CODEX ALIMENTARIUS COMMISSION



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Agenda Item 3

CX/NFSDU 13/35/4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-fifth Session Bad Soden am Taunus, Germany 4 – 8 November 2013

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

(Prepared by Australia and members of an Electronic Working Group representing Brazil, Canada, Chile, China, European Union, Ghana, Indonesia, Japan, Malaysia, the Netherlands, New Zealand, United States of America, Uruguay, FoodDrink Europe, International Alliance of Dietary/Food Supplement Associations, International Council of Beverages Associations, International Council of Grocery Manufacturers Associations, International Food Policy Research Institute, National Health Federation).

Comments are not requested as no Nutrient Reference Values are proposed in this document.

1 BACKGROUND

1.1 Previous Consideration by CCNFSDU

At its 34th session (2012), CCNFSDU agreed to advance to step 5/8 the proposed draft Nutrient Reference Values – Requirements (NRVs-R) for vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate , vitamin B12, pantothenate, biotin, calcium and iodine with the conversion factors for folate and niacin (Appendix VII, REP13/NFSDU, 2012). These were adopted by the Commission in 2013.

CCNFSDU also agreed to establish an electronic Working Group (eWG), chaired by Australia and working in English (paragraph 102, REP13/NFSDU) with the following Terms of Reference (TOR):

- 1. Recommend draft additional or revised NRVs-R for vitamins A, D, E, C, magnesium, selenium, iron and zinc and relevant conversion factors, developed according to the following process:
 - a. select one or more recognized authoritative scientific bodies (RASB) according the Committee's working definition of RASBs;
 - b. derive candidate NRVs-R from daily intake reference values that are reported by each selected RASB and WHO/FAO for the above vitamins and minerals in accordance with the relevant General Principles;
 - c. i) evaluate the characteristics of candidate NRVs-R for the purpose of international applicability and the relevant conversion factors and determine draft recommendations;
 - ii) determine whether some or all of the evaluation in c-i) should be referred to FAO/WHO for scientific advice and if so, draft appropriate questions for FAO/WHO.
- 2. Review the NRV-R for protein in accordance with the relevant General Principles and as appropriate, recommend a draft revised NRV-R for protein.
- 3. Review the working definition of RASB, and as appropriate, recommend a final definition of RASB.

1.2 Conduct of the Electronic Working Group

In February 2013, CCNFSDU members were invited to participate in the eWG to consider NRVs-R for eight vitamins and minerals, and protein as given in the eWG's TOR.

The eWG considered two Consultation Papers prepared by Australia that were circulated in March and July 2013 respectively. Thirteen government and 6 international non-government members responded to the first Consultation Paper, whereas 9 government and 5 international non-government members responded to the second Consultation Paper. Unfortunately, very late responses could not be considered. All participating members are acknowledged above.

1.3 Terminology

1.3.1 Nutrient reference values

Nutrient reference values (NRVs) and NRVs-R as shown in Appendix VI, REP 13/NFSDU, endorsed by CCFL in Appendix III, REP13/FL and as adopted by the Commission in 2013, are defined as:

Nutrient Reference Values (NRVs) are a set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims. They comprise the following two types of NRVs:

Nutrient Reference Values – Requirements (NRVs-R) refer to NRVs that are based on levels of nutrients associated with nutrient requirements.

1.3.2 Daily intake reference value

The term 'daily intake reference values' (DIRVs) as shown in Appendix IV, REP 13/NFSDU and as adopted by the Commission in 2013, is defined as:

Daily intake reference values as used in these Principles refer to reference nutrient intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g., as a single value or range), and are applicable to the general population or to a segment of the population (e.g., recommendations for a specified age range).

1.3.3 Recognized, scientific, authoritative body

The term 'recognized, scientific, authoritative body' (RASB) is mentioned in three of the General Principles (GP) (see Section 1.4) and in the definition of DIRVs. The current working definition of RASB (paragraph 93, REP 13/NFSDU) is:

For the purposes of establishing Codex Nutrient Reference Values, a recognized, scientific, authoritative body is an organization supported by a government(s) or competent national and/or regional authorities or FAO and/or WHO that provides independent and transparent* authoritative scientific advice on daily intake reference values upon request, and for which such advice is recognised through its use in the development of policies in one or more countries.

* In providing transparent scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value

1.4 General Principles for Establishing NRVs-R

The *General Principles for Establishing NRVs* (General Principles) in the form of a consolidated draft Annex to the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) given in Appendix IV, REP 13/NFSDU were considered by the CCFL (Annex II, CX/FL 13/41/2) and endorsed with a minor amendment to General Principles for NRVs-NCD (paragraph 59, REP13/FL). The Commission adopted the consolidated version of the Draft General Principles in 2013. The General Principles relevant to NRVs-R are shown as follows.

GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R

3.1 Selection of Suitable Data Sources to Establish NRVs

3.1.1 Relevant and recent daily nutrient intake values provided by/FAO/WHO that are based on a recent review of the science should be taken into consideration as primary sources in establishing NRVs.

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

3.1.3 The daily intake reference values should reflect intake recommendations for the general population.

3.2 Selection of Nutrients and Appropriate Basis for NRVs

3.2.1 Selection of Nutrients and Appropriate Basis for NRVs-R

3.2.1.1 The NRVs-R should be based on Individual Nutrient Level 98 (INL_{98}). In cases where there is an absence of an established INL_{98} 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. The derivation of these values should be reviewed on a case-by-case basis.

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

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

3.3 Consideration of Daily Intake Reference Values for Upper Levels

The establishment of general population NRVs should also take into account daily intake reference values for upper levels established by FAO/WHO or other recognized authoritative scientific bodies where applicable (e.g. Upper Level of Intake, Acceptable Macronutrient Distribution Range).

2 CONSIDERATIONS

The eWG addressed TORs 1 (except 1cii), 2 and 3.

2.1 Nominated RASBs (TOR 1a)

The eWG was requested to nominate information about scientific bodies that satisfied the working definition of RASB (Section 1.3.3). Nominations and supporting documentation, for 6 scientific bodies, detailed in Attachment 1 were found to be acceptable. Other scientific bodies were also nominated but without sufficient information to enable assessment of the extent to which they met all components of the working definition of RASB and so they were not further considered.

Scientific bodies nominated as RASB	Supporting government or authority
European Food Safety Authority (EFSA)	European Union
Institute of Medicine (IOM)	United States of America;
	Canada
International Zinc Nutrition Consultative Group (IZiNCG)	Thailand; UNICEF
National Health and Medical Research Council & New Zealand Ministry of	New Zealand; Australia
Health (NHMRC/MOH)	
National Institute of Health and Nutrition (NIHN)	Japan
Technical Working Group on Nutritional Guidelines (TWG)	Malaysia

The eWG expressed strong support for EFSA and the IOM; major support for NHMRC/MOH and IZiNCG; and some support for NIHN and TWG because of the limited supplementary information available at that time. In addition, several eWG members commented that primary evaluation of the data underpinning DIRV recommendations was an important consideration.

RECOMMENDATION 1

From an assessment of the credentials of the scientific bodies at Attachment 1, and in addition to WHO/FAO, it is recommended that CCNFSDU accept the following scientific bodies as RASBs to enable their DIRVs to be further considered in determining NRVs-R for the eight vitamins and minerals, and for protein.

- European Food Safety Authority (EFSA)
- United States Institute of Medicine (IOM)
- Australia National Health and Medical Research Council & New Zealand Ministry of Health (NHMRC/MOH)
- Japan National Institute of Health and Nutrition (NIHN)
- Malaysia Technical Working Group on Nutritional Guidelines (TWG)
- International Zinc Nutrition Consultative Group (IZiNCG)

Please note that the term 'accepted RASBs' has been used throughout this agenda paper on the assumption that the Committee adopts Recommendation 1.

2.2 Reference to the Term *Bioavailability*

At the 34th session, the Committee referred to the eWG a recommendation on the possible replacement of the term *bioavailability* by *absorption* (paragraph 101, REP13/NFSDU) as that matter had not been specifically discussed by the Committee. The WHO/FAO (2004)¹ explanation of bioavailability refers only to absorption and not to metabolism. The replacement was proposed because WHO/FAO's meaning of *bioavailability* was inconsistent with the different definition of this term in the Codex Nutritional Risk Analysis Principles and Guidelines (CAC, 2011)² which refers to utilization in metabolism as well as absorption.

The eWG supported the use of the term *absorption* and therefore it has been adopted throughout this agenda paper.

RECOMMENDATION 2

That CCNFSDU adopt the term *absorption* in place of *bioavailability* when the evidence refers to dietary absorption only and not to utilization in metabolism.

2.3 DIRVs from Accepted RASBs (TOR 1b and TOR 1ci)

The following supporting information, previously considered necessary to effectively evaluate the DIRVs from accepted RASBs, was collected in association with submitted DIRVs from eWG members who nominated RASBs. These details were adapted from the Committee's request to WHO/FAO (Appendix III, REP 11/NFSDU, 2010).

- DIRVs (i.e. value, unit) for males and females in one or more age ranges that span 19-50 years
- Physiological endpoints used to establish the INL₉₈, or the AI
- Reason for the choice of physiological endpoint(s)
- Coefficient of variation used to derive INL₉₈
- Whether primary evaluation or adopted or adapted from DIRVs from one or more countries
- Reference body weights for males and females aged 19-50 years and their basis i.e. current population data or recommendations for health, as appropriate
- Percentage dietary absorption and its basis
- Year of scientific evaluation of DIRV

¹ World Health Organization and Food and Agricultural Organization (2004) Vitamin and Mineral Requirements in Human Nutrition, 2nd edition. WHO, Geneva <u>whqlibdoc.who.int/publications/2004/9241546123.pdf</u> Accessed 24 September 2013.

² Codex Alimentarius Commission (2011) Procedural Manual, 20th edition. Food and Agriculture Organization, Rome

- Year of latest reference cited in the evaluation.
- Whether DIRVs are based on primary evaluation.

For the eight vitamins and minerals, the adult male and female DIRVs in the correct age range extracted from publications (references in Attachment 1) by each of the nominated RASBs are shown at Attachment 2. In addition, details for the relevant WHO/FAO RNIs are included because the Committee considered them to be only *potentially* unsuitable. Members are encouraged to review the evidence base from the weblinks to publications given in the footnotes for WHO/FAO documents and in Attachment 1 for the publications of other RASBs.

Australia has applied the General Principles in Section 1.4 to the selection of DIRVs for eight vitamins and minerals from the nominated RASBs, as described in the Table below.

GP	Application of GPs to selection of DIRVs for vitamins and minerals listed in TOR 1 from
	accepted RASBs
3.1.1	The Committee agreed that the NRVs-R derived from WHO/FAO RNIs for the eight vitamins and
	minerals were <i>potentially</i> unsuitable (paragraph 86, REP13/NFSDU).
3.1.2	Australia reviewed all DIRVS from the accepted RASBs and only those that were determined by
	primary evaluation of the scientific evidence were selected. This is consistent with this principle
	which accords higher priority to those DIRVs evaluated through systematic review.
3.1.3	All DIRVs related to males and females aged 19-50 years, previously decided as appropriate to
	reflect the general population.
3.2.1.1	All selected DIRVs were classified by the RASB as INL ₉₈ or equivalent.
3.2.1.2	The selected DIRVs for each sex from the RASB were averaged and rounded if necessary.
3.2.1.3	No selected DIRVS represent recommendations for pregnant or lactating women.
3.3	See next Table and related discussion.

Upper level of intake

The highest average DIRV was compared with the corresponding Upper Level of Intake (UL) from IOM and/or EFSA for two young age groups and all highest DIRVs except certain % dietary absorptions of iron and zinc were found to be below the ULs (see next Table).

