CODEX ALIMENTARIUS COMMISSION

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Agenda Item 4 **CX/NFSDU 15/37/4**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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Bad Soden am Taunus, Germany

23 – 27th November 2015

Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the *Guidelines on Nutrition Labelling*

(Prepared by an Electronic Working Group led by Australia)[1]

(At Step 3)

Governments and interested international organizations are invited to submit comments on the Recommendations 1 - 19 and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: German Secretariat for CCNFSDU, email: ccnfsdu@bmel.bund.de with copy to Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Rome, Italy, email codex@fao.org **by 16 October 2015.**

1 INTRODUCTION

1.1 Consideration by CCNFSDU, 2014 and Codex Alimentarius Commission, 2015

At its 36th session, 2014, CCNFSDU accepted the six listed scientific bodies as Recognized Authoritative Scientific Bodies (RASBs) as final and further modified the RASB working definition to explain the term 'primary evaluation'. The Committee then clarified GP 3.2.1.1 to allow more recent Daily Intake Reference Values (DIRVs) that were not INL_{98} to be considered. It also revised the Nutrient Reference Values – Requirement (NRVs-R) for vitamin C and zinc, and established NRVs-R for selenium, molybdenum and manganese but not for fluoride (paragraphs 51-79, REP15/NFSDU). All of these decisions were adopted by the 38th session of the Codex Alimentarius Commission (REP15/CAC) and are included in the current version of the Guidelines on Nutrition Labelling (CAC/GL 2-1985[2]).

CCNFSDU36 also agreed to establish an electronic Working Group (eWG), chaired by Australia and working in English (paragraph 79, REP15/NFSDU) with the following Terms of Reference (TOR):

1. Recommend revised or additional NRVs-R for vitamin A, vitamin D, vitamin E, magnesium, phosphorus, chromium, copper, chloride as well as iron in accordance with the revised working definition of RASB and the General Principles for establishing NRVs for the general population.

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[1] Brazil, Canada, Chile, China, Columbia, Costa Rica, Greece, Ghana, India, Indonesia, Iran, Japan, Malaysia, the Netherlands, New Zealand, United States of America, Council for Responsible Nutrition, Federation of European Specialty Food Ingredients Industries, FoodDrink Europe, International Alliance of Dietary/Food Supplement Associations, International Council of Beverages Associations, International Special Dietary Foods Industries, National Health Federation

[2] Adopted in 1985. Revision: 1993 and 2011. Amendment: 2003, 2006, 2009, 2010, 2012 and 2013. ANNEX adopted in 2011. Revision: 2013 and 2015.

2. Recommend relevant supporting information for the vitamins and minerals in TOR1.
3. Consider the approach for establishing NRVs-R for 6–36 months of age for the nutrients for which NRVs-R are established for the general population.

1.2 Conduct of the Electronic Working Group

In December 2014, Codex members and observers were invited to participate in the eWG for 2015. The eWG considered three consultation papers circulated in February, May and July 2015. Responses to these papers were received from 15, 13 and 9 members and 6, 5 and 3 international non-government observer organisations, respectively.

1.3 Context for NRVs-R in Codex Guidelines

There are two Codex Guidelines that provide the context for NRVs-R. These Guidelines and relevant provisions are:

Guidelines on Nutrition Labelling (CAC/GL 2-1985)

3.2.6.1 Only vitamins and minerals for which recommended intakes have been established and/or which are of nutrition importance in the country concerned should also be declared.

Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005)

3.1.1 *Vitamin and mineral food supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognised by FAO and WHO.*

5.5 Information on vitamins and minerals should also be expressed as a percentage of the nutrient reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labelling.

The status of nutrients as vitamins and minerals is internationally recognised by WHO/FAO (2004), WHO/FAO (2006) and WHO (1996) (trace elements). All of the vitamins and minerals under consideration except phosphorus and chloride have nutrient requirements reported by WHO/FAO.

1.3.1 NRV-R for zinc

Because of the relevance to consideration of the NRV-R for iron, the revised NRV-R for zinc and related information is reproduced below from the *Guidelines on Nutrition Labelling*.

Zinc**	11 (30% dietary absorption; Mixed diets, and lacto-ovo vegetarian diets that are not based on unrefined cereals grains or high extraction rate (>90%) flours) 14 (22% dietary absorption; Cereal-based diets, with >50% energy intake from cereal grains or legumes and negligible intake of animal protein)

** Competent national or regional authorities should determine an appropriate NRV-R that best represents the dietary absorption from relevant diets.

1.4 Definitions

The following definitions are relevant to the consideration of NRVs-R.

a) Nutrient Reference Values

Definitions of nutrient reference values (NRVs) including NRVs-R and NRVs-NCD in the *Guidelines on Nutrition Labelling* are:

> **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.
>
> **Nutrient Reference Values – Noncommunicable Disease (NRVs-NCD)** refer to NRVs that are based on levels of nutrients associated with reduction in the risk of diet-related noncommunicable diseases not including nutrient deficiency diseases.

b) Daily Intake Reference Values, INL_{98} and UL

Definitions of daily intake reference values (DIRVs), INL_{98}, and Upper level of intake (UL) in the Annex to the *Guidelines on Nutrition Labelling* are:

> **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).
>
> **Individual Nutrient Level 98 (INL_{98})** is the daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in a specific life stage and sex group.
>
> **Upper Level of Intake (UL)** is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

c) Working Definition of Recognized Authoritative Scientific Body (RASB)

In 2014, the Committee agreed to a second footnote (paragraph 77, REP15/NFSDU) to the working definition (paragraph 31, REP14/NFSDU). The definition of RASB is:

> For the purposes of establishing Codex Nutrient Reference Values, a recognized, authoritative, scientific body other than FAO and/or WHO is an organization supported by a competent national and/or regional authority(ies) that provides independent, transparent*, scientific and authoritative advice on daily intake reference values through primary evaluation** of the scientific evidence upon request and for which such advice is recognized 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.
>
> ** Primary evaluation involves a review and interpretation of the scientific evidence to develop daily intake reference values, rather than the adoption of advice from another RASB.

The following RASBs met this working definition and were previously accepted by the Committee.

RASB	**Region or Member State**
FAO and/or WHO	International
European Food Safety Authority (EFSA)	European Union
Institute of Medicine (IOM)	United States and Canada
National Health and Medical Research Council & New Zealand Ministry of Health (NHMRC/MOH)	Australia and New Zealand
National Institute of Health and Nutrition (NIHN)	Japan
Nordic Council of Ministers	Nordic countries
International Zinc Nutrition Consultative Group (IZiNCG) [zinc only]	International

1.5 General Principles for Establishing NRVs-R

The *General Principles for Establishing NRVs for the General Population* (General Principles) are given in the Annex to the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985). General principles relevant to NRVs-R are as follows:

GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R

3.1 Selection of Suitable Data Sources to Establish NRVs

3.1.1 Relevant daily intake reference 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, or an older, established INL_{98} for a nutrient for a specific sub-group(s), it may be appropriate to consider the use of other daily intake reference values or ranges that have been more recently 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 Codex Alimentarius Commission 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-R, 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).

1.6 Application of General Principles to Selection of DIRVs from Accepted RASBs

The General Principles have been applied to guide selection of candidate DIRVs for vitamins A, D and E and the six minerals under consideration:

GP	Application of General Principles
3.1.1	The Committee previously considered that pNRVs-R derived from WHO/FAO (2004) DIRVs for vitamin A, vitamin D, vitamin E and magnesium would require further consideration because of potential unsuitability (REP13/NFSDU, paragraph 86). Reasons to find WHO/FAO DIRVs potentially unsuitable could include more recent evidence or improved methodology.
3.1.2	All candidate DIRVs from accepted RASBs other than WHO/FAO are reviewed and only those determined by primary evaluation of the scientific evidence (or based on population dietary intake) are further considered.
3.1.3	All candidate DIRVs relate to the general population.
3.2.1.1	All candidate DIRVs for vitamin A are classified by the source RASBs as INL_{98}; candidate DIRVs for vitamin D, vitamin E, magnesium, phosphorus and copper are classified by the source RASBs as either INL_{98} or AI; the candidate DIRVs for chromium are classified by the source RASBs as either INL_{98} or AI or not determined; and the candidate DIRV for chloride is classified as AI.
3.2.1.2	The male and female candidate DIRVs for 19-50 years from relevant RASBs are averaged and rounded as necessary.
3.2.1.3	No candidate DIRVs represent recommendations for pregnant or lactating women.
3.3	The ULs set by RASBs are taken into account.

1.7 Stepwise Process

The Stepwise process followed during the eWG's consideration of NRVs-R is as shown.

Step 1	Consider the potential unsuitability of DIRVs from FAO and/or WHO according to GP 3.1.1.
Step 2	Identify DIRVs established by the accepted RASBs (section 1.4 (c)) for the vitamins and minerals under consideration and according to GP 3.1.2.
Step 3	For each vitamin and mineral, calculate candidate DIRVs from accepted RASBs, including FAO and/or WHO where applicable, in accordance with GPs 3.2.1.1, 3.2.1.2 and 3.2.1.3 (INL_{98} or AI, mean adult 19-50 years, nonpregnant/nonlactating)
Step 4	Compare each candidate DIRV with GP 3.3 ($UL_{young\ children}$ (IOM and EFSA)) and set aside those found to be unsuitable.
Step 5a	From consideration of the differences between suitable candidate DIRVs, recommend the most appropriate NRV-R OR
Step 5b	From consideration of the difference between highly similar and suitable candidate DIRVs, average the DIRVs to recommend a representative NRV-R.

1.8 Reference Adult Body Weight

Based on the CCNFDSU's 2013 consideration of protein NRV-R, the reference mean adult body weight is currently 60 kg (FAO, 1988) (paragraph 26, REP14/NFSDU).

1.9 Attachments to this Paper and Approach to ESFA Scientific Opinions

The eWG was able to consider several draft or final EFSA scientific opinions that became available during 2015. This paper notes where draft DIRVs were finalised after eWG consideration. Where final scientific opinions were amended after eWG's consideration of the draft, e.g. phosphorus, the details of both draft and final scientific opinions are given in section 3 and the Attachments.

Appendix 1 provides the male and female contributors to candidate DIRVs and the reasons for excluding certain DIRVs.

Appendix 2 is arranged in several tables and provides details of:

- the scientific basis of each candidate DIRV
- dietary equivalents for vitamins A and E
- national adult body weights from CX/NFSDU 13/35/4 plus those from the Nordic Council.

Appendix 3 provides all RASB references for candidate DIRVs, ULs and other information.

2 COMPARISON WITH ULs FOR YOUNG CHILDREN

Candidate DIRVs are compared to the ULs for young children in the next table in accordance with GP 3.3. Candidate DIRVs that do not exceed all quantified ULs, or if a UL applies to fortificants only, candidate DIRVs survive for further consideration.

Most candidate DIRVs do not exceed the UL for young children. However, some DIRVs for vitamin A, copper and chloride either equal or exceed the ULs for young children aged 1–3 years but not the ULs for children in the next bracket aged 4–6/4–8 years. Comparison of candidate DIRVs with ULs for children needs to be carefully considered particularly when information on requirements, absorption, metabolism and excretion of nutrients in children is extremely limited. The ULs for young children are usually extrapolated from ULs for adults and therefore these values reflect a higher degree of uncertainty.

Vitamin or Mineral (INL_{98} unless indicated by AI)	**US & Canada**	**EU**	**Aust & NZ**	**Japan**	**Nordic Council**	**WHO/ FAO**	**UL 1-3/4-8 yrs; US & Canada**	**UL 1-3/4-6 yrs; EU**
Vitamin A (µg RAE or RE)	800 (RAE)	700 (RE)	NPE	765 (RE)	NPE	550 (RE)	600/900 (retinol only)	800/ 1100 (retinol only)

Vitamin or Mineral (INL_{98} unless indicated by AI)	**US & Canada**	**EU**	**Aust & NZ**	**Japan**	**Nordic Council**	**WHO/ FAO**	**UL 1-3/4-8 yrs; US & Canada**	**UL 1-3/4-6 yrs; EU**
Vitamin D (µg)	15	N/A	5 AI	5.5 AI	10	5 AI	63/75	25/25
Vitamin E (mg αTE, or α-toc)	15 (α-toc)	12 (α-toc) AI	8.5 (αTE) AI	6.8 (α-toc) AI	9 (α-toc) AI	8.8 (αTE/ α-toc) AI	200/300 * (α-toc only)	100/120
Magnesium (mg)	365	325 (AI)	NPE	320	315 (?AI)	240	65/110*	ND/250*
Phosphorus (mg)	700	Draft 700 Final 550 AI	1000	950 AI	600	N/A	3000/ 3000	ND/ND
Iron (mg) (% absorption)	13 (18%)	Draft 13.5 (17%)	NPE	9 (15%)	12 (15%)	14.4 (15%) 21.6 (10%)	40/40	ND
Copper (µg)	900	Draft 1450 AI	1450 AI	800	NPE	N/A	1000/ 3000 [1500; WHO (1996), 1-6 yrs]	1000/ 2000
Chromium (µg)	30 AI	ND	NPE	35 AI	ND	N/A	ND/ND	ND/ND
Chloride (mg)	2300 AI	N/A	N/A	N/A	N/A	N/A	2300/ 2900	ND/ND

* Fortificant and supplement forms only, does not include natural forms in food.

RAE retinol activity equivalents; RE retinol equivalents

αTE alpha tocopherol equivalents; α-toc alpha tocopherol

ND Not determined due to insufficient data; N/A DIRV not available

NPE Not derived by primary evaluation

To assist CCNFSDU's consideration, the basis for the young age ULs for vitamin A, copper and chloride is shown in the following table.

Nutrient	**RASB**	**UL For Young Children**
Vitamin A (retinol only)	IOM	UL extrapolated from adult UL on basis of relative body weights. For adults, teratogenicity (women of child bearing age) or liver abnormalities were selected as the critical endpoints, but UL same for all adults, 3000 µg.
	EFSA	UL extrapolated from adult UL (same for all adults, 3000 µg) on basis of relative body surface area. Adult UL based on teratogenicity and applied to all adults as UL would be 2.5 fold lower than lowest intake associated with hepatotoxicity.
Copper	IOM	UL extrapolated from adult UL on basis of relative body weights. For adults, liver damage selected as critical endpoint. NOAEL taken from double blind study of copper supplement intake for 12 weeks in healthy subjects.
	WHO	UL extrapolated from adult UL based on a level that seems to have no detrimental effect on human health (same value as IOM NOAEL).
Chloride	IOM	UL extrapolated from adult UL on basis of relative median energy intakes. For adults, UL set on equimolar basis with sodium UL which was set on basis of

Nutrient	RASB	UL For Young Children
		LOAEL from trials examining the relationship between sodium intake and blood pressure.

