CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

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Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 4 **CRD06**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVS-R FOR PERSONS AGED 6 - 36 MONTHS AND THE NRVS-R FOR PERSONS AGED 6 - 36 MONTHS

Summary of comments in reply to CL 2024/51-NFSDU for discussion at the PWG on Tuesday 1st October

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

Introduction

A request for comments in reply to CL 2024/51-NFSDU was posted in July 2024, with a revised Part B posted in early September 2024. By the 20th of September 2024, comments were submitted by 22 Codex Members (CMs) and 3 Codex Observers (COs) (see CX/NFSDU 24/44/4 Add.1).

Comments were collated to identify areas of general agreement, areas requiring clarification and further consideration. Further work was undertaken by the Chair and Co-Chairs to address issues raised and provide further clarification.

Proposals are made to progress agreement on the three areas outlined in the Agenda Paper (CX/NFSDU 24/44/4, Part A and CX/NFSDU 24/44/4, Part B Rev):

A. Draft General Principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months (CX/NFSDU 24/44/4, Part A
B. Revised Stepwise Process CX/NFSDU 24/44/4, Part B Rev. 1
C. Proposed NRVs-R for persons aged 6 – 36 months CX/NFSDU 24/44/4, Part B Rev. 1

Purpose

This CRD summarises feedback and the outcomes of further work recently undertaken by the Chair and Co-Chairs to address issues raised.

This will be used to guide discussions at the PWG to progress agreement on the Draft General Principles, Revised Stepwise Process and proposed NRVs-R for persons aged 6 – 36 months.

General comments received in reply to CL 2024/51-NFSDU

There was widespread appreciation for the substantive work that the EWG completed over the 18 months since CCNFSDU43. While there was broad support for the recommendations to progress the three areas outlined in the Agenda Paper documents, specific areas requiring further clarification were identified. Comments submitted included rationale and some suggestions on how to address these issues to progress agreement.

The Chair and Co-Chairs are very grateful for this feedback. Further work has been undertaken the outcomes of which are outlined under the three areas in this CRD.

A. Draft General Principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months (CX/NFSDU 24/44/4, Part A

An updated draft of the General Principles is outlined in **Appendix I**. Two areas remain in [ ].

1. **Adequate Intake**

The definition for Adequate Intake in [ ] was provided by FAO/WHO expert group that is updating the nutrient intake values for infants and young children. There was unanimous support for adopting this definition.

Recommendation 1

The definition for Adequate Intake outlined below be adopted.

[**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.]

2. Age Groups

Feedback in the CL on age groups raised concerns that the General Principles were silent on establishing the NRVs-R for 6-12 months and 12-36 months. The Chair and Co-Chairs recommend this be addressed under 3.2. by adding additional text within the [ ] on how combined NRVs-R for the 6-36 months age group is determined. The Chair and Co-Chairs have drafted this additional text (*see* bold underlined text in within the [ ] **Recommendation 2** *below)*

The other age group issue within [ ] under 3.2 relates to how the **combined NRV-R value for persons aged 6–36 months age group** should be determined. Feedback in the CL continues to be mixed on the three options. The rationale provided for each option is summarised below:

Option 1: select 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.

While this continues to be supported as the most appropriate way to establish combined NRVs-R for persons aged 6-36 months, there are concerns:

i) Always selecting the highest value (Option 1) may be inappropriate if the food for the combined age rage (6-36 months) is targeted more at the younger age group (6-12 months - Older Infants) as the requirements specified will be higher than necessary.

ii) Unknown potential risk for this vulnerable age group due to excessive intake of nutrients where no UL has been set.

Option 2: Select the lower value of the proposed NRVs-R for older infants and young children.

While this continues to be supported, there are concerns

i) Selection of the lower value will not reflect the INL98 of the older age group (Young Children) and will, therefore, not align with the draft General Principles under 3.2 where 'Ideally, the NRVs-R should be based on Individual Nutrient Level 98 (INL98)'.

ii) Selection of the higher value will be higher that the INL98 of the Older Infants

In fact, none of the three Options can establish NRVs-R that align with the INL98 of all persons aged 6-36 months. Choosing Option 1 over Option 2 (or vice versa) result in a 'seesaw situation' where risks associated with higher or lower NRVs-R are exchanged between those persons at the younger or older ends of the age range 6 – 36 months.

