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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

Summary of comments in reply to CL 2022/74/OCS-NFSDU for discussion at the PWG on Monday 6th March

(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 2022/74/OCS-NFSDU was posted in December 2022. By the 10th February 2023, comments were submitted by 21 Codex Members (CMs) and 3 Codex Observers (COs) (see CX/NFSDU 23/43/5 Add.1).

These comments were collated to identify areas where there is general agreement and areas that require further consideration. Feedback is summarised and, where possible, proposals are made to progress agreement on three areas outlined in the Agenda Paper (CX/NFSDU 23/43/5):

1. Draft General principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months (CX/NFSDU 23/43/5, Appendix II, Part A)
2. Pilot stepwise approach on the application of the draft General principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months (CX/NFSDU 23/43/5, Appendix II, Part B)
3. NRVs-R for persons aged 6 – 36 months for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C (CX/NFSDU 23/43/5, Appendix II, Part C)

Purpose

To guide discussions at the PWG to progress the three areas for consideration in Agenda Item 5 at Plenary.

General comments received in reply to CL 2022/74/OCS-NFSDU

There was widespread appreciation for the substantive work that the EWG completed over the 16 months since CCNFSDU42.

Some comments received from CMs expressed support for the draft General Principles, the stepwise approach and the proposed NRVs-R outlined in the Agenda Paper (CX/NFSDU 23/43/5). Other comments identified specific points where further discussion would be welcomed at the PWG session within the three areas under consideration at Plenary. These points include:

- consideration of appropriate data and review of data to determine strength and quality of evidence (related to the General Principles)
- the recognition of FAO/WHO as the primary source for the NRVs-R in the stepwise process
- the lack of differentiation between the use of INL98 versus AI values in the stepwise process
- the potential need to consider the DIRVs of all RASBs for the establishment of NRVs-R for iodine and vitamin C.

Specific points on the three areas for consideration

1. General principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months (CX/NFSDU 23/43/5, Appendix II, Part A)

The proposed draft General Principles in the Agenda Paper (CX/NFSDU 23/43/5) fall into three sections (1) Preamble, (2) Definitions and (3) General Principles for establishing NRVs-R. For ease of discussion at the PWG, the proposed draft text of these three sections is repeated separately along with all relevant comments received.

Comments have been collated to identify areas within these separate sections where there is general agreement and areas that require further consideration. Where possible, feedback is summarised and proposals developed for discussion.

Table 1. Feedback Responses to CL 2022/74/OCS-NFSDU on Proposed Draft General Principles

<p>PREAMBLE proposed in Agenda Paper (CX/NFSDU 23/43/5)</p> <p>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.</p> <p>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.</p>
<p>Areas where there is general agreement</p> <p>Comments submitted by the majority of CMs and COs supported the proposed Preamble text.</p>
<p>Areas where further discussion is required and EWG Chair and Co-Chairs proposal</p> <ol style="list-style-type: none"> 1. Clarification on foods considered as FSDU for this age group was raised and it was suggested that the relevant standards and guidelines covered by these General Principles should be listed in the Preamble. <p>EWG Chair and Co-Chairs proposal</p> <p>The Committee agreed (para 120, REP19/NFSUD) to continue work to develop NRVs-R for the four Codex texts identified, which include i) processed cereal-based foods for infants and young children; ii) canned baby foods; iii) formulated complementary foods for older infants and young children, and iv) follow-up formula for older infants. With this clear understanding, continued use of “FSDU texts”, is more appropriate in the Draft General Principles, while reference to specific FSDU texts would enter the main body of CXG 2-1985 (after 3.4.4.1). This is where clarification on the foods the NRVs-R for persons aged 6-36 months applies to is best placed.</p> <ol style="list-style-type: none"> 2. The proposed Preamble text includes ‘are for use’ rather than ‘may be used’ in the Annex of CAC/GL 2-1985. <p>EWG Chair and Co-Chairs proposal</p> <p>To align with the Annex of CAC/GL 2-1985, the term ‘may be used’ should replace ‘are for use’ in the second sentence of the Preamble.</p> <ol style="list-style-type: none"> 3. The last two sentences of the Preamble omit ‘food labelling’ and ‘food label’ from the Annex of CAC/GL 2-1985. <p>EWG Chair and Co-Chairs proposal</p> <p>To align with the Annex of CAC/GL 2-1985, the proposed text should be amended to include ‘food labelling’ and ‘food label’ in the last two sentences of the Preamble.</p> <ol style="list-style-type: none"> 4. Could the inclusion of ‘of nutrients’ be added after ‘healthful dietary intake’ for clarity? <p>EWG Chair and Co-Chairs proposal</p>