Exceedance of ULs also occurred in 2014 for some candidate DIRVs for manganese (all AIs). These DIRVs exceeded the ULs for younger child age group, but were lower than, equal to, or exceeded the ULs for the older child age group. The CCNFSDU took account of these results in accordance with GP 3.3 and accepted an NRV-R for manganese that exceeded the UL for 1-3 years and was equal to the UL for 4-8 years because the general population was described from 4 years.

Taking into account the uncertainties associated with ULs for vitamin A, copper and chloride for young children including from extrapolation, and the fact that the vitamin A UL refers only to retinol, as well as the very conservative nature of a comparison with ULs for very young children, it is proposed that all candidate DIRVs continue to be considered.

3 CONSIDERATION OF NRVs-R

3.1 Recommendations for NRVs-R (TOR 1)

In considering the recommendations for the NRVs-R, the eWG updated the DIRVs and supporting information previously listed in CX/NFSDU 13/35/4 in accordance with the revised working definition of RASB and the six accepted and relevant RASBs. With the need for DIRVs to be established through primary evaluation, some DIRVs previously shown in 2013 were reclassified as NPE (not derived by primary evaluation) and omitted from further consideration.

Section 3 presents the recommendations for NRVs-R and candidate DIRVs for three vitamins and six minerals listed in TOR 1. After three rounds of eWG consultation, the two most preferred candidate DIRVs (or three where close) for each nutrient were ranked according to the relative level of support for the first, second and possibly third preference: very strong majority (≥3:1); strong majority (2:1–<3:1); majority (1.2:1–<2:1) and narrow majority (1:1–<1.2:1). For example, a very strong majority indicates that at least 3 times as many members preferred candidate DIRV1 to candidate DIRV2. These descriptors are used to indicate the eWG's level of support for the highest ranked candidate DIRV(s) as the basis of the NRV-R. Note that where two or more DIRVs (or averages) attracted equal eWG support, these are shown as equally ranked. Recommendations to CCNFSDU are based on cumulative support for a particular reference value. For example for vitamin A, overall support for a first and third preferred DIRV of the same value narrowly exceeded other values/average that attracted equal but overall smaller support.

Also, where the current NRV-R and supported DIRV are the same, the candidate DIRV is preferred so to provide a documented basis for the NRV-R (see section 6).

3.2 Vitamin A NRV-R

eWG preferences	RASB	Candidate DIRV (µg*) (All INL_{98})
3	IOM (United States & Canada) or current NRV-R	800
=2	EFSA (European Union)	700
	NIHN (Japan)	765
	WHO/FAO	550
=2	Average of IOM, EFSA, NIHN	(800 + 700 + 765)/3 rounded to 750
1	*Current NRV-R*	*800*

* see section 4.1 for dietary equivalents

No Primary Evaluation (NPE) NHMRC/MOH and Nordic Council sourced from IOM

The eWG noted that several candidate DIRVs are based on the same factorial approach and physiological endpoint and preferred a candidate DIRV in the range 700–800 µg. According to Step 5b, the eWG also considered the average of DIRVs from three RASBs to which rounding was applied to the nearest 50 µg consistent with the smallest rounding increment of the original adult male and female DIRVs in RASB reports. Based on narrow majority eWG support by value, the recommendation is for 800 µg and based on IOM INL_{98} in order to provide a documented rationale. All candidate DIRVs were above the IOM younger age UL but below the ULs for the other three age-RASB groups.

RECOMMENDATION 1 – NRV-R for Vitamin A

That CCNFSDU agrees to retain the NRV-R as 800 µg and based on IOM.

3.3 Vitamin D NRV-R

eWG preferences	RASB	INL_{98} or AI	Candidate DIRV (µg)
=1	IOM (United States & Canada)	INL_{98}	15
	NHMRC/MOH (Australia & New Zealand	AI	5
	NIHN (Japan)	AI	5.5
=1	Nordic Council	INL_{98}	10
	WHO/FAO	RNI (AI)	5
2	Average of IOM, Nordic Council	INL_{98}	(15 + 10)/2 rounded to 13
	Current NRV-R		*5*

The eWG preferred the candidate DIRV to be based on INL_{98} in the range 10–15 µg. The eWG also considered the average of DIRVs from two RASBs based on same physiological endpoint (albeit with slightly different levels of sunlight exposure – see section 3.3.1), both classified as INL_{98}, to which rounding to the nearest whole number was applied. Based on the level of eWG support, the recommendation is to revise upwards the NRV-R to either 10 µg or 15 µg. All candidate DIRVs were below the UL. At the time of writing, EFSA had not issued a draft scientific opinion on a dietary reference value for vitamin D.

RECOMMENDATION 2 – NRV-R for Vitamin D

That CCNFSDU agrees to:

A revise upward the NRV-R from 5 µg

B select either 10 µg or 15 µg and based on relevant RASB.

3.3.1 Footnote to NRV-R for vitamin D

Former versions of the Nutrition Labelling Guidelines applied a footnote to the NRVs-R for vitamin D, iodine and niacin referring to application of national discretion. The eWG considered developing a new footnote to indicate that the NRV-R for vitamin D assumed limited exposure to sunlight but views were evenly divided. Those in support said the footnote would inform decision making by national authorities that use the NRVs-R to establish their reference values, whereas those not in support questioned the meaning and complexity of determining 'limited exposure'. For example, the IOM DIRV assumes minimal sun exposure all year whereas the lower value Nordic Council DIRV is based on the intake needed to maintain the physiological endpoint during winter and takes account of a contribution to sun exposure from summer outdoor activity.

Given the previous application of a footnote to the vitamin D NRV-R and the wide range of global sunlight exposure and other relevant factors, a footnote similarly expressed to the current zinc footnote is recommended. The footnote text refers to 'minimal' instead of 'limited' and has two options subject to the CCNFSDU decision on Recommendation #2: [throughout the year] if 15 µg is preferred, or [in winter] if 10 µg is preferred.

> *The NRV-R is based on minimal sunlight exposure [throughout the year] [in winter]. Competent national and/or regional authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors.*

RECOMMENDATION 3 – Footnote to NRV-R for Vitamin D

That CCNFSDU agrees to:

A establish a footnote to the NRV-R

B adopt footnote wording including selection of text in square brackets in line with decision on Recommendation #2.

3.4 Vitamin E NRV-R

The eWG considered the candidate DIRVs including the draft EFSA Scientific Opinion on Dietary Reference Values for Vitamin E. The final Scientific Opinion was published in July 2015 without amendment to the adult DIRVs.

eWG preferences	RASB	INL_{98} or AI	Candidate DIRV (mg*)
=1	IOM (United States & Canada)	INL_{98}	15
= 2	EFSA (European Union)	AI	12
	NHMRC/MOH (Australia & New Zealand	AI	8.5
	NIHN (Japan)	AI	6.8
=2	Nordic Council	INL_{98}	9
=2	WHO/FAO	RNI (AI)	8.8 (rounded to) 9
=3	Average of IOM, Nordic Council of Ministers, EFSA	INL_{98} ± AI	(15 + 9 + 12)/3 = 12
=2	Average of EFSA, NHMRC/MOH, NIHN, WHO/FAO	AI	(12 + 8.5 + 6.8 + 8.8)/4 = 9.025 rounded to 9
=3	Average of IOM, WHO/FAO	INL_{98} ± AI	(15 + 9)/2 = 12
	Current NRV-R		*N/A*

* see section 4.2 for dietary equivalents

The eWG preferred candidate DIRVs in the range 9–15 mg and were evenly divided by value between 9 mg (WHO/FAO, Nordic Council or average) and 15 mg (IOM DIRV); followed closely by 12 mg (EFSA or average). The lower two values 9 and 12 mg are based on estimates of dietary intake directly or in relation to dietary intake of PUFA. However, in their comments, the US and Canada advised that the IOM INL_{98} of 15 mg may be an overestimate of vitamin E requirements. Appendix 2 also provides comments from some RASBs about the IOM recommendation. Taking this into account, the recommendation is based on the eWG's greater level of support for 9 mg. All candidate DIRVs were below the UL.

RECOMMENDATION 4 – NRV-R for Vitamin E

That CCNFSDU agrees to establish a NRV-R of 9 mg and based equally on Nordic Council, and average of EFSA, NHRMC/MOH, NIHN, WHO/FAO (all AIs).

3.5 Iron NRV-R

eWG preferences	RASB	Candidate DIRV (All INL_{98} except EFSA: INL_{95})
	IOM (United States & Canada)	13 mg (18% absorption)
	EFSA (European Union) Draft	13.5 mg (17% absorption)
	NIHN (Japan)	9 mg (15% absorption)
1 (15% & 10%) Strong majority 2 (15% only)	WHO/FAO	14 mg (15% absorption); 22 mg (10% absorption)
	Nordic Council	12 mg (15% absorption)
	Current NRV-R	*14 mg*

NPE NHMRC/MOH sourced from IOM

In 2012, the Committee agreed that the issues related to the NRV-R for iron (including the need for multiple NRVs-R) would require further consideration (paragraph 91, REP13/NFSDU). The 2013 eWG preferred more than one NRV-R according to % absorption, although minority view was concerned about the paucity of data for lower % absorptions and preferred a single NRV-R. The 2014 eWG continued to strongly prefer DIRVs from WHO/FAO as they were internationally derived and consistent with single % absorption DIRVs more recently derived by other RASBs. Two of the four possible WHO/FAO % absorptions of 15% and 10% were selected because they represented likely dietary absorptions in many countries. WHO/FAO (2004) states "..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". Very strong preference was expressed for these two DIRVs. All candidate DIRVs were below the UL.

The 2015 eWG considered EFSA's draft scientific opinion which was finalised in July 2015 without amendment to the adult DIRVs. The previous strong support for WHO/FAO DIRVs at the two % dietary absorptions put forward at the CCNFSDU 2014 session continued. The alternative view in support of only the lower % absorption based on the paucity of data was also reiterated and citing EFSA's opinion that:

> *DRVs do not need to be derived for vegetarians as a separate population group because the bioavailability of iron from European vegetarian diet is not substantially different from diets containing meat*.

However, one member noted EFSA also stated that:

> *at phytate:iron molar ratios >6, iron absorption is greatly inhibited from meals containing small amounts of enhancing components, whereas in cereal or soy meals with no enhancers, non-haem iron absorption is greatly inhibited by a molar ratio > 1*.

It was pointed out that regional phytate intakes varied widely around the world and the amount consumed in high income countries was less than half that consumed in regional diets in parts of Africa and Asia, and the Middle East[3] and that two NRVs-R of differing % absorption was globally relevant.

RECOMMENDATION 5 – NRV-R for Iron

That CCNFSDU agrees to:

A modify the NRV-R to refer to % dietary absorption

B revise the NRV-R from 14 mg to 14 mg (15% dietary absorption) and 22 mg (10% dietary absorption) and based on WHO/FAO.

3.5.1 Dietary description for iron

Noting the strong preference for WHO/FAO as the basis of the NRV-R, previous years' eWGs considered the dietary descriptions from Table 3.3 and footnote to Table 7.2 of WHO/FAO (2006) that corresponded to 15% and 10% dietary absorptions as shown:

Table 3.3 (WHO/FAO (2006))	**% absorption**	**Footnote to Table 7.2 WHO/FAO (2006)**	**% absorption**
Diversified diet containing greater amounts of meat, fish, poultry and/or foods high in ascorbic acid	High >15	For diets rich in vitamin C and animal protein	15
Diet of cereals, roots or tubers, with some foods of animal origin (meat, fish or poultry) and/or containing some ascorbic acid (from fruits and vegetables).	Intermediate 10–15	For diets rich in cereals but including sources of vitamin C	10

The 2014 eWG considered that these dietary descriptions could be better expressed in food terms by interpreting *foods of animal origin* as *meat, fish, poultry*; and *ascorbic acid* as *fruit and vegetables;* and *greater amounts of* as *rich in* as shown:

[3] Phytate intakes **<1200 mg/day** in high income countries, S and tropical L America, Central and Eastern Europe; **1200 – < 2000 mg** in China, East and Southeast Asia and Pacific, Sub-Saharan Africa, Central and Andean Latin America and Caribbean; **>2000 mg/day** in Sub-Saharan Africa, South Asia, Central Asia, North Africa, and Middle East. (Wessells KR, Brown KH (2012) *Estimating the global prevalence of zinc deficiency: results based on zinc availability in national food supplies and the prevalence of stunting*. PLoS ONE 7(11): e50568. doi:10.1371/journal.pone.0050568.t001)

Dietary descriptions adapted from WHO/FAO (2006)	% absorption
Diets rich in meat fish, poultry, and/or rich in fruit and vegetables	15
Diets rich in cereals, roots or tubers, with some meat, fish, poultry and/or containing some fruit and vegetables.	10

The 2015 eWG also continued to very strongly support the use of dietary descriptions relating to 10% and 15% dietary absorption adapted from WHO/FAO (2006). Two members suggested re-inserting 'diversified' at the beginning of the dietary description corresponding to 15%. The dietary descriptions are therefore updated and presented in the format of the dietary descriptions for zinc in the *Guidelines on Nutrition Labelling.*

Iron**	14 (15% dietary absorption; Diversified diets, rich in meat fish, poultry, and/or rich in fruit and vegetables 22 (10% dietary absorption; Diets rich in cereals, roots or tubers, with some meat, fish, poultry and/or containing some fruit and vegetables

RECOMMENDATION 6 – Dietary Description for Iron

Subject to agreement to Recommendation 5, that CCNFSDU agrees to the dietary descriptions adapted from WHO/FAO (2006) that correspond to the selected NRVs-R.

3.5.2 Footnote for iron

CCNFSDU36 agreed to apply the following footnote to zinc.

** Competent national or regional authorities should determine an appropriate NRV-R that best represents the dietary absorption from relevant diets.

Subject to CCNFSDU's agreement with Recommendation 5, it is recommended that the same footnote be also applied to iron.

RECOMMENDATION 7 – Footnote to NRV-R for Iron

Subject to agreement with Recommendation 5, that CCNFSDU agrees to also attach to iron the ** footnote indicator currently attached to zinc.