Option 3: Select the mean value of the proposed NRVs-R for older infants and young children

The Chair and Co-Chairs continue to recommend selecting Option 3 as this represents a compromise where agreement may be achieved.

Recommendation 2

[**NRV-Rs shall be derived for persons aged 6-12 months and 12-36 months from suitable data sources 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.]

B. Revised Stepwise Process CX/NFSDU 24/44/4, Part B Rev. for applying the draft General Principles to establish nutrient reference values (NRVs-R) (CX/NFSDU 24/44/4, B Rev. 1

An updated draft of the revised Stepwise Process is outlined in **Appendix II**. In **2A** the Stepwise process is described visually in a schematic figure. In **2B** the text of the updated Stepwise Process is shown (changes are in **bold/underlined** or ~~strikethrough~~ mode).

A broad summary of feedback included:

General

- In general, there was widespread support for the Revised Stepwise Process as a means of applying the draft General Principles to establish NRVs-R.

  In particular, the consistency and clarity on provided on the implementation of Section 3 of the draft General Principles to derive the NRVs-R was appreciated. Nonetheless, some areas were identified for amendment.

Recent

- In general, there was support for the proposed Approach 1 where "recent" is included in the application of the draft Stepwise Process to propose NRVs-R. Limiting the data to more recent publications was viewed as aligning with the draft General Principles
- There were some exceptions to this where concerns were raised that omission of older data from RASBs may exclude important data.
- In contrast to this, those in support of restricting RASB data to more recently available publications, compared with using all available data (Approach 1 recent vs. Approach 2 all data) were reassured that there is very little variation in the resulting NRVs-R values for most nutrients
- The decision to avoid defining "recent" in the Stepwise Process was supported. This agreed with the Chair and Co-Chairs recommendation to allow for flexibility in the future so the most appropriate DIRV data from RASBs can be used.
- There were some concerns that "recent" is not being applied to FAO/WHO values. It was suggested that this could be addressed if the FAO/WHO data was validated by comparison with the RASB data. This included applying interpretation of "recent" so that updated FAO/WHO data would be treated differently.

  These comments are at variance with the strong feedback in Consultations on the importance of the status of FAO/WHO data as the primary source.

Data quality assessment

- Some valuable feedback and comments on the Stepwise Process related to how it performed in establishing NRVs-R for all nutrients. The anomalies identified in some NRVs-R required a deeper review of the evidence and scientific basis for derivation of DIRVs available from RASBs.
- As can be seen in **Appendix II** from 2 A and 2 B, the updated revised Stepwise Process includes a new **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.

  How this is applied will be demonstrated in the **PWG** using examples which show:

1. The case-by-case Data Quality Assessment in Step 4 which identifies NRVs-R with different outcomes from application of Approach 1 *vs.* Approach 2; or NRVs-R where anomalies are evident (*e.g., a higher NRVs-R for the 6-12 months that is not reflected in the FAO/WHO or RASBs data*)
2. The procedures used in Step 4 to determine how the most appropriate NRV-R should be established on a case-by-case basis

Recommendation 3

The Updated Revised Stepwise Process outlined in Appendix II be adopted.

C. Proposed NRVs-R for persons aged 6 – 36 months CX/NFSDU 24/44/4, Part B Rev. 1

Updated proposed NRVs-R are outlined in **Appendix III** in **Summary Tables 1, 2a and 2b**. This provides an overview of amendments required after Step 4 (and to correct minor errors in these tables in the Agenda Paper).

In summary, after **Step 4** the following amendments were required:

- Due to the lack of scientific data, Approach 2 (using all available data) was most appropriate to establish the following NRVs-R:
    - Pantothenic Acid for persons aged 12-36 months
    - Copper for persons aged 6-12 months
    - Magnesium for persons aged 6-12 months
    - Magnesium for persons aged 6-36 months
    - Vitamin B12 for persons aged 6-36 months

  Nutrient intakes are the basis for derivation of DIRVs in these cases. Therefore Approach 2 is more appropriate to establish the global NRVs-R as this approach takes account of all data on nutrient intakes.

D. *'Green light' vs. 'Amber light' in the p*roposed list of NRVs-R for persons aged 6 – 36 months (outlined in Tables 1, 2 and 3 in Appendix IV)

NRVS-R for persons aged 6-12 months, 12-36 months and 6-36 months were categorised in terms of those nutrients where proposed NRVs-R may be easy to agree on ***('Green light')*** and those that may require further consideration ***('Amber light'***).