The inclusion of 'of nutrients' added after 'healthful dietary intake', changes original text in the Annex of CAC/GL 2-1985. Retaining original text as far as possible from the Annex was strongly supported in feedback from both consultations. Therefore, 'of nutrients' should not be added.

5. Retention of text on 'population-weighted values' in the second para of the draft Preamble to align with text in the Annex of CAC/GL 2-1985. Concerns were raised that the two sets of values currently being derived are based on physiological requirements for persons aged 6-12 months and 12-36 months and this assumption may not be correct.

EWG Chair and Co-Chairs proposal

It is understood that this feedback relates to concerns about how this might apply to the values for the combined age group (6-36 months). However, the reference to 'population-weighted values' for the general population in the Annex of CAC/GL 2-1985 relates to the variation among populations in terms of proportions of age-sex groups in national census data. This is not relevant for the narrow population age range of persons aged 6-36 months.

The references to 'population-weighted values' was omitted from the Preamble based on strong feedback back to EWG Consultations that this is not relevant to the 6-36 month old population. In REP22/NFSDU it was agreed that the text in the Annex of CAC/GL 2-1985 would 'only, when necessary, be adjusted to include specific requirements for other population groups for persons aged 6-36 months' (para 130; REP22/NFSDU).

6. The application of these NRVs-R to FSDU only, or to general foods targeting persons aged 6–36 months.

One CM does not support the proposed text that the NRVs-R are for use in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6–36 months. In support of this view, previous discussions by the Committee on differing views whether these NRVs-R should apply only to FSDU or to general foods targeting this age group are noted (paras 144-145 REP20/NFSDU).

The second sentence in the proposed draft preamble (see above) states that these values are for use in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6–36 months and does not mention general foods. This needs to be agreed.

EWG Chair and Co-Chairs proposal

While divergent views have been expressed on this, majority feedback supports application of NRVs-R in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6–36 months only. This feedback does not support in application in the labelling of pre-packaged general foods. Therefore, at this point it is proposed to limit application to FSDU intended for persons aged 6–36 months only.

Please see Appendix where revised text on the Preamble according to the feedback discussed above, is outlined as part of the Revised Draft General Principles for discussion at the PWG

DEFINITIONS proposed in Agenda Paper (CX/NFSDU 23/43/5)

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.

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 up-per 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).

Areas where there is general agreement

There was widespread agreement on the Definitions.

Areas where further discussion is required and EWG Chair and Co-Chairs proposal

1. A slight alteration of the first sentence in the definition of Recognized Authoritative Scientific Body (RASB) from the original text in the Annex of CAC/GL 2-1985 was noted by a CM. There was concern that the original text was purposefully written to indicate that the FAO and WHO are also considered recognised and authoritative in their work on DIRVs.

The original text in the Annex of CAC/GL 2-1985 used in the definition of Recognized Authoritative Scientific Body (RASB) is outlined below:

“Other than FAO and/or WHO (FAO/WHO), a Recognized Authoritative Scientific Body (RASB) as used in these Principles 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.”

EWG Chair and Co-Chairs proposal

The Chairs note that in the proposed text RASB was moved to the beginning of the sentence to align with the format of the other definitions. The recognition of FAO/WHO as authoritative and a primary source of DIRVs are stated in **3.1 Selection of suitable data sources to establish NRVs-R**. The Chairs suggest retaining the proposed text.

2. The original reference for the Adequate Intake (AI) definition should be listed rather than citing its use in 2007 by UNU/FAO/WHO/UNICEF.