3.6 Magnesium NRV-R

The eWG considered the candidate DIRVs including the draft EFSA Scientific Opinion on Dietary Reference Values for Magnesium. The final Scientific Opinion was published in July 2015 without amendments to the adult DIRVs.

eWG preferences	RASB	INL_{98} or AI	Candidate DIRV (mg)
=2	IOM (United States & Canada)	INL_{98}	365
	EFSA (European Union) Draft	AI	325
	NIHN (Japan)	INL_{98}	320
	Nordic Council	RI (no EAR)	315
	WHO/FAO	INL_{98}	240
	Average of IOM, NIHN, Nordic Council, EFSA	INL_{98} + RI + AI	(365 + 320 + 315 + 325)/4 = 331.25 rounded to 330
1	Average of IOM, NIHN, WHO/FAO ± Nordic Council	INL_{98} ± RI	(365 + 320 + 240)/3 = 308.3 rounded to 310; or (365 + 320 + 315 +240)/4 = 310
=2	*Current NRV-R*		*300*

NPE NHMRC/MOH sourced from IOM

A majority of eWG favoured 310 mg derived from an average of IOM, NIHN, WHO/FAO with or without Nordic Council that represented all INL_{98} ± RI estimated from balance studies.

All candidate DIRVs were above the UL but since the UL is based on fortificant and supplement forms only and not natural forms in food, the UL is not relevant in this context. Based on majority eWG support and the preference for a documented basis of the NRV-R, the recommendation is to revise the NRV-R to 310 mg.

RECOMMENDATION 8 – NRV-R for Magnesium

That CCNFSDU agrees to revise the NRV-R from 300 mg to 310 mg and based on average of IOM, NIHN, WHO/FAO ± Nordic Council (INL_{98} ± RI).

3.7 Phosphorus

The eWG considered the candidate DIRVs including the draft EFSA Scientific Opinion on Dietary Reference Values for Phosphorus. However, since the eWG's consideration, EFSA finalised its Scientific Opinion in late July and revised down the AI for adults from 700 mg to 550 mg.

The following table shows the eWG preferences including consideration of the draft EFSA opinion. Nearly all the eWG selected DIRVs in the range 700–800 mg represented by IOM, draft EFSA or an average based on INL_{98}. Rounding of averages was taken to the nearest 100 mg consistent with the smallest rounding of the original adult male and female DIRVs in the RASB reports.

Since the IOM and draft EFSA DIRVs were equivalent in value, a strong majority of the eWG preferred 700 mg without necessarily basing their preference on a particular RASB report or method of derivation. Where a basis was indicated, preference for the IOM DIRV was due to its status as INL_{98} whereas preference for draft EFSA DIRV was due to its very recent assessment. All candidate DIRVs were below the UL.

eWG preferences	RASB	INL_{98} or AI	Candidate DIRV (mg)
=1	IOM (United States & Canada)	INL_{98}	700
=1	EFSA (European Union) Draft only	AI	700
	NHMRC/MOH (Australia & New Zealand	INL_{98}	1000
	NIHN (Japan)	AI	950
	Nordic Council of Ministers	INL_{98}	600
2	Average of IOM, NHMRC/MOH, Nordic Council of Ministers	INL_{98}	(700 + 1000 + 600)/3 = 767 rounded to 800
	Average of IOM, NHMRC/MOH.	INL_{98}	(700 + 1000)/2 = 850 unrounded

Based on the level of eWG support prior to the release of the final EFSA report, the eWG's preference was to establish an NRV-R of 700 mg. The eWG did not support candidate DIRVs lower than 700 mg at the time.

RECOMMENDATION 9 – NRV-R for Phosphorus

On the basis of eWG consideration, that CCNFSDU agrees to establish a NRV-R of 700 mg and based on IOM.

3.8 Copper NRV-R

The eWG considered the candidate DIRVs and noted the draft EFSA Scientific Opinion on Dietary Reference Values for Copper may be adopted before the next session of CCNFSDU. The eWG noted CCNFSDU's convention to date of using the units *mg* > 1 mg and *µg* ≤ 1 mg for NRVs-R but also noted that the NRV-NCD for sodium was expressed as 2000 mg rather than 2 grams. All candidate DIRVs are expressed in their original units. Rounding of the average was taken to the nearest 100 µg consistent with the smallest rounding of the original adult male and female DIRVs in the RASB reports.

eWG preferences	RASB	INL_{98} or AI	Candidate DIRV (µg, or mg where shown)
=1	IOM (United States & Canada)	INL_{98}	900
	EFSA (European Union) Draft	AI	1.5 mg
	NHMRC/MOH (Australia & New Zealand)	AI	1.5 mg

eWG preferences	RASB	INL_{98} or AI	Candidate DIRV (µg, or mg where shown)
	NIHN (Japan)	INL_{98}	800
=1	Average of IOM, NIHN.	INL_{98}	(900 + 800)/2 = 850 rounded to 900
	Current NRV-R		*Value to be established*

The eWG supported DIRVs in the unrounded range 850–900 µg based on evidence from depletion/repletion studies. In the second round of consultation before release of the EFSA draft, the eWG strongly supported the IOM DIRV instead of the average of IOM and NIHN. The eWG considered the NRV-R for copper again in round 3 including the draft EFSA scientific opinion. This time, respondents (fewer than round 2) gave equal support to the IOM DIRV because it is an INL_{98} or to the average of IOM and NIHN as they are both INL_{98}. Overall, a narrow majority supported the IOM DIRV. It is recommended that the NRV-R for copper be established at 900 µg.

RECOMMENDATION 10 – NRV-R for Copper

That CCNFSDU agrees to establish a NRV-R of 900 µg and based on IOM.

3.9 Chromium NRV-R

eWG preferences	RASB	INL_{98} or AI or ND	Candidate DIRV (µg)
=1	IOM (United States & Canada)	AI	30
2	EFSA (European Union) or Nordic Council of Ministers	ND	Not determined due to insufficient data
=1	NIHN (Japan)	INL_{98}	35

The eWG strongly supported establishing a NRV-R for chromium and equally supported either of the two candidate DIRVs, one based on INL_{98} tentatively derived from the results of a balance test in the elderly (NIHN) and the other based on AI derived from a well-balanced, theoretical dietary intake at mean energy levels (IOM) because of insufficient experimental data on which to establish an INL_{98}. Given the tentative nature of the INL_{98} conclusion, it is recommended that an NRV-R based on the IOM DIRV be established.

RECOMMENDATION 11 – NRV-R for Chromium

That CCNFSDU agrees to establish a NRV-R of 30 µg and based on IOM.

3.10 Chloride NRV-R

In assessing candidate DIRVs for chloride, the eWG noted that only one candidate DIRV from IOM was available and the *Guidelines on Nutrition Labelling* had established a NRV-NCD for sodium at 2000 mg. A strong majority of the eWG preferred chloride units in milligrams because the NRV-NCD for sodium is expressed in milligrams.

The IOM established an AI for chloride (2300 mg) based on molar equivalence (65 mmol) with its AI for sodium (1500 mg) since dietary intake and systemic metabolism of chloride matches closely that of sodium and is interdependent with sodium. Furthermore, almost all dietary chloride accompanies the sodium added during processing or consumption of foods. Codex recently established a higher NRV-**NCD** for sodium at 2000 mg (87 mmol) based on WHO's recommendation. Applying the IOM rationale to Codex, the molar equivalent of the sodium NRV-NCD corresponds to 3100 mg chloride. This amount exceeds the UL for young children. However, the Codex sodium NRV-NCD also slightly exceeds the sodium ULs[4] for young children although there is no GP relating to exceedance of ULs for young children for NRVs-NCDs.

[4] IOM ULs for sodium 1-3 yrs: 1500 mg; 4-8 yrs: 1900 mg; IOM. ULs for chloride are given in section 2.

RASB	AI	Candidate DIRV (mg)	Basis
IOM (United States & Canada)	AI	2300 (65 mmol)	Equimolar with IOM sodium DIRV of 1500 mg
Equimolar NRV-R	N/A	3089 (87 mmol)	Equimolar with Codex sodium NRV-NCD of 2000 mg

In considering the way forward, the eWG considered whether a:

- NRV- R should established
- NRV-NCD should be established, either instead of NRV-R or in addition to NRV-R
- NRV should be based on molar equivalence with the NRV-NCD for sodium or not.

The Committee had previously considered the question of whether both types of NRV could be established for the same nutrient but no conclusion was reached (REP13/NFSDU, paragraph 77)[5]. In 2014, the Committee did not establish both types of NRV for potassium (only NRV-NCD) and also decided not to set a NRV-R for fluoride.

The eWG very strongly supported establishing a single NRV for chloride and evenly supported a NRV-R or NRV-NCD. However, determining a value for NRV-NCD is outside the eWG's terms of reference. Reasons for establishing a NRV-R are that it is the only option that reflects intake requirements; also, criteria for establishing a NRV-NCD were not met because a NCD endpoint specific to chloride intake was not identified. The reason for establishing a NRV-NCD was to maintain relativity with the sodium NRV-NCD consistent with IOM's rationale in setting its AI for chloride. It is noted that the NRV could still be established as NRV-R given that the IOM has set AIs for both sodium and chloride. A minority of eWG members who supported not setting a NRV were concerned that basing international NRVs-R on DIRVs with limited evidence might imply equivalent importance and rigour of evidence with other NRVs-R whose nutrients were of greater public health importance.

On a technical issue, the eWG noted that if equimolar NRVs for sodium and chloride were established based on the Codex sodium NRV-NCD, these two NRVs could sum to ~5.1 g, thus slightly exceeding the WHO recommendation of 5 g salt/day. The molar amount of 87 mmol corresponds to 2001 mg sodium and 3089 mg chloride respectively which then total 5.09 g salt. Conversely, the WHO recommendation of 5 g salt/day strictly comprises 1966 mg sodium and 3034 mg chloride. A footnote was suggested to explain this apparent discrepancy however, the chloride NRV-R could be rounded down to 3000 mg, thus the sodium and chloride NRVs would total 5 g salt and avoid the need for a footnote.

eWG preferences	RASB	AI	Candidate DIRV (mg)
=1	IOM (United States & Canada)	AI	2300 (65 mmol)
=1	Equimolar NRV-R with sodium NRV-NCD	N/A	3000 (~87 mmol)
2	Do not set NRV-R	N/A	N/A
=3	Set both NRV-R and NRV-NCD	N/A	N/A
=3	Await EFSA draft scientific opinion	N/A	N/A

Based on eWG considerations, it is recommended that a NRV-R for chloride be established based on either of the two proposed values.

[5] "The Committee agreed that whether NRVs could be established according to both dietary adequacy and reduction of risk of NCD would require further discussion at a later stage."

RECOMMENDATION 12 – NRV-R for Chloride

That CCNFSDU agrees to:

A establish a NRV-R for chloride

B select 2300 mg or 3000 mg and based on relevant rationale or RASB.

4 VITAMIN DIETARY EQUIVALENTS (TOR 2)

The eWG further considered the details of vitamin dietary equivalents (name, natural vitamin isomers, conversion factors) of the DIRVs for vitamin A and vitamin E (see Table 2C, Appendix 2), including whether these details should be those associated with the selected candidate DIRV(s) or should be determined independently. The eWG generally supported separate determination of the details of dietary equivalents from the value of the DIRV(s) that were selected as the basis of the NRV-R. Information on dietary equivalents is useful in determining the label declaration of vitamin content.

4.1 Vitamin A Isomers Occurring Naturally in Food

From the table below, there is international inconsistency in the alignment of the name and conversion factors of vitamin A dietary equivalents. Retinol Activity Equivalents (RAE) was devised by IOM to distinguish from previous use of older conversion factors to avoid confusion because Retinol Equivalents (RE) represented a different meaning of the vitamin A activity in fruits and vegetables. No other RASB has adopted that name. WHO uses RE in guidelines, including in their more recent publications e.g. WHO (2011a), (2011b). The eWG evenly supported the name RAE or RE. One member suggested that RAE could be adopted for more conservative factors (1:12:24) and RE for less conservative factors (1:6:12) in line with the general convention.

RASB	Name of Unit	Vitamin A isomer	Conversion factors
WHO/FAO (2004)	*Retinol Equivalent (RE)*	retinol β-carotene other provitamin A carotenoids	1 6 12
WHO/FAO (2006)	*Retinol Equivalent (RE)*	all-trans-retinol all-trans-β-carotene other provitamin A carotenoids	1 12 24
IOM (US & Canada)	*Retinol Activity Equivalent (RAE)*	all-trans-retinol all-trans-β-carotene other provitamin A carotenoids (α-carotene and β-cryptoxanthin)	1 12 24
EFSA (European Union)	*Retinol Equivalent (RE)*	retinol β-carotene other provitamin A carotenoids	1 6 12
NHMRC/MOH (Australia & New Zealand)	*Retinol Equivalent (RE)*	all-trans-retinol all-trans-β-carotene α-carotene, β-cryptoxanthin and other provitamin A carotenoids	1 6 12
NIHN (Japan)	*Retinol Equivalent (RE)*	retinol β-carotene α-carotene, β-cryptoxanthin and other provitamin A carotenoids	1 12 24
Nordic Council of Ministers	*Retinol Equivalent (RE)*	retinol β-carotene α-carotene, β-cryptoxanthin and other provitamin A carotenoids	1 12 24

A strong majority supported the conversion factors 1:12:24. On the other hand, EFSA noted the large uncertainty in establishing equivalence ratios from the whole diet of large populations and that current evidence was insufficient to amend conversion factors conventionally associated with RE. Three options were considered by the eWG and comments in support of them are shown in the next table.

eWG preference	Conversion factors	eWG comments
1	1:12:24	Adopted by several RASBs on the basis of a comparison of bioconversion of β-carotene from fruit and vegetables with β-carotene dissolved in oil in healthy populations.
3	1:6:12	Support based on recent EFSA research which reiterates that there is not enough evidence to support increasing the vitamin A ratios. It is premature to revise conversion factors prior to a clear statement from WHO/FAO as to the international applicability of RAE. Several RASBs: NHMRC, EFSA and WHO (2004) all stated that they would not amend the bio-equivalency ratios for β-carotene and other carotenes until more definitive research became available.
2	No total vitamin A; but declaration of retinol alone, or with carotenes	No general consensus in favour of one set or the other in food. Could consider declaring retinol and carotenes separately. Establish a retinol only NRV-R and further document the carotene content of food. EFSA noted that the extent of absorption of β-carotene in man reported in the literature varied between 10% and 90% and inter- and intra-variability in apparent absorption is rather high.

In relation to the term 'all trans' β-carotene, it was suggested that the simpler term β-carotene should be preferred to avoid practical problems associated with a dynamic interplay of isomers. The eWG was informed that β-carotene present in food is a dynamic mixture of the all-trans isomer and its geometric isomers, particularly 9-cis and 13-cis β-carotene. Since RASBs vary in their reference or otherwise to 'all trans' β-carotene, it is recommended that the simpler description be adopted as β-carotene and without reference to the trans isomer.

