

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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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 5

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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

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

Codex members and Observers wishing to submit comments on the recommendations in this document should do so as instructed in CL 2022/74/OCS-NFSDU available on the Codex webpage/Circular Letters: <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

Summary and recommendations

Background

1. At the 42nd session of CCNFSDU the Committee agreed to:
 - i. continue its work on NRVs-R for persons aged 6 – 36 months;
 - ii. re-establish the EWG, chaired by Ireland, and co-chaired by Costa Rica and the United States of America, working in English and Spanish; and
 - iii. keep open the possibility of a Physical Working Group (PWG), chaired by Ireland and co-chaired by Costa Rica and the United States of America to meet prior to the next session to consider written comments submitted and prepare a revised proposal for consideration by CCNFSDU43.
2. The Terms of Reference (ToR) for the work of this 2022 eWG (REP22/NFSDU) were:

- a) Finalize the General Principles for establishing NRVs-R for persons aged 6 to 36 months including presenting the new structure for Annex 1 in CXG 2-1985, taking account of discussion at the session and any written comments submitted, for circulation for comments and consideration by CCNFSDU43; and
- b) Pilot the draft General Principles on the following nutrients: vitamin B12, iodine, vitamin B6, riboflavin and, if time permits, thiamine, niacin and vitamin C.

Conduct of the EWG

3. The EWG was established in January 2022 and has 38 members (30 Codex Members, 1 Codex Member Organisation and 7 Codex Observers). A list of participants can be found in Appendix III.
4. The Chairs developed two Consultation Papers to explore ToR A and ToR B separately.

Responses to the 1st Consultation Paper exploring ToR A:

16 EWG members responded

- 13 Codex Members
- 1 Codex Member Organisation
- 2 Codex Observers

Responses to the 2nd Consultation Paper exploring ToR B:

17 EWG members responded

- 14 Codex Members
- 1 Codex Member Organisation
- 2 Codex Observers

CONCLUSIONS AND RECOMMENDATIONS

5. Consistent with the TORs, the EWG has completed its task by redrafting the General Principles for Establishing NRVs-R for Persons Aged 6 – 36 Months, including the preamble and definitions sections. The EWG is also presenting a set of NRVs-R for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C based on the proposed draft General Principles and the pilot stepwise approach on the application of the General Principles. The full report of the EWG is presented in Appendix I which provides the background to the discussions and the recommendations for consideration by CCFSDU43.

Recommendations

6. The Committee is **invited** to consider:

- a) The proposed draft General Principles for Establishing Nutrient Reference Values (NRVs-R) for Persons Aged 6 – 36 Months (Appendix II, Part A) taking into account the discussion in Appendix I, Section A.
- b) The revised pilot stepwise approach on the application of the proposed Draft General Principles for Establishing Nutrient Reference Values (NRVs-R) for Persons Aged 6 – 36 Months (Appendix II, Part B).
- c) The proposed draft NRVs-R for persons aged 6 – 36 months for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C (Appendix II, Part C) taking into account the proposed stepwise approach for application of the General Principles for establishing NRVs-R for persons aged 6 – 36 months and discussions provided in Appendix I, Section B).

APPENDIX I

Summary of discussion and recommendations of the EWG and/or chairs of the EWG

Introduction

1. At the 42nd session of CCNFSDU (REP22/NFSDU), the following was agreed:
 - that the Annex on General Principles for the establishment of NRVs for the General Population in the *Guidelines on Nutrition Labelling* (CXG 2-1985) should be retained to the extent possible and only, when necessary, be adjusted to include specific requirements for other population groups such as persons aged 6–36 months (para 130).
 - that draft General Principles for establishing nutrient reference values for persons aged 6 to 36 months should be outlined under Section B of the Annex in the *Guidelines on Nutrition Labelling* (para 162–164).
2. It was also noted by the EWG Chairs that the decision on whether or not to combine the two sets of NRVs-R (one for older infants 6–12 months and one for young children 12–36 months) would be made depending on the actual values in these two sets (REP19/NFSDU). In the meantime, separate sets of NRVs-R for older infants and for young children would be prepared (REP19/NFSDU).

Terms of Reference

3. The Terms of Reference (ToR) agreed for this 2022 eWG work (REP22/NFSDU) were as follows:

- a) Finalize the General Principles for establishing NRVs-R for persons aged 6 to 36 months including presenting the new structure for Annex 1 in CXG 2-1985, taking account of discussion at the session and any written comments submitted, for circulation for comments and consideration by CCNFSDU43; and
- b) Pilot the draft General Principles on the following nutrients: vitamin B12, iodine, vitamin B6, riboflavin and, if time permits, thiamine, niacin and vitamin C.

Participation and methodology

Management of eWG work

4. In January 2022, Codex Delegates were invited to participate in the EWG for 2022 through the Codex Platform. The EWG is made up of 29 Codex Members (CMs), 1 Codex Member Organisation (CMO) and 7 Codex Observers (COs). The following abbreviations have been used throughout the paper:

CM(s) = Codex Member(s)

CMO = Codex Member Organisation

CO(s) = Codex Observer(s)

Consultations

5. Two consultations were carried out. The first Consultation Paper addressed ToR A and was held between April and May 2022. There were 16 responses to the first Consultation Paper (13 CMs, 1 CMO and 2 COs). The second Consultation Paper addressed ToR B and was held between October and November 2022. There were 17 responses to the second Consultation Paper (14 CMs, 1 CMO and 2 COs).

Mentorship

6. Janine Lewis offered to continue assisting as a mentor/technical advisor to the EWG Chairs. This offer was gratefully accepted by the Chairs and the insight and knowledge that Janine Lewis provided to the work is acknowledged.

SECTION A (TOR A)

Work completed under ToR A

7. Draft General Principles (Section B of the *Guidelines on Nutrition Labelling* (CXG 2-1985)) were initially developed taking account of discussion at the CCNFSDU42 and circulated in Consultation Paper 1 (CP1) for consideration by the EWG in May 2022. These draft General Principles were adjusted based on feedback to CP1. (Analysis of the feedback received is available [here](#)). These adjusted draft General Principles were piloted to guide the establishment of NRVs-R for persons aged 6-36 months for the seven nutrients as outlined in ToR B and circulated to the EWG in October 2022 in Consultation Paper 2 (CP2). Further adjustments were made to the draft General Principles based on feedback received to CP2.

Amendments to the draft General Principles following feedback from CP1 and CP2

8. There was strong feedback at CCFSDU42 and from CP1 and CP2 that the original text in Annex 1: General Principles for the establishment of NRVs for the General Population of *Guidelines on Nutrition Labelling* (CXG 2-1985) (hereafter referred to as Annex 1 of the GNL) should be retained as far as possible. The amendments made to the draft General Principles are summarized below for each section. The updated draft General Principles are provided in text box 1 below.