EWG Chair and Co-Chairs proposal

The reference in the footnote should be amended to include the original reference (King JC, Vorster HH, Tome DG (2007). Nutrient intake values (NIVs): a recommended terminology and framework for the derivation of values. Food Nutr Bull. 28 (1 Suppl International): S16-26') in addition to UNU/FAO/WHO/UNICEF (2007).

3. An alternative definition for the Adequate Intake (AI) *based on an average observed daily level of nutrient intakes* was proposed.

EWG Chair and Co-Chairs proposal

For this age group there is a dearth of data on dietary intakes and in most cases the AI is developed using scaling methods (scaling up from younger infants or down from adults). Therefore, the current definition should be retained, and the alternative not adopted.

Please see Appendix where revised text on the Definitions according to the feedback discussed above, is outlined as part of the Revised Draft General Principles for discussion at the PWG

GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R proposed in Agenda Paper (CX/NFSDU 23/43/5)

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 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.

Areas where there is general agreement

Comments submitted by CMs and COs were generally supportive of the approaches used in section 3.

Areas where further discussion is required and EWG Chair and Co-Chairs proposal

1. Under '3.2 Appropriate Basis for Establishing NRVs-R', an area that needs to be addressed is the inconsistent use of the terms AI and INL98 by different RASBs. A CM proposed text that addresses this, as follows:

"NRVs-R should be based on Individual Nutrient Level 98 (INL98), higher priority should be given to values derived from relevant physiological evidence from the target age group (REF:2021 FAO)".

This would enable the text to more accurately reflect the process undertaken in the pilot.

With this amendment the second sentence in 3.2 (referring to use of AI) can be deleted as it represents an unnecessary addition to this set of principles and deviates from the original text in the Annex of CAC/GL 2-1985. This is supported by others.

Furthermore, an AI would be considered within the third sentence as it is another DIRV ('Where there is an absence of, or an older, established INL98...').

This CM also proposes amending text in the last sentence under 3.2, as follows:

"The derivation of these values should be reviewed on a case-by case basis [taking into account the strength and quality of evidence underpinning the DIRV]." These changes retain the original text used in the Annex of CAC/GL 2-1985. The [] around the strength and quality of evidence reflects how different methods for derivation are prioritized in the 2021 FAO report, rather than judging the strength and quality of evidence. Furthermore, most RASBs have not evaluated the strength and quality of evidence in this manner, which may be partly due to the paucity of data available.

EWG Chair and Co-Chairs proposal

It is proposed to accept all the changes above to 3.2 with the exception of the final sentence which include the text but remove the [] as follows:

"The derivation of these values should be reviewed on a case-by case basis taking into account the strength and quality of evidence underpinning the DIRV."

The Chair and Co-Chairs agree with the CM that these revisions to 3.2 align the text more closely with the recent 2021 FAO report and utilise the term 'derivation' which is more appropriate. Furthermore, these

changes retain original text in the Annex of CAC/GL 2-1985. This revised text under 3.2 is outlined in full at the Appendix – **Revised proposed text for '3.2 Appropriate Basis for Establishing NRVs-R'**)

2. Under '3.2 Appropriate Basis for Establishing NRVs-R', the addition of text 'informed by relevant evidence (2021 FAO report⁵)' and footnote 5 may be unnecessary because these data sources are described under 3.1.

EWG Chair and Co-Chairs proposal

The reference to the 2021 FAO report and related footnote is a crucial element of 3.2 because the derivation of DIRVs for persons aged 6-36 months reflect a variety of methods due to the paucity of data available. This differs significantly from how NRVs-R can be established for the general population. Reference to the 2021 FAO report describes this and feedback strongly supports its inclusion.

3. The inclusion of text to cover the establishment of NRVs-R for the combined age group of persons aged 6–36 months was considered important.

EWG Chair and Co-Chairs proposal

It is noted that the Committee agreed (para 115 & 116, REP19/NFSDU) to decide on whether or not to combine the two sets of NRVs-R depending on the actual values of nutrient requirements.

Now that separate values have been proposed for NRVs-R for the first 7 nutrients under review, the Committee may consider approaches for the development of an NRVs-R for the combined age range of 6–36 months. This would have the advantage of piloting the development of values for the combined 6-36 month age group to progress completion of this work.

