



JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-fourth Session

Dresden, Germany

REPORT OF THE PHYSICAL WORKING GROUP ON THE DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES (NRVS-R) FOR PERSONS AGED 6 – 36 MONTHS

1 October 2024

(Prepared by the Physical Working Group chaired by Ireland and co-chaired by the USA and Costa Rica)

Introduction

1. The Physical Working Group (PWG) met on 1st October 2024 prior to the 44th session of the CCNFSDU. The focus of the working group was to discuss the proposed revisions outlined in CRD06:

- i. Agree on the text in [] in the General Principles for NRVs-R.
- ii. Agree and Finalise the Revised Stepwise Process.
- iii. Consider and recommend NRVs-R for persons aged 6–12 months, 12–36 months and 6–36 months resulting from the stepwise process.

Summary of the PWG discussion and recommendation:

2. The PWG Chair explained data from 2020 NIH data had been included and analyzed. The analysis assumed that the derivation method was the same as in the previous report. The analysis showed that inclusion of the updated NIH data did not change proposed NRVs-R values.

3. The PWG agreed with Recommendation 1.

Recommendation 1.

The tables in the 2021 FAO Report (updated with new NCM DIRVs) will be updated further with the new NIH data.

*This requires further information from NIH on the derivation of the new values.

4. The PWG agreed that the Committee would reconsider any NRVs-R that changed based on new information on the derivation of the NIH values.

Summary of the PWG discussion and recommendation 2 (see Appendix I):

5. The PWG widely agreed to include the definition for Adequate Intake submitted by FAO/WHO. An observer suggested adding “or insufficiency” at the end of the definition. The WHO clarified that Adequate Intake is not based on insufficiency. The PWG agreed with Recommendation 2.

Recommendation 2.

The PWG recommends that the Committee adopt the definition of Adequate Intake currently in square brackets.

[Adequate intake (AI)] is a reference value for a specified population based on observed or experimentally determined approximations or estimates of nutrient intakes by a group (or groups) of presumably healthy people with no known evidence of deficiency.]

Summary of the PWG discussion and recommendation 3 (see Appendix I):

6. The Chair proposed adding a sentence in the beginning of the square brackets to clarify that 3 sets of values will be derived from suitable data sources. Many members expressed agreement. The PWG discussed the text and agreed on the text in Recommendation 3.

7. The PWG considered 3 options for establishing NRVs-R for the combined age group: the higher value,

the lower value, and the mean of the 2 values. The PWG discussed the merits of each option. A new option was proposed, if there is no UL available for older infants or young children, but a UL exists for another age range, the combined value will be calculated by averaging the NRVs-R for the two age groups. If no UL exists for any age range, the highest NRV-R value of older infants and young children will be selected.

8. The PWG agreed to adopt option 3, the mean value. The PWG agreed to remove [] in Recommendation 3 below:

Recommendation 3.

The PWG recommends that the Committee adopt the text:

[NRV-Rs should be derived for persons aged 6-12 months and 12-36 months from suitable data sources according to 3.1 and the appropriate basis described above. The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.]

Summary of the PWG discussion and recommendation 4 (see Appendix II):

9. The PWG Chair proposed edits to the Stepwise process in Appendix II, Figure 1, CRD 06 at Step 1, 3A and 4.

- Step 1 - One member suggested that Step 1 could flow into Step 4 in the stepwise process flow diagram to allow for flexibility in clarifying values from FAO/WHO. The Chair amended Step 1 to allow the Committee to seek clarification from WHO/FAO on the new values selected in Step 1. There was agreement that the revision to step 1 was not intended as a scrutinizing step but rather as a clarification step. The PWG agreed to the edits to Step 1 in Recommendation 4 below.
- Step 3A - One member noted that the mean is preferred over the median. The PWG discussed how to consider the 2004 FAO/WHO values. The PWG agreed to edit Step 3.A to be consistent with Step 3B and 3C.
- Step 4 - The PWG widely supported the addition of Step 4. The PWG discussed how and where to consider recent reports. Members supported including consideration of health-based guidance values (HBGV) for nutrients in Step 4. The Chair clarified that the term “all evidence” includes HBGV and confirmed that they were already considered when available. The PWG agreed on Step 4 in Recommendation 4 below.