Preamble

9. Text was amended to be more consistent with Annex 1 of the GNL. Strong feedback from CMs, COs and CMO proposed inclusion of further text to clarify that these NRVs-R are for use in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6–36 months.

10. Several CMs and COs supported deletion of the sentence referring to population weighted values at the national level because this is not relevant for older infants and young children. This was not supported by the CMO who wanted to retain this sentence for flexibility to adapt values to the national situation. However, the Chairs did not consider this necessary given the reference to 'specific segments' included in the last sentence of the preamble which allows for different groupings of the 6–36 month population. This last sentence on 'specific segments' was amended for clarity and conciseness as the preamble overall states the Principles apply to persons 6–36 months and encompasses options for separate and combined sets of NRVs-R for this population.

Definitions

11. There were differing views on the necessity to add text on age ranges to the definition for DIRVs as two sets of NRVs-R will be established, one for each age group. However, a single value may be derived for the combined age group, and this would require text to reflect the distinction between a combined value and specific values for each age group. Therefore, the Chairs kept text in square brackets which can be revised to accommodate the future decision on age groups.

12. Supported by feedback, the acceptable macronutrient distribution range (AMDR) definition was removed as it is not required for the NRVs-R that are being developed. The definition for Recognized Authoritative Scientific Body (RASB), as outlined in the Annex 1 of the GNL, was included in this draft Section B. Given this deletion, the heading of Section B was clarified to apply only to NRV-Requirement.

13. Majority feedback supported retaining the proposed text on adequate intake (AI), so part of this was retained with a shortened footnote in line with feedback received. Feedback indicated inclusion of reference to AI as an alternative to INL98 was important given that the INL98 definition already exists. However, based on feedback from the CMO, this reference was moved to section 3.2 given it concerns how the AI and INL98 are to be used rather than a definition.

General Principles for establishing NRVs-R

14. Additional amendments were made to the draft General Principles to retain original text from Annex 1 of the GNL as much as possible (see Text Box 1 below).

15. Under section 3.2, the heading for 3.2 Appropriate Basis for Establishing NRVs-R was retained. While Annex 1 of the GNL included 'Selection of Nutrients' in the heading, the Chairs noted that the selection of nutrients for NRVs-R for persons 6–36 months occurred independent of the General Principles. Therefore, the Chairs suggest not including the text 'Selection of Nutrients' in the heading of 3.2 for accuracy, clarity, and consistency with the Principles.

16. Text under 3.2 was amended to include the first para under 3.2.1 in Annex 1 of the GNL. The first sentence of this para was amended to include "*informed by physiological evidence*". This reflects the scientific rigour of category 1 based on the scientific advice requested by CCFSDU [Review Of Derivation Methods For Dietary Intake Reference Values For Older Infants And Young Children](#) (hereafter referred to as the "2021 FAO report") and CP1 feedback. One CM proposed that the INL50 would be preferable to the INL98 because it is a closer reflection of most individuals' requirements compared with the INL98. The INL98 was retained as the Committee agreed to align with Annex 1 of the GNL as much as possible.

17. Further amendments to this para under 3.2 take account of discussions at CCFSDU42 and CP1 feedback in favour of the equal importance of the ranking, underlying data quality, strength of evidence. These amendments included original text from Annex 1 of the GNL "*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*". Another amendment under 3.2 added text "*The rigour of scientific methods, and quality and strength of evidence used to establish these values should be reviewed on a case-by-case basis*". These amendments enabled removal of the ranking table, in line with the feedback received in CP1.

18. For the pilot testing of the draft General Principles under ToR B (CP2), the Chairs referred to the WHO Handbook for Guideline Development¹ to provide guidance on the concepts of quality and strength of evidence. However, feedback received on CP2 indicated this was confusing and not helpful, so it was removed.

19. Other CP1 feedback noted the text '*based on a more recent independent review of science*' in para 3.2.1.1 was already stated in section 3.1. Considering this and the above amendments to para 3.2, the text under 3.2.1.1 was redundant and therefore removed.

20. In addition, the subheading 3.2.1 Selection and Priority of Derivation Methods for Establishing NRVs-R was removed as it no longer accurately described the following paragraph and is not in Annex 1 of the GNL.

21. Based on majority support, the same approach of taking existing ULs into account (as per General Principles for the general population) was adopted. This was seen to allow for future-proofing the principles as ULs are subject to change as new data becomes available. Feedback to CP1 noted requesting scientific advice for the two identified nutrients (vitamin A and magnesium) was unnecessary.

¹ WHO's Guidelines Review Committee. WHO Handbook for Guideline Development. Geneva, World Health Organization (WHO), 2014 (<https://apps.who.int/iris/handle/10665/145714>)

Text Box 1. Draft General Principles updated according to feedback from CP1 and CP2**Section B****Draft General Principles for Establishing Nutrient Reference Values-Requirement for Persons aged 6 to 36 months****1. PREAMBLE**

These Principles apply to the establishment of Codex Nutrient Reference Values-Requirement (NRVs-R) for persons aged 6–36 months. These values are for use 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 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] NRVs-R for specific segments ~~or a larger group of the population~~ of persons aged 6 – 36 months ~~to provide for specific labelling requirements~~.

2. DEFINITIONS

Daily Intake Reference Values (DIRV) as used in these Principles 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.

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.

Adequate Intake (AI) is the observed or experimentally derived intake by a defined population group that appears to sustain health^{3,4}. ~~This value is established when an INL98 cannot be determined.~~

Recognized Authoritative Scientific Body (RASB) as used in these Principles refers to an organization other than FAO and/or WHO (FAO/WHO), that is 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

The NRVs-R should be based on Individual Nutrient Level 98 (INL98) informed by relevant evidence (2021 FAO report⁵). Where the INL98 cannot be determined, the AI should be used. Where there is an absence of, or an older, established INL98 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 rigor of scientific methods, and quality and strength of evidence used to establish these values should be reviewed on a case-by-case basis.

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.

¹Different 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).

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

³Growth and development is considered as a part of the broader term “sustain health” in persons 6 – 36 months of age.