The basis of the ***'Green light'*** categorisation is the consistent similarity of proposed NRVs-R regardless of:

- whether Approach 1 or Approach 2 was applied; or
- whether median or mean values were used; and included
- NRVs-R requiring amendment after Step 4 Data Quality Assessment

The basis of the ***'Amber light'*** categorisation is the variation in proposed NRVs-R:

- when Approach 1 and Approach 2 were applied; or
- variation between median and mean values of proposed NRVs-R.

'Amber light' NRVs-R require deeper review at Step 4 Data Quality Assessment

*NOTE: The **'Green light' vs. 'Amber light'** categorisation only apply in the establishment of NRVs-R for persons aged 6-12 months and 12-36 months because the combined NRVs-R for persons aged 6-36 months are calculated from these NRVs-R.*

Recommendation 4

a) The NRVs-R listed as ***'Green Light'*** in Tables 1 and 2 in Appendix IV be adopted for Older Infants (6-12 months) and Young Children (12-36 months).

b) The combined NRVs-R for 6-36 months listed as ***'Green light'*** in Tables 4a and 4b in Appendix IV be adopted

c) The 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

E. Finally in **Appendix V** Tables 1 and 2 outline Dietary Intake Reference Values (DIRVs) from NIHN (Japan) published in 2020 where these recent values differ from previous DIRVs (2015).

An assessment carried out by the Chair (Ireland) did not identify any changes required in the proposed NRVs-R as a consequence of the availability of these updated DIRVs from NIHN

Recommendation 5

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

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

Appendix I: Revised proposed text for the Draft General Principles following the feedback to CL 2024/51-NFSDU as discussed above *(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)[1] 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.

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 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.

Appendix II: Updated Revised Stepwise Process

Figure 1: Schematic Outline of Updated Revised Stepwise Process for establishing NRVs-R for persons aged 6-36months