Vitamins and Minerals	Highest Average DIRV in Sections 2.3.1 – 2.3.8	UL 1-3/4-8 yrs; IOM ³	UL 1-3/4-6 yrs; EFSA ⁴	UL, 1-6 yrs WHO(2002) ⁵	NOAEL/UF** 1-3/4-8 yrs; IZiNCG ⁶
Vitamin A (µg)	800	600/900 (retinol only)	800/1100 (retinol only)		
Vitamin D (µg)	15	50/50	25/25		
Vitamin E (mg)	15	200*/300*	100/120		
Vitamin C (mg)	100	400/650	ND/ND		
Magnesium (mg)	365	65*/110*	ND/250*		
Selenium (µg)	65	90/150	60/90	Not established	

³ Institute of Medicine. 2006. Otten JJ, Hellwig JP, and Meyers LD, Editors. *Dietary reference intakes (DRI): The essential guide to nutrient requirements*. Summarizing reference values on micronutrients from reports 1997, 1998, 2000, 2001, 2006: National Academies Press, Institute of Medicine of the National Academies, Washington. D.C.

whqlibdoc.who.int/publications/1996/9241561734_eng_fulltext.pdf Accessed 24 September 2013.

⁴ Scientific Committee on Food and European Food Safety Authority. 2006. *Tolerable Upper Intake Levels for Vitamins and Minerals*. EFSA, Parma

⁵ World Health Organization and Food and Agricultural Organization and International Atomic Energy Association (2002) *Trace Elements in Human Health and Nutrition*, 2nd edition. WHO, Geneva

⁶ 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)

Vitamins and Minerals	Highest Average DIRV in Sections 2.3.1 – 2.3.8	UL 1-3/4-8 yrs; IOM ³	UL 1-3/4-6 yrs; EFSA ⁴	UL, 1-6 yrs WHO(2002) ⁵	NOAEL/UF** 1-3/4-8 yrs; IZiNCG ⁶
Iron and Zinc, Internation	nal DIRVS (only	those support	ted in Sections		
2.3.7 and 2.3.8 are shown)					
Iron (mg) (unknown %		40/40	ND/ND		
absorption)					
Iron (mg) (10%	22				
absorption, WHO/FAO)					
Iron (mg) (15%	14				
absorption, WHO/FAO)					
Zinc (mg) (unknown %		7/12	7/10	23	8/14
absorption)					
Zinc (mg) (30%	6				
absorption, WHO/FAO)					
Zinc (mg) (15%	12				
absorption, WHO/FAO)					
Zinc (mg) (30%	11				
absorption, IZiNCG)					
Zinc (mg) (22%	14				
absorption, IZiNCG)					

* Fortificant and supplement forms; does not include natural forms in food

** NOAEL means No observed adverse effect level. IZiNCG set NOAELs divided by an Uncertainty Factor of 1.5 for children but indicated that insufficient data existed to set a UL.

For the four vitamins, selenium and iron, the highest average DIRV for each of these nutrients in Section 2.3 is equal to or lower than at least 3 of the 4 ULs for that nutrient. For magnesium, the highest (and nearly all) average DIRVs in Section 2.3.5 exceed the UL, but it should be noted that the UL relates to fortificant and supplement forms only.

IZiNCG's review indicates that there is a lack of adequate data to better define upper levels for children. It notes that both the IOM UL and IZiNCG upper level for children were extrapolated from one (different) study in infants based on differences in reference body weights. WHOError! Bookmark not defined. extrapolated ULs from adult males (45 mg/day) to other age groups based on differences in metabolic rates.

Most of the average DIRVs in Section 2.3.7 exceed the EFSA UL, but the % dietary absorption applied to the UL is unknown. EFSAError! Bookmark not defined. states that "the available studies show that the mean zinc intakes of adults and children in EU countries are below the UL. The 97.5 percentile of total zinc intakes for all age groups are close to the ULs, which, in the view of the Committee, are not a matter of concern". IZINCG refer to data from US NHANES III indicating that "many children 1-3 years old would have exceeded the IOM UL for that age group" and comment that "given the unlikelihood that the described toxic effects of excessive zinc intakes occur in such a large proportion of children from this relatively healthy US population, the degree of confidence in the UL is relatively low". In the light of the uncertainty surrounding the UL for young children, Australia considers that all average DIRVs for zinc in Section 2.3.7 should be further considered.

Stepwise process

In addition to these General Principles, the eWG reviewed the stepwise process suggested in the 2012 agenda paper (CX/NFSDU 12/34/8). The eWG considered the possibility of calculating a NRV-R from average DIRVs from more than one RASB (Step 6a or 6b) but without considering a specific calculation method. The eWG did not reach consensus but was inclined to prefer a NRV-R based on the selection of the most appropriate average DIRV rather than calculating an aggregate of several average DIRVs.

Average DIRVS

The following Sections 2.3.1 - 2.3.8 present the average male and female DIRVs (INL₉₈) for eight vitamins and minerals taken from:

- nominated RASBs in Section 2.1 that conducted a primary evaluation of the evidence listed in alphabetic order
- the WHO/FAO (2004)Error! Bookmark not defined. DIRVs
- the current NRV-R where it exists.

Each of these Sections also contains a short commentary on some key differences in the supporting information given in Attachment 2. However, recommendations on specific DIRVs as the basis of NRVs-R are not given because the eWG did not reach consensus on any vitamin or mineral under consideration, except for iron. It should be noted that the eWG did not have the opportunity to consider supporting information from Japan which is now available in Attachment 2.

RECOMMENDATION 3

That CCNFSDU:

- 1 Determine whether the average DIRV from [one OR more than one] RASB should constitute the basis of a NRV-R.
- 2 Select one or more suitable average DIRVs as the basis of the NRV-R in accordance with the General Principles and the Committee's response to the first recommendation after consideration of:
 - a) the average DIRVs in Section 2.3
 - b) the supporting information in Attachment 2.

2.3.1 Vitamin A

The units for vitamin A expressed as equivalents are discussed in Section 2.7.1.

IOM (United States & Canada)Error!	800 μg
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NIHN (Japan) ⁷	770 μg
WHO/FAO	550 µg (recommended safe intake)
Current NRV-R	800 µg

The IOM and NIHN selected maintenance of liver stores as the physiological endpoint whereas WHO/FAO extrapolated from infant requirements based on the vitamin A content of human milk.

2.3.2 Vitamin D

IOM (United States & Canada)	15 µg
WHO/FAO	5 μg
Current NRV-R	5 µg

The IOM recommendation was updated in 2010-11 and represent the most recent assessment of the evidence. Serum 250HD levels associated with maintenance of bone health were selected as the physiological endpoint.

In setting DIRVs for vitamin D, the WHO/FAO recognised that, for most locations of the world in a broad band around the equator, the most physiologically relevant and efficient way of acquiring vitamin D is to synthesize it endogenously in the skin from 7-dehydrocholesterol by sunlight exposure. The WHO/FAO adopted the IOM Adequate Intake (AI) (1997) based on the amount needed to maintain plasma 250HD levels above 27 nmol/L, the level necessary to ensure normal bone health.

⁷ *Dietary Reference Intakes for Japanese*, 2010. J Nutr Science and Vitaminology (2013). 59: supplement ISSN 0301-4800.

2.3.3 Vitamin E (see also Section 2.10)

The units for vitamin E expressed as equivalents are discussed in Section 2.7.2.

IOM (United States & Canada)	15 mg
WHO/FAO	8.8 mg (best estimate, not INL_{98})

The IOM selected the prevention of hydrogen peroxide induced erythrocyte hemolysis as the physiological endpoint for the INL_{98} whereas WHO/FAO states that there was insufficient evidence to enable an RNI to be based on the additional health benefits obtainable from nutrient intakes above those usually found in the diet (p101). WHO/FAO adult DIRVs appear to be the mean of DIRVs (AIs) set by the United Kingdom (1991) and the United States (1989) based on their respective median intakes. It was noted that these intakes were also above the suggested adequate vitamin E:polyunsaturated fatty acid ratio for diets in the United Kingdom.

Section 2.10 discusses the situation where there is a difference of view among nominated RASBs assessing the same evidence as whether an INL_{98} should be established or not. This is the case for vitamin E.

2.3.4 Vitamin C

IOM (United States & Canada)	83 mg
(NHRMC/MOH) Australia & New Zealand ⁸	45 mg
NIHN (Japan)	100 mg
WHO/FAO	45 mg
Current NRV-R	60 mg

The physiological endpoint selected by IOM was near maximal neutrophil concentrations and by NIHN was optimal antioxidant activity in plasma (50 μ g/L). In contrast, the physiological endpoint selected by WHO/FAO and NHMRC/MOH was 50 % tissue saturation i.e. halfway between tissue saturation and the point at which clinical signs of scurvy appear.

The European Commission advised the eWG that EFSA is currently working on finalising an opinion on DIRVs for Vitamin C tentatively to be completed in October 2013. The draft for endorsement for public consultation is found at <u>http://www.efsa.europa.eu/en/consultationsclosed/call/130628.htm</u>.

2.3.5 Magnesium

IOM (United States & Canada)	365 mg
NIHN (Japan)	321 mg
WHO/FAO	240 mg
Current NRV-R	300 mg

The physiological endpoints selected by the IOM and NIHN were both balance studies. The WHO/FAO (p 221) stated that it is questionable whether more reliable estimates of magnesium requirements could be made until data from balance studies are supported by the use of biochemical indexes of adequacy that could reveal the development of manifestations of suboptimal status. Therefore, only limited information from balance studies that gave little or no indication of response by the body to inadequacy in magnesium supply had to be used.

⁸ National Health and Medical Research Council and New Zealand Ministry of Health (2006) Nutrient Reference Values for Australia and New Zealand. NHMRC, Canberra

2.3.6 Selenium

IOM (United States & Canada)	55 mg
NHRMC/MOH (Australia & New Zealand)	65 mg
NIHN (Japan)	28 mg
WHO/FAO	30 mg
Current NRV-R	Value to be established

The physiological endpoint selected by the IOM was maximal plasma glutathione peroxidase (GP_X) activity and by the NIHN was 2/3 maximal plasma GP_X activity. NHMRC/MOH also used plasma GP_X activity assessed at various supplemental selenium intakes but omitted one key study used by the IOM because of quality concerns.

2.3.7 Zinc

At the 34th session, the Committee agreed that the issues relate to NRVs-R for zinc would require further consideration (paragraph 91, REP13/NFSDU).

The eWG considered the matter of one or more NRVs-R and the majority of members supported more than one NRV-R according to % absorption, although some others were concerned about the paucity of data for lower % absorptions and preferred a single NRV-R. Also, the eWG preferred international recommendations over other those of other RASBs but did not reach consensus on whether WHO/FAO or IZiNCG provided more appropriate values.

Australia notes that IZiNCG reviewed the DIRV recommendations of IOM and WHO/FAO but revised the factorial contribution to endogenous zinc losses for men and women from more studies of the same methodologic type than IOM or WHO/FAO. Furthermore, in its assessment of % dietary absorption, IZiNCG included total diet studies only (not single meal studies as included by WHO/FAO), and excluded semi-purified formula diets likely having a very low phytate:zinc molar ratio similar to animal foods (as included by IOM), or diets containing added zinc. Also, IZiNCG reported that the WHO/FAO average DIRV of 3.6 mg at 50% dietary absorption is based on low cereal fibre, high animal food diet with a low phytate:zinc molar ratio of <5 and includes evidence from semi-purified formula diets. (For comparison, IZiNCG reported the phytate:zinc molar ratio of *refined* cereal grains as 16-54, although the ratio for bread made with yeast is reported as 3.)

Australia therefore excluded the WHO/FAO average DIRV of 3.6 mg at 50% dietary absorption from the Table below to leave two % dietary absorptions. Also, no matter which DIRVs in the Table are selected, the UL for young children is likely to be about the same magnitude.

Dietary descriptions for zinc are discussed in Section 2.6.1 and Footnote 9 referring to national choice of relevant % absorption is discussed in Section 2.5.

IOM (United States & Canada)	10 mg (41% absorption)
NIHN (Japan)	11 mg
IZiNCGError! Bookmark not defined.	11 mg (30% absorption); 14 mg (22% absorption)
WHO/FAO	6 mg (30% absorption); 12 mg (15% absorption)
Current NRV-R	15 mg

2.3.8 Iron

At the 34th session, the Committee agreed that the issues related to NRVs-R for iron (including the need for multiple NRVs-R) would require further consideration (paragraph 91, REP13/NFSDU).

The eWG considered the matter of one or more NRVs-R and the majority of members supported more than one NRV-R according to % absorption, although some others were concerned about the paucity of data for lower % absorptions and preferred a single NRV-R.