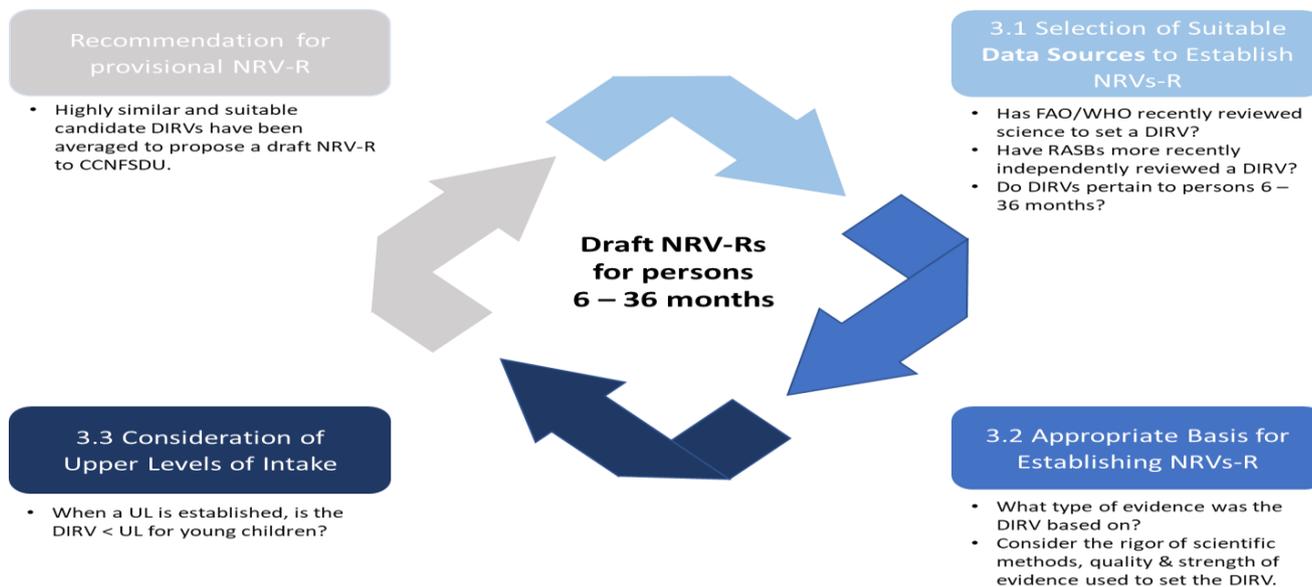
⁴UNU/FAO/WHO/UNICEF (2007).

⁵FAO 2021. Review of Derivation Methods For Dietary Intake Reference Values For Older Infants And Young Children.

SECTION B (TOR B)

Work completed under ToR B

22. The draft General Principles (updated based on feedback to CP1) were piloted to establish draft NRVs-R for vitamin B12, iodine, vitamin B6, riboflavin and, thiamine, niacin and vitamin C. Section 3 of the updated draft General Principles were applied as outlined graphically in the flow chart below.



23. Given agreement that NRVs-R should be based on INL98 informed by physiological evidence, the scientific rigour of DIRVs provided by FAO/WHO in 2004 and by more recent reviews of the RASBs, was assessed using the scientific advice requested by CCNFSDU in the 2021 FAO report. The application of this process and the resulting draft NRVs-R for the seven nutrients were outlined for consultation in October 2022 (CP 2).

Feedback received on the pilot process applying the draft General Principles as outlined in CP2

24. Feedback to CP2 was comprehensive (the analysis of the feedback received is available [here](#)). There was consistency in the comments which identified the following outstanding areas that need to be addressed:

- a) The FAO/WHO DIRVs need to be more central in the analysis used to establish NRVs-R for older infants and young children as the primary source of DIRVs for global application.

This is addressed in the revised pilot process outlined below.

- b) The approach used to identify DIRVs that have been 'more recently established' by RASBs (i.e. those outlined in more recent publications) was rejected as earlier independent reviews of the science by RASBs used the same data. A revised process that includes all RASBs, as well as FAO/WHO (primary source), would be expected to provide a more globally representative value.

This was addressed by including all RASBs, regardless of publication date, in the revised pilot process outlined below.

- c) The reference to the WHO Handbook for Guideline Development was confusing and did not address 'data quality'. Furthermore, it is unclear if any of the proposed RASBs have assessed the strength and quality of evidence in accordance with the WHO Handbook.

This was addressed by removing the reference to the WHO Handbook for Guideline Development from the revised pilot process outlined below.

- d) The draft General Principles, with some further text modifications, are acceptable but how these are applied to establish NRVs-R needs further clarification. The original stepwise approach to establish NRVs-R for the general population was referred to.

This was addressed by updating the most recently used stepwise approach (as part of the review of the Standard for Follow-up Formula (CXS 156-1987)) in the revised pilot process outlined below.

- e) Specific feedback on the reference body weights used by FAO/WHO and the RASBs suggested that these may be lower than current body weight status of the 6–36 month old population.

This was addressed by comparing the WHO Child Growth Standards (WHO, 2006) for older infants and young children with the reference body weights used to derive DIRVs by the FAO/WHO and the RASBs. As outlined in Table 1, the body weights used by FAO/WHO and the RASBs are comparable with the WHO Child Growth Standards (WHO, 2006), therefore this concern is not warranted.

Table 1. Reference body weights used to derive DIRVs by the RASBs and FAO/WHO* compared with the reference body weights from the WHO Child Growth Standards (2006)**

Region	Older infants	Young children
WHO Child Growth Standards (2006)	6–<12 months Boy = 8.7 kg Girl = 8.0 kg	12–<36 months Boy = 12.0 kg Girl = 11.4 kg
NHMRC (2006)	7–12 months 9 kg	1–3 years 13 kg
IOM (1997, 2001, 2005)	7–12 months 9 kg	1–3 years 13 kg (to 2001) 12 kg (from 2002)
EFSA (2010, 2013, 2014, 2017)	7–11 months Boy = 8.9 kg Girl = 8.6 kg Mean = 8.6 kg	1–3 years Boy 13.0 kg; Girl 12.5 kg (2012) Boy 12.2 kg; Girl 11.5 kg (from 2013) Mean = 11.9 kg
WHO (2004)	7–12 months 9 kg	1–3 years 12 kg (Zn, Mg) or 13 kg (Fe)
NIHN (2015)	6–11 months Boy = 8.8 kg Girl = 8.1 kg	1–2 years Boy = 11.7 kg; Girl = 11.0 kg
NCM	6–11 months 9 kg	2 years Boy = 13.2 kg Girl = 12.5 kg 2–5 years 16.1 kg
IZiNC (2004)	6–11 months 9 kg	1–3 years 12 kg

*FAO (2021) [Review Of Derivation Methods For Dietary Intake Reference Values For Older Infants And Young Children](#).

**WHO (2006) WHO child growth standards: length/height-for-age, weight-for-age, weight-for-length, weight-for-height and body mass index-for-age: methods and development.
[online] Available at: <https://www.who.int/publications/i/item/924154693X>.

Revised pilot process for application of the draft General Principles to establish NRVs-R for persons aged 6–36 months

25. In the feedback received on CP2, a reference to earlier work on nutrient requirements for older infants and young children undertaken by New Zealand as part of the review of the *Standard for Follow-up Formula* (CXS 156-1987) outlined how the above areas (see points 1–4) could be addressed. The work undertaken by New Zealand updated the stepwise approach used to establish NRVs for the general population in order to establish nutrient requirements for persons aged 6–36 months. The FAO/WHO DIRVs were central in this approach, which is outlined in [CX/NFSDU 14/36/7 Appendix pg 16–42](#).