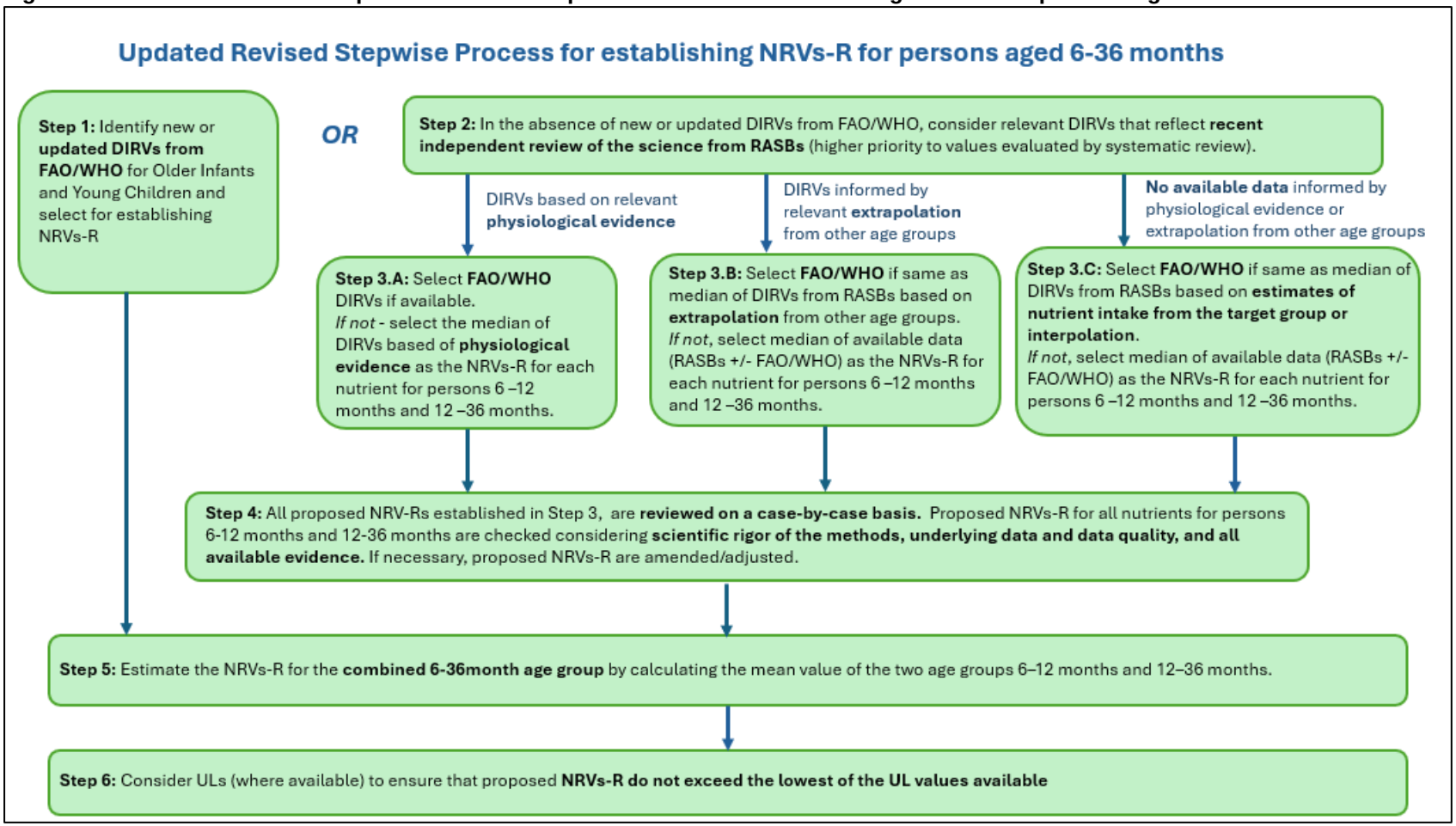

Table 1: Text of Updated Revised Stepwise Process (changes are in **bold/underlined** or ~~strikethrough~~ mode).

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 Summary Tables of Candidate NRVs-R

Summary Table 1: Proposed NRVs-R for older infants (6-12 months) and young children (12-36 months): on application of revised Stepwise Process using Approach 1 (consideration of data from FAO/WHO & 'more recent RASBs'[1] only) and Approach 2 (consideration of data from FAO/WHO + 'all RASBs'[2])

Nutrient	Older Infants (6-12 months)		Young Children (12-36 months)		General Population NRV-R[3]
	Approach 1	Approach 2	Approach 1	Approach 2	
Vitamin A (µg RAE or RE)	**250**	250	**300**	300	800
Vitamin D (µg)	**5**	5	**5**	5	5-15
Vitamin C (mg)	**30**	25	**30**	23	100
Vitamin K (µg)	**10**	10	**15**	15	60
Vitamin E (mg)	**5**	5	**7**	6	9
Thiamin (mg)	**0.3**	0.3	**0.5**	0.5	1.2
Riboflavin (mg)	**0.4**	0.4	**0.6**	0.5	1.2
Niacin (mg NE)	**4**	4	**6**	6	15
Vitamin B6 (mg)	**0.3**	0.3	**0.6**	0.5	1.3
Folate[4] (µg DFE)	**80**	80	**120**	150	400
Vitamin B12 (µg)	1.5	**0.5**	1.2	**0.9**	2.4
Pantothenic Acid (mg)	**3**	3	~~3~~2	**3**	5
Biotin (µg)	**6**	6	**14**	8	30
Calcium (mg)	**400**	400	450	450	1000
Magnesium (mg)	80	**75**	~~170~~70	**80**	310
Iron (mg)	**6.2 (15%)** **9.3 (10%)**	6.2 (15%) 9.3 (10%)	**3.9 (15%)** **5.8 (10%)**	3.9 (15%) 5.8 (10%)	14 (15%) 22 (10%)
Zinc (mg)	**2.5 (50%)** **4.1 (30%)** **8.4 (15%)**	2.5 (50%) 4.1 (30%) 8.4 (15%)	**2.4 (50%)** **4.1 (30%)** **8.3 (15%)**	2.4 (50%) 4.1 (30%) 8.3 (15%)	11 (30%) 14 (22%)
Iodine (µg)	**78**	78	**95**	90	150

[1] 'More recent RASBs' include those from 2014 onwards NASEM (2019), NCM (2024), Japan NIHN (2015) and EFSA (2014, 2015, 2016, 2017).
[2] 'All RASBs' include IOM (1998, 2011), NHMRC (2006), NIHN (2015), EFSA (2012, 2013, 2014, 2015, 2016, 2017) and NCM (2024).
[3] Source - CXG 2-1985 Guidelines on Nutrition Labelling
[4] Folate DIRV data was restricted to Dietary Folate Equivalents which excluded NIHN (2015) data based on folic acid.

