ; Iodine (µg) 150 ⁵	Vitamin D (µg) 5 ^{5(delete)} [tbd] ; Niacin (mg NE) 48 ^{5(delete)} [tbd] ; Iodine (µg) 150 ^{5(delete)}

Footnote number		Codex Nutrition Labelling Guidelines	Appendix IV	eWG Recommendations
	Number and text	5) NRVs for vitamin D, Niacin and Iodine may not be applicable for countries where national nutrition policies or local conditions provide sufficient allowance to ensure that individual requirements are satisfied. See also section 3.2.4.1 of the Codex Guidelines on Nutrition Labelling	5) NRVs for vitamin D and Iodine may not be applicable for countries where national nutrition policies or local conditions provide sufficient allowance to ensure that individual requirements are satisfied. See also section 3.2.6.1 of the Codex Guidelines on Nutrition Labelling	5) NRVs for vitamin D and Iodine may not be applicable for countries where national nutrition policies or local conditions provide sufficient allowance to ensure that individual requirements are satisfied. See also section 3.2.6.1 of the Codex Guidelines on Nutrition Labelling
6	Anchor text, no.		Vitamin E (mg) 8.8 ⁶	Vitamin E (mg) 8.8 ^{6(delete)} [tbd]
	Number and text		6) α -TE= α -tocopherol equivalents: 1 mg <i>RRR</i> - α -tocopherol (<i>d</i> - α -tocopherol) = 1 mg α -TE; 1 mg β -tocopherol = 0.5 μ g α -TE; 1 mg γ -tocopherol = 0.1 α -TE; 1 mg α -tocotrienol = 0.3 α -TE.; 1 mg all- <i>rac</i> - α -tocopherol (<i>dl</i> - α -tocopherol) = 0.74 α -TE	6) α-TE=α-tocopherol equivalents: 1 mg <i>RRR</i>-α-tocopherol (<i>d</i>-α-tocopherol) = 1 mg α-TE; 1 mg β-tocopherol = 0.5 μg α-TE; 1 mg γ-tocopherol = 0.1 α-TE; 1 mg α-tocotrienol = 0.3 α-TE.; 1 mg all-<i>rac</i>-α-tocopherol (<i>dl</i>-α-tocopherol) = 0.74 α-TE
7	Anchor text, no.		Niacin (mg NE) 48 ⁵ 15 ⁷	Niacin (mg NE) 15 ^{7(delete)}
	Number and text		7) NE = niacin equivalents; 60-to-1 conversion factor for tryptophan to niacin.	7) NE = niacin equivalents; 60 to 1 conversion factor for tryptophan to niacin.
8	Anchor text, no.		8) Folate (μ g DFE) 400 ⁸	Folate (μ g DFE) 400 ^{8(delete)}
	Number and text		DFE = dietary folate equivalents; 1 μ g food folate = 1 μ g DFE, 1 μ g folic acid = 1.7 μ g DFE	DFE = dietary folate equivalents; 1 μg food folate = 1 μg DFE, 1 μg folic acid = 1.7 μg DFE
9	Anchor text, no.		Iron (mg) (% bioavailability) ⁹ ; Zinc (mg) (% bioavailability) ⁹	Iron (mg) (% bioavailability-absorption) ⁹ ; Zinc (mg) (% bioavailability-absorption) ⁹

Footnote number		Codex Nutrition Labelling Guidelines	Appendix IV	eWG Recommendations
	Number and text		9) Countries should determine the appropriate NRV that best represents the bioavailability of iron and of zinc in national diets. Guidance on determining the iron and zinc bioavailability of national diets can be found in the publication: FAO/WHO (2004) Vitamin and mineral requirements in human nutrition	9) Countries should determine the appropriate NRV that best represents the bioavailability of iron and of zinc in national diets. Guidance on determining the iron and zinc bioavailability of national diets can be found in the publication: FAO/WHO (2004) Vitamin and mineral requirements in human nutrition

ATTACHMENT 4

Data Calculation Steps for Comparator derived from FAO/WHO Spreadsheet

The following provides an explanation of the data calculation steps used to derived comparators derived from the FAO/WHO corrected spreadsheet.

1) The mean of the adult male and female daily intake reference values (AI or INL_{98}) for each country in the revised spreadsheet was calculated. No regional weighting was applied even though the lack of representation from certain regions was noted. The averaging was a simple task if a single value was given for same age range as WHO/FAO i.e. males (19-65 years) and females (19-50 years). However, where countries gave a range for an age/sex group, the midpoint was taken. Also, the daily intake reference values of a minority of countries are divided into finer age groups within these respective age ranges. In such cases, before calculating the mean of male and female values, Australia determined a weighted daily intake reference value for each sex according to the relative proportion of years in each age group within the relevant age range. Values for males above 50 years were not included in these weighted calculations, which effectively meant that the male age range was reduced from 19-65 years to 19-50 years, equivalent to the female age range. (Note: A single daily intake reference value for males aged 19-65 years is the same value for a subset of males aged 19-50 years).