Given the diverse international, regional and national positions, it is recommended that both RAE and RE and their respective conventional conversion factors be listed in the Nutrition Labelling Guidelines as alternatives, to enable application of discretion as appropriate. This is consistent with the current text under the second table to paragraph 3.4.4.1 which indicates that this information provides supporting information for authorities to determine the application of NRVs-R at national level.

4.2 Vitamin A Isomers Added to Food

On the basis of relative molecular weights (retinol: 286.45; vitamin A acetate: 328.49; vitamin A palmitate 524.86), 1 µg retinol activity is equivalent to (or provided by):

- 1.15 µg all-trans-retinyl acetate
- 1.83 µg all-trans-retinyl palmitate
- 2 µg all-trans-β-carotene in oil as a supplement.

WHO (2006) notes that vitamin A acetate and vitamin A palmitate are the principal forms of commercially available vitamin A added to food in either oily or dry forms, and states that absorption of all these forms is good (around 90%). On this basis of eWG consideration, the suggested conversion factors for the acetate and palmitate isomers of vitamin A added to food is recommended. Since the conversion factor for β-carotene in oil as a supplement refers to 'all trans' and only 'in oil', it is recommended that this item be omitted.

The recommendations for naturally occurring and added forms of vitamin A are shown in the format of the second table to paragraph 3.4.4.1 of the Nutrition Labelling Guidelines.

Vitamin	Dietary equivalents	
Niacin etc	…..	……
Vitamin A occurring naturally in food	1 µg retinol activity equivalents (RAE) = **OR**	1 µg retinol 12 µg β-carotene 24 µg other provitamin A carotenoids
	1 µg retinol equivalents (RE) =	1 µg retinol 6 µg β-carotene 12 µg other provitamin A carotenoids
Vitamin A added to food	1 µg retinol =	1.15 µg retinyl acetate* 1.83 µg retinyl palmitate*

* calculated by stoichiometry from retinol

RECOMMENDATION 13 – Vitamin A Dietary Equivalents and Conversion Factors

That CCNFSDU agrees to:

A insert an entry for vitamin A in the second table to paragraph 3.4.4.1 of the *Guidelines on Nutrition Labelling*

B include both RAE and RE and their conventional conversion factors as alternative dietary equivalents for Vitamin A occurring naturally in food as discussed in section 4.1

C include two principal forms of retinol that are added to food as shown in section 4.2

D delete the * currently attached to vitamin A NRV-R and related footnote relating to declaration of β-carotene.

4.3 Vitamin E Isomers Occurring Naturally in Food

From the table below, there is no international consistency in the use of alpha tocopherol only or alpha-Tocopherol Equivalents (α-TE) and its conversion factors.

RASB	Name of Unit	Vitamin E isomer	Conversion factor
WHO/FAO (2004)	α-Tocopherol Equivalents	RRR-α-tocopherol (d-α-tocopherol) β-tocopherol γ-tocopherol α-tocotrienol β-tocotrienol	1 2 10 3.3 20
IOM (US & Canada); WHO/FAO (2006)	α-Tocopherol	RRR-α-tocopherol (also 2R-stereoisomers)	1
European Union	α-Tocopherol	RRR-α-tocopherol (also 2R-stereoisomers)	1
NHMRC/MOH (Australia & New Zealand)	α-Tocopherol Equivalents	RRR-α-tocopherol (d-α-tocopherol) RRR-β-tocopherol RRR-γ-tocopherol α-tocotrienol	1 2.5-4.0 10 2.5-3.3
NIHN (Japan)	α-Tocopherol	α-tocopherol	None specified
Nordic Council of Ministers	α-Tocopherol Equivalents (applies to supplements only)	RRR-α-tocopherol	1

A majority of the eWG supported identifying vitamin E as α-tocopherol rather than applying dietary equivalents. The eWG comments in support of either option are shown in the next table.

eWG preferences	Name of unit	eWG comments
2	α-Tocopherol Equivalents	Referred to the rat fetal resorption assay (1981) which determined that various forms of tocopherols and tocotrienols have different biological activities and also noted that the intake of total tocopherols (either weighted or unweighted) was greater than α-tocopherol alone.
1	α-Tocopherol	Of the 8 naturally occurring isomers (four tocopherols and four tocotrienols), only naturally occurring RRR-α-tocopherol and the 2R stereoisomers (synthetic forms) are maintained in the plasma.

On the basis of more recent evidence, it is recommended that the vitamin E unit is α-tocopherol.

4.4 Vitamin E Isomers Added to Food

Several forms of vitamin E (α-tocopherol) are added to foods and are listed below. These are based on the relative molecular weights of the various forms of α-tocopherol (RRR-α-tocopherol: 430.71; RRR-α-tocopheryl acetate: 472.74; RRR-α-tocopheryl palmitate: 530.78). Also, the *all-rac* forms comprising all 8 stereoisomers: (2R: RRR-, RSR- RRS-, RSS-; 2S: SRR- SSR-, SRS- SSS-) have double the values based on half the activity of RRR-α-tocopherol forms.

1 mg RRR-α-tocopherol activity is equivalent to (or provided by):

- 1.10 mg *RRR*-α-tocopheryl acetate
- 1.23 mg *RRR*-α-tocopheryl succinate
- 2.00 mg *all-rac*-α-tocopherol
- 2.20 mg *all-rac*-α-tocopheryl acetate
- 2.46 mg *all-rac*-α-tocopheryl succinate.

A majority of the eWG supported these conversion factors based on stoichiometry and, in relation to *all-rac* forms, that the 2S stereoisomers provide no vitamin E activity. An entry in the second table to paragraph 3.4.4.1 showing the proposed information similar to the entry for vitamin A is shown below. To limit the information to key examples, the *all-rac* information is limited to the tocopherol form only.

Vitamin	Dietary equivalents	
Niacin etc	…..	……
Vitamin E occurring naturally in food	1 mg α-tocopherol =	1 mg RRR-α-tocopherol (d-α-tocopherol) =
Vitamin E added to food	1 mg RRR-α-tocopherol =	1.10 mg *RRR*-α-tocopheryl acetate** 1.23 mg *RRR*-α-tocopheryl succinate** 2.00 mg *all-rac*-α-tocopherol (dl-α-tocopherol)***

** calculated by stoichiometry from RRR-α-tocopherol

*** conversion factor for all-*rac*-α-tocopherol based on half of activity of RRR-α-tocopherol

It is therefore recommended that these forms be also added to the second table to paragraph 3.4.4.1 in the *Guidelines on Nutrition Labelling*.

RECOMMENDATION 14 – Vitamin E Dietary Equivalents and Conversion Factors

That CCNFSDU agrees to:

A insert an entry for vitamin E in the second table to paragraph 3.4.4.1 of the *Guidelines on Nutrition Labelling*

B include α-tocopherol as the active form of vitamin E occurring naturally in food as shown in section 4.3

C include three common forms of vitamin E that are added to food as shown in section 4.4.

4.5 Format of Second Table to Paragraph 3.4.4.1

If recommendations #13 and #14 are agreed, the following revisions to the heading and footnote of the second table to paragraph 3.4.4.1 are proposed as shown.

Heading

Conversion factors for ~~niacin and folate~~ vitamin equivalents

Footnote

The conversion factors for vitamin equivalents in the Table provide supporting information ~~for national authorities~~ to enable **competent regional or** national authorities to determine ~~the~~ **appropriate** application of NRVs**-R** ~~at national level~~.

RECOMMENDATION 15 – Second Table Heading and Footnote

That CCNFSDU agrees to the proposed revisions in section 4.5 above.

5 INCLUSION OF DEFINITION OF RASB IN NUTRITION LABELLING GUIDELINES

The term Recognized Authoritative Scientific Body (RASB) is currently undefined and occurs several times in the General Principles. Now that the working definition of RASB is finalised, the eWG strongly supported including the definition in the Definitions section of the Annex to the *Guidelines on Nutrition Labelling* at new paragraph 2.5.

The proposed definition is based on the working definition agreed by CCNFDSU at its last session and slightly modified to include FAO and/or WHO within the scope of RASBs consistent with GP 3.1.2. It also adopts the following wording used in Definition 2.1: *as used in these Principles*.

> **2.5 Recognized Authoritative Scientific Body (RASB) as used in these Principles refers to FAO and/or WHO (FAO/WHO), or** an organization supported by a competent national and/or regional authority(ies) that provides independent, transparent*, scientific and authoritative advice on daily intake reference values through primary evaluation** of the scientific evidence upon request and for which such advice is recognized 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.
>
> ** Primary evaluation involves a review and interpretation of the scientific evidence to develop daily intake reference values, rather than the adoption of advice from another RASB.

RECOMMENDATION 16 – RASB Definition in *Guidelines on Nutrition Labelling*

That CCNFSDU agrees to insert the definition of RASB in the Annex to *Guidelines on Nutrition Labelling* at new paragraph 2.5.

6 RECORD OF DERIVATION OF NRVs-R

The eWG unanimously supported developing a record of the current revision of NRVs-R in Codex documentation, specifically in the Annex to the Nutrition Labelling Guidelines at new section 4.

The next table contains the details from this revision of NRVs-R: nutrient, NRV-R value and type, RASB source documents and associated CCNFSDU record of decision, including where a NRV-R was considered but not established e.g. fluoride. The NRVs-R are presented in the same order as the Nutrition Labelling Guidelines.

Derivation of NRVs-R

Nutrient	NRV-R	INL_{98}, AI, or both	RASB source documents for derivation of NRVs-R	CCNFSDU Report
Vitamins				
Vitamin A				
Vitamin D				
Vitamin C	100 mg	INL_{98}	Average EFSA (2013), NIHN	REP 15/NFSDU, 2014

Nutrient	NRV-R	INL_{98}, AI, or both	RASB source documents for derivation of NRVs-R	CCNFSDU Report
			(2013)	
Vitamin E				
Vitamin K	60 µg	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Thiamin	1.2 mg	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Riboflavin	1.2 mg	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Niacin	15 mg NE	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Vitamin B_6	1.3 mg	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Folate	400 µg DFE	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Vitamin B_{12}	2.4 µg	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Pantothenate	5 mg	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Biotin	30 µg	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Minerals				
Calcium	1,000 mg	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Magnesium				
Iron				
Zinc	11 mg, 14 mg	INL_{98}	iZiNCG (2004)	REP 15/NFSDU, 2014[1]
Iodine	150 µg	INL_{98}	WHO/FAO (2004)	REP 13/NFSDU, 2012
Copper				
Selenium	60 µg	INL_{98} and AI	Average IOM (2000), NHMRC/MOH (2006), EFSA (2014), NIHN (2013), Nordic Council (2013)	REP 15/NFSDU, 2014
Manganese	3 mg	AI	Average EFSA (2013), IOM (2001)	REP 15/NFSDU, 2014
Molybdenum	45 µg	INL_{98}	IOM (2001)	REP 15/NFSDU, 2014
Phosphorus				
Chromium				
Chloride				
Other				
Protein	50 g	INL_{98}	WHO/FAO (2007)	REP 14/NFSDU, 2013
Fluoride	Not established			REP 15/NFSDU, 2014

[1] Also footnote and dietary description

RECOMMENDATION 17 – RECORD of NRV-R DECISIONS

That CCNFSDU agrees to:

A record the details of all NRVs-R from this revision in the Annex to the *Guidelines on Nutrition Labelling*

B insert the table in section 6 into the Annex at new section 4 updated to include decisions from this session of CCNFSDU.

7 APPROACH TO ESTABLISH NRVS-R FOR OLDER INFANTS AND YOUNG CHILDREN (TOR3)

In accordance with eWG's 3rd term of reference, an approach was considered to establishing NRVs-R for labelling purposes for older infants and young children, aged 6–36 months for the same nutrients for which NRVs-R are established for the general population. The following sections consider the purpose of these NRVs-R, the population groups and their age ranges, calculation issues and the relative value of NRVs-R for older infants and young children compared with those for the general population.

7.1 Purpose of NRVs-R for Older Infants and Young Children in Codex Nutrition Labelling Guidelines

The eWG considered the purpose of establishing NRVs-R for older infants and young children for inclusion in the *Guidelines on Nutrition Labelling*. Establishing NRVs-R for older infants and young children would provide reference values to enable label declaration of protein, vitamin and mineral content expressed as a percentage NRV-R when present in amounts greater than 5% NRV-R (subparagraph 3.2.6.2) in a nutrition statement on general foods. One aspect for future consideration is whether the NRVs-R could be used for general foods for the population at large, or only for general foods for older infants and young children.

Two of the recently reviewed Codex standards for food for special dietary uses[6] for older infants and young children (*Standard for Processed Cereal-Based Foods for Infants and Young Children* (STAN 74-1981); *Guidelines for Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991) either apply or recommend that nutrition labelling be undertaken in accordance with the *Guidelines on Nutrition Labelling*. However, the Annex to the Guidelines for Formulated Complementary Foods lists reference nutrient intakes (INL_{98}) for young children for 22 vitamins and minerals, mostly from WHO (2004), for the purpose of guiding micronutrient composition. Since this Codex text recommends that labelling be in accordance with the *Guidelines on Nutrition Labelling*, it is unclear whether new NRVs-R for older infants and young children or the 22 reference values listed in the Annex should be, or could be, applied to nutrition labelling of these products. However, Section 10.2.3(c) of these Guidelines refers to vitamin and mineral declaration as "expressed in metric units". The other Codex standards for special dietary uses – Follow-Up Formula (STAN 156-1987) and Canned Baby Foods (STAN 73-1981) do not refer to the Guidelines on Nutrition Labelling although specific paragraphs deal with declaration of nutritional value, but none of them refer directly to NRVs.

The eWG noted that the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) indicate that nutrition (e.g. nutrient content) and health claims shall not be permitted on foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation (paragraph 1.4). There are no specific permissions for nutrition or health claims in the aforementioned four Codex standards for special dietary use. The general conditions for 'source' and 'high' content claims based on a respective minimum % NRV-R in these Guidelines would not apply to the aforementioned Codex standards for infants and young children, but could do so for any nutrition claims on food for infants and young children that are established in national legislation.

The eWG noted the usefulness of a future review of all relevant nutrition labelling provisions in the Nutrition Labelling Guidelines and Codex standards for foods for special dietary use for older infants and young children to clarify the appropriate use of NRVs-R developed for this age group.