The eWG then considered Australia's suggestion to prefer DIRVs from WHO/FAO as they were internationally derived, and to select two of the four possible % absorptions of 15% and 10% because they represented likely dietary absorptions from diets in many countries. WHO/FAO (p 270) states "It is obvious that absorbed iron requirements need to be adjusted to different types of diets, especially for vulnerable

groups.for developing countries, it may be more realistic to use the figure of 5% and 10%. In populations consuming more Western-type diets, two levels would be appropriate -12% and 15% – depending mainly on meat intake".

WHO/FAO also estimated that, at the higher 15% absorption, only 10-15% of fertile 55 kg women would have no iron stores but that this proportion of women would increase to 40-50% at 10% iron absorption and to 100% at 5% absorption. Having no iron stores represents iron deficiency. Given that the DIRVs are established for apparently healthy populations (in this case, having some iron stores), the lowest % absorption was excluded.

The eWG generally supported WHO/FAO DIRVs for the two nominated % dietary absorptions of 15% and 10%.

Dietary descriptions for iron are discussed in Section 2.6.2 and Footnote 9 referring to national choice of relevant NRV-R is discussed in Section 2.5

IOM (United States & Canada)	13 mg (18% absorption)
NIHN (Japan)	9 mg (15% absorption)
WHO/FAO	14 mg (15% absorption); 22 mg (10% absorption)
Current NRV-R	14 mg

2.4 Protein (TOR 2)

The eWG considered the NRV-R for protein (TOR 2) in two components: the recommendation for i) protein g/kg body weight/day and ii) protein g/day.

2.4.1 Protein (g/kg body weight/day)

The eWG considered the recommendations from WHO/FAO (2007)⁹ as a primary source and other nominated RASBs in accordance with the General Principles as described in Section 1.4.

GP	Application of GPs to selection of DIRVs for protein from accepted RASBs
3.1.1	The NRV-R for protein g/kg body weight/day, recommended by WHO/FAO as a primary source
	was considered.
3.1.2	DIRVs and supporting information from nominated RASBs that conducted a primary evaluation
	of the evidence were also considered. (See Attachment 2, Table 2D)
3.1.3	The DIRVs are relevant to males and females aged 19-50 years. Most RASBs recommended the
	same DIRV g/kg b wt/day for adult males and females.
3.2.1.1	The WHO/FAO adopted the term <i>safe intake</i> , rather than INL_{98} , and defined it as the 97.5 th
	percentile of the distribution of individual requirements, nominally the average value for the
	population + 1.96 SD. This definition is taken to be equivalent to INL_{98} . Average DIRVs
	nominated from EFSA, IOM, NHMRC/MOH, and NIHN that were INL ₉₈ were also reviewed.
3.2.1.2	The selected DIRVs for each sex from WHO/FAO and from accepted RASBs were averaged and
	rounded if necessary.
3.2.1.3	No selected DIRVs represent recommendations for pregnant or lactating women.
3.3	No ULs for protein for young children were found. Some RASBs made recommendations for
	protein expressed as a macronutrient distribution range, however Australia understands that these
	do not apply to young children. WHO/FAO makes the general comment that an adult protein
	intake (g/day) at twice the recommended safe intake is unlikely to be associated with any risk, but
	advises caution at 3-4 times the safe intake.

Australia therefore determined the % difference between the WHO/FAO DIRV recommendation and the mean of DIRVs from accepted RASBs, similar to the approach applied in 2012 to the DIRVs for vitamins and minerals.

⁹ World Health Organization and Food and Agricultural Organization (2007) Protein and Amino Acid Requirements in Human Nutrition. Report of a joint WHO/FAO/UNU Expert Consultation. WHO TRS 935. WHO, Geneva whqlibdoc.who.int/trs/who trs 935 eng.pdf Accessed 24 September 2013.

WHO/FAOError! Bookmark not defined.	0.83 g/kg b wt/day
EFSA (Europe Union) ¹⁰	0.83 g/kg b wt/day
IOM (United States & Canada) ¹¹	0.8 g/kg b wt/day
NHMRC/MOH (Australia & New Zealand) ⁸	0.8 (average M, F) g/kg b wt/day
NIHN (Japan) ⁷	0.9 g/kg b wt/day

The WHO/FAO advised (p 242-3) that the g/kg b wt/day recommendation applied to adults within the acceptable range for height. The WHO/FAO average DIRV lies within $\pm 10\%$ of the mean of the average DIRVs from accepted RASBs (0.84 \pm 0.08 g/kg body weight/day). The eWG strongly supported adopting the WHO/FAO average DIRV of 0.83 g/kg body weight/day as the first component in determining the NRV-R for protein.

The eWG also supported the need for a footnote if the selected average DIRV provided information about the dietary protein quality on which it was based. Depending on the RASB, the DIRV may be accompanied by information given about the dietary protein quality.

However, the WHO/FAO (p 113) advise that "the differences in efficiency of individual plant compared with animal protein sources are often less than the differences seen between studies with the same protein" and that "the biological value would have to differ by more than 50% before significant differences could be demonstrated with realistic numbers of subjects" and "protein utilization in humans may be dependent on complex extrinsic factors that influence the behaviour of the body but that have not been captured in short-term nitrogen balance studies, as well as by the intrinsic properties of the protein, such as the amino acid content".

RECOMMENDATION 4

That CCNFSDU find as suitable the WHO/FAO DIRV of 0.83 g/kg body weight/day as the first component in determining the NRV-R for protein.

If the Committee supports this recommendation, there is no basis for a footnote indicating protein quality.

2.4.2 Protein (g/day)

The second component of the decision making relates to selection of reference body weights for adult males and females. The WHO/FAO recommended DIRVs for protein expressed as g/day only in 10 kg increments of adult body weight and advised that the requirements per person within the acceptable ranges of body weights could either be based on the actual weight or normalized to the median weight for height according to the objectives for which they are to be used.

Therefore the eWG considered the following reference adult body weights from accepted RASBs.

¹⁰ EFSA Panel on Dietetic Products, Nutrition and Allergies (2012) Scientific Opinion on Dietary Reference Values for protein; EFSA Journal 10(2):2557

¹¹ Institute of Medicine (2002/2005). Food and Nutrition Board. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids.* National Academies Press, Washington. D.C.

RASB (Age range (yrs)) Reference adult body		adult body	Basis
	weight (kg)		
	Male Female		
WHO/FAO ¹² (18+)	65	55	Based on (US) NCHS/CDC 1977 growth reference
			data as cited by IZiNCG
European Commission ¹³	74.6	62.1	Weighted mean body weights of European men and
(18+)*			women from 11 studies
EFSA (European Union) ¹⁴	68.1	58.5	Median body weight based on measured body
(18-79) [from 2013]			heights and assuming BMI of 22 kg/m ²
IOM (USA & Canada)	70 (76)	57 (61)	2002 onwards: CDC/NCHS growth charts using
(19+) [from 2002]			median height and median BMI for 19 year olds
			(22.5 (M); 21.5 (F))
NHMRC/MOH (Australia	76	61	Average body weights for 19-30 year olds from Aust
& New Zealand) (19+)			or NZ national health surveys: 1995, 1997, 2002
NIHN (Japan) (18-29/30-	63.5/68	50/52.7	Median body weights for 18-29/30-49 year old men
49)			and women from 2005 and 2006 National Health and
			Nutrition Surveys in Japan.

*included because ESFA applied these body weights to EU adult protein DIRVs

To test the impact of different body weights in determining the NRV-R for protein, the respective mean adult male and female reference body weights in the previous Table were applied to the recommended DIRV in Section 2.4.1 (0.83 g protein/kg body weight/day). The result ranged from 49-57 g/day. The DIRV (g/day) calculated using WHO/FAO reference mean adult body weights (49.8 g rounded to 50 g) lies within $\pm 10\%$ of the mean of the average DIRVs (g/day) calculated from the mean adult body weights from accepted RASBs, as shown in following Table.

Accepted RASB	Reference mean adult body weight	DIRV (g/day)
	(kg)	(0.83 x kg b wt/day)
WHO/FAO	60	50
European Commission*	68	56
EFSA (European Union) [from 2013]	63	53
IOM (USA & Canada) [from 2002]	64	53
NHMRC/MOH (Australia & New	69	57
Zealand)		
NIHN (Japan)	59	49
MEAN without EC*	64	53
Current NRV-R		50

*included because ESFA applied these body weights to EU adult protein DIRVs

The eWG supported the adoption of the WHO/FAO reference mean adult body weights.

RECOMMENDATION 5

That CCNFSDU adopt the reference mean adult body weight from WHO/FAO as the second component in determining the NRV-R for protein and therefore adopt 50 g as the NRV-R for protein.

If adopted, an NRV-R for protein of 50 g/day would correspond to the current NRV-R which was derived as 0.75 g/kg b wt/day for a 70 kg man (52.5 g) rounded down to 50 g/day.

¹² Food and Agriculture Organization (1988) *Requirements of Vitamins A, Iron, Folate, and Vitamin B*_{12.} Report of Joint FAO/WHO Expert Consultation. FAO, Rome

¹³ European Commission (1993) Reports of the Scientific Committee for Food (Thirty-first series) *Nutrient and energy intakes for the European Community*. Commission of the European Communities, Luxembourg

¹⁴ EFSA Panel on Dietetic Products, Nutrition and Allergies (2013) Scientific Opinion on Dietary Reference Values for energy. EFSA Journal, 11(1):3005, 112 pp.

2.5 Footnote Referring to Iron and Zinc

At the 34th session, the Committee agreed that the proposed deletion of the second sentence in Footnote 9 for iron and zinc in CX/NFSU 12/34/8 would require further consideration by the eWG (paragraph 100, REP13/NFSDU).

Footnote '9', (2012):

Countries should determine the appropriate NRV that best represents the bioavailability of iron and 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. 2^{nd} ed. World Health Organization, Geneva.

The eWG agreed that the second sentence could be deleted because reference to particular publications can become outdated. The footnote therefore has been revised including substituting *dietary absorption* in place of *bioavailability* (see Section 2.2).

However, a footnote might not be needed (if only one % dietary absorption is selected) or be misinterpreted as limiting the choice of national NRV-R to between the two stated % dietary absorptions. This is not the intent of the text in the preamble of the draft Annex to the Codex Guidelines on Nutrition Labelling which states that *Governments may establish reference values for food labelling that take into account country or specific factors that affect nutrient absorption, utilization, or requirements*.

The Committee may therefore wish to consider the revised text of this footnote including whether it is needed or adds value.

Countries should determine the appropriate NRV-**R** that best represents the **dietary absorption** bioavailability of iron and 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.

RECOMMENDATION 6

That CCNFSDU consider the need for this footnote related to iron and zinc and if so, whether to adopt the revised footnote.

2.6 Dietary Descriptions for Zinc and Iron

At the 34th session, the Committee referred to the eWG a recommendation on the possible inclusion of dietary descriptions corresponding to the established % dietary absorptions for iron and zinc (paragraph 101, REP13/NFSDU) as that matter had not been specifically discussed by the Committee. The eWG generally supported inclusion of dietary descriptions corresponding to the selected % dietary absorption(s).

2.6.1 Dietary description for zinc

The eWG considered the dietary descriptions corresponding to 50%, 30% and 15% dietary absorptions as given in the footnote to Table 7.2 in WHO/FAO (2006)¹⁵. These dietary descriptions as well as those from WHO/FAO (2004)**Error! Bookmark not defined.**, and IZiNCG reproduced from CX/NFSDU 12/34/8 are presented in the next two Tables. Although the eWG generally supported dietary descriptions, no preference was concluded given the need to first select the DIRVs.

Australia considers that the extensive detail from WHO/FAOError! Bookmark not defined. in the first table is not appropriate for a short footnote. The WHO/FAOError! Bookmark not defined. descriptions are light on detail of the key dietary components. However, information from WHO/FAOError! Bookmark not defined. was summarised into shorter dietary descriptions by IZiNCG (footnote to Table 1.8, p S115). These dietary descriptions for the two lower % absorptions are shown in the second table.