The Committee needs to consider how the values for the combined age group can be derived. From extra work completed by Ireland (piloting the application of the draft General Principles proposed in the Agenda Paper CX/NFSDU 23/43/5 to establish NRVs-R for all the nutrients) it would be feasible to select the higher value of the proposed NRVs-R for older infants and young children for the combined age range *as long as it does not exceed the UL for older infants and young children, where available.*

This has significant advantage over using a mean value of the values proposed for the two age groups. This is because the requirement for some nutrients is higher for older infants than for young children e.g., potassium, and it is important to cover the higher requirements in an NRV-R for the combined population group.

In summary, selecting the higher value of the proposed NRVs-R for older infants and young children for the combined age range would provide 'population coverage'.

If this is agreed, the draft General Principles can be amended to include this text outlining how the higher value of the two proposed NRVs-R for older infants and young children is selected for the combined age range as long as it does not exceed the UL for older infants and young children, where available.

Please see Appendix where revised text on the GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R according to the feedback discussed above, is outlined as part of the Revised Draft General Principles for discussion at the PWG

2. Pilot stepwise approach on the application of the General principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months (CX/NFSDU 23/43/5, Appendix II, Part B)

Table 2. Proposed stepwise approach

<p>General comments on the stepwise approach</p> <ol style="list-style-type: none"> Text of draft General Principles should be agreed before work on how to establish the values. EWG Chair and Co-Chairs proposal Based on the work undertaken over the past 16 months by the EWG outlined in the Agenda Paper CX/NFSDU 23/43/5 (and extra work undertaken by Ireland, described above), the application of draft General Principles needs to be piloted to inform the final content of these Principles. One CM requested an explanation of using median instead of average in the calculation of NRVs-R. EWG Chair and Co-Chairs proposal The median is more correct to use especially in the context of using a small number of values. This is because the median is a safer measure of the centre in general as it is not impacted by outliers. One CM and one CO would welcome inclusion of the stepwise process in the General Principles, for clarity, consistency and transparency. EWG Chair and Co-Chairs proposal Inclusion of the stepwise process in the General Principles requires the agreement of the Committee. Getting such agreement should not delay progress in establishing these NRVs-R which are interim values.
<p>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.</p>
<p>Areas where there is general agreement</p> <p>There was unanimous support for Step 1.</p>
<p>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). <i>Should this include the FAO/WHO DIRV, this is selected for the establishment of NRVs-R for persons aged 6–36 months.</i> <i>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.</i></p>
<p>Areas where there is general agreement</p> <p>There was unanimous support for Step 2. <i>EWG Chair and Co-Chairs note that the wording used in Step 2 where the terms INL98 and AI are used interchangeably, may need to be amended if the changes to the text under 3.2 of the General Principles (see Appendix) are agreed.</i></p>
<p>Step 3: Potentially unsuitable DIRVs (Category 3 in 2021 FAO report) are excluded due to the lower scientific rigour of such values.</p>
<p>Areas where there is general agreement</p> <p>There was unanimous support for Step 3.</p>
<p>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</p>

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.

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

Areas where there is general agreement

There was majority support for Step 4 and rich feedback provided greater clarity to Steps 4a, 4b and 4c.

Areas where further discussion is required and EWG Chair and Co-Chairs proposal

1. One CM proposes that the selection of RASBs and identification of DIRVs are combined into one step instead of two; DIRVs from FAO/WHO and RASBs are equally considered unless deemed potentially unsuitable; and the median of all suitable DIRVs are used rather than in some cases defaulting to FAO/WHO when DIRVs from RASBs are the same.

This CM also proposes alternative text for easier comprehension of the steps.

EWG Chair and Co-Chairs proposal

The Committee needs to discuss the proposal to consider the DIRVs from FAO/WHO and RASBs equally (unless deemed potentially unsuitable) and to use the median of all suitable DIRVs rather than defaulting to FAO/WHO when DIRVs from RASBs are the same.

The stepwise approach needs to be agreed first before plain language edits for easier comprehension can be considered.

2. In Steps 4a and 4b reference is made to situations where the 'FAO/WHO DIRV and the median of the RASBs DIRV are 'similar' whereas the application of the stepwise process interprets 'similar' as 'same'.