7.2 Do Older Infants and Young Children Constitute One, Two or Three Groups?

Codex standards for foods for special dietary uses apply to one group of older infants *and* young children whereas generally traded foods may be labelled for older infants or for young children or both. The lower and upper bounds of age ranges for these two population groups in national or regional food regulations are not known and probably vary. The 2007 project document does not specify whether one set of NRVs-R should be applied to one group of older infants and young children, or as separate sets of older infants and of young children.

Based on the views of the eWG, it is anticipated that most internationally traded general products for this young age group are labelled for either older infants or young children. A strong majority of the eWG preferred separate sets of NRVs-R for each population group and questioned the usefulness of developing one set of NRVs-R for the combined group based on the differing nutritional needs of older infants and young children. In addition, combining the two groups into one age range was considered to be inappropriate and would confuse the basis of the NRV-R since DIRVs for older infants and for

[6] Food for special dietary uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological conditions and/or specific diseases and disorders and which are presented as such (*General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses* (CODEX STAN 146-1985)).

young children are based on different types of endpoints (dietary intake versus experimental data) and are generally established by RASBs as separate population groups.

Therefore NRVs-R for the combined group are not further considered.

7.3 Codex Age Ranges for Older Infants and Young Children

Since the eWG preferred to establish NRVs-R for both older infants and young children, the boundaries of each age group should be defined. For guidance, the age details in Codex standards and guidelines for special dietary uses for older infants and young children were consulted and are shown in the next table. The inclusion or exclusion of '36 months' (the first month after a child turns 3 years old) as the upper bound is not clear as the context of this term can be interpreted as 'up to and including' or 'up to and excluding'. For the purposes of this paper, this month is assumed to be excluded so that the oldest age within scope becomes <36 months. The eWG noted a possible inconsistency with the lower bound of the age range in the *Guidelines on Nutrition Labelling* which is given as **older than** 36 months.

Codex texts for special dietary uses	**Description of age groups**	**Minimum age**
Follow-up formula (STAN 156–1987)	Infant not more than 12 months Young children more than 12 months–up to 3 years (36 months) [23 month span]	For infants from the 6th month*
Processed cereal-based foods (STAN 74–1981 Rev.1-2006)	Infant not more than 12 months Young children more than 12 months–up to 3 years (36 months) [23 month span]	For infants from the age of 6 months
Canned baby foods (STAN 73–1981)	Infant not more than 12 months Young children more than 12 months–up to 3 years (months not given) [23 month span]	Infant's normal weaning period
Formulated complementary foods for Older Infants and Young Children (CAC/GL 8–1991 Rev 2013)	Older infant 6-12 months [7 month span] Young children more than 12 months–up to 3 years (36 months) [23 month span]	Table in Annex guides vits & mins composition ≥50% daily ration [INL_{98} for 1-3 yrs WHO/FAO (2004) or IOM (1997/2001).]

* = that is, from 5 months

An infant's youngest age is from birth but the age of introduction of follow-up formula or complementary foods varies, but is generally relevant to an older infant. The recently reviewed Guidelines on Formulated Complementary Foods appears to be the only Codex text that specifically defines the age of an *older* infant as a person from the age of 6 months and not more than 12 months.

Codex consistently defines an infant as not older than 12 months, and young children as more than 12 months so that a natural point of delineation between older infants and young children is at 13 months. The upper bound of the age of young children is not consistently expressed but is assumed to be consistently up to (but not including) 36 months (or <3 years).

The eWG supported consideration of the age ranges in the Guidelines on Formulated Complementary Foods as applicable to NRVs-R for general foods for older infants and for young children. However, before a final position was determined, the eWG also considered the DIRV age ranges and one member suggested that, if necessary, the age ranges in the Codex texts could be subsequently amended for consistency with the finally determined NRV-R age ranges.

7.4 Age Ranges for DIRVs

The accepted RASBs establish DIRVs for older infants and young children as shown in the next table.

RASB	**Older infant age range**	**Young children age range**
WHO/FAO	7-12 months [6-month span]	1-3 years [36-month span]
IOM (US & Canada)	7-12 months [6-month span]	1-3 years [36-month span]
EFSA (Europe)	7-11 months [5-month span]	1-3 years [36-month span] or 1-<3 years [24 month span], 3-<X years
NHMRC/MOH (Aust/NZ)	7-12 months [6-month span]	1-3 years [36-month span]
NIHN (Japan)	6-11 months [6-month span]	1-2 years [24-month span]; 3-5 years

RASB	Older infant age range	Young children age range
Nordic Council of Ministers	6-11 months [6-month span]	12-23 months [12-month span]; 2-5 years

Generally, there is no overlap in consecutive age ranges in the RASB reports beyond infancy e.g. 1–3 years; 4–8 years etc. thus indicating that each age range is inclusive. RASBs define the lower bound of the older infant age group as 6 or 7 months and the inclusive upper bound as 11 or 12 months. Even more variations occur in the names and age ranges of the next age group up as either toddlers, young children, or children; with age ranges (when expressed in years) as 1–<2 or 1–2 years; 1–3 or 1–<3 years; and followed by 2–5 or 3–5 years.

Although the age ranges of the two groups are generally discrete, 3 RASBs report the upper bound of the older infant age range as 12 months and the lower bound for the next age group up as 1 year. If these bounds are regarded as inclusive, consistent with the general interpretation of discrete age groups in these RASB reports, an anomalous one-month overlap occurs between 7–12 months and 1–3 years. This is because a child can be described as 12 months old up to 29 or 30 days after reaching 1 year of age.

Therefore, the age ranges defined in the Codex texts do not always align with the age ranges of DIRVs from accepted RASBs.

7.5 Alignment of DIRV Age Range with Agreed NRV-R Age Range for Older Infants

The Codex definition of older infants is 6–12 months whereas DIRVs apply to infants aged from 6 or 7 months. Moreover, the Codex definition spans 7 months whereas no DIRV spans 7 months; instead the span is 5 or 6 months. Where the age range or span of a DIRV for older infants differs from that agreed by CCNFSDU, the eWG considered two possible options:

1) the age range of all candidate DIRVs could be standardised to the agreed NRV-R age range

2) the slight differences in ages and span of candidate DIRVs could be accepted as originally reported so that no adjustment for age or span is made.

Option 1) Apply standardisation procedure

This option applies the same standardisation procedure (as applied to some general population DIRVs of various age ranges) to adjust all selected DIRVs from one RASB to represent the agreed NRV-R age range. The following is an example of DIRV standardisation for NRVs-R applicable to 6–12 months by adjusting a 6-month span to a 7-month span adding one month on to either end of the 6-month age range and using the DIRVs for iodine from RASBs having different age ranges.

If DIRVs from WHO/FAO; IOM; NHMRC were selected, the calculation would be

$$1/7 \times DIRV_{0\text{-}6 \text{ months (1 month span)}} + 6/7 \times DIRV_{7\text{-}12 \text{ months (6-month span)}}$$

If DIRVs from NIHN; Nordic Council were selected, the calculation would be

$$6/7 \times DIRV_{6\text{-}11 \text{ months (6-month span)}}) + 1/7 \times DIRV_{12\text{-}47 \text{ months (1 month span)}}$$

IOM
0–6 months 110 µg
7–12 months 130 µg
$NRV\text{-}R_{older\ infants}$ 1/7 x 110 + 6/7 x 130 = 890/7 = **127 µg**
Nordic Council
6–11 months 50 µg
12–23 months 70 µg
$NRV\text{-}R_{older\ infants}$ 6/7 x 50 + 1/7 x 70 = 370/7 = **53 µg**

Option 2) Do not standardise DIRVs

This option would select DIRVs for older infants without reference to particular age range or span based on a general understanding of the age of an older infant. This is a simpler approach that recognises the lack of precision of DIRVs around this age. Under this option, a DIRV for older infants aged 7–11 months could be adopted as the NRV-R for older infants defined as 6–12 months. In this case and using the examples above, the $NRV\text{-}R_{older\ infants}$ would be 50 µg or 130 µg. The differences between the two options for each RASB are insignificant. Not standardising also avoids the complexity of considering young infant DIRVs (to account for infants aged 6 months) which may be established separately for breastfed and formula-fed infants.

The eWG equally supported either option. Experience with NRVs-R for the general population suggests that a DIRV from one RASB or the average of DIRVs from several RASBs may be selected. Option 1 would become more even more complicated under an averaging arrangement.

Therefore, no standardisation procedure is proposed to be applied to DIRVs for older infants in light of lack of precision and calculation complexity.

7.6 Alignment of DIRV Age Range with Agreed NRV-R Age Range for Young Children

For young children, the Codex definition is taken as 13–35 months whereas DIRVs apply to young children from 12 or 13 months. Moreover, the Codex definition spans 23 months whereas the age ranges of DIRVs span one year, two years or three years across one or two DIRV age groups. The age ranges of DIRVs for young children span variable numbers of years and therefore DIRVs from the same RASB should be weighted according to contribution to total age range where necessary. This may be straightforward depending on which RASB is selected as a source of DIRVs. DIRVs from WHO/FAO, IOM, NHMRC/MOH, NIHN and most EFSA are established for 1–3 years (12–47 months) which can be applied without change to the smaller span of 13–35 months (23-months). However, DIRVs established by Nordic Council for 12–23 months need to account for a 12-month contribution from 2–5 years to represent the 13–35 months range. For the following example calculations, the age of 12 months can either be excluded because it has been assigned to older infants or ignored.

The following is an example of DIRV standardisation for NRVs-R applicable to 13–35 months by using DIRVs for iodine from Nordic Council

$11/23 \times DIRV_{13\text{-}23 \text{ months (11-month span)}} + 12/23 \times DIRV_{2\text{-}5 \text{ years (12-month span, 24--35 months)}}$

Nordic Council	
12–23 months	70 µg
2–5 years	90 µg
$NRV\text{-}R_{young\ children}$	$11/23 \times 70 + 12/23 \times 90 =$ **80.4 µg** rounded to **80 µg**

Given the small difference and uncertainty for DIRVs at this age, no standardisation procedure is proposed to be applied to candidate DIRVs for young children from Nordic Council.

7.7 Combining Different Types of DIRVs

DIRVs of different types could potentially be combined if averaging of candidate DIRVs from RASBs occurred. DIRVs for older infants are typically given as AIs whereas DIRVs for young children are given as AI or INL_{98} although a RASB usually adopts the same type of DIRV across the children's age groups. Older infant AIs are often based on dietary intake of breast milk and complementary food, but they can also be extrapolated from AIs of either younger infants or adults based on dietary intake or occasionally calculated from relevant physiological data. AIs for young children are similarly derived from dietary intake or extrapolated from reference values for other age groups. Occasionally, an older infant DIRV exceeds the DIRV for young children because a different derivation was applied.

The General Principles for the general population (section 1.5) are silent on whether averaging DIRVs could combine INL_{98} and AI, or AIs of different types. However, that approach is reflected in the stepwise approach (section 1.7) and was recently adopted for the selenium NRV-R for the general population, noting that the contributing AI was based on limited scientific data rather than on population dietary intake. The eWG considered the approach to deriving a NRV-R from more than one type of DIRV from these options:

- all types of DIRVs
- INL_{98} and AIs (limited scientific evidence)
- INL_{98} and AIs (dietary intake)
- AIs (limited scientific evidence) and AIs (dietary intake)
- none [i.e. only one type of DIRV as the basis of a NRV-R]
- case by case.

The majority of the eWG supported a case by case approach but some members also supported combining DIRVs based only on the same type of scientific information or physiological endpoint, that is either dietary intake or experimental data. Therefore, a case by case approach is proposed.

7.8 RASB Reports of DIRVs

The eWG considered the selection of candidate DIRVs that could be drawn from different RASB reports to contribute to NRVs-R for older infants and young children. It was noted that adult DIRVs for the same nutrient sometimes compared markedly from different RASBs although within one RASB report, the DIRVs usually change in a more graduated manner with increasing age. DIRVs for the same nutrient for older infants and for young children could be theoretically sourced from:

- any accepted RASB
- the same accepted RASB
- the same RASB as used to establish the NRV-R for general population for that nutrient.

DIRVs for the same nutrient selected from different RASBs may differ markedly in value. Depending on the particulars, this may result in a very wide or very narrow difference between the NRV-R for older infants and the NRV-R for young children and possibly the NRV-R for the general population. At the extreme, a NRV-R for older infants may even be higher than a NRV-R for young children.

The eWG considered the importance of maintaining an appropriate gradation between the NRVs-R for older infants and for young children. The eWG generally supported selecting appropriate DIRVs based on the best available evidence and potentially sourcing from any RASB report. With no constraints on the selection of candidate DIRVs, the amount of work to review the candidate DIRVs for both age groups could be considerably more than for the general population. However, it was pointed out that much of this work had already been completed in the consideration of follow-up formula. The eWG considered that there should be general coherence and congruency between NRVs-R for the same nutrient for the two age groups, but the need to maintain the same gradation as for DIRVs in one RASB report was of secondary importance.

Therefore, DIRVs for older infants and for young children could be selected from different accepted RASBs.

8 DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NRVS-R FOR OLDER INFANTS AND YOUNG CHILDREN

In accordance with the eWG's third terms of reference, General Principles have been drafted based on the General Principles for the general population (section 1.5) and incorporating the eWG's preferences as discussed in Section 7.

In summary, the considerations are:

- NRVs-R should be established separately for older infants and for young children but not for a combined group.
- For labelling purposes, the NRV-R age range for older infants is 6–12 months (7 month span) and the NRV-R age range for young children is 13–35 months (23 months span). These age ranges require no changes to the Codex standards for special dietary uses (except perhaps Follow-up formula). However consequential amendments should be made to revise 'older than 36 months' to '36 months and older' in paragraph 3.4.4, the Annex Preamble and GP 3.2.1.2 in the Nutrition Labelling Guidelines.
- DIRVs for the two population groups can be drawn from any of the accepted RASBs and considered on a case by case basis taking account of relevant considerations.
- A pragmatic approach is proposed in which DIRVs for population groups identified as older infants and as young children (irrespective of precise age range and span) are potentially considered to be the basis for NRVs-R without the need to weight the DIRVs to match the Codex age ranges.

A General Principle on comparison of older infant or young child DIRVs with younger age ULs, similar to that for general population NRVs-R, is not proposed because very few ULs have been set for younger infants. Furthermore, the significance of a NRV-R for older infants or young children that exceeds the UL of a young infant is not clear. This is because young infants are not recommended to be fed complementary foods or follow-up formula and the labelling of % contribution to the recommended intakes of older infants and/or young children of such foods is not relevant to young infants.

Therefore the Draft General Principles for NRVs-R for older infants and young children are presented below in the same format and based on similar wording to the General Principles for NRVs-R for the general population.

GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R FOR OLDER INFANTS AND YOUNG CHILDREN

X.1 Selection of population groups for NRVs-R [new heading]

NRVs-R should be established for older infants and for young children as defined in the Codex Nutrition Labelling Guidelines i.e. older infants 6-12 months; young children 13-<36 months.

X.2 Selection of Suitable Data Sources to Establish NRVs-R

X.2.1 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-R.

X.2.2 Relevant daily intake reference values (DIRV) that reflect recent independent review of the science, from recognized authoritative scientific bodies (RASBs) 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.

X.2.3 The DIRVs should reflect intake recommendations for older infants within an age range of 6–<13 months, and for young children within an age range of 1–<4 years.

X.3. Selection of Nutrients and Appropriate Basis for NRVs-R

X.3.1.1 The NRVs-R should be based on Individual Nutrient Level 98 (INL_{98}). In cases where there is an absence of, or an older, established INL_{98} for a nutrient for a specific sub-group(s), it may be appropriate to consider the use of other DIRVs that have been more recently established by RASBs. The derivation of these values should be reviewed on a case by case basis.

X.3.1.2 The older infant NRVs-R should be determined by selecting the most appropriate DIRV or an average of highly similar DIRVs for older infants.

X.3.1.3 The young children NRVs-R should be determined by selecting one or more appropriate DIRVs, combined or weighted where necessary, to reflect the age range for young children in X.1.

X3.1.4 DIRVs may be selected from any of the suitable data sources in X.2 to derive NRVs-R for older infants, and to derive NRVs-R for young children.

RECOMMENDATION 18 – Draft General Principles for NRVs-R for Older Infants and Young Children

That CCNFSDU agrees to the draft General Principles presented in section 8.

RECOMMENDATION 19 – Consequential amendments to age of general population in Nutrition Labelling Guidelines

Subject to agreement to Recommendation #18, that CCNFSDU agrees to revise 'older than 36 months' to '36 months and older' in paragraph 3.4.4, the Annex Preamble and GP 3.2.1.2.in the *Guidelines on Nutrition Labelling*.

CONCLUSION

This paper concludes consideration of all the NRVs-R (general population) for vitamins and minerals plus protein that commenced with CCNFDU's agreement to the 2007 project document (ALINORM 08/31/26, Appendix VII).

The Committee is **invited** to consider the recommendations 1 – 19 of the eWG presented above.

Appendix 1

Table 1: Male and Female INL_{98} or AI for Candidate DIRVs for Vitamins A, D and E, and 5 Minerals from Accepted RASBs including WHO/FAO

VITAMIN OR MINERAL (TYPE DIRV)	19-50 yrs	United States & Canada	European Union	Australia & New Zealand	Japan	Nordic Council of Ministers	WHO/FAO
Vitamin A (µg) (INL_{98})	Male	900	750	NPE	850	NPE	600
	Female	700	650		680		500
Vitamin D (µg) (INL_{98} or AI)	Male	15	N/A	5 (AI)	5.5 (AI)	10	5 (AI)
	Female	15		5 (AI)	5.5 (AI)	10	5 (AI)
Vitamin E (mg) (INL_{98} or AI)	Male	15	13 (AI)	10 (AI)	7 (AI)	10 (AI)	10 (AI)
	Female	15	11 (AI)	7 (AI)	6.5 (AI)	8 (AI)	7.5 (AI)
Iron (mg) (INL_{98} or INL_{95})	Male	8 (18%)	11 (16%) (INL_{95}) Draft	NPE	7.3 15%)	9 (15%)	9.1 (15%) 3.7 (10%)
	Female	18 (18%)	16* (18%) (INL_{95}) Draft		10.8* (15%)	15 (15%)	19.6 (15%) 29.4 (10%)
Magnesium (mg) (AI)	Male	410	350 (AI)	NPE	355	350 (?AI)	260
	Female	315	300 (AI		285	280 (?AI)	220
Phosphorus (mg) (INL_{98} or AI)	Male	700	700 (AI) Draft 550 (AI) Final	1000	1000 (AI)	600	N/A
	Female	700	700 (AI) Draft 550 (AI) Final	1000	900 (AI)	600	
Copper (µg or mg as shown) (INL_{98} or AI)	Male	900	1.6 mg (AI) Draft	1.7 mg (AI)	900	NPE	N/A

	Female	900	1.3 mg (AI) Draft	1.2 mg (AI)	700		
Chromium (µg) (AI)	Male	35	ND	NPE	40	ND	N/A
	Female	25			30		
Chloride (mg) (AI)	Male	2300	N/A	N/A	N/A	N/A	N/A
	Female	2300					

NPE DIRVs not derived by primary evaluation; N/A DIRV not available; ND DIRV not determined due to insufficient data

xx% % dietary absorption; * DIRV is for menstruating or premenopausal women, (19-50) yrs

Appendix 2

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

Assume all % values divided by 100 in calculations

	Physiological endpoint for EAR or choice of AI	**Reason for choice of endpoint(s)**	**Relevant parameters in calculation of EAR/AI**	**EAR and Coefficient variation; or AI** **Calculation EAR/AI**	**Year(s) evaluated (Year latest literature)**
Vitamin A					
United States & Canada	Amount of dietary vitamin A required to maintain a given body pool size in well-nourished subjects using the factorial calculation: (A x B x C x D x E x 1/F).	A daily vitamin A intake (EAR) can be determined that will assure vitamin A reserves cover increased needs during periods of stress and low intake.	A = % body vitamin A lost per day when on a vitamin A free diet B = minimum acceptable liver vitamin A reserve C = ratio of liver weight: body weight D = reference body weight (M or F) E = ratio of total body: liver vitamin A reserves F = efficiency of storage of ingested vitamin A.	EAR M; 625 µg; F 500 µg RAE 20% CV; INL_{98} rounded to nearest 100 µg. EAR (M) = 0.005 x 20 x 0.03 x 76 x 1.1 x 2.5 = 627 µg RAE EAR (F) = 0.005 x 20 x 0.03 x 61 x 1.1 x 2.5 = 503 µg RAE	1999–2001 (2000)

European Union	Concentration of 20 µg retinol/g liver is assumed to maintain adequate plasma retinol concentrations, prevent clinical signs of deficiency and provide adequate stores. Factorial approach using the calculation: A x B x C x D x 1/E x F x 10^3. This concentration is indicative of an adequate vitamin A status (or body pool) at which the different functions of vitamin A in the body can be fulfilled.	Plasma/serum retinol is under tight homeostatic control and does not reflect vitamin A intakes (or status) until body stores are very low (or very high). Measures of total body or liver content by stable isotope dilution methods have shown good correlations with habitual vitamin A intake, over a wider range of intakes.	A = target liver store B = body/liver retinol stores ratio C = liver/body weight ratio (%) D = fractional catabolic rate of retinol (%) E = efficiency of body storage (%) F = reference body weight (M or F)	EAR M; 570 µg; F 490 µg 15% CV; DIRV rounded to nearest 50 µg. EAR (M) = 20 x 1.25 x 0.024 x 0.007 x 1/0.5 x 68.1 x 10^3 = 570 µg after rounding EAR (F) = 20 x 1.25 x 2.4 x 0.7 x 1/0.50 x 58.5 x 10^3 = 490 µg after rounding	? - 2014 (2014)
Japan	Dietary intake required to maintain minimal hepatic vitamin A storage. Inadequate intake does not lead to decreased plasma retinol concentrations unless hepatic vitamin A storage is below 20 µg/g. Factorial approach using the calculation: A = B x C x 1/D x E.	Plasma retinol concentration cannot be used as an index of vitamin A status.	A = daily disposal amount /kg b wt B = minimum hepatic concentration (µg/g) C = liver weight (g/kg b wt) D = % body vitamin A stored in liver E = daily disposal rate	EAR M; 600 µg; F 483 µg 20% CV EAR = 20 x 21 x 1/0.9 x 0.02 = 9.3 µg/kg b wt x M or F b wt	2008–2009 (2008)
WHO/FAO	Minimum daily intake of vitamin A to prevent xerophthalmia in the absence of clinical or subclinical infection (4-5 µg/kg/day) proposing requirements of M, 300 and F, 270 µg/day.	RNI (Safe intake) defined as the average continuing intake of vitamin A required to permit Vitamin A dependent functions and to maintain an acceptable total body store of the vitamin (9.3 µg/kg/day)		EAR (back calculated from RNI, WHO/FAO (2006)) M; 429 µg; F 357µg 20% CV.	1998–2004 (1998)

Vitamin D					
United States & Canada	50 nmol/L is the serum 25(OH)D level that consistent with coverage of the requirements for nearly all adults, 19-50 years. Between 30 nmol/L and 50 nmol/L is consistent with maximal calcium absorption. DIRV based on these considerations as well as intake-serum response and accounting for uncertainties.	The requirement distribution based on serum 25(OH)D concentrations and the intake estimated to achieve such concentrations are the basis of the reference values assuming minimal sunlight exposure.	From regression curve of intake and serum level, 40 nmol/L 25(OH)D level is consistent with median requirements of adults, 19-50 years.	EAR M 10 µg; F 10 µg CV not applied	2009–2011 (2010)
Australia & New Zealand	The intake amount to maintain serum 25(OH)D at a minimum of at least 27.5 nmol/L in the absence of sunlight exposure.	27.5 nmol/L is the level necessary to ensure normal bone health in the absence of sunlight exposure.	Based on twice the median dietary intake of women whose serum 25(OH)D levels were at least 27.5 nmol/L in summer and winter. This estimate then doubled to cover needs of all adults regardless of sunlight exposure and data from women.	AI (see Table 1)	?–2005 (2005)
Japan	The intake amount to maintain serum 25(OH)D sufficiently high to maintain normal calcium availability and avoid elevation of serum PTH level in limited sunshine exposure.	50 nmol/L is considered necessary to avoid elevation of serum PTH level and a decrease in bone mineral density.	The median dietary intake of women 50-69 yrs whose average serum 25(OH)D was above 50nmol/L then applied to younger adult age groups.	AI (See Table 1)	2008–2009 (2008)
Nordic Council of Ministers	50 nmol/L is the serum 25(OH)D level that is used as an indicator of sufficient status. The risk of rickets increases with serum 25OHD concentrations below 50nmol/L.	The requirement distribution based on serum 25(OH)D concentrations and the intake estimated to achieve such concentrations are the basis of the reference values assuming minimal sunlight exposure in winter but some contribution from outdoor activities in summer.	From regression curve of intake in winter and serum level, 7.2 µg/day EAR would maintain a mean serum 25OHD concentration of about 50nmol/L 25OHD.	EAR M 7.5 µg; F 7.5 µg Based on supplement studies, INL_{98} set at 10 µg	?–2013 (2013)

WHO/FAO	The intake amount to maintain serum 25(OH)D at a minimum of at least 27.5 nmol/L in limited exposure to sunshine, skin pigmentation or other factors.	This level is the level necessary to ensure normal bone health in the absence of sunlight exposure or other factors.	Many studies had established 27.5 nmol/L as the lower limit of the normal range. The corresponding dietary intake was rounded then doubled to cover the needs of all individuals irrespective of sunlight exposure. These intakes previously given as AI were applied as RNI	EAR (not back calculated from RNI)	1998–2004 (1998)
Vitamin E					
United States & Canada	Erythrocyte fragility under conditions of induced vitamin E deficiency in humans. Vitamin E intakes sufficient to prevent in vitro H2O2 induced haemolysis. The biomarker was plasma α-tocopherol concentration that limited H2O2 induced haemolysis to 12% or less in 50% of the experimental population.	One of the few tests in which erythrocyte lysis has been correlated with a health deficit (decreased erythrocyte survival) that has been shown to be corrected by supplemental vitamin E.	Plasma tocopherol concentrations and in vitro H2O2 lysis of erythrocytes at those concentrations in men.	EAR M 12 mg; F 12 mg 10% CV	1996–2000 (1999)
European Union		Available data on markers of α-tocopherol intake/status/function, on α-tocopherol kinetics and body pools, on the relationship between PUFA intake and α-tocopherol intake/requirements can be used neither on their own nor in combination to derive the requirement for α-tocopherol in adults.	Observed dietary intakes in healthy population groups with no apparent α-tocopherol deficiency, suggesting current levels are adequate. Dietary intakes as α-tocopherol or α-TE based on approximate mid points of surveys.	AI (see Table 1).	? - 2015 (2014)
Australia & New Zealand	[Comments on IOM approach: Interpretation of data is problematic as data are dichotomous, not continuous thus preventing an accurate dose-response analysis. Changing the choice of cutoff makes a large difference to the estimated requirements.]	Therefore chose AI	Based on Median intake from 1995, 1997 national nutrition surveys in ANZ - with no apparent vitamin E deficiency.	AI (see Table 1).	?–2005 (2003)

Japan			Based on median of dietary intakes reported in 2005 and 2006 NHNS 18-29 yrs. These intakes are expected to yield blood α-tocopherol level > 12 µmol/L.	AI (see Table 1).	2008–2009 (2008)
Nordic Council of Ministers	[Comments on IOM approach: Study diets contained high amounts of corn oil estimated to provide linoleic acid at 11-12% energy (above most dietary recommendations).]	Therefore chose SCF recommendation	Based on SCF recommendation of 0.4 α-TE/g PUFA intake and an average PUFA intake of 5% energy.	EAR M 6 mg; F 5 mg ?30% CV (back calculated from EAR and INL_{98})	?-2013 (2012)
WHO/FAO	No DIRVs established in WHO/FAO (2004) but DIRVs are shown in Table 7.1 WHO/FAO (2006) of adult M 10 mg; F 7.5 mg without citation of source.		Assumed from WHO/FAO (2004) text that values are taken from an average of 'safe' dietary intakes approximating median intakes from UK and US of M 10 mg αTE and F 7.5 mg αTE (ave of 7mg UK; 8mg US).	EAR (back calculated from RNI) M 8 mg; F6 mg 15% CV (M) 10% CV (F)	1998–2004 (2002)

Table 2B: Supplementary Information: Fe, Mg, P, Cu, Cr, Cl

	Physiological endpoint for EAR	**Reason for choice of endpoint(s)**	**Relevant parameters in calculation of EAR/AI**	**EAR; Coefficient variation** **Calculation EAR**	**Yr(s) evaluated (latest Yr)**
1 Iron					
United States & Canada	Factorial modelling of factors: basal loss, menstrual loss, dietary absorption. Because distribution of iron requirement is skewed i.e. not normally distributed, the simple addition of requirement components is inappropriate. Monte Carlo simulation generated a large theoretical population for each factor. Median and 97.5th percentiles of each distribution used in calculation of EAR and RDA respectively.	Total need for absorbed iron can be estimated	Basal loss (median) (M) 1.08 mg (F) 0.896 mg; Menstrual loss (median) (F) 0.51 mg Dietary absorption (upper value) 18%	EAR M 6 mg; F 8.1 mg %CV not applied (RDA derived as 97.5th percentile distribution of iron requirements) EAR (M) = basal loss/absorption (F) = (basal loss + menstrual loss)/absorption	1998–2000 (2000)