¹⁵ World Health Organization and Food and Agricultural Organization (2006) Guidelines on food fortification with micronutrients. WHO, Geneva <u>http://www.who.int/nutrition/.../guide_food_fortification_micronutrients.pdf</u> Accessed 24 September 2013.

% absorption	Dietary descriptions for% zinc absorption, WHO/FAO (2004)Error! Bookmark not defined.	Dietary descriptions for % zinc absorption, WHO/FAO (2006)Error! Bookmark not defined.
50	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.	Diets rich in animal protein
30	Mixed diets containing animal and fish protein. 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).	Diets rich in legumes or pulses or diets that include fermented cereals
15	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 (>1g 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.	Diets poor in animal protein or zinc-rich plant foods

%	Dietary descriptions for % zinc absorption, IZiNCG		
absorption			
30%	Mixed diets, and lacto-ovo vegetarian diets that are not based on unrefined cereal grains or high extraction rate (>90%) flours		
22%	Cereal-based diets, with >50% energy intake from cereal grains or legumes and negligible intake of animal protein		

RECOMMENDATION 7

That CCNFSDU adopt short dietary descriptions that correspond to the Committee's selection of % dietary absorptions for zinc under Section 2.3.7.

2.6.2 Dietary description for iron

The eWG considered the dietary descriptions corresponding to 15% and 10% absorptions as given in the footnote to Table 7.2 in WHO/FAOError! Bookmark not defined.

Dietary descriptions corresponding to % iron absorption, WHO/FAO (2006)Error! Bookmark not defined.	% absorption
Diets rich in vitamin C and animal protein	15
Diets rich in cereals but including sources of vitamin C	10

Although the eWG generally supported dietary descriptions, one member closely examined the dietary descriptions corresponding to iron dietary absorptions of 10 and 15% in both WHO/FAO reports**Error! Bookmark not defined.** The member concluded that neither report provided clear, unambiguous descriptions of diets that correspond with each level of absorption and suggested that the Committee may wish to seek clarification from the FAO/WHO Joint Expert Meeting on Nutrition (JEMNU).

Tables 13.3 and 13.4 in WHO/FAOError! Bookmark not defined. (p 269-70) provide short dietary descriptions corresponding to 'bioavailablity' (described as the amount of iron absorbed) based on a 55 kg woman with no iron stores. The diets correspond to:

• 15% bioavailability: Moderate meat and fish in two main meals daily, low phytate and [low] calcium

• 10% bioavailability: Low meat intake, high phytate, often one main meal.

Consistent with the dietary descriptions for zinc, these two sets of dietary descriptions for iron could be used to express the descriptions in terms of food by interpreting *animal protein* as *meat and fish*; replacing *vitamin C* with *fruit and vegetables*; and high phytate with *rich in cereals*.

Dietary descriptions modified from WHO/FAOError! Bookmark not defined. and WHO/FAOError! Bookmark not defined.	% absorption
Diets rich in meat and fish, fruit and vegetables	15
Diets rich in cereals, containing fruit and vegetables, and small amounts of meat and fish.	10

Alternatively, the Committee may wish to seek clarification from JEMNU (TOR 1.4) as to appropriate dietary descriptions for the % dietary absorptions of 15% and 10%.

RECOMMENDATION 8

That CCNFSDU consider the following options:

- 1. Adopt the dietary descriptions related to iron from WHO/FAOError! Bookmark not defined.; <u>OR</u>
- 2. Adopt the dietary descriptions related to iron <u>modified</u> from WHO/FAOError! Bookmark not defined. ; <u>OR</u>
- 3. Seek clarification from JEMNU (TOR 1.4) as to appropriate dietary descriptions for the % dietary absorptions of 15% and 10%.

2.7 Conversion Factors for Vitamin A and Vitamin E

At the 34th session, the Committee agreed that the conversion factors for vitamins A and E should be further considered at the next session (paragraph 98, REP13/NFSDU).

The eWG considered conversion factors for vitamins A and E published by WHO/FAOError! Bookmark not defined. Error! Bookmark not defined. and also collected conversion factors from other accepted RASBs (see Attachment 3). For vitamin A, all accepted RASBs had adopted conversion factors for natural isomers consistent with either WHO/FAOError! Bookmark not defined. or WHO/FAOError! Bookmark not defined. therefore the eWG considered the WHO/FAO factors from both publications. For vitamin E, additional natural isomers to those published by WHO/FAO were also suggested by some members. Also, since the CCNFSDU previously agreed to conversion factors for folic acid as dietary folate equivalents, the eWG agreed to consider extracted or synthetic isomers also for vitamins A and E.

2.7.1 Conversion factors for Vitamin A

Vitamin equivalent units and associated conversion factors for natural isomers given in WHO/FAOError! **Bookmark not defined.** are shown in the following Table. Although the WHO/FAO conversion factors were revised in the 2006 publication, the <u>name</u> of the vitamin A equivalents, as retinol equivalents, was not changed.

Conversion factors for natural isomers of Vitamin A			
WHO/FAO (2004)Error! Bookmark not defined.	WHO/FAO (2006)Error! Bookmark not defined.		
1 μg Retinol Equivalents =	1 μg Retinol Equivalents =		
1 µg retinol	1 µg retinol		
$6 \mu g \beta$ -carotene	12 μ g β-carotene		
12 µg other provitamin-A carotenoids	24 µg other provitamin-A carotenoids		
(Footnote to Annex 2)	(Footnote to Table 7.1)		
"The present consultation concluded that the 1:6	"In a mixed diet, the conversion rate of β -carotene to		
bioconversion factors originally derived on the basis	retinol is approximately 12:1 (higher, i.e. less		
of balance studies should be retained until there is	efficient than previously believed). The conversion		
firm confirmation of more precise methodologies	of the other provitamin-A carotenoids to retinol is		
from ongoing studies." (p 29)	less efficient, the corresponding conversion rate		
	being of the order of 24:1" (p 51)		

The eWG generally supported the conversion factors for natural isomers listed in WHO/FAOError! Bookmark not defined.

The eWG also considered the following isomers and their conversion factors for extracted and synthetic isomers for vitamin A that had been proposed by some eWG members:

1 μg Vitamin A equivalents =	1.15 µg all-trans-retinyl acetate
	1.82 µg all-trans-retinyl palmitate
	$2 \mu g$ all-trans- β -carotene in oil as a supplement

The eWG supported these conversion factors for extracted and synthetic isomers.

2.7.1.1 Name of units expressed as equivalents

The eWG considered the choice of Retinol Equivalents or Retinol Activity Equivalents as the name of the units but held different views as to whether the name of vitamin A equivalents should be Retinol Equivalents (as given in WHO/FAO**Error! Bookmark not defined.**) or Retinol Activity Equivalents, as used by the IOM to distinguish the use of revised factors. WHO (2009)¹⁶ cites the IOM conversion factors but retained the term Retinol Equivalents.

RECOMMENDATIONS 9

That CCNFSDU consider all three recommendations:

- 1. Adopt the conversion factors for natural isomers of vitamin A listed in WHO/FAOError! Bookmark not defined.
- 2. Adopt the extracted and synthetic isomers of vitamin A and their conversion factor listed in Section 2.7.1.
- 3. Consider the term: Retinol Activity Equivalents (RAE) as the name of vitamin A equivalents.

2.7.2 Conversion factors for Vitamin E

Vitamin equivalent units and associated conversion factors for natural isomers given in WHO/FAOError! Bookmark not defined. are shown in the following Table. In WHO/FAOError! Bookmark not defined., the units were revised from vitamin E equivalents to α -tocopherol only and conversion factors published in 2004 were not included in the 2006 publication, although no explanation for the change was given. One eWG member referred to the IOM statement which determined that β and γ tocopherols and forms of tocotrienols do not bind to the α -tocopherol transfer protein and therefore have no biological activity.

¹⁶ 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 24 September 2013.

WHO/FAO conversion factors for natural isomers of Vitamin E			
WHO/FAO (2004)Error! Bookmark not defined.	WHO/FAO (2006)Error! Bookmark not defined.		
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 20 mg β -tocotrienol (Footnote to Annex 2) Table 5.1 gives approximate biological activity.	RRR-α-tocopherol only; no equivalents given. No explanation given for the change from WHO/FAO Error! Bookmark not defined.		

The eWG held divergent views on a preferred approach.

The eWG also considered the following isomers and their conversion factors for extracted and synthetic isomers for vitamin E that had been proposed by some eWG members although different factors were submitted for one isomeric form of vitamin E.

1 mg Vitamin E equivalents = $1.10 \text{ mg } RRR-\alpha$ -tocopheryl acetate

1.23 mg RRR- α -tocopheryl succinate

1.49 OR 2.22 mg *all-rac*-α-tocopheryl acetate

2.44 mg *all-rac*-α-tocopheryl succinate

The eWG generally supported having conversion factors for the above listed isomers. However, on the advice of industry members, *all-rac-* α -tocopherol (dl- α -tocopherol) was not further listed because it is used as an antioxidant in oils and fats, is added in trace amounts, and is unstable in food. Therefore Australia assumes that this form is unlikely to be used as a source of added vitamin E. In relation to the choice of two values for the conversion factor for *all-rac-* α -tocopheryl acetate, the data from eWG members shown in Attachment 3 indicate that the value 2.22 is based on the relative molecular weight of *all-rac-* α -tocopheryl acetate/RRR- α -tocopheryl acetate whereas no basis for 1.49 was submitted.

RECOMMENDATIONS 10

That CCNFSDU consider all three recommendations:

- 1. Consider whether to establish conversion factors for natural isomers of vitamin E, and if so, to consider those listed in WHO/FAOError! Bookmark not defined.
- 2. Adopt the extracted and synthetic isomers of vitamin E and their conversion factors listed in Section 2.7.2 (except for the alternative factors for *all-rac*- α -tocopheryl acetate).
- 3. Select 2.22 as the conversion factor for *all-rac*- α -tocopheryl acetate.

2.8 Working Definition of RASB (TOR 3)

The eWG's third TOR is to review the working definition of RASB as shown in Section 1.3.3 and to recommend as appropriate, changes to wording following use of the working definition in the assessment of nominated scientific bodies.

2.8.1 Competent national and/or regional authority

Paragraph 93, REP13/NFSDU indicates that CCNFSDU referred a request to the Codex secretariat to clarify the appropriate term for 'national and/or regional authorities' currently used in the working definition.

However, Australia notes the following excerpt on DEFINITION FOR THE TERM "COMPETENT AUTHORITY" (ALINORM 10/33/33, CCGP, 2010) with a view to seeking advice on this matter in session from the Codex secretariat.

- 59. The Committee recalled that the 32nd Session of the Commission noted the discussion that took place in the Executive Committee in relation to the different terms and definitions used in a variety of Codex texts for "competent authority" and endorsed the recommendation of the Executive Committee that the CCFL and CCNFSDU harmonize the terms used within their remit and that the Committee on General Principles be requested to look into the merit of developing a general definition for "competent authority" for inclusion in the Procedural Manual."
- 60. The Delegation of Australia speaking as Chair of the CCFICS said that the CCFICS had discussed the issue and concluded that the term "competent authority" was taken to mean "the government agency having jurisdiction" and was highly relevant to the work of CCFICS and was extensively used in 8 of the 9 texts developed by CCFICS; the CCFICS had considered defining the term at previous sessions but concluded that the term was self-explanatory and defined through its use in CCFICS texts and, therefore, a general definition would impact on each of these texts; and the term was used by many governments and thus a general definition should not exclude any of these uses.
- 61. Many delegations agreed with the opinion of the CCFICS that the term was rather self-explanatory and it was mentioned that the diversity of definitions proposed in the comments meant that a general definition would either have to be very general to encompass all possible uses or very complicated which would restrict its usefulness. It was also mentioned that the current existing definitions in Codex texts had been drafted to allow flexibility. It was also mentioned that no problem had been identified with the absence of a general definition and it would be appropriate to leave the definition of the tasks and role of the competent authority to Codex members.
- 62. Several delegations were of the opinion that a Codex definition for the term "competent authority" could be useful to harmonize the term and to give guidance especially to developing countries. A number of delegations had proposed a definition in their comments. Some of the delegations that had favoured a definition of competent authority in their comments said that the arguments of the CCFICS had convinced them that the problems with creating such a definition might outweigh the benefits.