10. The PWG presented Steps 5 and 6. There were no objections by the PWG for Steps 5 and 6.

11. A member noted that Appendix II, Table 1 had not been discussed by the PWG. The Chair agreed and noted that Table 1 can be discussed at plenary.

12. The Committee agreed to adopt the Stepwise Process with revised Step 1, revised Step 3A, and Step 4.

Recommendation 4.

The Updated Revised Stepwise Process outlined in Appendix II, Figure 1 CRD06 with the revised Step 1, revised Step 3A and Step 4 be adopted.

Step 1 – Identify new or updated DIRVs from FAO/WHO for older infants and young children. Clarify DIRVs with FAO/WHO if needed and select for establishing NRVs-R.

Step 3.A.- Select FAO/WHO if available and same as median of DIRVs from RASBs based on physiological evidence. If not - select the median of available data based on physiological evidence (RASBs+/- FAO/WHO) as the NRVs-R for each nutrient for persons 6 –12 months and 12 –36 months.

Step 4 - All proposed NRV-Rs established in Step 3, are **reviewed on a case-by-case basis**. Proposed NRVs-R for all nutrients for persons 6-12 months and 12-36 months are checked considering **scientific rigor of the methods, underlying data and data quality, and all available evidence**. If necessary, proposed NRVs-R are amended/adjusted.

Summary of the PWG discussion and recommendation 5 (see Appendix III):

13. The PWG Chair presented the ‘Green Light’ nutrients to the PWG. A member proposed moving iron and vitamin E to the ‘Amber Light’ group. The PWG discussed Vitamin E and noted that the conversion factors of vitamin equivalents are addressed in the Guidelines on Nutrition Labelling (CXG 2-1985) and that according to the Advisory Lists on nutrient compounds only α -Tocopherol can be used (CXG-10 1979). The PWG agreed

to recommend adopting NRVs-R using Approach 1 for the 'Green Light' nutrients (Vitamin A, Vitamin E, thiamin, riboflavin, niacin, vitamin B-6, iodine, potassium, and protein). The PWG agreed to move iron to the 'Amber Light' list. The PWG Chair asked, "Do you realize that this is a moment?" The PWG applauded in agreement.

14. The PWG Chair discussed how 4 nutrients (pantothenic acid, magnesium, copper, vitamin B12) were considered under step 4. The PWG agreed to recommend to adopt NRV-Rs for pantothenic acid using Approach 1 for older infants and Approach 2 for young children and Copper using Approach 2 for older infants and Approach 1 for young children).

15. The PWG agreed to discuss Magnesium and Vitamin B12 at plenary.

16. The PWG agree to Recommendation 5 below.

Recommendation 5.

The PWG recommends that the Committee adopt the:

- a. NRVs-R listed as 'Green Light' (vitamin A, vitamin E, thiamin, riboflavin, niacin, vitamin B6, iodine, potassium, protein, pantothenic acid, copper) be adopted for Older Infants (6-12 months) and Young Children (12-36 months).
- b. Combined NRVs-R for 6-36 months listed as 'Green light' (vitamin A, vitamin E, thiamin, riboflavin, niacin, vitamin B6, iodine, potassium, protein, pantothenic acid, and copper) be adopted.
- c. NRVs-R listed as 'Amber Light' in Tables 3 and 4a and 4b in Appendix IV be carried forward for deeper review by an EWG, with addition of iron.

Summary of the PWG discussion and recommendation:

17. A member noted that the PWG did not discuss rounding. The PWG Chair confirmed that rounding will be discussed with the Committee at plenary.

Revised proposed text for the Draft General Principles following PWG (*note: new text is underlined, and older text crossed out*)

1. PREAMBLE

These Principles apply to the establishment of Codex Nutrient Reference Values-Requirement (NRVs-R) for persons aged 6–36 months. These values may be used in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6–36 months to help consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products.

Governments are encouraged to use the NRVs-R, or alternatively, consider the suitability of the general principles below including the level of evidence required, and additional factors specific to a country or region in establishing their own NRVs-R. In addition, governments may establish NRVs-R for food labelling that take into account country or region-specific factors that affect nutrient absorption, utilization, or requirements. Governments may also consider whether to establish separate or combined food label NRVs-R for specific segments of persons aged 6–36 months.