	Physiological endpoint for EAR	**Reason for choice of endpoint(s)**	**Relevant parameters in calculation of EAR/AI**	**EAR; Coefficient variation** **Calculation EAR**	**Yr(s) evaluated (latest Yr)**
European Union (Draft)	Estimate of physiological iron requirement using whole body iron loss data derived from isotope studies (2009) in 29 men and 19 menstruating women.	This considered more accurate than combining all losses from the different routes and magnifying the uncertainty of estimate.	(M) 50th and 97.5th percentile model-based distribution of iron turnover and daily losses ~ 0.95 and 1.72 mg/day. Assumed serum ferritin 30 ug/L and associated with dietary absorption of 16%. (F) 50th and 95th percentile model-based distribution of iron losses ~ 1.34 and 2.80 mg/day. Assumed serum ferritin 30 ug/L and associated with dietary absorption of 18%.	EAR M 6 mg; F 7 mg	? (2014)

	Physiological endpoint for EAR	**Reason for choice of endpoint(s)**	**Relevant parameters in calculation of EAR/AI**	**EAR; Coefficient variation** **Calculation EAR**	**Yr(s) evaluated (latest Yr)**
Japan	Factorial calculation of factors: Basal loss (mostly faecal), menstrual loss, iron storage, dietary absorption.	Total need for absorbed iron can be estimated	Basal loss 0.96 mg/day for 68.6 kg extrapolated to B wt each sex using 0.75^{th} power of a B wt ratio. Menstrual loss 0.55 mg Dietary absorption 15%	EAR M 6.3 mg; F 8.8 mg (menstruation 19-50 yrs) 10% CV Basal loss (M) = 0.96 x $[B\ wt\ (M)/68.6)]^{0.75}$ Basal loss (F) = 0.96 x $[B\ wt\ (F)/68.6)]^{0.75}$ EAR (M) = basal loss (M)/absorption EAR (F) = (basal loss (F) + menstrual loss)/absorption	2008–2009 (2003)
Nordic Council of Ministers	Amounts needed to cover basic losses and growth for approximately 95% for the individuals. For women of childbearing age, amounts that meets the needs of approximately 90% or menstruating women	Iron needs for growth, basal losses, menstrual losses	Iron absorption of 15%	EAR M 7 mg; F 9 mg %CV not presented EAR=((need for growth+ median basal loss + median menstrual loss)/15)*100	?-2013 (2013)

	Physiological endpoint for EAR	**Reason for choice of endpoint(s)**	**Relevant parameters in calculation of EAR/AI**	**EAR; Coefficient variation** **Calculation EAR**	**Yr(s) evaluated (latest Yr)**
WHO/FAO	Because distribution of iron requirement is skewed for menstruating women i.e. not normally distributed, the simple addition of requirement components is inappropriate. Median and 95th percentiles of each distribution for losses used in calculation.	The RNIs are based on the 95th percentile of the absorbed iron requirements/dietary absorption.	Basal loss: (M) 1.05 mg (median); 1.37 mg (95th percentile) (F) 0.87 mg (median) + menstrual loss 0.48 mg (median); or 1.90 mg (95th percentile) Total absolute requirements: (M) 1.05 mg (median); 1.37 mg (95th percentile) (F) 1.46 mg (median); 2.94 mg (95th percentile) Selected dietary absorption 15% & 10%	EAR (Back calculated from RNI, males only) M 7.2 mg (15%); 10.8 (10%) 15% CV EARs cannot be calculated from RNIs for adult females 19-50 years because of the skewed distribution of requirements.	1998–2004 (1998)

2 Magnesium					
United States & Canada	Magnesium balance conducted 4 times in year-long study of young men and women. Average Mg intake for 5/9 young men and 3/8 young women were probably in Mg balance. Another study showed more positive balances for women at slightly higher intake than first study.	Balance studies of intake, urinary and stool excretion. Minimum criteria for study inclusion were either adaptation period of at least 12 days or a determination of balance while subject consumed self-selected diet.	Average intake, 5/9 men probably in balance 333 ± 120 mg (4.3 mg/kg) Average intake, 3/8 women in balance 239 ± 80/day mg (4.2 mg/kg) but another study showed somewhat more positive balances at average intake of 255 mg/day.	EAR M; 330 mg; F 255 mg 10% CV.	1995–1997 (1991
European Union	AIs for men and for women above 18 years based on observed intakes in healthy populations in the EU.	Recent pooled analysis of well-controlled balance studies in adults suggests that zero magnesium balance may occur at Mg intake of 165 mg/day. However, balance studies may also reflect adaptive changes before a new steady state is reached.	Considering the large differences in Mg intakes between men and women AIs set according to sex.	AI (see Table 1)	? 2014
Japan	Magnesium balance in Japanese subjects.		Magnesium balance of 4.5 mg/kg body weight in Japanese subjects	EAR M; 300 mg; F 240 mg 10% CV.	2008–2009 (2008)
Nordic Council of Ministers	Magnesium balance.	Mg research hampered by lack of good biomarkers of Mg status.		No EAR established. Assume AI. See Table 1.	?–2013 (2012)

WHO/FAO (2004)	For young children, derived from studies of Mg-potassium relationships in muscle and clinical recovery of young children rehabilitated from malnutrition with or without Mg fortification of therapeutic diets. Data for other age groups are more scarce and confined to Mg balance studies, some of which paid little attention to the influence of variations in dietary Mg content and of the effects of growth rate before and after puberty on the normality of Mg-dependent functions.	Makes greater allowance for developmental changes in growth rate and in protein and energy requirements.	Provisional estimates. Query whether other estimates are overestimated.	?	1998–2004 (1997)
3 Phosphorus					
United States & Canada	Average dietary intake required from a typical mixed diet to reach the lower point of the normal range of serum $P_{inorganic}$.	Relationship between serum $P_{inorganic}$ in those with adequate renal function and absorbed intake allows estimation of the intake associated with $P_{inorganic}$ values within the range typically considered normal.	Lower point of the normal range of serum $P_{inorganic}$ is 0.87 mmol/L. Assume absorption efficiency of 60-65%.The variance cannot be determined from available data, thus assume 10% CV.	EAR M; 580 mg; F 580 mg 10% CV	1995–1997 (1997)

European Union (Draft)	Derived as equimolar relationship between Ca and P given lack of consistent other evidence and that P and Ca are present in the body in approximately equimolar amounts.	Absence of suitable biomarkers of intake and status and data on balances studies and on P intake and health outcomes cannot be used for setting DIRVs.	The fractional absorption of P is higher compared to Ca but as absorption of both minerals may vary with age and other dietary components, the exact Ca to available P ratio cannot be determined and thus DRV based on equimolar Ca to P ratio observed in the body.	AI (see Table 1).	? – 2015 (2015)
European Union (Final)	Derived from lower bound of molar ratio Ca: P (1.4:1) in whole body noting DRV for calcium of 950 – 1000 mg depending on age +18 yrs. Lower bound accounts for higher P intakes in western diets.	No reliable biomarkers of intake status. Wide variation of dietary absorption and excretion losses so factorial approach unsuitable. Data on balances studies and on P intake and health outcomes cannot be used for setting DIRVs.	The fractional absorption of P is higher than that of Ca but as absorption and retention of both minerals cannot be determined, the AI based solely on the molar ratio Ca: P in the body.	AI (see Table 1).	? – 2015 (2015)
Australia & New Zealand	Average dietary intake required from a typical mixed diet to reach the lower point of the normal range of serum $P_{inorganic}$	CA:P ratio has little relevance in adults when assessing requirements. The ratio does not account for different bioavailabilities and adaptive responses of the 2 nutrients. Ca:P molar ratios of 0.08:2.4 had no effect on either Ca balance or absorption .	Assume absorption efficiency of 62.5%. %CV based on the increased intake required to raise serum $P_{inorganic}$ from lower end of normal range to 1 mmol/L, the fasting level attained by most well-nourished adults.	EAR M; 580 mg; F 580 mg 35% CV.	?–2005 (1997)
Japan			Median intake from 2005 and 2006 NHNS	AI (see Table 1).	2008–2009 (2008)

Nordic Council of Ministers	400 mg considered adequate to maintain plasma concentration of 0.8 mmol/L	SCF suggested that P intakes should correspond on a molar basis with Ca and therefore proposed AR 400 mg/day and PRI of 550/day.	Equimolar relationship calcium to phosphorus (40:30.9) is basic principle	EAR M; 450 mg; F 450 mg ?% CV	?–2013 (2013)
4 Copper					
United States & Canada	Combination of indicators in controlled depletion/repletion studies using specific amounts of copper in men or women.	If significant decreases in serum Cu, ceruloplasmin, superoxide, dismutase (SOD) on experimental diet and reversed with added copper, then diet was deficient and insufficient to maintain status. A lack of change in copper status indicates that the level of copper in the experimental diet is adequate to maintain status.	3 studies, M or F. Indicators included plasma and platelet Cu, ceruloplasmin, superoxide, dismutase (SOD).	EAR M; 900 µg; F 900 µg 15% CV.	1999–2001 (2000)
European Union (Draft)	No biomarkers of copper status are sufficiently robust to be used to derive requirements for copper. Significant limitations to copper balance studies such as possibly reflecting only adaptive changes before reaching a new steady state, or conditions for maintenance of nutrient stores for a given diet.	Although significant limitations to copper balance studies, they may be used together with observed dietary intakes to set DRVs.	Average copper intakes from 8 EU countries for M and non-pregnant F aged 18+ years, rounded up, and M consistent with finding of zero copper balance at 1.6 mg/day.	AI	?- 2015 2015

Australia & New Zealand	Small data sets were insufficient to set EAR		Based on highest mean adult intake from 1995 and 1997 national dietary surveys in Australia and New Zealand.	AI (see Table 1)	?–2005 (1999)
Japan	Saturation of biomarkers of copper status: plasma Cu, urinary Cu and salivary Cu and plasma CuSOD activity.		Minimal intake to achieve saturation of selected biomarkers as 0.72 mg/day (for males) and extrapolated by body weight (see Table 3) for females	EAR M 700 µg; F 600 µg 15% CV	2008–2009 (1998)
5 Chromium					
United States & Canada	Chromium potentiates the action of insulin. Essentiality demonstrated in TPN patients. Estimated intakes derived from the average amount of chromium/1000 kcal of balanced dietary and average energy intake.	Insufficient data to establish EAR. No national dietary intake data.	Mean of 22 model, well balanced adult diets. Mean Cr intake 13.4 µg/1000 kcal. Energy intake estimate M, 2,800 kcal/day; F, 1,850 kcal/day.	AI (see Table 1). M: 13.4 x 2,800 = 35 F: 13.4 x 1,850 = 25	1999–2001 (1999)

European Union	No mechanism or role in essential function substantiated.	Inconsistent results from animal deficiency studies; no evidence of essentiality in animal nutrition. Evidence from improvements in TPN patients were the most convincing but insufficient information on reversibility of any deficiency or dose response curve, thus EAR not appropriate. Since no difference in glucose metabolism of normoglycaemic subjects between placebo and Cr-supplemented periods and no evidence of beneficial effects of Cr intake in healthy subjects, AI also not appropriate.		Not determined	?–2014 (2014)
Japan	No means of determining metabolic balance of Cr in adults.		EAR tentatively based on the results of a balance test in the elderly in which a positive balance was observed in subjects whose average Cr intake of 12.8 µg /1,000 kcal and energy of physical level II.	EAR M 35 µg; F 25 µg 10% CV	2008–2009 (2001)

Nordic Council of Ministers	To be an essential nutrient Cr must have a specific role as an enzyme cofactor and deficiency should produce a disease or impairment of functions.	The lack of reliable biomarkers for Cr status combined with absence of clear-cut Cr deficiency considerations are the main reasons for the current uncertainties about the biological significance of Cr as an essential trace element.		Not determined	?–2013 (2012)
6 Chloride					
United States & Canada	Data are inadequate to set EAR.	AI for chloride set as a molar equivalent to IOM sodium recommendations since almost all dietary chloride comes with the sodium added during processing or consumption of foods. Chloride losses usually accompany sodium losses from the body.	AI for chloride equimolar to IOM sodium DIRV (1500 mg, 65 mmol) = 2300 mg (65 mmol).	AI (see Table 1).	?–2005 (2001)

Table 2C: Supplementary Information Vitamins A and E dietary equivalents

	Physiological endpoint for units of equivalents	**Relevant parameters in calculation of units of equivalents**	**Calculation of units of equivalents**	**Year(s) evaluated (Year latest literature)**
Vitamin A				
United States & Canada	1) Carotenoid:retinol equivalency ratio based on the amount of ingested low dose retinol or β carotene that corrected visual adaption to darkness in vitamin A deficient subjects. 2) Efficiency of relative absorption β carotene in oil and β carotene in mixed vegetable diet measured by increases in plasma β carotene [(5-26%) for individual vegetables. 3) Adjustment of absorption efficiency to account for 50% efficiency of dark green leafy veg *.c.f* orange fruits and veg, then offset by smaller contribution of β carotene from fruit than from vegetable sources.	1) Carotenoid:retinol equivalency ratio purified β carotene in oil of ~2:1. 2) Efficiency of relative absorption of β carotene in oil and β carotene in mixed vegetable diet (14%). 3) Adjustment of absorption efficiency $carotenoid_{veg}$:$carotenoid_{oil}$ from 7:1 (14%) to $carotenoid_{f\&v}$:$carotenoid_{oil}$ 6:1 (16%) accounting for orange fruit and veg and offset by smaller contribution of β carotene from fruit than from vegetable sources. 4) Equivalence of activity of other provitamin A carotenoids is 50% that of β carotene	1 µg RAE = 1 µg all-trans-retinol 2 µg supplemental all-trans-β-carotene 12 µg dietary all-trans-β-carotene 24 µg other provitamin A carotenoids	1999-2001 (1999)
European Union	Recent data (2012) shows β carotene absorption from plant sources range 5-65% and retinol equivalency ratios for β carotene ranged from 3.8:1 to 28:1 Confirmed greater retinol conversion from fruit than veg. High variability in retinol equivalency ratios from host-related or food-related factors. Data insufficient to support a change from previously stated equivalency.	1) Retinol equivalency ratio for low dose purified β carotene in oil is 2:1 2) Previously proposed efficiency of relative absorption of β carotene in oil and dietary β carotene (33%). 3) Equivalence of activity of other provitamin A carotenoids 30-50% activity of β carotene	1 µg RE = 1 µg retinol, 6 µg dietary-β-carotene, 12 µg other provitamin A carotenoids	? - 2014 (2012)