Conclusion

63. The Committee agreed that there was no merit in having a general definition of the term "competent authority".

2.8.2 Other potential amendments

The eWG considered other amendments to the working definition of RASB. It is noted that suggestions for changes to the working of the working definition by individual members of the eWG did not affect their positions as to which nominated RASBs were considered appropriate. The eWG generally supported Australia's suggestion to move 'FAO and/or WHO' forward in the text to be separate from the criteria applied to other RASBs. More extensive amendments were proposed by some eWG members relating to stakeholder consultation, weight of evidence approach, and a broader range of documents in which DIRVS were used in policy development. The amendments proposed or supported by these members are:

"...that provides independent utilizes an open, deliberative provides independent and transparent* scientific process in which stakeholders are able to participate formally, and communicate directly with the authoritative body through written and oral comments to provide authoritative advice on daily intake reference values upon request. These values are determined through a weight of evidence approach and for which such advice is recognized thought its use in the development of policies governmental regulations, periodic reports, monographs or peer-reviewed publications in one or more countries. [The recognized authoritative scientific body does not engage in advocacy.]"

Further suggestions were made in response to the eWG's consideration of this text in relation to weight of <u>scientific</u> evidence; and publications <u>for a primary evaluation</u> in one or more countries.

In response to the suggestions made, Australia considered that:

- inclusion of a description of the deliberative process complicates the definition
- details of the process for the determination of the DIRVs are not needed as they are covered by the General Principles

- 'weight of evidence' was implicit in the term 'scientific'
- the term 'policies' was sufficiently broad to encompass a range of documents.

However, Australia considers that insertion of 'government' to describe 'policies' could strengthen the status of the policies based on RASB advice. *Primary evaluation* was considered by many eWG members to be an important factor in evaluating the candidate potential NRVs-R. This term is not found in the General Principles, but Australia considers that the concept is implicit in GP 3.1.2 referring to systematic review.

2.8.3 Proposed amendment to working definition of RASB

Small amendments to the working definition below are proposed since the acceptance of suitable RASBs is only an initial step in the revision of a NRV-R. It is considered that these amendments do not disqualify any of the RASB nominations in Section 2.1 including IZiNCG whose recommendations were used to inform government zinc intake recommendations of Australia and New Zealand.

Amended working definition

For the purposes of establishing Codex Nutrient Reference Values, a recognized, scientific, authoritative body is **FAO and/or WHO or** an organization supported by a government(s) or [competent national and/or regional authority] or FAO and/or WHO that provides independent, and transparent*, authoritative **and** scientific advice on daily intake reference values upon request and for which such advice is recognised through its use in the development of **government** policies in one or more countries.

* In providing transparent scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value.

RECOMMENDATIONS 11

That CCNFSDU consider all three recommendations:

- 1 Consider the advice from the Codex secretariat on the text in square brackets in the working definition.
- 2 Consider the proposed amendment to the working definition of RASBs.
- 3 Adopt the outcome of Recommendation 2 as the final definition for use in the current review and development of NRVs-R.

2.9 Appendix III, REP 13/FL

Paragraph 99, REP 13/NFDSU records that the Committee agreed to delete the **footnote attached to vitamin D, niacin and iodine because the preamble of the General Principles provided for the situation mentioned in that footnote. However, this footnote and a separate entry for folic acid were retained in the amendments to Section 3.4.4.1 to the Codex Guidelines on Nutrition Labelling in Appendix III, Part A, REP13/FL which were subsequently adopted by the Commission.

RECOMMENDATION 12

That CCNFSDU advise CCFL that the **footnote and entry for folic acid (Appendix III, REP13/FL) should be deleted.

2.10 General Principle 3.2.1.1

GP 3.2.1.1 The NRVs-R 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. The derivation of these values should be reviewed on a case-by-case basis.

Australia wishes to draw the attention of the Committee to an issue that arose but was not discussed by the eWG due to lack of time. The issue relates to the case where more than one RASB establishes DIRVs according to the same evidence base and around the same time but judges differently as to whether or not the quality of evidence is sufficient to establish an INL_{98} (e.g. vitamin E, see Attachment 2). The current GP 3.2.1.1 does not deal with this case but assumes international consistency in application of terminology that

WHO/FAO's observation in 2011 (Attachment 4, CX/NFSDU 12/34/8) in relation to the DIRVs in their report, *Review of existing daily vitamin and mineral intake reference values* (CX/NFSDU 11/33/4) is relevant to this discussion.

"Challenges arose because of a lack of [defined] 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".

From Australia's perusal of the data in the 2011 WHO/FAO report, this case might be encountered again in considering the next batch of minerals (paragraph 92, REP13/NFSDU). Also the relative weighting given to the year of the evidence review when assessing DIRVs based on a mix of INL₉₈ and AI will need consideration, particularly in the case of older INL₉₈ compared with newer AI. For example, the DIRV for molybdenum is listed as INL₉₈ by IOM (2001) and NHMRC/MOH (2006) but EFSA's DIRV¹⁷ for this trace element was given as an AI in 2013 because the evidence was considered to be insufficient to set an INL₉₈. This case might be covered by current GPs depending on whether the newer evidence base overturned older evidence used to establish the INL₉₈. One interpretation of GP 3.2.1.1 (which refers to an <u>absence</u> of an established INL₉₈,) is that a contemporary but older INL₉₈ would be preferred over a newer AI.

RECOMMENDATION 13

The Committee may wish to refer this matter to the 2014 eWG for further consideration and possibly defer a decision on vitamin E until the matter is concluded.

2.11 Realistic timeframe

At Agenda Item 2, Matters referred (paragraph 17, CX/13/35/2), the Codex Executive Committee encouraged the CCNFSDU to set a realistic timeframe to complete the work for the remaining NRVs-R.

Australia notes that the original project document for this work (ALINORM 08/31/26, Appendix VII) anticipated that the work to revise an extended list of NRVs-R (for the general population) could be undertaken in 5 years and completed in 2012. Furthermore, the project document states that, once the NRVs-R for the general population are reviewed, NRVs-R for infants and young children aged 6-36 months would be established for the same range of NRVs-R.

The following is a revised timeframe for the remaining work assuming that the accelerated step procedure would be followed:

	CCNFSDU Stor 5/8	Commission
	Step 5/8	
Vitamin A, D, E, Mg, Se, Fe, Zn, Protein	2013	2014
If necessary, subset of NRVs-R for which JEMNU advice is received	2014	2015
by eWG before next session		
P, Cl, Cu, F, Mn, Cr, Mb	2014	2015
If necessary, those NRVs-R for which JEMNU advice is received by	2015	2016
eWG before next session		
NRVs-R (6–36 months)		
13 vitamins, 13 minerals, protein (based on same decisions as for	2016	2017
general population)		

¹⁷ EFSA Panel on Dietetic Products, Nutrition and Allergies (2013) *Scientific Opinion on Dietary Reference Values for Molybdenum*. EFSA Journal 2013;11(8):3333 [35 pp.]. <u>http://www.efsa.europa.eu/en/efsajournal/pub/3333.htm</u> Accessed 17 September 2013.

ATTACHMENT 1

SUBSTANTIATION OF NOMINATED RASBS

Table 1A: United States & Canada; European Union

	United States & Canada	European Union
RASB	Institute of Medicine of the National Academies of Sciences (IOM)	European Food Safety Authority (EFSA):
1) Supported by one or more government(s) or competent national or regional authorities.	In 1995, the Food and Nutrition Board of the IOM, with support from the governments of Canada and the U.S., established the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes (DRIs) to oversee the development of DRIs for nutrients. To date, this comprehensive effort has resulted in a series of DRI reports published between 1997 and 2010	The European Food Safety Authority was legally established by a European Parliament and Council Regulation No178/2002. Adopted on 28 January 2002, the Regulation laid down the basic principles and requirements of food law. It also stipulated that EFSA should be an independent scientific source of advice, information and risk communication in the areas of food and feed safety. The risk assessment and risk communication work carried out by EFSA is underpinned by strict legal criteria. EFSA has its own legal personality and while funded from the Community budget, it operates independently of the community institutions such as the European Commission and the Parliament. It is not therefore managed by the European Commission but by an Executive Director, who in turn is answerable to an independent Management Board.
2) Provides independent and transparent* authoritative scientific advice on DIRVs upon request. *In providing transparent scientific advice, The Committee would have access to what was considered	a) <u>Independent</u> authoritative scientific advice. The IOM is an independent, nonprofit organization established in 1970 as a branch of the National Academy of Sciences that works outside of government to provide unbiased and authoritative advice to decision makers and the public. ¹⁸ The IOM applies a rigorous research process in which committee members are carefully selected to ensure the necessary expertise and to avoid conflicts of interest. ¹⁹ The committees work independently to come to consensus on questions raised, with information gathered from many sources in public meetings. The IOM study process involves checks and balances at	It provides independent and transparent authoritative scientific advice on daily intake reference values upon request. The European Food Safety Authority (EFSA) is an independent European agency funded by the EU budget that operates separately from the European Commission, European Parliament and EU Member States. In the European food safety system, risk assessment is done independently from risk management. As the risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions. Since its creation, EFSA has established key operating principles and rules which have been adopted by its Management Board. They include a commitment to openness and transparency in all of the Authority's work. In addition the Authority is bound by European Union legislation on issues such as public access to documents. In accordance with its Founding Regulation EFSA is legally obliged to publish on its website
The Committee would have	consensus on questions raised, with information gathered from many sources in public meetings. The	Since its creation, EFSA has established key operating principles and rules which have been Management Board. They include a commitment to openness and transparency in all of the A

 ¹⁸ About IOM page. Institute of Medicine Web Site. <u>http://www.iom.edu/About-IOM.aspx</u> Accessed April 4, 2013.
 ¹⁹ IOM Study Process page. Institute of Medicine Web Site. <u>http://www.iom.edu/About-IOM/Study-Process.aspx</u>. Accessed April 4, 2013.

	United States & Canada	European Union
RASB	Institute of Medicine of the National Academies of Sciences (IOM)	European Food Safety Authority (EFSA):
daily intake reference values in order to understand the derivation of the value.	IOM is transparent. The full content of each IOM report on Dietary Reference Intakes is available at no charge at the website below. In these reports, the Committee would have access to what was considered by the IOM in establishing daily intake reference values, and be able to understand the derivation of the values. About reports page: <u>http://www.iom.edu/Reports.aspx?page=1&Serie s=%7b508F5CFF-EE88-4FF6-92BF- 8D6CAB46F52E%7d</u>	 excellence in science, independence, openness and transparency, and responsiveness. In developing its scientific opinions, EFSA follows a workflow that runs from the moment EFSA receives a request for scientific advice or initiates its own activity to the moment it publishes and communicates its scientific findings. EFSA has developed a comprehensive body of good risk assessment practices to guide its Scientific Panel and Committee experts to help ensure EFSA opinions respect the highest scientific standards. EFSA implements a quality assurance system to continually review and strengthen the quality of its scientific work. http://www.efsa.europa.eu/en/efsahow/workflow.htm http://www.efsa.europa.eu/en/efsahow/rapractice.htm With respect to dietary reference values, a process of endorsing a draft scientific opinion has been established; performing a public consultation for at least 6 weeks, considering relevant comments received and modifying the opinion accordingly, finally adoption of the opinion together with a technical report on how the comments received were dealt with. EFSA's role is to assess and communicate on all risks associated with the food chain. Since EFSA's advice serves to inform the policies and decisions of risk managers, a large part of EFSA's work is undertaken in response to specific requests for scientific advice. Requests for scientific assessments are received from the European Commission, the European Parliament and EU Member States. EFSA also undertakes scientific work on its own initiative, so-called self-tasking. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In carrying out its work, EFSA also considers the possible impact of the food chain on the biodiversity of plant and animal habitats. The Authority performs environmental risk assessments of genetically modified crops, pesticides, feed additives, and plant pests. In all these fields, EFSA's most criti
3) Is one whose advice on DIRVs is recognised through use in policy development in one or more	The IOM Dietary Reference Intakes provide the scientific basis for dietary guidelines in both the U.S. and Canada, and have been considered in the development of Codex and other international nutrition texts. In the U.S., the IOM Dietary Reference Intakes are used to develop policies in many areas including food labelling and food fortification, evaluation of food assistance	EFSA's independent scientific advice underpins the European food safety system. Accordingly, EFSA's advice frequently supports the risk management and policy-making processes. These may involve the process of adopting or revising European legislation on food or feed safety, deciding whether to approve regulated substances such as pesticides and food additives, or, developing new regulatory frameworks and policies for instance in the field of nutrition. EFSA is not involved in these management processes, but its independent advice gives them a solid scientific foundation. In the Regulation No178/2002, the responsibility for risk assessment is clearly separated from that of risk management. While EFSA advises on possible risk related to food safety, the responsibility for risk