26. The Chairs revised this updated stepwise approach to align with the draft General Principles and incorporate the scientific rigour outlined in the 2021 FAO report. This updated approach addresses the issues outlined in feedback to CP2 summarised in points 1–4 above. Notably, this stepwise process is based on the one used in the revision of the *Standard for Follow-up Formula* (CXS 156-1987) - one of the FSDUs where the NRVs-R for the 6–36 month population will be used.

27. This revised stepwise approach to apply the draft General Principles for establishing NRVs-R for persons aged 6–36 months is presented in text box 2.

Text Box 2. Revised stepwise approach on application of the draft General Principles to establish NRVs-R for persons aged 6–36 months

Note: The stepwise process is not proposed to be included in the General Principles.

Step 1: Using the 2021 FAO report, DIRVs established by FAO/WHO and the RASBs for the vitamins, minerals and protein under consideration for older infants and young children, were identified.

Step 2: The scientific rigour of the derivation methods used to establish these DIRVs (outlined in the 2021 FAO report) were used to identify nutrients where DIRVs are based on INL98/AI informed by relevant physiological evidence (Category 1 in 2021 FAO report).

Should this include the FAO/WHO DIRV, this is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

In cases where the FAO/WHO DIRV is not included, the median of the Category 1 DIRVs from the RASBs is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

Step 3: Potentially unsuitable DIRVs (Category 3 in 2021 FAO report) are excluded due to the lower scientific rigour of such values.

Step 4: Where the scientific rigour of the derivation methods of the DIRVs established by the FAO/WHO and any of the RASBs are of similar ranking (Category 2 in the 2021 FAO report), the median and range of these RASB DIRVs are compared with the FAO/WHO DIRV (if included) to provide an overview of the potentially suitable DIRVs.

Step 4a: If the FAO/WHO DIRV and the RASBs DIRVs are similar¹, the FAO/WHO DIRV is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

Step 4b: If the FAO/WHO DIRV and the RASBs DIRVs are *not* similar¹, the median of the DIRVs from the FAO/WHO and the RASBs is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

Step 4c: If the FAO/WHO DIRV is not included (not a Category 2 in the 2021 FAO report), the median of the DIRVs from the RASBs is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

Note: for Steps 2, 4a, 4b and 4c consideration was given to the UL.

¹The median of the FAO/WHO and RASBs DIRVs is the same as the FAO/WHO DIRV (when rounded up).

Pilot application of draft General Principles using the revised stepwise process to establish NRVs-R for persons aged 6–36 months on a case-by-case basis

Vitamin B12

Step 1: The DIRVs for vitamin B12 for older infants and young children are outlined in Table 2.

Table 2. Vitamin B12 Dietary intake Reference Values (DIRVs) for Older Infants and Young Children (adapted from Page 39 of the 2021 FAO report)

Vitamin B12 Country/region RASB	Older Infants						Young Children					
	Age range (months)	AI (µg)	INL50 (µg)	INL98 (µg)	UL	KEY*	Age range (years)	AI (µg)	INL50 (µg)	INL98 (µg)	UL	KEY*
Australia & New Zealand NHMRC /MOH (2006)	7-12	0.5			N/A	2c	1-3		0.7	0.9	N/A	2d
United States & Canada IOM (1998)	7-12	0.5			N/A	2c	1-3		0.7	0.9	N/A	2d
Europe EFSA (2015)	7-11	1.5			N/A	2d	1-3	1.5			N/A	2d
FAO/WHO (2004) ^A	7-12		0.6	0.7	N/A	3j	1-3		0.7	0.9	N/A	2d
Japan NIHN (2015)	6-11	0.5			N/A	2c and 2d	1-2		0.7	0.9	N/A	2d
Nordic Countries NCM (2014)	6-11			0.5	N/A	2h	1-<2 2-5			0.6 0.8**	N/A	2h

^ASingle DIRV for general population NRVs-R

*Derivation key/scientific rigour

2c Allometric scaling up from DIRVyoung infant

2d Allometric scaling down from DIRVadult

2h Linear scaling from unit measure and: average of two specified methods

3j Interpolation

Older infants

Step 2: This was not applied as none of the DIRVs for vitamin B12 for older infants established by FAO/WHO or RASBs are informed by relevant physiological evidence (Category 1 2021 FAO report)

Step 3: Potentially unsuitable DIRVs (Category 3 in 2021 FAO report) were identified and thus the FAO/WHO DIRV was removed.

Step 4: The median and range of DIRVs established by RASBs that are derived by methods of higher scientific ranking (Category 2 in FAO 2021 report) were calculated as follows:

	Older infants		
	FAO/ WHO	RASBs*	
		Median	Range
Vitamin B12	-	0.5	0.5-1.5

*NHMRC, IOM, EFSA, NIHN and NCM

Step 4a: Not applicable.

Step 4b: Not applicable.

Step 4c: This process results in an NRV-R for vitamin B12 for older infants of 0.5 µg.

Young children

Step 2: This was not applied as none of the DIRVs for vitamin B12 for young children established by FAO/WHO or RASBs are informed by relevant physiological evidence (Category 1 2021 FAO report)

Step 3: No potentially unsuitable DIRVs (Category 3 in 2021 FAO report) were identified.

Step 4: The DIRV established by FAO/WHO and the median and range of DIRVs established by the RASBs that are derived by methods of higher scientific ranking (Category 2 in FAO 2021 report) are outlined below to provide an overview of potentially suitable DIRVs:

	Young children		
	FAO/ WHO	RASBs*	
		Median	Range
Vitamin B12	0.9	0.9	0.7-1.5**

*NHMRC, IOM, EFSA, NIHN and NCM

**The DIRVs set by NCM young children cover two age ranges; 0.6 µg for 1–<2-year-olds and 0.8 µg for 2–5-year-olds. For the 1–3-year-old age range the NCM DIRV is estimated as follows: (0.6 µg + 0.8 µg + 0.8 µg)/3 = 0.7 µg).

Step 4a: This process results in selecting the FAO/WHO DIRV of 0.9 µg as the NRV-R for vitamin B12 for young children.

Step 4b: Not applicable.

Step 4c: Not applicable.

Iodine

Step 1: The DIRVs for iodine for older infants and young children are outlined in Table 3.