Nutrient	Older Infants (6-12 months)		Young Children (12-36 months)		General Population NRV-R[3]
	Approach 1	Approach 2	Approach 1	Approach 2	
Copper (µg)		**220**	**300**	320	900
Selenium (µg)	**15**	15	**15**	18	60
Manganese (mg)	**0.3**	0.3	**1.0**	0.5	3
Phosphorus (mg)	**165**	165	**250**	460	700
Potassium (mg)	**725**	725	**850**	850	-
Protein (g)	**11.3**	11.3	**12.5**	12.5	50

[3] Source - CXG 2-1985 Guidelines on Nutrition Labelling

Summary Table 2a: Proposed NRVs-R for vitamins according to Options 1, 2 & 3[5] for persons aged 6-36 months: on application of revised Stepwise Process using Approach 1 (consideration of data from FAO/WHO & 'more recent RASBs'[6] only) and Approach 2 (consideration of data from FAO/WHO + 'all RASBs'[7])

Nutrient	**6–36-months age group Option 1**		**6–36-months age group Option 2**		**6–36-months age group Option 3**		**Lowest UL value for 6-36 months**	**General Population NRV-R[8]**
	Approach 1	Approach 2	Approach 1	Approach 2	**Approach 1**	Approach 2		
Vitamin A (µg RAE or RE)	300	300	250	250	**275**	275	600	800
Vitamin D (µg)	5	5	5	5	**5**	5	-	5-15
Vitamin C (mg)	30	25	30	23	**30**	24	400	100
Vitamin K (µg)	15	15	10	10	**13**	13	-	60
Vitamin E (mg)	7	6	5	5	**6**	6	-	9
Thiamine (mg)	0.5	0.5	0.3	0.3	**0.4**	0.4	-	1.2
Riboflavin (mg)	0.6	0.5	0.4	0.4	**0.5**	0.5	-	1.2
Niacin (mg NE)	6	6	4	4	**5**	5	10	15
Vitamin B6 (mg)	0.6	0.5	0.3	0.3	**0.4**	0.4	5	1.3
Folate (µg DFE)	120	150	80	80	**100**	115	200	400
Vitamin B12 (µg)	1.5	0.9	1.2	0.5	1.4	**0.7**	-	2.4
Pantothenic Acid (mg)	3	3	3	3	**3**	3	-	5
Biotin (µg)	14	8	6	6	**10**	7	-	30

[5] *Option 1 = highest value without exceeding the UL for either age group, Option 2 = lowest value, Option 3 = mean value.
[6] CXG 2-1985
[7] More recent RASBs' include those from 2014 onwards NASEM (2019), NCM (2024), Japan NIHN (2015 with the exception of folate, where DIRV data was restricted to Dietary Folate Equivalents which excluded NIHN data on folic acid) and EFSA (2014, 2015, 2016, 2017)
[8] All RASBs' include IOM (1998, 2011), NHMRC (2006), NIHN (2015 with the exception of folate, where DIRV data was restricted to Dietary Folate Equivalents which excluded NIHN data on folic acid), EFSA (2012, 2013, 2014, 2015, 2016, 2017) and NCM (2024).

Summary Table 2b: Proposed NRVs-R for minerals and protein according to Options 1, 2 & 3[9] for persons aged 6-36 months: on application of revised Stepwise Process using Approach 1 (consideration of data from FAO/WHO & 'more recent RASBs'[10] only) and Approach 2 (consideration of data from FAO/WHO + 'all RASBs'[11])

Nutrient	**6–36-months age group Option 1**		**6–36-months age group Option 2**		**6–36-months age group Option 3**		**Lowest UL value for 6-36 months**	**General Population NRV-R[12]**
	Approach 1	Approach 2	Approach 1	Approach 2	**Approach 1**	Approach 2		
Calcium (mg)	450	450	400	400	**425**	425	2500	1000
Magnesium (mg)	170	80	80	75	125	**78**	-	310
Iron (mg)	6.2 (15%) 9.3 (10%)	6.2 (15%) 9.3 (10%)	3.9 (15%) 5.8 (10%)	3.9 (15%) 5.8 (10%)	**5.1 (15%) 7.6 (10%)**	5.1 (15%) 7.6 (10%)	20	14 (15%) 22 (10%)
Zinc (mg)	2.5(50%) 4.1 (30%) 8.4 (15%)	2.5(50%) 4.1 (30%) 8.4 (15%)	2.4(50%) 4.1 (30%) 8.3 (15%)	2.4(50%) 4.1 (30%) 8.3 (15%)	**2.5 (50%) 4.1 (30%) 8.4 (15%)**	2.5 (50%) 4.1 (30%) 8.4 (15%)	-	11 (30%) 14 (22%)
Iodine (µg)	95	90	78	78	**86**	84	200	150
Copper (µg)	300	320		220	**260**	270	1	900
Selenium (µg)	15	18	15	15	**15**	17	-	60
Manganese (mg)	1.0	0.5	0.3	0.3	**0.6**	0.4	-	3
Phosphorus (mg)	250	460	165	165	**208**	313	-	700
Potassium (mg)	850	850	725	725	**788**	788	-	-
Other								
Protein (g)	12.5	12.5	11.3	11.3	**11.9**	11.9	-	50