2. DEFINITIONS AS USED IN THESE PRINCIPLES

Daily Intake Reference Values (DIRV) refer to reference nutrient intake values provided by FAO/WHO or recognized authoritative scientific bodies that may be considered in establishing an NRV for persons aged 6–36 months based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g., as single values or a range), and are applicable to persons aged 6–36 months or to a segment of this age group (e.g. recommendations for a specified age range).

Individual Nutrient Level 98 (INL98)¹ is the daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in the population aged from 6 to 36 months.

Adequate intake (AI) is a reference value for a specified population based on observed or experimentally determined approximations or estimates of nutrient intakes by a group (or groups) of presumably healthy people with no known evidence of deficiency.

Upper Level of Intake (UL)² is the maximum level of habitual intake from all sources of a nutrient judged to be unlikely to lead to adverse health effects in persons aged 6 to 36 months.

Other than FAO and/or WHO (FAO/WHO), a Recognized Authoritative Scientific Body (RASB) refers to 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.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R

3.1 Selection of suitable data sources to establish NRVs-R

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-R.

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

The daily intake reference values should reflect intake recommendations for persons aged 6 to 36 months.

¹ Different countries may use other terms for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), or Population Reference Intake (PRI).

² Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range

3.2 Appropriate Basis for Establishing NRVs-R

Ideally, the NRVs-R should be based on Individual Nutrient Level 98 (INL98). In certain cases, where there is an absence of, or an older, established FAO/WHO DIRV for a nutrient, it may be more 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.

Nevertheless, the derivation of these values from recognized authoritative scientific bodies, shall take into account the following elements: the rigour of scientific methods, the underlying data quality, the strength of evidence used to establish these values and the most recent independent review of the science.

~~[The combined NRV-R value for persons aged 6–36 months should be determined by selecting the higher value of the proposed NRVs-R for older infants and young children as long as it does not exceed the UL for older infants and/or young children, where available.]~~

OR

~~The combined NRV-R value for persons aged 6–36 months should be determined by selecting the lower value of the proposed NRVs-R for older infants and young children.~~

OR

NRV-Rs shall be derived for persons aged 6-12 months and 12-36 months from suitable data sources according to identified in 3.1 and the appropriate basis described above. The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.}

3.3 Consideration of Upper Levels of Intake

The establishment of NRVs-R for persons aged 6 to 36 months should also take into account upper levels of intake (UL) established by FAO/WHO or recognized authoritative scientific bodies where/if available.

Updated Revised Stepwise Process

Figure 1: Schematic Outline of Updated Revised Stepwise Process for establishing NRVs-R for persons aged 6-36months with agreed changes following the PWG

Updated Revised Stepwise Process for establishing NRVs-R for persons aged 6-36 months