	United States & Canada	European Union
RASB	Institute of Medicine of the National Academies of Sciences (IOM)	European Food Safety Authority (EFSA):
	http://www.iom.edu/Reports/2000/Dietary- Reference-Intakes-Applications-in-Dietary- Assessment.aspx	ie EU Member States). It is the role of the EU institutions, taking into account EFSA's advice as well as other considerations, to propose and adopt legislation as well as regulatory and control measures when and where required.
RASB publication(s)	See Table 1A(i).	Protein: Scientific Opinion on Dietary Reference Values for protein, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); EFSA Journal 2012;10(2):2557 http://www.efsa.europa.eu/en/efsajournal/pub/2557.htm

Table 1A(i): IOM references

Name of publication	Year of	Bibliographic Reference	Official Weblink (if available)
	Publication		
(For Vitamin D)	2011	IOM (Institute of Medicine). 2011. Dietary Reference Intakes for	http://www.nap.edu/catalog.php?record_id=13050
Dietary Reference Intakes for Calcium and		Calcium and Vitamin D. Washington, DC: The National	
Vitamin D.		Academies Press.	
(For Vitamin A, Iron, Zinc)	2001	IOM (Institute of Medicine). 2001. Dietary Reference Intakes for	http://www.nap.edu/catalog.php?record_id=10026
Dietary Reference Intakes for Vitamin A,		Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine,	
Vitamin K, Arsenic, Boron, Chromium,		Iron, Manganese, Molydenum, Nickel, Silicon, Vanadium and	
Copper, Iodine, Iron, Manganese,		Zinc. Washington, DC: The National Academy Press.	
Molybdenum, Nickel, Silicon, Vanadium			
and Zinc.			
(For Vitamin C, E, Selenium)	2000	IOM (Institute of Medicine). 2000. Dietary Reference Intakes for	http://www.nap.edu/catalog.php?record_id=9810
Dietary Reference Intakes for Vitamin C,		Vitamin C, Vitamin E, Selenium, and Carotenoids. Washington	
Vitamin E, Selenium, and Carotenoids.		DC: National Academy Press.	
(For Magnesium)	1997	IOM (Institute of Medicine). 1997. Dietary Reference Intakes for	http://www.nap.edu/catalog.php?record_id=5776
Dietary Reference Intakes for Calcium,		Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride.	
Phosphorus, Magnesium, Vitamin D and		National Academy Press.	
Fluoride.			
(For Protein)	2005	IOM (Institute of Medicine). Food and Nutrition Board. Dietary	http://www.nap.edu/catalog.php?record_id=10490
Dietary Reference Intakes for Energy,		Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty	
Carbohydrate, Fiber, Fat, Fatty Acids,		Acids, Cholesterol, Protein and Amino Acids. Washington DC:	
Cholesterol, Protein and Amino Acids.		National Academies Press, 2002.	

Table 1B: Japan; Malaysia

	Japan	Malaysia
RASB	National Institute of Health and Nutrition (NHIN)	Technical Working Group on Nutritional Guidelines
1) Supported by one or more government(s) or competent national or regional authorities.	The cabinet ministers affiliated with NIHN are the Ministry of Health, Labour and Welfare and the Consumer Affairs Agency, both belonging to the government of Japan. A part of research funding and administrative budget have been provided by the government of Japan.	TECHNICAL WORKING GROUP ON NUTRITIONAL GUIDELINES was established under the directive of the National Coordinating Committee on Food and Nutrition (NCCFN), Ministry of Health Malaysia. This is a high level committee chaired by the Deputy Director General of Health Malaysia and comprises membership from several government ministries and agencies, academia, professional bodies and industry association.
2) Provides independent and transparent* authoritative scientific advice on DIRVs upon request.	NIHN became Incorporated Administrative Agency in 2001 and has been collecting the basic data necessary to establish the DRIs for Japanese, which are the basic data for NRVs. The institute also conducts research to generate evidence for DRIs for Japanese, and undertakes practical research on its application.	TECHNICAL WORKING GROUP ON NUTRITIONAL GUIDELINES is an independent group that consists of scientific experts from government departments, research institutes, universities and professional bodies. This TWG has been given the responsibility to prepare the Recommended Nutrition Intake for Malaysia, and the Malaysian Dietary Guidelines. The works of the TWG are based on available scientific data and is not biased towards any specific organisation or institution.
3) Is one whose advice on DIRVs is recognised through use in policy development in one or more countries.	NIHN contributed to establish NRVs for Labelling purposes for nutrients in 2005. The values have been using for regulation system of nutrition labelling of foods in Japan.	The Recommended Nutrient Intakes (RNI) for Malaysia was developed by the TECHNICAL WORKING GROUP ON NUTRITIONAL GUIDELINES. The RNI provides the dietary recommendations based on scientific evidences. The RNI also provides brief write-ups on deficiencies, food sources, factors affecting requirements, setting requirements, toxicity and tolerable upper intake (UL) levels for each nutrient to enable the government, organizations and industries to better plan , monitor and evaluate nutrition programmes and policies towards achieving optimal nutritional well-being of the Malaysian population.
RASB publication(s)	Dietary Reference Intakes for Japanese, 2010; 2013; Journal of Nutritional Science and Vitaminology vol. 59, supplement ISSN 0301- 4800 Dietary Reference Intakes for Japanese, 2010; 2012; http://www0.nih.go.jp/eiken/info/pdf/dris2010en2.pdf	Recommended Nutrient Intakes (RNI) for Malaysia; 2005; NCCFN (National Coordinating Committee on Food and Nutrition) (2005). Recommended Nutrient Intakes (RNI) for Malaysia. A Report of the Technical Working Group on Nutritional Guidelines. Ministry of Health Malaysia, Putrajaya. <u>http://www.moh.gov.my/images/gallery/rni/front_pages.pdf</u> <u>http://www.moh.gov.my/images/gallery/rni/insert.pdf</u>

Table 1C: New Zealand & Australia; IZiNCG

	New Zealand & Australia	New Zealand
RASB	National Health and Medical Research Council and New Zealand Ministry of Health (NHMRC/MOH)	International Zinc Nutrition Consultative Group (IZiNCG)
1) Supported by one or more government(s) or competent national or regional authorities.	In 2001, the Commonwealth Department of Health and Ageing asked the National Health and Medical Research Council (NHMRC) to undertake a scoping study in relation to a potential revision of the Australian/New Zealand RDIs. The New Zealand Ministry of Health funded some initial work for the review process that provided expert input into the revision of the two key nutrients iodine and selenium. The NHMRC was then commissioned in 2002 to manage the joint Australian/New Zealand revision process.	The IZiNCG committee was supported by the Ministry of Public Health, Thailand, UNICEF, the United Nations University's Food and Nutrition Program for Human and Social Development (UNU/FNP) to conduct the review of zinc requirements. IZiNCG is an international group whose primary objectives are to promote and assist efforts to reduce global zinc deficiency, with particular emphasis on the most vulnerable populations of low-income countries.
	http://www.nhmrc.gov.au/publications/synopses/_files/n27.pdf	Acknowledgements (p S95) "This work was carried out with the aid of a grant from the Micronutrient Initiative and financial assistance from UNICEF (New York, USA), and the International Zinc Association (Brussels, Belgium). Support for the preparation of this document was also provided by the International Nutrition Foundation, the University of California, Davis, the Institute of Nutrition at Mahidol University, the Ministry of Public Health, Thailand, Padaeng Industry (Thailand), the International Union of Nutritional Sciences (IUNS), and the United Nations University's Food and Nutrition Program for Human and Social Development (UNU/FNP)." <u>http://archive.unu.edu/unupress/food/fnb25-1s-IZiNCG.pdf</u>
2) Provides independent and transparent* authoritative scientific advice on DIRVs upon request.	IndependentNHMRC became an independent statutory agency within the portfolio of the Australian Government Minister for Health and Ageing, operating under the National Health and Medical Research Council Act 1992 (NHMRC Act) on 1 July 2006.The National Health and Medical Research Council (NHMRC) is Australia's peak body for supporting health and medical research; for developing health advice for the Australian community, health professionals and governments; and for providing advice on ethical behaviour in health care and in the conduct of health and medical research.http://www.nhmrc.gov.au/about/organisation-overview/nhmrcs-roleTransparent authoritative scientific advice	As noted above, the IZiNCG committee was requested to do this work by several parties including UNICEF and the Ministry of Public Health, Thailand. The scientific advice provided by IZiNCG was provided by an independent expert group. The IZiNCG is an independent, nonprofit organization established in 2000 and is now an affiliated body of the International Union of Nutritional Sciences. The full content of the IZiNCG assessment of zinc requirements is freely available from the United Nations University website - <u>http://archive.unu.edu/unupress/food/fnb25-1s-IZiNCG.pdf</u> In this report, the Committee would have access to the data used to establish the zinc daily intake reference values and be able to understand the derivation of the values, and how they differ to those set by the FAO/WHO and IOM and to evaluate their applicability to a global reference value The IZiNCG document was prepared by the Steering Committee (SC) of International Zinc Nutrition Consultative Group (IZiNCG) and several other experts in zinc nutrition

	New Zealand & Australia	New Zealand
RASB	National Health and Medical Research Council and New Zealand Ministry of Health (NHMRC/MOH)	International Zinc Nutrition Consultative Group (IZiNCG)
	representation from both Australia and New Zealand. The working group were asked to complete a pro forma that asked them to assess the suitability of the IOM recommendations at the time of review and assess their suitability for use in Australia and New Zealand. The expert reviewers used the 'NHMRC Levels of Evidence' to assess the evidence used to underpin the evidence base of the IOM review, in addition to recommendations from other key countries and bodies and to assess the relevance of any new data that had been published since these reviews. All evidence tables and decision making is documented and is freely available online.	Nations University's Food and Nutrition Program for Human and Social Development (UNU/FNP) and the International Union of Nutritional Sciences (IUNS). The document was reviewed by 10 independent experts selected by the UNU/FNP and the IUNS. The IZiNCG's response to the reviews was assessed by two additional reviewers appointed by the UNU/FNP and IUNS. Therefore, IZiNCG publication reflects the input from experts both within and outside the IZiNCG SC.
L	http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n37.pdf	
3) Is one whose advice on DIRVs is recognised through use in policy development in one or more countries.	The NHMRC Nutrient Reference Values are used as the scientific basis for dietary guidelines in both Australia and New Zealand, regulatory nutrient reference values for labelling purposes (although not yet updated to the most recent publication), informing public health nutrition interventions. <u>http://www.nhmrc.gov.au/publications/synopses/_files/n27.pdf</u>	The work of the IZiNCG were adopted Australia and New Zealand in the development of their DIRVs. Zinc DIRV established by IZiNCG and adopted by Australia and New Zealand have been used to inform public health guidelines. The advice of the IZiNCG is likely to have been recognised in other countries, but New Zealand is not currently aware of the policies in which they have been recognised. <u>http://www.nhmrc.gov.au/publications/synopses/_files/n27.pdf</u>
RASB	Nutrient Reference Values for Australia and New Zealand; 2006;	International Zinc Nutrition Consultative Group (IZiNCG)
publication(s)	Australian Government Department of Health and Ageing, New Zealand Ministry of Health and National Health and Medical Research Council; <i>Nutrient reference values for Australia and New Zealand</i> . Canberra, Australia	Technical Document #1; 2004; Food and Nutrition Bulletin, vol. 25, no. 1 (supplement 2) © 2004, The United Nations;
	NRVs-	http://archive.unu.edu/unupress/food/fnb25-1s-IZiNCG.pdf
	http://www.nhmrc.gov.au/publications/synopses/ files/n27.pdf	
	Evidence appendix - http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n37.pdf	