Table 3. Iodine Dietary Intake Reference Values (DIRVs) for Older Infants and Young Children (adapted from Page 22 of the 2021 FAO report)

Iodine Country/ region RASB	Older Infants						Young Children					
	Age range (mont hs)	AI (µg)	INL 50	INL98 (µg)	UL	KEY *	Age range (years)	AI (µg)	INL50 (µg)	INL98 (µg)	UL	KEY*
Australia & New Zealand NHMRC /MOH (2006)	7-12	110			N/A	2c	1-3		65	90	200 µg	1b
United States & Canada IOM (2001)	7-12	130			N/A	2c	1-3		65	90	200 µg	1b
Europe EFSA (2015)	7-11	70			N/A	1b	1-<3	90			200 µg	1b
FAO/WHO (2004) ^a Recommendation for 0<5 yrs from (UNU/FAO/WHO / UNICEF(2007)	7-12			90	140 µg/kg/day	3j	1-3			90	50 µg/kg/day	3j
Japan NIHN (2015)	6-11	130			250 µg/day	2c	1-2		35	50	250 µg	2d
Nordic Countries NCM (2014)	6-11			50	N/A	2f	1-<2 2-5			70 90**	N/A	2f

^aSingle DIRV for general population NRVs-R

***Derivation key/scientific rigour**

- 1b Maintenance biomarker/absence deficiency;
- 2c Allometric scaling up from DIRV/young infant
- 2d Allometric scaling down from DIRV/adult
- 2f Isometric scaling down from DIRV/adult
- 3j Interpolation

Older infants

Step 2: As the DIRV established by EFSA is informed by relevant physiological evidence (Category 1 2021 FAO report), this process results in selecting the EFSA DIRV of 70 µg as the NRV-R for iodine for older infants.

Step 3: Not applicable.

Step 4: Not applicable.

Step 4a: Not applicable.

Step 4b: Not applicable.

Step 4c: Not applicable.

Young children

Step 2: As the DIRVs established by NHMRC, IOM and EFSA are informed by relevant physiological evidence (Category 1 2021 FAO report), this process results in selecting the median of these DIRVs of 90 µg as the NRV-R for iodine for young children.

Step 3: Not applicable.

Step 4: Not applicable.

Step 4a: Not applicable.

Step 4b: Not applicable.

Step 4c: Not applicable.

Vitamin B6

Step 1: The DIRVs for vitamin B6 for older infants and young children are outlined in Table 4.

Table 4. Vitamin B6 Dietary intake Reference Values (DIRVs) for Older Infants and Young Children (adapted from Page 37 of the 2021 FAO report)

Vitamin B6 Country/region RASB	Older Infants						Young Children					
	Age range (months)	AI (mg)	INL 50	INL98 (mg)	UL	KEY*	Age range (years)	AI	INL50 (mg)	INL98 (mg)	UL	KEY*
Australia & New Zealand NHMRC /MOH (2006)	7-12	0.3			N/A	2c	1-3		0.4	0.5	15mg	2d
United States & Canada IOM (1998)	7-12	0.3			N/A	2c and 2d	1-3		0.4	0.5	30mg	2d
Europe EFSA (2016)	7-11	0.3			N/A	2c and 2d	1-3		0.5	0.6	5mg	2d
FAO/WHO (2004) ^a	7-12			0.3	N/A	2c	1-3			0.5	N/A	2d
Japan NIHN (2015)	6-11	0.3			N/A	2c and 2d	1-2		0.4	0.5	10mg	2g
Nordic Countries NCM (2014)	6-11			0.4	N/A	2g	1-<2 2-5			0.5 0.7**	N/A	2g

^aSingle DIRV for general population NRVs-R

***Derivation key/scientific rigour**

2c Allometric scaling up from DIRVyoung infant

2d Allometric scaling down from DIRVadult

2g Linear scaling down from DIRVadult and: average of two specified methods

Older infants

Step 2: This was not applied as none of the DIRVs for vitamin B6 for older infants established by FAO/WHO or RASBs are informed by relevant physiological evidence (Category 1 2021 FAO report)

Step 3: No potentially unsuitable DIRVs (Category 3 in 2021 FAO report) were identified.

Step 4: The DIRV established by FAO/WHO and the median and range of DIRVs established by the RASBs that are derived by methods of higher scientific ranking (Category 2 in FAO 2021 report) are outlined below to provide an overview of potentially suitable DIRVs:

	Older infants		
	FAO/ WHO	RASBs*	
		Median	Range
Vitamin B6	0.3	0.3	0.3-0.4

*NHMRC, IOM, EFSA, NIHN and NCM

Step 4a: This process results in selecting the FAO/WHO DIRV of 0.3 µg as the NRV-R for vitamin B6 for older infants.

Step 4b: Not applicable.

Step 4c: Not applicable.

Young children

Step 2: This was not applied as none of the DIRVs for vitamin B6 for young children established by FAO/WHO or RASBs are informed by relevant physiological evidence (Category 1 2021 FAO report)

Step 3: No potentially unsuitable DIRVs (Category 3 in 2021 FAO report) were identified.

Step 4: The DIRV established by FAO/WHO and the median and range of DIRVs established by the RASBs that are derived by methods of higher scientific ranking (Category 2 in FAO 2021 report) are outlined below to provide an overview of potentially suitable DIRVs:

	Young children		
	FAO/ WHO	RASBs*	
		Median	Range
Vitamin B6	0.5	0.5	0.5-0.6**

*NHMRC, IOM, EFSA, NIHN and NCM

**The DIRVs set by NCM for young children cover two age ranges; 0.5 mg for 1–<2-year-olds and 0.7 mg for 2–5-year-olds. For the 1–3-year-old age range the Nordic Countries NCM DIRV is estimated as follows: (0.5 mg + 0.7 mg + 0.7 mg)/3 = 0.6 mg).

Step 4a: This process results in selecting the FAO/WHO DIRV of 0.5 µg as the NRV-R for vitamin B6 for young children.

Step 4b: Not applicable.

Step 4c: Not applicable.

Riboflavin

Step 1: The DIRVs for riboflavin for older infants and young children are outlined in Table 5.

Table 5. Riboflavin Dietary Intake Reference Values (DIRVs) for Older Infants and Young Children (adapted from Page 35 of the 2021 FAO report)

Riboflavin Country/region RASB	Older Infants						Young Children					
	Age range (months)	AI (mg)	INL 50	INL98 (mg)	UL	KEY*	Age range (years)	AI	INL50 (mg)	INL98 (mg)	UL	KEY*
Australia & New Zealand NHMRC /MOH (2006)	7-12	0.4			N/A	2c and 2d	1-3		0.4	0.5	N/A	2d
United States & Canada IOM (1998)	7-12	0.4			N/A	2c and 2d	1-3		0.4	0.5	N/A	2d
Europe EFSA (2017)	7-11	0.4			N/A	2c	1-3		0.5	0.6	N/A	2d
FAO/WHO (2004) ^A	7-12			0.4	N/A	2c	1-3			0.5	N/A	2d
Japan NIHN (2015)	6-11	0.4			N/A	2c and 2d	1-2		0.5	Boy=0.6 Girl=0.5* *	N/A	2g
Nordic Countries NCM (2014)	6-11			0.5	N/A	2g	1-<2 2-5			0.6 0.7**	N/A	2g

^ASingle DIRV for general population NRVs-R

***Derivation key/scientific rigour**

2c Allometric scaling up from DIRVyounginfant

2d Allometric scaling down from DIRVadult

2g Linear scaling down from DIRVadult

and: average of two specified methods

Older infants

Step 2: This was not applied as none of the DIRVs for riboflavin for older infants established by FAO/WHO or RASBs are informed by relevant physiological evidence (Category 1 2021 FAO report)

Step 3: No potentially unsuitable DIRVs (Category 3 in 2021 FAO report) were identified.