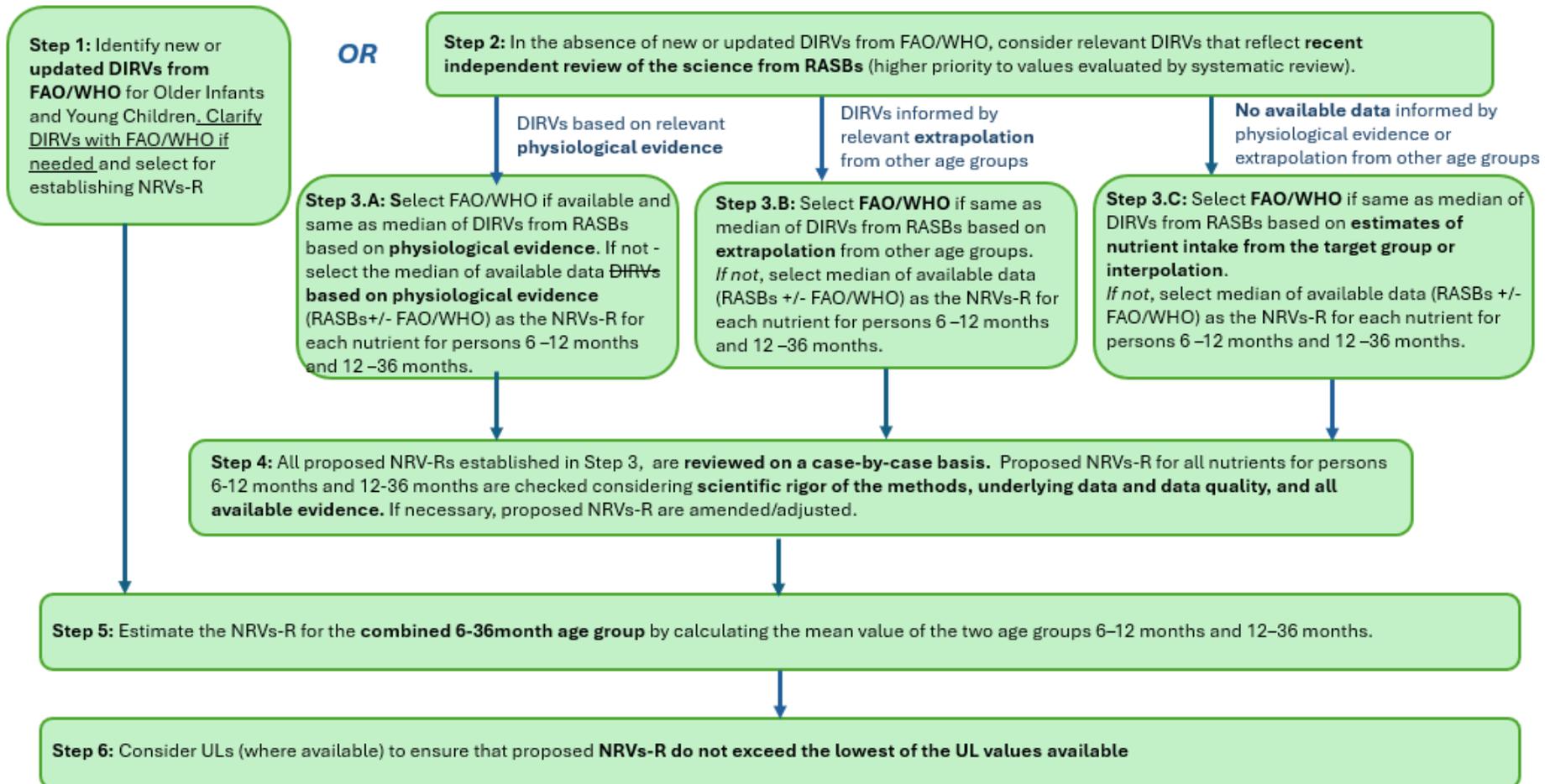


Table 1: Text of Updated Revised Stepwise Process (changes are in **bold/underlined** or ~~strikethrough~~ mode) to be discussed at plenary.

Stepwise Process

Step 1: Identify new or updated daily intake reference values (DIRVs) from FAO/WHO for older infants and young children and select for establishing NRVs-R.

Step 2: Aligned with General Principle 3.1, when updated DIRVs have not been established by FAO/WHO for the nutrients relevant DIRVs that reflect recent independent review of the science from RASBs can be considered, with higher priority given to values where evidence has been evaluated by a systematic review.

Step 3: In the absence of updated daily intake reference values (DIRVs) from FAO/WHO, the establishment of the NRVs-R should involve consideration, on a case-by-case basis, of the derivation of DIRVs more recently established by RASBs along with existing data from FAO/WHO. This assessment shall take account of the rigour of scientific methods, the underlying data quality and strength of evidence used to derive the DIRVs in these data sources. DIRVs are selected based on the totality of this evidence as NRVs-R in the following priority order:

A. To be applied when DIRVs informed by relevant physiological evidence are available

DIRVs informed by relevant physiological evidence from the target group are selected to establish NRVs-R for persons aged 6–36 **12 months and 12-36 months**. In cases where this includes the FAO/WHO DIRV, this is selected for the establishment of NRVs-R for persons aged 6–36 **12 months and 12-36 months**. In cases where this does not include the FAO/WHO DIRV, the median of the DIRVs from the RASBs is determined and selected to establish NRVs-R for persons aged 6–36 **12 months and 12-36 months**. **In the absence of DIRVs informed by relevant physiological evidence, go to Step 3 B.**

B. To be applied when ~~there are no~~ DIRVs informed by relevant physiological evidence extrapolation from other age groups are available

DIRVs informed by extrapolation of DIRVs from other age groups are selected to establish NRVs-R for persons aged 6–36 **12 months and 12-36 months**. Suitable DIRVs are selected by considering how the original DIRVs established for these other age groups are derived.