The impact of excluding a higher or lower reference value for males aged 51-65 years from the average male value for the affected countries was tested by reworking the calculations for calcium. This mineral was chosen because 15 countries reported different (mostly higher) calcium intake reference values for men aged above and below 50 years. When males 51-65 years with different intake reference values were included in the weighting, the median AI ($n = 10$) did not change, the median INL_{98} ($n = 40$) increased from 885 to 900 mg and the median combined $INL_{98} + AI$ ($n = 50$) rose from 900 to 901 mg.

Given that a system to weight finer age groups within the age range was needed, the inclusion of males aged 51-65 years appears to make little practical difference. Basing NRVs on the same age range for both sexes is a simpler and more equitable approach. Australia considers that it is not necessary to maintain an inequitable age range for males and females and therefore reduced the age range for males to 19-50 years in the analysis so that both sexes span 19-50 years. Since GP 3.2.2 refers to only 'the widest applicable age range', this decision remains consistent with that General Principle.

2) The median of the averaged national/regional daily intake reference values for males and females aged 19-50 years was calculated for INL_{98} , AI, and combined $INL_{98} + AI$ and rounded where appropriate. The number of countries having INL_{98} or AI values, and the total number of countries having both reference values was also recorded.

3) The three medians described in Step 2 provide a benchmark of daily intake reference values around the world.

4) Australia selected the median combined $INL_{98} + AI$ because the difference between the related medians is often small, and the combined median is based on the greatest sample number. The rationale for combining $INL_{98} + AI$ daily intake reference values is also due to WHO/FAO's comment on the data compilation (p. 8, CX/NFSDU 11/33/4):

"Challenges arose because of a lack of terminology among the various countries. Many countries and scientific bodies use different terms to describe the same concept. Also many countries and scientific bodies use the same term to describe different concepts. A weakness of this review is that in order to classify and present the data, terms with varied definitions were categorized into one of three conditions. For the purposes of this review, values were categorized as either an INL_{98} , AI or unclear."

5) The difference between the pNRV and the combined median $INL_{98} + AI$ (unrounded) as a percentage of that median was calculated from the equation:

$$(\text{pNRV} - \text{median combined } INL_{98} + AI) \times 100 / \text{median combined } INL_{98} + AI$$

The results of these calculations are presented in Table 1A.

Table 1A: WHO/FAO-based pNRVs, medians from other data sources, and difference between pNRV and median combined INL₉₈ + AI for comparison

Vitamins and Minerals	pNRVs Appendix IV	Median AI (N)	Median INL ₉₈ (N)	Median INL ₉₈ + AI combined (N)	Difference pNRV and combined median combined median)	b/w and (%)
VITAMINS (13)						
Vitamin A (µg RE)	550	700 (6)	800 (45)	800 (51)	-31	
Vitamin D (µg)	5	5 (15)	5 (34)	5 (49)	0	
Vitamin E (mg α-TE)	8.8*	11 (14)	12 (29)	12 (43)	-27	
Vitamin K (µg)	60	69 (15)	65 (15)	65 (30)	-8	
Vitamin C (mg)	45	80 (2)	75 (49)	75 (51)	-40	
Thiamin (mg)	1.2*	1.1 (2)	1.2* (46)	1.2* (48)	0	
Riboflavin (mg)	1.2	1.5 (2)	1.3 (49)	1.3 (51)	-8	
Niacin (mg NE)	15	15 (3)	15 (47)	15 (50)	0	
Vitamin B6 (mg)	1.3	1.3* (2)	1.4* (44)	1.3* (46)	-2	
Folate (µg DFE)	400	400 (3)	400 (44)	400 (47)	0	
Vitamin B12 (µg)	2.4	2.2 (2)	2.4 (47)	2.4 (49)	0	
Pantothenate (mg)	5	5 (19)	6* (6)	5 (25)	0	
Biotin (µg)	30	30 (20)	50 (5)	30 (25)	0	
MINERALS (6)						
Calcium (mg)	1000	1000 (10)	885 (40)	900 (50)	11	
Magnesium (mg)	240	325 (5)	321 (42)	324 (47)	-26	
Iodine (µg)	150	150 (1)	150 (46)	150 (47)	0	
Iron (mg) unknown bio		15.5 (4)	13.0 (45)	13.0 (49)		
Iron (mg) (15% bio)	14.4*				10	
Iron (mg) (12% bio)	18.0*				38	
Iron (mg) (10% bio)	21.6*				66	
Iron (mg) (5% bio)	43.1				231	
Zinc (mg) unknown avail		8.0 (2)	9.5 (46)	9.5 (48)		
Zinc (mg) (high, 50%	3.6				-62	