Step 4: The DIRV established by FAO/WHO and the median and range of DIRVs established by the RASBs that are derived by methods of higher scientific ranking (Category 2 in FAO 2021 report) are outlined below to provide an overview of potentially suitable DIRVs:

	Older infants		
	FAO/ WHO	RASBs*	
		Median	Range
Riboflavin	0.4	0.4	0.4-0.5

*NHMRC, IOM, EFSA, NIHN and NCM

Step 4a: This process results in selecting the FAO/WHO DIRV of 0.4 mg as the NRV-R for riboflavin for older infants.

Step 4b: Not applicable.

Step 4c: Not applicable.

Young children

Step 2: This was not applied as none of the DIRVs for riboflavin for young children established by FAO/WHO or RASBs are informed by relevant physiological evidence (Category 1 2021 FAO report)

Step 3: No potentially unsuitable DIRVs (Category 3 in 2021 FAO report) were identified.

Step 4: The DIRV established by FAO/WHO and the median and range of DIRVs established by the RASBs that are derived by methods of higher scientific ranking (Category 2 in FAO 2021 report) are outlined below to provide an overview of potentially suitable DIRVs:

	Young children		
	FAO/ WHO	RASBs*	
		Median	Range
Riboflavin	0.5	0.6	0.5-0.7**

*NHMRC, IOM, EFSA, NIHN and NCM

**The NIHN DIRV for boys (0.6 mg/day) and girls (0.5 mg/day) was averaged (0.55 mg/day) and rounded to 0.6 mg/day.

The DIRVs set by NCM for young children cover two age ranges; 0.6 mg for 1–<2-year-olds and 0.7 mg for 2–5-year-olds. For the 1–3-year-old age range the Nordic Countries NCM DIRV is estimated as follows: (0.6 mg + 0.7 mg + 0.7 mg)/3 = 0.7 mg).

Step 4a: Not applicable.

Step 4b: This process results in selecting the median of the FAO/WHO and RASBs DIRV of 0.6 mg as the NRV-R for riboflavin for young children.

Step 4c: Not applicable.

Thiamine

Step 1: The DIRVs for thiamine for older infants and young children are outlined in Table 6.

Table 6. Thiamine Dietary Intake Reference Values (DIRVs) for Older Infants and Young Children (adapted from Page 34 of the 2021 FAO report)

Thiamine Country/region RASB	Older Infants						Young Children					
	Age range (months)	AI (mg)	INL50 (mg/ MJ)	INL98 (mg)	UL	KEY*	Age range (years)	AI	INL50	INL98 (mg)	UL	KEY*
Australia & New Zealand NHMRC /MOH (2006)	7-12	0.3			N/A	2d	1-3yr		0.4mg	0.5	N/A	2d
United States & Canada IOM (1998)	7-12	0.3			N/A	2d	1-3yr		0.4mg	0.5	N/A	2d
Europe EFSA (2016) **	7-11		0.072	6mo Boy 0.27 Girl 0.24 11mo Boy 0.31 Girl 0.28**	N/A	2g	1-<3yr		0.072 mg/MJ	1yr Boy 0.33 Girl 0.30 2yr Boy 0.43 Girl 0.40**	N/A	2g
FAO/WHO (2004)A	7-12			0.3	N/A	2c	1-3yr			0.5	N/A	2d
Japan NIHN (2015)	6-11	0.2			N/A	2c and 2d	1-2yr		0.4mg	0.5	N/A	2g
Nordic Countries NCM (2014)	6-11			0.4	N/A	2h	1-<2yr 2-5yr			0.5 0.6g**	N/A	2g

^ASingle DIRV for general population NRVs-R

***Derivation key/scientific rigour**

2c Allometric scaling up from DIRVyoung infant

2d Allometric scaling down from DIRVadult

2g Linear scaling down from DIRVadult

2h Linear scaling from unit measure and: average of two specified methods

**Europe EFSA (2016)-No single value for age range; INL98 (OI) set by month and INL98 (YC) by year; 6 mo, 11 mo, 1 yr and 2 yr selected

Older infants

Step 2: This was not applied as none of the DIRVs for thiamine for older infants established by FAO/WHO or RASBs are informed by relevant physiological evidence (Category 1 2021 FAO report)

Step 3: No potentially unsuitable DIRVs (Category 3 in 2021 FAO report) were identified.

Step 4: The DIRV established by FAO/WHO and the median and range of DIRVs established by the RASBs that are derived by methods of higher scientific ranking (Category 2 in FAO 2021 report) are outlined below to provide an overview of potentially suitable DIRVs:

	Older infants		
	FAO/ WHO	RASBs*	
		Median	Range
Thiamine	0.3	0.3	0.2-0.4**

*NHMRC, IOM, EFSA, NIHN and NCM

**The DIRVs set by EFSA cover two age ranges and sexes; 0.27 mg and 0.24 mg for 7-month-old boys and girls respectively, and 0.31 mg and 0.28 mg for 11-month-old boys and girls respectively. The EFSA DIRV is estimated as follows: $(0.27 \text{ mg} + 0.24 \text{ mg} + 0.31 \text{ mg} + 0.28)/4 = 0.28 \text{ mg} \sim 0.3 \text{ mg}$.

Step 4a: This process results in selecting the FAO/WHO DIRV of 0.3 mg as the NRV-R for thiamine for older infants.

Step 4b: Not applicable.

Step 4c: Not applicable.

Young children

Step 2: This was not applied as none of the DIRVs for thiamine for young children established by FAO/WHO or RASBs are informed by relevant physiological evidence (Category 1 2021 FAO report)

Step 3: No potentially unsuitable DIRVs (Category 3 in 2021 FAO report) were identified.

Step 4: The DIRV established by FAO/WHO and the median and range of DIRVs established by the RASBs that are derived by methods of higher scientific ranking (Category 2 in FAO 2021 report) are outlined below to provide an overview of potentially suitable DIRVs:

	Young children		
	FAO/ WHO	RASBs*	
		Median	Range
Thiamine	0.5	0.5	0.4-0.6*

*NHMRC, IOM, EFSA, NIHN and NCM

**The DIRVs set by EFSA cover two age ranges and sexes; 0.33 mg and 0.30 mg for 1 year-old boys and girls respectively, and 0.43 mg and 0.40 mg for 2 year-old boys and girls respectively. The EFSA DIRV is estimated as follows: $(0.33 \text{ mg} + 0.30 \text{ mg} + 0.43 \text{ mg} + 0.40)/4 = 0.37 \text{ mg} \sim 0.4 \text{ mg}$. The DIRVs set by NCM cover two age ranges; 0.5 mg/day for 1–<2 years and 0.6 mg/day for 2–5 years. The NCM DIRV is estimated as follows: $(0.5 + 0.6 + 0.6)/3 = 0.6 \text{ mg}$

Step 4a: This process results in selecting the FAO/WHO DIRV of 0.5 mg as the NRV-R for thiamine for young children.