B.1. If the FAO/WHO DIRV and the median of the RASBs DIRVs are the same, the FAO/WHO DIRV is selected for the establishment of NRVs-R for persons aged 6–36 **12 months and 12-36 months**.

B.2. If the FAO/WHO DIRV and the median of the RASBs DIRVs are not the same, a new median of the DIRVs from the FAO/WHO and relevant RASBs is calculated and selected for the establishment of NRVs-R for persons aged 6–36 **12 months and 12-36 months**.

B.3. If the FAO/WHO DIRV is not included, the median of the DIRVs from the RASBs is selected for the establishment of NRVs-R for persons aged 6–36 **12 months and 12-36 months**.

C. To be applied when there are no DIRVs informed by either relevant physiological evidence or extrapolation from other age groups available

DIRVs informed by estimates of nutrient intake from the target group or interpolation, are selected to establish NRVs-R for persons aged 6–36 **12 months and 12-36 months**.

C.1. If the FAO/WHO DIRV and the median of the RASBs DIRVs are the same, the FAO/WHO DIRV is selected for the establishment of NRVs-R for persons aged 6–36 **12 months and 12-36 months**.

C.2. If the FAO/WHO DIRV and the median of the RASBs DIRVs are not the same, a new median of the DIRVs from the FAO/WHO and relevant RASBs is calculated and selected for the establishment of NRVs-R for persons aged 6–36 **12 months and 12-36 months**.

Step 4: **All proposed NRV-Rs established in Step 3, are reviewed on a case-by-case basis. Proposed NRVs-R for all nutrients for persons 6-12 months and 12-36 months are checked considering scientific rigor of the methods, underlying data and data quality, and all available evidence. If necessary, proposed NRVs-R are amended/adjusted.**

Step 5: Estimate the NRVs-R for the combined 6–36month age group according to the ~~three options outlined below:~~

~~Option 1: The combined NRV-R value for persons aged 6–36 months should be determined by selecting the higher value of the proposed NRVs-R for older infants and young children if it does not exceed the UL for older infants and/or young children, where available.~~

~~Option 2: The combined NRV-R value for persons aged 6–36 months should be determined by selecting the lower value of the proposed NRVs-R for older infants and young children.~~

~~Option 3: The combined NRV-R value for persons aged 6–36 months should be determined by calculating the mean value of the two age groups 6–12 months and 12–36 months.~~

~~The three optional NRVs-R for the combined age group (6–36 months) are considered relative to the NRVs-R established for the two age groups (6–12 months and 12–36 months) and any UL where available.~~

~~Option 1 (selecting the higher value of the proposed NRVs-R for older infants and young children that does not exceed the UL for either age group) as the NRV-R for the combined age range 6–36 months is selected.~~

Step 6: Consideration of ULs (where available) is given to ensure that the proposed NRVs-R do not exceed the lowest of the UL values available.

Appendix III

Table 1: 'Green Light' NRVs-R for nutrients not affected by changes due to NIHN (2020).

Nutrient	Older Infants (OI) 6-12months	Young Children (YC) 12-36months	6–36-month age group
Vitamin A (µg)	250	300	275
Thiamin (mg)	0.3	0.5	0.4
Riboflavin (mg)	0.4	0.6	0.5
Vitamin B ₆ (mg)	0.3	0.6	0.4
Protein (g)	11.3	12.5	11.9

Table 2: 'Green Light' NRVs-R for nutrients with minor changes due to NIHN (2020)

Nutrient	Older Infants (OI) 6-12months	Young Children (YC) 12-36months	6–36-month age group
Vitamin E (mg)	5	7	6
Niacin (mg)	4	6	5
Pantothenic acid (mg)	3	3 ³	3
Copper	220 ⁴	300	260
Iodine (µg)	78	95	86
Potassium (mg)	725	850	788

³ Approach 2 (all RASBs) used⁴ Approach 2 (all RASBs) used

Table 3: 'Green Light' NRVs-R requiring amendment at Step 4 requiring further discussion at plenary.