EWG Chair and Co-Chairs proposal

That the text amendments, suggested by a CM, for Step 4a and 4b be adopted as follows:

“Step 4a: 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 months.

Step 4b: If the FAO/WHO DIRV and the median of the RASBs DIRVs are *not* the same, 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.”

Footnote 1 can be deleted ('The median of the FAO/WHO and RASBs DIRVs is the same as the FAO/WHO DIRV (when rounded up)') as a result of these changes.

3. There was a suggestion to add an overarching statement that addresses 'rounding rules' for all situations e.g., when rounding the average DIRV when RASBs provide these separately for boys and girls, when rounding DIRVs estimated from different age ranges for 1–3-year-olds and for steps 4a and 4b.

EWG Chair and Co-Chairs proposal

It is intended to provide statements to clarify 'rounding rules', however, this can only be completed when all NRVs-R have been established. This is due to the necessary assessment of the actual NRVs-R before deciding on how these values should be rounded.

3.NRVs-R for persons aged 6 – 36 months for vitamin B12, iodine, vitamin B6, riboflavin, niacin and vitamin C (CX/NFSDU 23/43/5, Appendix II, Part C)

Table 3. Proposed NRVs-R for persons aged 6 – 36 months for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C

<p>Vitamin B12</p> <p>Older infants 0.5 µg</p> <p>Young children 0.9 µg</p>
<p>Areas where there is general agreement</p> <p>The was general agreement on the proposed NRV-R for young children.</p>
<p>Areas where further discussion is required and EWG Chair and Co-Chairs proposal</p> <p>Some CMs and a CO proposed NRV-R for older infants of 0.5 µg should be increased to 0.7 µg.</p> <p>They noted that populations affected by food insecurity (LMIC countries) have low intakes of B12 due to low consumption of foods of animal origin. This public health issue may be compounded by folic acid food fortification programmes which mask B12 deficiency and allow it to progress.</p> <p>Reference to the increased AI for B12 set by EFSA in more recent years was noted leading to concerns that older infants may require higher intake levels of B12 (0.7 µg rather than 0.5 µg) especially if affected by food insecurity.</p> <p>EWG Chair and Co-Chairs proposal</p> <p>The comments on this pilot and the concerns expressed are appreciated. The stepwise process, also used as a basis for the NRVs for the general population and FUF composition, aims to apply the General Principles with a scientific evidence-based approach.</p> <p>To make progress on the draft General Principles, the discussion on the value derived (in this case for B12) should be paused, while the stepwise process is amended to include consideration of public health prevalence/ global applicability.</p> <p>In the case of B12, this involves amending the Stepwise process so that public health issues that vary in different countries for this nutrient can be accommodated (e.g. lower availability of dietary sources of B12 and the impact of folic acid food fortification)</p> <p>The decision on actual values for NRVs-R for B12 is a ‘next step’ that will include considering the evidence-base for increasing the NRV-R for B 12 for older infants and consideration of this in LMIC where dietary sources of this nutrient may be limited.</p>
<p>Iodine</p> <p>Older infants 70 µg</p> <p>Young children 90 µg</p>
<p>Areas where there is general agreement</p> <p>The was general agreement on the proposed NRV-R for young children.</p>
<p>Areas where further discussion is required and EWG Chair and Co-Chairs proposal</p> <p>The proposed NRV-R for older infants of 70 µg should be increased to 80 µg.</p> <p>Several CMs and a CO were concerned that the value of 70 µg for older infants is too low and should be increased to 80 µg. The value proposed of 70 µg in the Agenda Paper (CX/NFSDU 23/43/5) aligns with EFSA based on higher scientific rigour (category 1 2021 FAO report), however it is a significantly lower value than that set by other RASBs (category 2 scientific rigour) and FAO/WHO (category 3 scientific rigour).</p> <p>Women with lower iodine intake will have lower breastmilk concentrations of iodine and there is concern about iodine deficiency among many populations globally.</p> <p>EWG Chair and Co-Chairs proposal</p> <p>The comments on this pilot and the concerns expressed are appreciated. The stepwise process, also used as a basis for the NRVs for the general population and FUF composition, aims to apply the General Principles with a scientific evidence-based approach.</p>