Vitamins and Minerals	pNRVs Appendix IV	Median AI (N)	Median INL ₉₈ (N)	Median INL ₉₈ + AI combined (N)	Difference pNRV and combined median (% b/w and combined median)
avail)					
Zinc (mg) (moderate, 30% avail)	6.0*				-37
Zinc (mg) (low, 15% avail)	11.9				25
Selenium (µg)	30	50 (6)	55 (41)	54 (47)	-44

* Rounded up

From Table 1A, three vitamins and minerals have medians that are all different; four have medians that are all the same; and the remainder have one median that differs from the other two.

The unrounded combined median INL₉₈ + AIs of eight vitamins and minerals equate to the pNRVs based on WHO/FAO RNIs. For another three vitamins and minerals, the pNRV is 10% lower than the combined median whereas the pNRV is 11% greater than the combined median. Very little data are available on the bioavailability assumptions underpinning national reference values for iron and zinc therefore only one set of medians was calculated for unknown bioavailability. As a result, the difference between the three medians of unknown bioavailability and the pNRVs of lower iron bioavailabilities and lowest zinc bioavailability is not very meaningful and so Australia suggests that the pNRVs for iron and zinc in Appendix IV remain. The remaining five vitamins and minerals have pNRVs lower than their respective combined medians by 26 – 44%. Those with the largest discrepancies (vitamins A, E and C; magnesium and selenium) correspond to those identified in previous comments to CCNFSDU.

6) The eWG is requested to provide its view on an appropriate difference between a pNRV based on WHO/FAO RNIs and the % combined median beyond which a pNRV is considered as unsuitable. Clearly, the wider the tolerable gap between the pNRV and the combined median, the greater the number of pNRVs based on WHO/FAO RNIs found suitable and the fewer found unsuitable (e.g. >±49%, all pNRVs found suitable). Conversely, the narrower the tolerable gap between the pNRV and combined median, the greater the number of pNRVs based on WHO/FAO RNIs found unsuitable (e.g. >±10%, no pNRVs found suitable). The suggested thresholds and affected vitamins and minerals are shown in Table 2A.

Table 2A: Thresholds to classify potentially ‘unsuitable’ pNRVs calculated from WHO/FAO RNIs

Potential thresholds for unsuitable pNRVs	Vitamins and minerals whose pNRVs calculated from WHO/FAO RNIs are potentially unsuitable
>±10%	vitamin A, vitamin C, vitamin E, calcium, magnesium, selenium
>±15%	vitamin A, vitamin C, vitamin E, magnesium, selenium
>±29%	vitamin A, vitamin C, selenium
>±39%	vitamin C, selenium
> ±49%	nil

The vitamins and minerals for which the eWG finds pNRVs calculated from WHO/FAO RNIs to be unsuitable can then be considered in accordance with GP 3.1.2.

Table 3A shows the medians compared to the UL for two young age groups in accordance with General Principle 3.3

Table 3A: pNRVs, medians from other data sources and ULs for two young age groups for comparison

Minerals	pNRVs Appendix IV	Median AI (N)	Median INL ₉₈ (N)	Median INL ₉₈ + AI combined	UL 1-3/4-8 yrs; USA &	UL 1-3/4-6 yrs; European
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				(N)	Canada	Union
IOM RDA-based pNRVs						
Copper (µg)	900	1330* (6)	900 (35)	1100 (41)	1000/3000	1000/2000
Molybdenum (µg)	45	65 (12)	45 (10)	45 (22)	300/600	100/200
Phosphorus (mg)	700	700 (3)	700 (43)	700 (46)	3000/3000	ND/ND
IOM AI-based pNRVs (limited evidence base)						
Chloride (mg)	2300	2300 (9)	2400 (6)	2300 (15)	2300/2900	ND/ND
Fluoride (mg)	3.5	3.5 (17)	3.0 (9)	3.5* (26)	1.3/2.2	1.5/2.5
IOM AI-based pNRVs (national intake data)						
Chromium (µg)	30	30 (18)	50 (5)	30 (23)	ND/ND	ND/ND
Manganese (mg)	2.1	3.5 (15)	2.1 (5)	2.2 (20)	2/3	ND/ND

* Rounded up

ND = Not determined; due to insufficient data