	Physiological endpoint for units of equivalents	Relevant parameters in calculation of units of equivalents	Calculation of units of equivalents	Year(s) evaluated (Year latest literature)
Australia & New Zealand	[Comments on IOM approach: The 14% adopted by the IOM is not appropriate for Australia New Zealand as green leaves are not an important contributor to dietary provitamin A. Carrots, 'other' fruiting vegetables and fruit are important. Hence, 14% absorption factor and 12:1 conversion factor, which is heavily influenced by the low absorption from spinach, to the whole Australian and New Zealand diet is not supported. Given these considerations the 6:1 factor for β-carotene and 12:1 factor for other provitamin A carotenoids was retained until more definitive data become available.]		1 µg RE = 1 µg retinol 6 µg dietary-β-carotene, 12 µg other provitamin A carotenoids	?-2005 (2000)
Vitamin E				
United States & Canada	Vitamin E forms are absorbed by the small intestine in chylomicrons but plasma concentration depends on the affinity for them by α-tocopherol transfer protein in the liver. Only the 2R stereoisomeric forms of α-tocopherol are preferentially secreted in VLDL into plasma; other forms such as a synthetic SRR α-tocopherol, or γ-tocopherol are poorly recognised by the transfer protein for secretion.	Of the 8 naturally occurring isomers, only α-tocopherol is maintained in the plasma. Of the synthetic forms, only the 2R stereoisomers (RRR-, RSR-, RRS-, RSS-) are maintained.	Not determined	1996–2000 (1997)
European Union	Only the naturally occurring RRR-α-tocopherol is considered to be the physiologically active vitamer, as blood α-tocopherol concentrations are maintained by the preferential binding of α-tocopherol transfer protein (α-TTP) compared to other tocopherols or tocotrienols.	Among chemically synthesized α-tocopherol forms, only 2R α-tocopherol stereoisomers were found to meet human nutrient requirements because the 2S stereoisomers present in all-rac α-tocopherol possess low affinity to α-TTP and are rapidly metabolized in the liver.	Not determined	? - 2015 (2014)

	Physiological endpoint for units of equivalents	**Relevant parameters in calculation of units of equivalents**	**Calculation of units of equivalents**	**Year(s) evaluated (Year latest literature)**
Australia & New Zealand	[Comments on IOM approach: α-TE should continue to be used for vitamin E, because it is premature to state that gamma (γ)-tocopherol, the other major tocopherol in foods, has no biological activity. Little is known about the exact biological functions of α-tocopherol, γ -tocopherol or other forms of vitamin E. γ-tocopherol is a commonly consumed component of the diet. All forms of naturally occurring vitamin E appear to be equally well absorbed and incorporated into chylomicrons. Plasma γ tocopherol concentrations are influenced by dietary intake and range from 5-20% of α-tocopherol concentrations despite the absence of a specific transport protein for γ-tocopherol. Moreover, there is evidence that γ-tocopherol is not inert, but has biological effects or is associated with reduced disease risk in humans.]		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	?-2005 (2003)
Nordic Council of Ministers	The naturally occurring form of α-tocopherol is RRR-α-tocopherol. Synthetic α-tocopherol (also known as all-rac-α-tocopherol or dl-α-tocopherol) contain an equal mixture of 8 different stereoisomers with equal antioxidative properties but only those with the 2R-configuration have biologically relevant activities.	Due to lower affinity that α-tocopherol transport protein has for 2S-isomers, the relative bioavailability of the synthetic form of all-rac -α-tocopherol is suggested to be only half that of the naturally occurring α-tocopherol. This means that only α-tocopherol in foods and 2R-α-tocopherols in vitamin E preparations contribute to vitamin E activity.	1 mg α-tocopherol = 1 mg RRR- and 2R-α-tocopherol 1.1 mg RRR-α-tocopherol acetate 2 mg all-rac-α-tocopherol 2.2 all-rac-α-tocopherol acetate	?–2013 (2013)

Table 3: Reference Body Weights published with DIRVS, Adults, 19-50 years

RASB (Age range (yrs))	Reference adult body weight (kg)			Basis
	Male	**Female**	**Mean**	
WHO/FAO (18+)	65	55	60	Based on (US) NCHS/CDC 1977 growth reference data (explanation given by IZiNCG)
IOM (USA & Canada) (19+)	76	61	64	Average body weights for 19-30 year olds from NHANES III corresponding to BMI (M) 24.4 (F) 22.8 kg/m^2
EFSA (European Union) (18-79)	68.1	58.5	63	Median body weight based on measured body heights and assuming BMI of 22 kg/m^2
NHMRC/MOH (Australia & New Zealand) (19+)	76	61	69	Average body weights for 19-30 year olds from Aust or NZ national health surveys: 1995, 1997, 2002
NIHN (Japan) (18-29/30-49)	63.5/68; [weighted mean 66.5]	50/52.7; [weighted mean 52.2]	59	Median body weights for 18-29/30-49 year old men and women from 2005 and 2006 National Health and Nutrition Surveys in Japan. Mean weight based on 19-50 yr age range.
Nordic Council of Ministers (18-30/31-60)	75.4/74.4 [weighted mean 74.8]	64.4/63.7 [weighted mean 64.0]	69	Reference weight corresponds to a body mass index (BMI) of 23 kg/m^2; data based on actual heights of populations in all Nordic Council of Ministers. Mean weight based on 19-50 yr age range.

Scaling (extrapolation) used to adjust DIRVs to reference body weights

RASBs sometimes applied scaling to convert male DIRVs to female DIRVs, or to adjust the results obtained from subjects of a certain body weight in experimental studies to reference body weights. Two scaling methods were used:

USA & Canada; European Union; Australia & New Zealand

Linear scaling: EAR (F) = EAR (M) x (Ref B wt F/Ref B wt M)

Japan

Because the efficiency of energy metabolism is highly correlated with body surface area, a formula estimating body surface from body height and/or body weight has been widely used to determine energy metabolism. Among the formulae developed to estimate body surface area from body height and/or weight, a formula developed in 1947 using the weight ratio to the 0.75^{th} power was used in determining the [Japanese] DRIs such that

$X = Xo * (W/Wo)^{0.75}$

where X is EAR or AI; Xo is reference value of EAR or A; W is reference body weight of the specific age group; Wo is the median or mean of body weight of group that provided EAR or AI reference value

Appendix 3

REFERENCES

Table 1: References for DIRVs, ULs and Dietary Descriptions

Nutrient (information)	Name of publication	Year Public-ation	Bibliographic Reference	Official Weblink
INTERNATIONAL: WHO/FAO or WHO				
Vitamins A, D, E, iron, magnesium (DIRV)	Vitamin and Mineral Requirements in Human Nutrition	2004	World Health Organization and Food and Agricultural Organization (2004) *Vitamin and Mineral Requirements in Human Nutrition,* 2nd edition. WHO, Geneva	whqlibdoc.who.int/publications/2004/9241546123.pdf
Vitamins A, D, E, iron, magnesium (Back calculated EAR) (iron dietary descriptions)	Guidelines on Food Fortification with Micronutrients	2006	World Health Organization and Food and Agricultural Organization (2006) *Guidelines on Food Fortification with Micronutrients*. WHO, Geneva	www.who.int/nutrition/.../guide_food_fortification_micronutrients,pdf
Copper (UL)	Trace Elements in Human Nutrition and Health	1996	World Health Organization and Food and Agricultural Organization and International Atomic Energy Association (1996) *Trace Elements in Human Nutrition and Health*. WHO, Geneva	whqlibdoc.who.int/publications/1996/9241561734_eng_fulltext.pdf

USA & CANADA				
Vitamin A, iron, copper chromium (DIRV, UL, Vit A units equivalents,)	Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium and Zinc.	2001	IOM (Institute of Medicine). 2001. *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium and Zinc.* Washington, DC: The National Academy Press.	http://www.nap.edu/catalog.php?record_id=10026
Vitamin D (DIRV, UL)	Dietary Reference Intakes for Calcium, and Vitamin D.	2011	IOM (Institute of Medicine). 2011. *Dietary Reference Intakes for Calcium and Vitamin D.* Washington, DC: The National Academies Press.	http://www.iom.edu/Reports/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D.aspx
Vitamin E (DIRV, UL, units equivalents)	Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids.	2000	IOM (Institute of Medicine). 2000. *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids.* Washington DC: National Academy Press.	http://www.nap.edu/catalog.php?record_id=9810
Magnesium, phosphorus (DIRV, UL)	Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride.	1997	IOM (Institute of Medicine). 1997. *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride.* National Academy Press.	http://www.nap.edu/catalog.php?record_id=5776
Chloride (DIRV, UL)	Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate.	2005	IOM (Institute of Medicine). 2005. *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate.* Washington, DC: The National Academies Press.	http://www.nap.edu/catalog/10925/dietary-reference-intakes-for-water-potassium-sodium-chloride-and-sulfate
EUROPEAN UNION				
Vitamin A (DIRV; units equivalents)	Scientific Opinion on Dietary Reference Values for Vitamin A	2014	EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. *Scientific Opinion on Dietary Reference Values for vitamin A*. EFSA Journal 2015;13(3):4028 doi:10.2903/j.efsa.2015.4028	http://www.efsa.europa.eu/en/efsajournal/pub/4028.htm

Vitamin E (DIRV; units equivalents)	Scientific Opinion on Dietary Reference Values for Vitamin E	2015	EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on Dietary Reference Values for vitamin E as α-tocopherol. EFSA Journal 2015;13(7):4149, 72 pp. doi:10.2903/j.efsa.2015.4149	http://www.efsa.europa.eu/en/efsajournal/pub/4149
Iron (Draft) (DIRV)	Draft Scientific Opinion on Dietary Reference Values for Iron	2015	EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. *Draft Scientific Opinion on Dietary Reference Values for Iron.* doi: 10.2903/j.efsa.20YY. NNNN	http://www.efsa.europa.eu/en/consultationsclosed/call/150526.htm
Magnesium (DIRV)	*Scientific Opinion on Dietary Reference Values for Magnesium*	2015	EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on Dietary Reference Values for magnesium. EFSA Journal 2015;13(7):4186, 63 pp. doi:10.2903/j.efsa.2015.4186	http://www.efsa.europa.eu/en/efsajournal/pub/4186
Copper, (Draft) (DIRV)	Draft Scientific Opinion on Dietary Reference Values for Copper	2015	EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. *Draft Scientific Opinion on Dietary Reference Values for Copper.* doi: 10.2903/j.efsa.20YY. NNNN	http://www.efsa.europa.eu/en/consultations/call/150629a.htm
Chromium (DIRV)	Scientific Opinion on Dietary Reference Values for Chromium	2014	EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. *Scientific Opinion on Dietary Reference Values for Chromium.* EFSA Journal 2014;12(10):3845, 25 pp. doi:10.2903/j.efsa.2014.3845	http://www.efsa.europa.eu/en/efsajournal/pub/3845
SCF/EFSA (UL)	Tolerable Upper Intake Levels for Vitamins and Minerals	2006	Scientific Committee on Food and European Food Safety Authority. 2006. *Tolerable Upper Intake Levels for Vitamins and Minerals*. EFSA, Parma	http://www.efsa.europa.eu/en/ndatopics/docs/ndatolerableuil.pdf

AUSTRALIA & NEW ZEALAND				
Vitamins A, D, E, iron, magnesium, phosphorus, copper, chromium (DIRV, Vit A & E units equivalents,)	Nutrient reference values for Australia and New Zealand	2006	*Nutrient Reference Values for Australia and New Zealand*; 2006; Australian Government Department of Health and Ageing, National Health and Medical Research Council; and New Zealand Ministry of Health; Canberra, Australia	http://www.nhmrc.gov.au/publications/synopses/_files/n27.pdf Evidence appendix - http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n37.pdf
JAPAN				
Vitamin A, D, E, iron, magnesium, phosphorus, copper, chromium (DIRV)	Dietary Reference Intakes for Japanese, 2010	2013	*Dietary Reference Intakes for Japanese, 2010*; 2013; Journal of Nutritional Science and Vitaminology vol. 59, supplement ISSN 0301-4800	https://www.jstage.jst.go.jp/browse/jnsv/59/Supplement/_contents
NORDIC COUNCIL OF MINISTERS				
Vitamin A, D, E, iron, magnesium, phosphorus, copper, chromium (DIRV, Vit E units of equivalents)	Nordic Nutrition Recommendations 2012 Integrating nutrition and physical activity	2013	Nordic Nutrition Recommendations 2012. Integrating nutrition and physical activity. ISBN 978-92-893-2670-4 All systematic reviews were published in Food & Nutrition Research Volume 57 (2013). Other background papers can be found on the Nordic Council of Ministers (NCM) website.	http://www.norden.org/en/publications/publikationer/2014-002

Table 2: Additional References

Information	Name of publication	Year Publication	Bibliographic Reference	Official Weblink
Reference body weights	*Requirements of Vitamins A, Iron, Folate, and Vitamin B_{12}*	1988	Food and Agriculture Organization (1988) *Requirements of Vitamins A, Iron, Folate, and Vitamin B_{12}.* Report of Joint FAO/WHO Expert Consultation. FAO, Rome	Not available
Reference body weights	*Scientific Opinion on Dietary Reference Values for Energy*	2013	EFSA Panel on Dietetic Products, Nutrition and Allergies (2013) Scientific Opinion on Dietary Reference Values for Energy. EFSA Journal, 11(1):3005, 112 pp	http://www.efsa.europa.eu/en/efsajournal/doc/3005.pdf
Vitamin A dietary equivalents	*Serum concentrations for determining the prevalence of vitamin A deficiency in populations.*	2011a	World Health Organization (2011a) *Serum concentrations for determining the prevalence of vitamin A deficiency in populations* Vitamin and Mineral Nutrition Information System. Geneva, WHO.	http://www.who.int/vmnis/indicators/retinol/en/
Vitamin A dietary equivalents	*Guideline. Vitamin A supplementation of infants and children 6-59 months of age.*	2011b	World Health Organization (2011b) *Guideline. Vitamin A supplementation of infants and children 6-59 months of age.* Geneva, WHO.	http://www.who.int/nutrition/publications/micronutrients/guidelines/vas_6to59_months/en/