Step 4b: Not applicable.

Step 4c: Not applicable.

Niacin

Step 1: The DIRVs for niacin for older infants and young children are outlined in Table 7.

Table 7. Niacin Dietary Intake Reference Values (DIRVs) for Older Infants and Young Children (adapted from Page 36 of the 2021 FAO report)

Niacin	Older Infants						Young Children						
	Country/region RASB	Age range (months)	AI (mg NE)	INL50 (mg/MJ NE)	INL98 (mg NE)	UL KEY*	Age range (years)	AI	INL50	INL98 (mg NE)	UL	KEY*	
Australia & New Zealand NHMRC /MOH (2006)		7-12	4			N/A	2d		1-3	5mg NE	6	10mg as nicotinic acid 150mg as nicotinamide**	2d
United States & Canada IOM (1998)		7-12	4			N/A	2d		1-3	5mg NE	6	10 mg ***	2d
Europe EFSA (2014)		7-11		1.3	6 mo ** Boy=4.2 Girl=3.7 11 mo Boy=4.8 Girl=4.4	N/A	2g		1-3	1.3m g/MJ NE	1yr** Boy=5.1 Girl=4.6 2yr Boy=6.7 Girl=6.2	2 mg as nicotinic acid 150mg as nicotinamide	2g
FAO/WHO (2004)A		7-12			4	N/A	2c		1-3		6	N/A	2d
Japan NIHN (2015)		6-11	3			N/A	2c and 2d		1-2	Boy 5mg NE Girl 4mg NE*	5	15 mg as nicotinic acid	2g

Australia & New Zealand NHMRC /MOH (2006)	7-12	30			N/a	2c		1-3		25	35	N/a	3j
United States & Canada IOM (2000)	7-12	50			N/a	2c and 3i		1-3		13	15	400 mg	2d
Europe EFSA (2013) ^b	7-11		Not set	20**	N/a	1b		1-3		15	20	N/a	2f
FAO/WHO (2004)	7-12			30	N/a	3j		1-3			30	N/a	3j
Japan NIHN (2015) ^b	6-11	40			N/a	2c and 2d		1-2		30	35	N/a	2d
Nordic Countries NCM (2014)	6-11			20	N/a	2f		1-<2 2-5			25 30*	N/a	2f

**EFSA – Arbitrary, 3 times amount to prevent scurvy (SCF, 1993)

^bMultiple DIRVs for general population NRVs-R

***Derivation key/scientific rigour**

- 1b Maintenance biomarker/absence deficiency;
- 2c Allometric scaling up from DIRVyoung infant
- 2d Allometric scaling down from DIRVadult
- 2f Isometric scaling down from DIRVadult
- 3i Nutrient intake estimate
- 3j Interpolation and: average of two specified methods

Older infants

Step 2: As the DIRV established by EFSA is informed by relevant physiological evidence (Category 1 2021 FAO report), this process results in selecting the EFSA DIRV of 20 mg as the NRV-R for vitamin C for older infants

Step 3: Not applicable.

Step 4: Not applicable.

Step 4a: Not applicable.

Step 4b: Not applicable.

Step 4c: Not applicable.

Young children

Step 2: This was not applied as none of the DIRVs for vitamin C for young children established by FAO/WHO or RASBs are informed by relevant physiological evidence (Category 1 2021 FAO report)

Step 3: Potentially unsuitable DIRVs (Category 3 in 2021 FAO report) were identified and thus the NHMRC and FAO/WHO DIRVs were removed.

Step 4: The median and range of DIRVs established by RASBs that are derived by methods of higher scientific ranking (Category 2 in FAO 2021 report) were calculated as follows:

	Young children		
	FAO/WHO	RASBs*	
		Median	Range
Vitamin C	-	24	15-35**

*IOM, EFSA, NIHN and NCM

**The DIRVs set by NCM cover two age ranges; 25 mg/day for 1–<2 years and 30 mg/day for 2–5 years. The NCM DIRV is estimated as follows: (25 + 30 + 30)/3 = 28 mg).

Step 4a: Not applicable.

Step 4b: Not applicable.

Step 4c: This process results in an NRV-R for vitamin C for young children of 24 mg.

Table 9. Summary of proposed NRVs-R for persons aged 6–36 months applying the draft General Principles using the revised stepwise approach

Nutrient	Older Infants	Young Children	General Population*
Vitamin B12 (µg)	0.5	0.9	2.4
Iodine (µg)	70	90	150
Vitamin B6 (mg)	0.3	0.5	1.3
Riboflavin (mg)	0.4	0.6	1.2
Thiamine (mg)	0.3	0.5	1.2
Niacin (mg NE)	4	6	15
Vitamin C (mg)	20	24	100

*CXG 2-1985

Planned work for the Physical Working Group (PWG) on 6th March 2023

28. Based on two consultations the draft General Principles were amended and are presented in this paper (see Text Box 1). Based on feedback from the EWG, the stepwise process used by New Zealand for establishing requirements for persons aged 6–36 months in the revision of the *Standard for Follow-up Formula* (CXS 156-1987) was updated by the Chair and used to apply the General Principles for the seven nutrients, as presented in this Agenda Paper.

29. From this work, the Chairs have identified the following:

- a) The stepwise process varies from nutrient to nutrient, which aligns with the draft General Principles (3.2) of examining nutrients on a case-by-case basis.
- b) The stepwise process has only been piloted for the seven nutrients, which, with the exception of iodine, are all water soluble.
- c) Therefore, the stepwise process may need adjustment depending on the outcomes of applying this process to the wider range of nutrients, which may be more variable.

30. The Chair is undertaking work on applying this stepwise process to all the remaining nutrients. The Chairs will develop a paper on the outcomes of this work for presentation and discussion at the PWG (to be held immediately prior to CCFSDU43).

31. Future work and next steps

- Pilot the draft General Principles on the remaining nutrients (vitamin A, vitamin D, vitamin E, vitamin K, folate, pantothenic acid, biotin, calcium, magnesium, iron, zinc, copper, selenium, manganese, phosphorus, potassium, sodium) using the revised stepwise approach.
- Identify any revisions required to the draft General Principles or to the revised stepwise approach.
- Propose a list of NRVs-R for persons aged 6–36 months.
- Consider whether separate NRVs-R for older infants and young children or a combined set of NRVs-R is needed.
- Finally, in collaboration with CCFL, identification of adjustments required to the Codex FSDU texts and the *Guidelines on Nutrition Labelling* (CXG 2-1985) for implementation of these NRVs-R for persons aged 6–36 months.