[9] Option 1 = highest value without exceeding the UL for either age group, Option 2 = lowest value, Option 3 = mean value.
[10] CXG 2-1985
[11] 'More recent RASBs' include those from 2014 onwards NASEM (2019), NCM (2024), Japan NIHN (2015) and EFSA (2014, 2015, 2016, 2017).
[12] 'All RASBs' include IOM (1998, 2011), NHMRC (2006), NIHN (2015), EFSA (2012, 2013, 2014, 2015, 2016, 2017) and NCM (2024).

Appendix IV Categorization of NRVs-R

Table 1[13]: '*Green Light*' NRVs-R: Nutrients where proposed NRVs-R are similar regardless of Approach applied and whether median or mean values are used.

	Older Infants (OI) 6-12months			Young Children (YC) 12-36months		
Nutrient	**Approach 1 Med** (Mean) % difference	**Approach 2** Med (Mean) % difference	**Any Med. differences** (mean)	**Approach 1 Med** (Mean) % difference	**Approach 2** Med (Mean) % difference	**% Difference Med. App 1 vs App 2** (% diff. using mean)
VITAMINS						
Vitamin A (µg)	**250** (250)	250 (250)	0%	**300** (308) -3% diff.	300 (308), -3% diff.	0%
Vitamin D (µg)[14]	***5** (5)*	*5 (5)*	*0%*	***5** (5)*	*5 (5)*	*0%*
Vitamin E (mg)	**5** (5)	5 (5)	0%	**7** (7)	6 (6)	**14% diff.** (14% diff.)
Thiamin (mg)	**0.3** (0.3)	0.3 (0.3)	0%	**0.5** (0.5)	0.5 (0.5)	0%
Riboflavin (mg)	**0.4** (0.4)	0.4 (0.4)	0%	**0.6** (0.6)	0.5 (0.5)	**17%** (17%)
Niacin (mg)	**4** (4)	4 (4)	0%	**6** (6)	6 (6)	0%
Vitamin B_6 (mg)	**0.3** (0.3)	0.3 (0.3)	0%	**0.6** (0.6)	0.5 (0.5)	**17%** (17%)
MINERALS						
Calcium (mg)	**400** (400)	400 (400)	0%	**450** (442) 2% diff.	450 (505) -12% diff	0% (-14% diff.)
Iron 15% (mg) **10% (mg)**	**6.2** (6.2) **9.3** (9.3)	6.2 (6.2) 9.3 (9.3)	0% 0%	**3.9** (3.9) **5.8** (5.8)	3.9 (3.9) 5.8 (5.8)	0% 0%
Zinc 50% (mg) *30% (mg)* *15% (mg)*	**2.5** (2.5) **4.1** (4.1) **8.4** (8.4)	2.5 (2.5) 4.1 (4.1) 8.4 (8.4)	0%	**2.4** (2.4) **4.1** (4.1) **8.3** (8.3)	2.4 (2.4) 4.1 (4.1) 8.3 (8.3)	*0%*
Iodine (µg)	**78** (78)	78 (78)	0%	**95** (95)	90 (93) -3 % diff.	**5% diff.** (2% diff.)
Potassium (mg)	**725** (725)	725 (725)	0%	**850** (833) 2% diff.	850 (833) 2% diff.	0%
Protein (g)	**11.3** (11.3)	11.3 (11.3)	0%	**12.5** (12.5)	12.5 (12.5)	0%

[13] Where differences from applying Approach 2 instead of the proposed Approach 1 (and where the mean is used instead of the proposed median) are 17% or less.

[14] New NRVs-R for vitamin D, calcium and zinc expected from FAO/WHO for persons aged 6-36months,

Table 2 : 'Green Light' NRVs-R requiring amendment after data quality assessment.