ATTACHMENT 2

VITAMINS, MINERALS AND PROTEIN DIRVs and SUPPLEMENTARY INFORMATION

Table 2A: Overview of DIRVs: Vitamins; Minerals; Protein (reference body weights)

	IOM (United States & Canada)	EFSA (EU)	NHMRC/MOH (Australia & New Zealand)	NIHN (Japan)	TWG (Malaysia)	IZiNCG	WHO/FAO (2004)
Vitamin A	M: 900 μg RAE F: 700 μg RAE	-	M: 900 μg RE F: 700 μg RE	M: 850 μg RE F: 683 μg RE	M: 600 μg RE F: 500 μg RE (AI)	-	M: 600 μg RE F: 500 μg RE (recommended safe intake)
Vitamin D	M: 15 μg F: 15 μg	-	M: 5 μg F: 5 μg (AI)	M: 5 μg F: 5 μg (AI)	M: 5 μg F: 5 μg	-	M: 5 μg F: 5 μg (not INL ₉₈)
Vitamin E	M: 15 mg α- tocopherol F: 15 mg α- tocopherol	-	M: 10 mg α -toc equiv F: 7 mg α -toc equiv (AI)	M: 8 mg F: 8 mg (AI)	M: 10 mg F: 7.5 mg (AI)	-	M: 10 mg α -TE F: 7.5 mg α -TE (best estimate, not INL ₉₈)
Vitamin C	M: 90 mg F: 75 mg	-	M: 45 mg F: 45 mg	M: 100 mg F: 100 mg	M: 70 mg F: 70 mg	-	M: 45 mg F: 45 mg
Magnesium	M: 413 mg F: 316 mg	-	M: 413 mg F: 316 mg	M: 359 mg F: 283 mg		-	M: 260 mg F: 220 mg
Selenium	M: 55 μg F: 55 μg	-	M: 70 μg F: 60 μg	M: 30 μg F: 25 μg	M: 33 μg F: 25 μg	-	M: 34 μg F: 26 μg
Iron	M: 8 mg F: 18 mg	-	M: 8 mg F: 18 mg	M: 7 mg F: 11 mg	M: 9-14 mg F: 20-29 mg	-	M: 9.1; 11.4; 13.7; 27.4 mg F: 19.6; 24.5; 29.4; 58.8 mg (15%; 12%; 10%; 5% absorption respectively)
Zinc	M: 11 mg F: 8 mg	-	M: 14 mg F: 8 mg	M: 12 mg F: 9 mg	M: 6.7 mg F: 4.9 mg	M: 13; 19 mg F: 8; 9 mg (30%; 22% absorption respectively)	M: .4.2; 7.0; 14.0 mg F: 3.0; 4.9; 9.8 mg (50%; 30%; 15% absorption respectively)
Protein (g/kg/day)	M: 0.8 F: 0.8	M: 0.83 F: 0.83	M: 0.84 F: 0.75	M: 0.9 F: 0.9	M: 1.00 F: 1.00	-	WHO/FAO (2007) M: 0.83 F: 0.83
Protein (g/day) (reference body weight)	M: 56 (70 kg) F: 46 (57 kg)	M: 62 (74.6 kg) F: 52 (62.1 kg)	M: 64 (76 kg) F: 46 (61 kg)	M: 60 (66 kg) F: 50 (52 kg)	M: 62 (62 kg) F: 55 (55 kg)	-	M: 54 (65 kg) F: 46 (55 kg)

	Physiological endpoint	Reason for choice of endpoint(s)	Coefficient variation	Primary evaluation?	Year(s) of evaluation	Year latest literature
1 Vitamin A						
United States & Canada	Maintain liver vitamin A stores	Assures vitamin A reserves to cover increased needs during periods of stress and low vitamin A intake	20% CV	YES	1998–2000	1999
Australia & New Zealand	Maintain given body-pool size in well-nourished individuals	-	20% CV rounded to nearest 100 μg	NO, based on IOM	-	-
Japan	Maintain liver vitamin A stores	Prevention of vitamin A deficiency	20% CV	YES	2008	2008
Malaysia	Enable adequate growth and permit vitamin A dependent functions to take place and maintain an acceptable total body reserve of the vitamin			NO, taken from FAO/WHO (2002)	-	-
WHO/FAO (2004)	Extrapolated from values derived as safe in late infancy, plus adequate growth and other vitamin A-dependent functions and to maintain an acceptable total body reserve of the vitamin	Enable adequate vitamin A dependent functions and to maintain an acceptable total body reserve of the vitamin.	-	YES	1998–2004	2002
2 Vitamin D						
United States & Canada	Serum 25OHD levels	Levels associated with bone health outcomes (maintenance)	-	YES	2010–2011	2010
Australia & New Zealand (AI)	Maintain serum 25OHD at level of at least 27.5nmol/L with minimal exposure to sunlight	Based on PTH secretion and various bone health indicators	-	YES	2005	2004
Malaysia	-	-	-	NO, based on FAO/WHO (2002); IOM (1997)	-	-
WHO/FAO (2004)	Maintain plasma 25OHD levels above 27nmol/L	Level necessary to ensure normal bone health.	-	NO, based on IOM, 1997	1998–2004	1998

Table 2B: Supplementary Information: Vitamins A, D, E and Mg

	Physiological endpoint	Reason for choice of endpoint(s)	Coefficient variation	Primary evaluation?	Year(s) of evaluation	Year latest literature
3 Vitamin E						
United States & Canada	Prevent hydrogen peroxide- induced erythrocyte hemolysis	Inversely correlated with plasma α-tocopherol concentrations in children & adults with vitamin E deficiency as defined by low vitamin E concentrations	10% CV	YES	1998–2000	2000
Australia &New Zealand (AI)	Not sufficient data to set EAR.	In the US DRI review of 2000, the amount of dietary vitamin E required to bring plasma α -tocopherol to a level where per cent haemolysis was low was used to estimate an EAR (Horwitt 1960, 1963). However, the interpretation of these data is problematic in relation to the level of plasma α -tocopherol at which adverse effects are seen, as there were no data available for plasma α -tocopherol concentrations between 5 and 12 µmol/L. All four subjects below 6 µmol/L plasma α -tocopherol (range 2–5 µmol/L) had haemolysis of about 80% or above and all 6 subjects with concentrations between 12 and 22 µmol/L, had haemodialysis of 12% or less. There has been disagreement as to whether the 'adequacy' cut off should be midway between these two clusters or at the lowest point showing low haemolysis. The data are dichotomous, not continuous, thus preventing an accurate dose-response analysis. Changing the cut-off point makes a large difference to the estimated requirement. In addition, the authors of the key paper themselves expressed concern about the validity of the technique for assessing vitamin E requirements (Horwitt 1960, 1963, 2001). Given these uncertainties, an AI rather than an EAR was set for vitamin E based on median population intakes in Australia and New Zealand – both healthy populations with no apparent vitamin E deficiency.		YES	2005	2003
Malaysia	-	-	-	NO, based on FAO/WHO (2002)	-	-
WHO/FAO (2004)	Average of UK and USA AI, based on dietary intake above vitamin E:PUFA ratio of 0.4 mg/g.	Erythrocytes of subjects below this concentration of vitamin E may show increasing tendency to haemolyse when exposed to oxidising agents.	10-15%?	NO, based on mean UK and US median intakes	1998–2004	2002

	Physiological endpoint	Reason for choice of endpoint(s)	Coefficient variation	Primary evaluation?	Year(s) of evaluation	Year latest literature
4 Magnesium	n					
United States & Canada	Balance studies	Principal measure of adequate dietary magnesium	10% CV	YES	1995–1997	1997
Australia & New Zealand	Maintenance of total body magnesium	Principal measure of adequate dietary magnesium	10% CV	NO, based on IOM	1997	1997
Japan	Balance studies	Principal measure of adequate dietary magnesium	10% CV	YES	2008	2004
WHO/FAO (2004)	Balance data plus margin 20% for methodological variability,	Exceeds critical magnesium:energy ratio 0.02	?	YES	1998–2004	1997

Table 2C: Supplementary Information: Vitamin C, Se, Fe and Zn

	Physiological endpoint	Reason for choice of endpoint(s)	% Dietary absorption and basis	Coefficient variation	Primary evaluation	Year(s) of evaluation	Year latest literature
5 Vitamin (
United States & Canada	Near-maximal neutrophil concentrations	Estimated to provide antioxidant protection	-	10% CV	YES	1998–2000	1996
Australia & New Zealand	Body pool to prevent deficiency (scurvy), vitamin C turnover studies and biochemical indices in man	EAR based on prevention of deficiency and half-way point to tissue saturation with a safety margin in recognition of limited data available across the various age bands	85% absorption efficient, catabolic rate of 2.9% (21% CV) and rounding	20% CV	YES	2005	2003
Japan	Optimal antioxidant activity in plasma (50µmol/L), and prevention of cardiovascular diseases	Estimated to provide antioxidant protection	-	10% CV	YES	2008	2000
Malaysia	-	-	70-90% of usual dietary intake of ascorbic acid (30-180 mg/day is absorbed (MOH 2005)	10% CV	NO, based on FAO/WHO (2002) and IOM (2000)	-	-
WHO/FAO (2004)	Body pool of vitamin C	Amount required to half saturate body tissues with vitamin C	85% absorption efficiency	25% CV	YES	1998–2004	1998

	Physiological endpoint	Reason for choice of endpoint(s)	% Dietary absorption and basis	Coefficient variation	Primary evaluation	Year(s) of evaluation	Year latest literature
6 Selenium							•
United States & Canada	Maximum plasma glutathione peroxidase (GP _X) activity	For EAR, the level of $+25$ µg/day was used; this is a value at which both the plasma and blood selenium to GPX ratios would have plateaued	-	10% CV rounded to nearest 5 µg	YES	2005	2005
Australia & New Zealand	Maximum glutathione peroxidase (GPx) activity	The level of $+25\mu g/day$ is a value at which both the plasma and blood selenium to GPx ratios would have plateaued.		10% CV rounded to nearest 5µg	YES	2005	2005
Japan	Maintain 2/3 of the maximum plasma glutathione peroxidase (GP _X) activity-	WHO concluded that Se deficiency is prevented when 2/3 of plasma GPX is maintained. (24.2µg/day for 60kg BW was used)	-	10% CV	YES	2008	1996
Malaysia	-	-	Highly absorbed varying 50-80%	-	NO. Adapted from FAO/WHO (2002) and IOM (2000).	-	-
WHO/FAO (2004)	GSHP _x activity and satisfactory plasma saturation	Satisfactory levels of plasma selenium and of GSHPx activity (>0.3mmol NADPH oxidised/min/L or approximately 2/3 of plasma saturation activity)		12.5 % CV	YES	1998–2004	1998
7 Iron							
United States & Canada	Factorial analysis	Total need for absorbed iron can be estimated	18%	NO	YES	1998–2000	2000
Australia & New Zealand	Factorial modelling	Total need for absorbed iron can be estimated	18% based on mixed western diet, including animal foods	NO	NO, based on IOM and additional papers	2005	2000
Japan	Factorial analysis-	Total need for absorbed iron can be estimated	15% (FAO/WHO, 1988)	10% CV	YES	2008	2003

	Physiological endpoint	Reason for choice of endpoint(s)	% Dietary absorption and basis	Coefficient variation	Primary evaluation	Year(s) of evaluation	Year latest literature
Malaysia	-	-	Adopted FAO/WHO (2002) 'bioavailability'-levels of 10% and 15%.	-	NO, based on FAO/WHO (2002) and IOM (2001)	-	-
WHO/FAO (2004)	Factorial analysis	Absorbed iron requirements can be estimated	5%, 10%, 12% and 15% 'bioavailability' diets.	NO	YES	1998–2004	1998
8 Zinc							
United States & Canada	Factorial analysis	Sufficient number of metabolic studies on zinc homeostasis to estimate zinc dietary requirements	Fractional absorption M: 0.41; F: 0.48	10% CV	YES	1998–2000	2000
Australia & New Zealand	Factorial modelling	Estimates based on minimal amount absorbed zinc necessary to match total dietary excretion of endogenous zinc. Factorial calculations based on metabolic/trace studies.	M: 24%; F: 31% Based on whole diet studies as assessed by IZiNCG	10% CV	NO, based on IZiNCG estimates adjusted to ANZ reference body weights	2005	2002
IZiNCG	Factorial modelling	Estimates based on minimal amount absorbed zinc necessary to match total dietary excretion of endogenous zinc. Factorial calculations based on metabolic/trace studies.	Mixed or refined vegetarian diet M 26% F 34% Unrefined cereal-based diet M 18% F 25%	12.5% CV	YES	2004	2002
Japan	Factorial analysis-	Estimates based on minimal amount absorbed zinc necessary to match total dietary excretion of endogenous zinc. Factorial calculations based on metabolic/trace studies.		10% CV	YES	2008	1992
Malaysia	-	-	Absorption levels of 30%	25% CV	NO, based on FAO/WHO (2002), mg/kg/day and reference body weights of Malaysians	-	-

	Physiological endpoint	Reason for choice of endpoint(s)	% Dietary absorption and basis	Coefficient variation	Primary evaluation	Year(s) of evaluation	Year latest literature
WHO/FAO (2004)	Factorial analysis	Obligatory loss during the early phase of zinc depletion before adaptive reductions in excretion take place.	 High availability – 50% - refined diets low in cereal fibre, phytic acid content adequate protein principally from meat and fish. Moderate availability – 30% Mixed diets containing animal or fish protein. Low availability: 15% Diets high in unrefined, unfermented an ungerminated cereal grain, especially when fortified with 	25% CV	YES	2004	1998
			inorganic calcium salts and intake of animal protein is negligible.				