<p>To make progress on the draft General Principles, the discussion on the value derived (in this case for iodine) should be paused, while the stepwise process is amended to include consideration of public health prevalence/ global applicability.</p> <p>In the case of iodine, this involves amending the Stepwise process so that public health issues that vary in different countries for this nutrient can be accommodated (e.g. the critical importance of iodine for this age group and the variable availability of dietary iodine linked to geographic location)</p> <p>The decision on actual values for NRVs-R for iodine is a 'next step' that will include considering the evidence-base for increasing the NRV-R for iodine for older infants. This may include consideration of UL for iodine and the policies on iodine food fortification in place in many countries globally.</p>
<p>Vitamin B6</p> <p>Older infants 0.3 mg</p> <p>Young children 0.5 mg</p>
<p><i>Areas where there is general agreement</i></p> <p>There was widespread support for the proposed NRV-R.</p>
<p>Riboflavin</p> <p>Older infants 0.4 mg</p> <p>Young children 0.6 mg</p>
<p><i>Areas where there is general agreement</i></p> <p>There was widespread support for the proposed NRV-R.</p>
<p>Thiamine</p> <p>Older infants 0.3 mg</p> <p>Young children 0.5 mg</p>
<p><i>Areas where there is general agreement</i></p> <p>There was widespread support for the proposed NRV-R.</p>
<p>Niacin</p> <p>Older infants 4 mg NE</p> <p>Young children 6 mg NE</p>
<p><i>Areas where there is general agreement</i></p> <p>There was widespread support for the proposed NRV-R.</p>
<p>Vitamin C</p> <p>Older infants 20 mg</p> <p>Young children 24 mg</p>
<p><i>Areas where there is general agreement</i></p> <p>There was general support for the proposed NRVs-R with some exceptions where a preference for higher values, especially for older infants, was expressed.</p>
<p><i>Areas where further discussion is required and EWG Chair and Co-Chairs proposal</i></p>

The proposed NRV of 20 mg for older infants provides an NRV-R for vitamin C that is lower than the amounts of vitamin C provided by breastmilk. Although the proposed NRV aligns with that set by EFSA on the basis of physiological evidence (category 1) it is significantly lower than DIRVs set by FAO/WHO and other RASBs.

There were some preferences expressed for increasing the value for young children.

EWG Chair and Co-Chairs proposal

The comments on this pilot and the concerns expressed are appreciated. The stepwise process, also used as a basis for the NRVs for the general population and FUF composition, aims to apply the General Principles with a scientific evidence-based approach.

To make progress on the draft General Principles, the discussion on the value derived (in this case for vitamin C) should be paused, while the stepwise process is amended to include consideration of public health prevalence/ global applicability.

In the case of vitamin C, this involves amending the Stepwise process so that public health issues that vary in different countries for this nutrient can be accommodated (e.g. the proposed NRV-R of 20 mg for vitamin C for older infants is lower than the amounts of vitamin C provided by breastmilk)

The decision on actual values for NRVs-R for vitamin C is a 'next step' that will include considering the evidence-base for increasing the NRV-R for vitamin C for older infants.

Appendix

Revised proposed text for the Draft General Principles following the feedback to CL 2022/74/OCS-NFSDU as discussed above (*note: new text is underlined, and older text crossed out*)

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~~ 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.

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.

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 up-per 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.

⁵ King JC, Vorster HH, Tome DG (2007). Nutrient intake values (NIVs): a recommended terminology and framework for the derivation of values. Food Nutr Bull. 28 (1 Suppl International): S16-26; and UNU/FAO/WHO/UNICEF (2007).

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~~, higher priority should be given to values derived from relevant physiological evidence⁶ from the target age group (2021 FAO report⁷). ~~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 derivation of these values should be reviewed on a case-by-case basis taking into account the strength and quality of evidence underpinning the DIRV. 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.

⁶The factorial summation of the various components involved in physiological growth, maintenance and loss in the target group. Also, the estimation of nutrient intake based on maintenance of a healthy plasma or urinary biomarker, or absence of deficiency disease in the target group.

⁷FAO 2021. Review of Derivation Methods for Dietary Intake Reference Values For Older Infants And Young Children.