Nutrients	Older Infants (OI) 6-12months			Young Children (YC) 12-36months			
	Approach 1 Med (Mean) % difference	Approach 2 Med (Mean) % difference	Notes on Older Infants (6- 12months)	Approach 1 Med (Mean) % difference	Approach 2 Med (Mean) % difference	% Difference App 1 vs App 2 Med	Notes on Young Children (12- 36months)
Vitamin B₁₂ (µg)	1.5 (1.2) 20% diff. Deeper review identifies more recent data influenced by outliers.	0.5 (0.9) Deeper review identifies 2 RASB outliers (note 80% difference in median and mean). Therefore, median should be used.	+200% diff. App 1 vs. App 2. Deeper review identifies strong influence of dietary intake on B12 status. Therefore, recommend App. 2 to represent global intakes.	1.2 (1.2)	0.9 (1.1) Deeper review identifies 2 RASB outliers. Therefore, median should be used.	33% diff. App 1 vs. App 2. Deeper review identifies strong influence of dietary intake on B12 status. Therefore, recommend App. 2 to represent global intakes.	Higher NRVs-R for OI vs. YC using App. 1 highlights a data quality issue. Deeper review on factors influencing the NRV-R for vitamin B12 is required.
Magnesium (mg)	80 (80) Based on 2 RASBs (<i>deeper review found these RASBs = Category 3</i>)	80 (80) Based on 2 RASBs. 75 (71) Based on all RASBs and FAO/WHO. Recommend using Approach 2 to represent global nutrient intakes.	Higher NRVs-R for OI vs. YC. Deeper review found all OI RASBs are Category 3 <i>not</i> Category 2.	70 Based on 1 RASB. Deeper review found 1 RASB = Category 3.	80 (77) Based on 3 RASBs. Deeper review recommends 80 (80) based on 2 RASBs for YC.	14% diff.	Deeper review found 1 YC RASB is Category 3 <i>not</i> Category 2.

Table 4: 'Amber Light' NRVs-R to be considered by an EWG

Nutrient	Older Infants (OI) 6-12months			Young Children (YC) 12-36months			
	Approach 1 Med (Mean) % difference	Approach 2 Med (Mean) % difference	% Difference Med. App 1 vs App 2 (% diff. using mean)	Approach 1 Med (Mean) % difference	Approach 2 Med (Mean) % difference	% Difference App 1 vs App 2 Med	% Difference App 1 vs App 2 Mean
Vitamin C (mg)	30 (30)	25 (25)	17% (17% diff.)	30 (30)	23 (24) -4% diff.	23% diff.	20% diff.
Folate (µg DFE)	80 (83) -4% diff.	80 (82) -3% diff.	0% (1% diff)	120 (130) -8% diff.	150 (138) 8% diff	-25% diff.	-6% diff.
Biotin (µg)	6 (7) -17% diff.	6 (7) -17% diff.	0%	14 (14)	8 (11) -38% diff.	43% diff.	21% diff.
Selenium (µg)	15 (17) -13% diff.	15 (17) -13% diff.	0%	15 (14) 7% diff.	18 (18)	-20% diff.	-29% diff.
Manganese (mg)	0.3 (0.3)	0.3 (0.3)	0%	1.0 (1.0)	0.5 (0.8) -60% diff.	0% diff.	20% diff.
Phosphorus (mg)	165 (165)	165 (165)	0%	250 (250)	460 (460)	-84% diff.	-84% diff.
Vitamin K	10 (10)	10 (7)	30% diff. using the mean	15 (26) Note 42% difference in median and mean, identifies 1 RASB outlier. Therefore, median should be used.	15 (26)	0%	0%
Iron 15%(mg)	6.2 (6.2)	6.2 (6.2)	0%	3.9 (3.9)	3.9 (3.9)	0%	0%
10%(mg)	9.3 (9.3)	9.3 (9.3)	0%	5.8 (5.8)	5.8 (5.8)	0%	0%