	Older Infants (OI) 6-12months			Young Children (YC) 12-36months			
Nutrients	**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)***
Pantothenic acid (mg)	**3** (3) Based on FAO/WHO and 3 RASBs.	3 (3) Based pan FAO/WHO and 5 RASBs.	Higher NRVs-R for OI vs. YC. Better evidence for OI - Recommend App. 1	2 (only FAO/WHO is Category 2)	**3** (3) all data used regardless of Category	**50% diff.**	Lack of evidence for YC; no UL. **Recommend App. 1 for OI. & App. 2 for YC**
Magnesium (mg)	80 (80) Based on 2 RASBs (*deeper review found these RASBs = Category 3)*	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 *not* 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 *not* Category 2.
Copper (µg)	400 Based on 1 RASBs (*deeper review found Category 3, not Category 2)*	**220** (292) Based on 5 RASBs	Recommend using Approach 2 for OI to represent global nutrient intakes.	**300** (320)	320 (320) Based on 2 RASB	**6% diff.**	Recommend using Approach 1 YC.

	Older Infants (OI) 6-12months			Young Children (YC) 12-36months			
Nutrients	**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 B_{12} (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.

Table 3: 'Amber Light' NRVs-R: Nutrients where application of the Stepwise Process results in proposed NRVs-R that vary according to Approach applied (Approach 1 vs. Approach 2) and whether median or mean values are used.

	Older Infants (OI) 6-12months			Young Children (YC) 12-36months			
Nutrient	**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%

Table 4a: Proposed combined NRVs-R for 6-36 months: categorization of vitamins into 'Green light´ and 'Amber light' vitamins.

Nutrient	6–36-months age group Option 1[15]		6–36-months age group Option 2[14]		6–36-months age group Option 3[14]		Lowest UL value for 6-36 months	General Population NRV-R[16]
	Approach 1[17]	Approach 2[18]	Approach 1	Approach 2	**Approach 1**	Approach 2		
Vitamin A (µg RAE or RE)	300	300	250	250	**275**	275	600	800
Vitamin D (µg)	5	5	5	5	**5**	5	-	5-15
Vitamin C (mg)	30	25	30	23	**30**	24	400	100
Vitamin K (µg)	15	15	10	10	**13**	13	-	60
Vitamin E (mg)	7	6	5	5	**6**	6	-	9
Thiamine (mg)	0.5	0.5	0.3	0.3	**0.4**	0.4	-	1.2
Riboflavin (mg)	0.6	0.5	0.4	0.4	**0.5**	0.5	-	1.2
Niacin (mg NE)	6	6	4	4	**5**	5	10	15
Vitamin B6 (mg)	0.6	0.5	0.3	0.3	**0.4**	0.4	5	1.3
Folate (µg DFE)	120	150	80	80	**100**	115	200	400
Vitamin B12 (µg)	1.5	0.9	1.2	0.5	1.4	**0.7**	-	2.4
Pantothenic Acid (mg)	3	3	3	3	**3**	3	-	5
Biotin (µg)	14	8	6	6	**10**	7	-	30

15 Option 1 = highest value without exceeding the UL for either age group; Option 2 = lowest value; Option 3 = mean value.
16 Source - CXG 2-1985 Guidelines on Nutrition Labelling

Table 4b: Proposed combined NRVs-R for 6-36 months: categorization of minerals and protein into *'Green light´* and *'Amber light'*

Nutrient	**6–36-months age group Option 1[19]**		**6–36-months age group Option 2[20]**		**6–36-months age group Option 3[21]**		**Lowest UL value for 6-36 months**	**General Population NRV-R[22]**
	Approach 1[23]	Approach 2[24]	Approach 1	Approach 2	**Approach 1**	Approach 2		
Calcium (mg)	450	450	400	400	**425**	425	2500	1000
Magnesium (mg)	170	80	80	75	125	**78**	-	310
Iron (mg)	6.2 (15%) 9.3 (10%)	6.2 (15%) 9.3 (10%)	3.9 (15%) 5.8 (10%)	3.9 (15%) 5.8 (10%)	**5.1 (15%) 7.6 (10%)**	5.1 (15%) 7.6 (10%)	20	14 (15%) 22 (10%)
Zinc (mg)	2.5(50%) 4.1 (30%) 8.4 (15%)	2.5(50%) 4.1 (30%) 8.4 (15%)	2.4(50%) 4.1 (30%) 8.3 (15%)	2.4(50%) 4.1 (30%) 8.3 (15%)	**2.5 (50%) 4.1 (30%) 8.4 (15%)**	2.5 (50%) 4.1 (30%) 8.4 (15%)	-	11 (30%) 14 (22%)
Iodine (µg)	95	90	78	78	**86**	84	200	150
Copper (µg)	300	320		220	**260**	270	1	900
Selenium (µg)	15	18	15	15	**15**	17	-	60