APPENDIX II**PART A****PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES
FOR PERSONS AGED 6 TO 36 MONTHS
(for comments at Step 3 through CL 2022/74/OCS-NFSDU)****1. PREAMBLE**

These Principles apply to the establishment of Codex Nutrient Reference Values-Requirement (NRVs-R) for persons aged 6–36 months. These values are for use 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 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] NRVs-R for specific segments of persons aged 6-36 months.

2. DEFINITIONS

Daily Intake Reference Values (DIRV) as used in these Principles 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 month or to a segment of this age group (e.g. recommendations for a specified age range).

Individual Nutrient Level 98 (INL98)² 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.

Upper Level of Intake (UL)³ 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.

Adequate Intake (AI) is the observed or experimentally derived intake by a defined population group that appears to sustain health^{4,5}.

Recognized Authoritative Scientific Body (RASB) as used in these Principles refers to an organization other than FAO and/or WHO (FAO/WHO), that is 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.

²Different 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).

³Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range.

⁴Growth and development is considered as a part of the broader term sustain health in persons 6-36 months of age.

⁵UNU/FAO/WHO/UNICEF (2007).

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

3.2 Appropriate Basis for Establishing NRVs-R

The NRVs-R should be based on Individual Nutrient Level 98 (INL98) informed by relevant evidence (2021 FAO report⁶). Where the INL98 cannot be determined, the AI should be used. Where there is an absence of, or an older, established INL98 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 rigor of scientific methods, and quality and strength of evidence used to establish these values should be reviewed on a case-by-case basis.

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.

⁶FAO 2021. Review of Derivation Methods for Dietary Intake Reference Values For Older Infants And Young Children.

APPENDIX II
PART B**PROPOSED PILOT STEPWISE APPROACH ON THE PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES (NRVS-R) FOR PERSONS AGED 6 – 36 MONTHS
(for comments through CL 2022/74/OCS-NFSDU)**

Step 1: Using the 2021 FAO report, DIRVs established by FAO/WHO and the RASBs for the vitamins, minerals and protein under consideration for older infants and young children, were identified.

Step 2: The scientific rigour of the derivation methods used to establish these DIRVs (outlined in the 2021 FAO report) were used to identify nutrients where DIRVs are based on INL98/AI informed by relevant physiological evidence (Category 1 in 2021 FAO report).

Should this include the FAO/WHO DIRV, this is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

In cases where the FAO/WHO DIRV is not included, the median of the Category 1 DIRVs from the RASBs is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

Step 3: Potentially unsuitable DIRVs (Category 3 in 2021 FAO report) are excluded due to the lower scientific rigour of such values.

Step 4: Where the scientific rigour of the derivation methods of the DIRVs established by the FAO/WHO and any of the RASBs are of similar ranking (Category 2 in the 2021 FAO report), the median and range of these RASB DIRVs are compared with the FAO/WHO DIRV (if included) to provide an overview of the potentially suitable DIRVs.

Step 4a: If the FAO/WHO DIRV and the RASBs DIRVs are similar¹, the FAO/WHO DIRV is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

Step 4b: If the FAO/WHO DIRV and the RASBs DIRVs are *not* similar¹, the median of the DIRVs from the FAO/WHO and the RASBs is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

Step 4c: If the FAO/WHO DIRV is not included (not a Category 2 in the 2021 FAO report), the median of the DIRVs from the RASBs is selected for the establishment of NRVs-R for persons aged 6 – 36 months.

Note: for Steps 2, 4a, 4b and 4c consideration was given to the UL.

¹The median of the FAO/WHO and RASBs DIRVs is the same as the FAO/WHO DIRV (when rounded up).

**APPENDIX II
PART C****Proposed draft NRVs-R for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C
(for comments at Step 3 through CL 2022/74/OCS-NFSDU)**

Nutrient	Older Infants	Young Children	General Population*
Vitamin B12 (µg)	0.5	0.9	2.4
Iodine (µg)	70	90	150
Vitamin B6 (mg)	0.3	0.5	1.3
Riboflavin (mg)	0.4	0.6	1.2
Thiamine (mg)	0.3	0.5	1.2
Niacin (mg NE)	4	6	15
Vitamin C (mg)	20	24	100

*CXG 2-1985

APPENDIX III**List of participants**

NUMBER	MEMBER NAME/OBSERVER NAME	PARTICIPANT NAME
1	Australia	Jenny Hazelton
2	Brazil	Ana Claudia Marquim Firmo de Araújo Ana Paula de Rezende Peretti Giometi Patrícia Ferrari Andreotti
3	Canada	Chantal Martineau Maya Villeneuve
4	Chile	Cristian Cofré
5	China	Aidong Liu Haiqin Fang Taotao Deng
6	Colombia	Blanca Cristina
7	Costa Rica	Amanda Lasso Cruz Alejandra Chaverri
8	Cuba	Yarisa Domínguez Ayllón
9	Egypt	Mohamed M. Abdelhameed
10	European Union	Stephanie Bodenbach Fruzsina Nyemecz Judit Krommer
11	Germany	Alina Steinert
12	Guatemala	Pamela Castillo
13	India	Narendra Tripathi Prema Ramachandran Madhawan Nair ARTI Gupta Shankar
14	Indonesia	Yusra Egayanti
15	Iran	Farahnaz Ghollasi
16	Japan	Masafumi Saito
17	Malaysia	Norlida Zulkafly Noor ul-Aziha Muhammad
18	Mexico	Tania Fosado
19	Morocco	TAHRI Samah BOUR Abdellatif Youssef Aboussaleh
20	New Zealand	Charlotte Channer Michelle Gibbs Kati Laitinen
21	Nigeria	Kemisola Ajasa
22	Norway	Gry Hay
23	Poland	Agnieszka Wozniak
24	Republic of Korea	Youngsin Kim
25	Russia	Alexey Petrenko
26	Rwanda	Justin Manzi Muhir
27	Saudi Arabia	Fahad AlBadr Abdulaziz Alangaree Tagreed Mohammad Alfuraih Atheer Alraqea
28	South Africa	Nolene Naicker Zandile Kubeka
29	Uganda	Sarah Ngalombi

		Denis Male Hanifa Bachou- Odyekoi Raymond Sylveria Alwoch Lilliane Namirembe Lucy Atim Harish Bhuptani Ruth Awio Rehema Meeme Hakim Mufumbiro
30	United States of America	Douglas Balentine Carolyn Chung Pamela Pehrsson Kristen Hendricks
31	Uruguay	Ximena Moratorio
32	HKI	Alissa Pries
33	IADSA	Cynthia Rousselot
34	ICBA	Simone SooHoo Joanna Skinner
35	ICGMA	Melissa A. San Miguel
36	IDF	Anabel Mulet Cabero
37	ISDI	Marian Brestovansky
38	WPHNA	Angela Carriedo