Table 2D: Supplementary Information: Protein

	Physiological endpoint	Reason for choice of	Protein quality	Coefficient	Primary	Year(s) of	Year latest
		endpoint(s)		variation	evaluation?	evaluation	literature
United States &	Nitrogen	Primary approach for		12% CV	YES	2000-2002	2001
Canada	equilibrium/balance	determining protein					
	_	requirements. Lack of					
		valid alternative					
		methods.					
European Union	Nitrogen balance		PD-CAAS value	12% CV	YES	2009-2012	2012
	_		of 1.0				
Australia & New	Factorial method	Estimates based on		12% CV	YES	2005	2003
Zealand		amount needed for					
		growth and					
		maintenance on a fat-					
		free mass basis					
Japan	Nitrogen	Primary approach for	-	12.5% CV	YES	2008	1992
	equilibrium/balance	determining protein					
		requirements. Lack of					
		valid alternative					
		methods.					

	Physiological endpoint	Reason for choice of endpoint(s)	Protein quality	Coefficient variation	Primary evaluation?	Year(s) of evaluation	Year latest literature
Malaysia	Factorial method	-	80% protein quality	-	NO, based on FAO/WHO/UNU (1985) recommendations after adjusting for 80% protein quality	-	-
WHO/FAO (2007)	Lowest level of protein intake that will balance the losses of N from the body and thus maintain the body protein mass in persons at energy balance with modest levels of physical activity.		Differences according to protein quality are often less than the differences seen between studies with the same protein.	12% CV	YES	2001–2002	2003

ATTACHMENT 3

VITAMIN A and VITAMIN E CONVERSION FACTORS

Table 3A: Vitamin A conversion factors

	Name vitamin A equivalent	Conversion factor; 1 µg vitamin A equivalent is provided by:	Basis	Comments
United States	Retinol Activity Equivalents (RAE)	 1 μg all-trans retinol 12 μg dietary all-trans-β-carotene 24 μg dietary α-carotene or β- cryptoxanthin Supplement: 2 μg all-trans-β-carotene 	The bioconversion of β -carotene to vitamin A in foods is 6 times less efficient than in dietary supplements. The bioconversion of β -carotene is twice as efficient as α -carotene or β -cryptoxanthin.	Propose RAE instead of Retinol Equivalents (RE) to avoid confusions because RE represents a different meaning of Vitamin A activity in fruit and vegetables (i.e. provitamin A carotenoids). These conversion factors can be used to determine the amount of provitamin A carotenoids and preformed vitamin A in foods as RAE to declare as vitamin A in nutrition labelling.
Canada	Retinol Activity Equivalents (RAE)	1 μg all- <i>trans</i> retinol	By definition	Does not support factors for dietary α -carotene or β -cryptoxanthin
		12 μg <i>all-trans</i> - β -carotene from the diet	Lower bioavailability from food matrices (natural and fortified)	
		Fortificant: 1.15 µg all- <i>trans</i> -retinyl acetate	Relative molecular weight all- <i>trans</i> -retinyl acetate/all- <i>trans</i> retinol	
		Fortificant:1.82 µg all- <i>trans</i> - retinyl palmitate	Relative molecular weight all- <i>trans</i> -retinyl palmitate/all- <i>trans</i> retinol	
		Supplement: 2 μ g all- <i>trans</i> - β -carotene in oil	High bioavailability and conversion rate at low doses	
New Zealand	Retinol Equivalents (RE)	1 μg all-trans retinol 6 μg dietary all-trans-β-carotene 12 μg dietary α-carotene or β- cryptoxanthin and other provitamin carotenoids	The bioefficacy factor 6 is derived from imperfect yield after cleavage of B-carotene (1 mol B-carotene yields 0.5 mol retinol) and estimated 1/3 B-carotene absorbed from mixed diet. Bioefficacy factor 12 derived from lower yield from intestinal cleavage of α -carotene and B-cryptoxanthin.	Supports the recent position of FAO that the current evidence base for a change is insufficient (WHO/FAO, 2004) such that RE conversion factors should be retained until more definitive data became available.
Japan	Retinol Equivalents (RE)	 1 μg retinol 12 μg β-carotene 24 μg α-carotene 24 μg β-cryptoxanthin 24 μg other provitamin A carotenoids 		

	Name vitamin A	Conversion factor; 1 µg vitamin A	Basis	Comments
	equivalent	equivalent is provided by:		
Malaysia	Retinol Equivalents	1 μg retinol		
	(RE)	12 μg β-carotene		
		24 µg other provitamin A carotenoids		
Indonesia	Retinol Equivalents	1 μg retinol		WHO (2006)
	(RE)	12 μg β-carotene		
		24 µg other provitamin A carotenoids		
Brazil	Retinol Equivalents	1 μg retinol		WHO (2006)
	(RE)	12 μg β-carotene		
		24 µg other provitamin A carotenoids		
Chile	RE/RAE	1 μg retinol		IOM/WHO (2006)
		12 μg β-carotene		
		24 µg other provitamin A carotenoids		
ICBA	AS for United			
	States			
IADSA		1 μg all-trans retinol		ALINORM 2009
		6 μg dietary all-trans- β -carotene		
		12 µg other provitamin carotenoids		
IFPRI	Suggests using		The average conversion factor is principally	
	RAE (but not the		affected by the complexity of the food	
	conversion ratio β-		matrix containing the provitamin A	
	carotene to retinol		carotenoids. Particularly for the conversion	
	for biofortified		of β -carotene to retinol from the similar food	
	crops).		matrix found in major biofortified staples	
			like cassava, sweet potato and maize, the	
			conversion ratio is in the range of $(3-13 \mu g$	
			of beta carotene to 1 μ g retinol). Therefore	
			the conversion from biofortified staple crops	
			is more efficient and the conversion factors	
			are closer to the 6:1 ratio established by	
			FAO/WHO than the 12:1 conversion ratio	
			established by the IOM.	

	Name Vitamin E Equivalent	Conversion factor; 1 mg vitamin E equivalent is provided by	Basis	Comments
United States	α-tocopherol	1 mg natural <i>RRR</i> -α-tocopherol 2 mg synthetic (<i>all rac-</i>) α-tocopherol		This conversion factor for the specified synthetic tocopherol can be used to determine the amount of Vitamin E in foods
Canada	α-tocopherol	1 mg natural <i>RRR</i> -α-tocopherol	Only α -tocopherol is maintained in the plasma and only the 2 <i>R</i> -sterioisomers are fully functional at the α -tocopherol transfer protein in the liver	The four 2S-stereoisomers of α -tocopherol, the other forms of tocopherol (beta, gamma, delta), and tocotrienols are not converted to α -tocopherol in humans (IOM, 2000 – <u>http://www.nap.edu/catalog.php?record_id=</u> <u>9810</u>
		1.10 mg <i>RRR</i> - α -tocopheryl acetate	Relative molecular weight <i>RRR</i> - α -tocopheryl acetate/ α -tocopherol	
		1.23 mg <i>RRR</i> -α-tocopheryl succinate	Relative molecular weight <i>RRR</i> -α- tocopheryl succinate/ α-tocopherol	
		2 mg <i>all-rac</i> -α-tocopherol	The 4 active 2R-stereoisomers (i.e. RRR, RSR, RRS, RSS) constitute ~50% the weight of synthetic <i>all-rac</i> -α-tocopherol.	
		2.22 mg <i>all-rac</i> -α-tocopheryl acetate	Relative molecular weight <i>all-rac-</i> α - tocopheryl acetate / <i>RRR-</i> α -tocopheryl acetate	
		2.44 mg <i>RRR</i> -α-tocopheryl succinate	Relative molecular weight <i>all-rac-α</i> - tocopheryl succinate / <i>RRR-α</i> -tocopheryl succinate	
New Zealand	α-tocopherol equivalents (α-TE)	1 mg natural RRR - α -tocopherol 1.10 mg RRR - α -tocopherol acetate 1.23 mg RRR - α -tocopherol succinate 1.35 mg <i>all</i> - <i>rac</i> - α -tocopherol 1.49 mg <i>all</i> - <i>rac</i> - α -tocopherol acetate 2.5-4 mg RRR - β -tocopherol 10 mg RRR - γ -tocopherol 3.33-4 mg α -tocotrienol		8 naturally occurring isomers. A-TE preferred because it is premature to state that gamma-tocopherol (other major tocopherol in food) has no biological activity. All forms of naturally occurring vitamin E appear to be equally well absorbed into chylomicrons. Some evidence that γ -tocopherol is not inert, but has biological effects.
Japan	α-tocopherol	1 mg natural <i>RRR</i> -α-tocopherol	α -tocopherol preferentially combines with α - tocopherol transfer protein. Most of vitamin E homologue in blood and tissues is α - tocopherol type.	

Table 3B: Vitamin E conversion factors

	Name Vitamin E Equivalent	Conversion factor; 1 mg vitamin E equivalent is provided by	Basis	Comments
Malaysia	α-tocopherol equivalents (α-TE)	1 mg natural $RRR-\alpha$ -tocopherol 2 mg $RRR-\beta$ -tocopherol 10 mg $RRR-\gamma$ -tocopherol 3.3 mg α -tocotrienol		Other forms of vitamin E found in mixed diet. Biopenticies, although weaker in comparison, should also be taken into consideration in the calculation of total vitamin E activity (Food and Nutrition Board, 1989)
Indonesia	α-tocopherol equivalents (α-TE)	1 mg natural $RRR-\alpha$ -tocopherol 2 mg $RRR-\beta$ -tocopherol 10 mg $RRR-\gamma$ -tocopherol 3.3 mg α -tocotrienol		WHO (2004)
Brazil	α-tocopherol equivalents (α-TE)	1 mg natural RRR -α-tocopherol 2 mg RRR -β-tocopherol 10 mg RRR -γ-tocopherol 3.3 mg α-tocotrienol		WHO (2004)
Chile	α-tocopherol equivalents (α-TE)	1 mg natural $RRR-\alpha$ -tocopherol 2 mg $RRR-\beta$ -tocopherol 10 mg $RRR-\gamma$ -tocopherol 33.3 RRR-deltα-tocopherol 3.3 mg α-tocotrienol 20 mg b-tocotrienol 1.35 mg <i>all-rac</i> -α-tocopherol		IOM (undated)
ICBA	As for United States			
IADSA		 1 mg natural <i>RRR</i>-α-tocopherol 2 mg <i>RRR</i>-β-tocopherol 10 mg <i>RRR</i>-γ-tocopherol 3.3 mg α-tocotrienol 1.35 mg <i>all-rac</i>-α-tocopherol 		ALINORM 2009