17 Consideration of data from FAO/WHO & 'more recent RASBs' only (those from 2014 onwards NASEM (2019), NCM (2024), Japan NIHN (2015 with the exception of folate, where DIRV data was restricted to Dietary Folate Equivalents which excluded NIHN data on folic acid) and EFSA (2014, 2015, 2016, 2017)
18 Consideration of data from FAO/WHO + 'all RASBs'. Al RASBs' include IOM (1998, 2011), NHMRC (2006), NIHN (2015 with the exception of folate, where DIRV data was restricted to Dietary Folate Equivalents which excluded NIHN data on folic acid), EFSA (2012, 2013, 2014, 2015, 2016, 2017) and NCM (2024).

[19] Option 1 = highest value without exceeding the UL for either age group
[20] Option 2 = lowest value
[21] Option 2 = lowest value
[22] Source - CXG 2-1985 Guidelines on Nutrition Labelling
[23] Consideration of data from FAO/WHO & 'more recent RASBs' only. More recent RASBs' include those from 2014 onwards NASEM (2019), NCM (2024), Japan NIHN (2015) and EFSA (2014, 2015, 2016, 2017).
[24] Consideration of data from FAO/WHO + 'all RASBs'. 'All RASBs' include IOM (1998, 2011), NHMRC (2006), NIHN (2015), EFSA (2012, 2013, 2014, 2015, 2016, 2017) and NCM (2024).

Manganese (mg)	1.0	0.5	0.3	0.3	**0.6**	0.4	-	3
Phosphorus (mg)	250	460	165	165	**208**	313	-	700
Potassium (mg)	850	850	725	725	**788**	788	-	-
Other								
Protein (g)	12.5	12.5	11.3	11.3	**11.9**	11.9	-	50

Appendix V Dietary Intake Reference Values (DIRVs) from NIHN (Japan) published in 2020 where these recent values differ from previous DIRVs
Table 1: Dietary Intake Reference Values (DIRVs) from Japan: Recent DIRVs (2020) for nutrients where differences arise compared to previous DIRVs (2015)

Nutrient	Older Infants (OI)		Young Children (YC)		Comment on derivation method for 2015 values
	2020	2015	2020	2015	
Vitamin D µg/day	5[25]	5[25]	Males – 3[26] Females – 3.5[26]	2[26]	*OI was 1b, YC was 2d*
Vitamin C mg/day	40[25]	40[25]	40[26]	35[26]	*OI was 2c and 2d, YC was 2d*
Vitamin K µg/day	7[25]	7[25]	Males – 50[25] Females – 60[25]	60[25]	*OI was 3i, YC was 2d*
Vitamin E mg/day	4[25]	4[25]	3[25]	3.5[1]	*OI was 2d, YC was 3i*
Niacin mg NE/day	3[25]	3[25]	Males – 6[26] Females – 5[26]	5[26]	*OI was 2c and 2d, YC was 2d*
Pantothenic Acid mg/day	5[25]	3[25]	Males – 3[1] Females – 4[1]	3[25]	*OI was 2c and 2d, YC was 3i*
Biotin µg/day	5[25]	10[25]	20[1]	20[25]	*OI was 2c and 2d, YC was 2d*
Copper µg/day	300[25]	400[25]	300[26]	300[26]	*OI was 3i, YC was 2d*
Potassium mg/day	700[25]	700[25]	900[25]	Males – 900[25] Females – 800[25]	*OI was 3i, YC was 2d*

Table 2: Tolerable Upper Intake Levels (ULs) from Japan: Recent ULs (2020) for nutrients where differences arise compared to previous ULs (2015)

Nutrient	Older Infants (OI)		Young Children (YC)	
	2020	2015	2020	2015
Iodine µg/day	250	250	300	250
Selenium µg/day	-		100	Males – 80 Females - 70

[25] Adequate Intake (AI)
[26] Recommended Daily Allowance (RDA)