

# CODEX ALIMENTARIUS COMMISSION



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Agenda Item 5

NFSDU/43 CRD05

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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#### REPORT OF THE PHYSICAL WORKING GROUP ON THE DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES (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*

#### Introduction

The physical Working Group (pWG) was held on the 6<sup>th</sup> March 2023 prior to the 43<sup>rd</sup> session of the CCFSDU. The focus of the working group was to progress the three areas for consideration in Agenda Item 5:

1. Draft General Principles for establishing Nutrient Reference Values Requirements (NRVs-R) for persons aged 6 – 36 months
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
3. NRVs-R for persons aged 6 – 36 months for vitamin B12, iodine, vitamin B6, riboflavin, thiamine, niacin and vitamin C

At the start of the meeting, the WHO provided an update on their systematic review of nutrient intake values for infants and young children (birth to 3 years). Draft values will be available by September 2023 for calcium, zinc and vitamin D (INL98 values with ULs set for zinc and vitamin D). Scoping reviews on iron, vitamin A, magnesium and folate are underway.

#### Discussion and recommendations on the three areas under consideration

1. Draft General Principles for establishing nutrient reference values (NRVs-R) for persons aged 6 – 36 months

A summary of the discussion and recommendations is presented below.

#### Preamble

The revised text presented at the PWG (CRD 08 Appendix) was accepted. The discussions focused on clarifying the foods that are considered as Food for Special Dietary Uses (FSDU), whether the relevant FSDU Codex texts should be listed, and the FSDU texts' provisions for labelling.

The Chair clarified that the FSDU to which the NRVs-R may be applied will be outlined in the body of CAC/GL 2-1985 along with the NRVs-R for persons aged 6-36 months when they are available. The Chair referred to para 120 REP19/NFSDU where these Codex texts are identified. Regarding comments on the lack of provisions for applying the NRVs-R, the co-chairs clarified that the work to adjust these texts accordingly would begin after the NRVs-R have been established.

The PWG generally agreed that the first sentence in the second paragraph of the preamble, as outlined the Appendix of CRD 08, was important to retain because it provides flexibility to consider factors specific to a country or a region. A request was made to include the sentence on "population-weighted values" from the Annex for the general population. The PWG discussed how this might provide flexibility but the Chair detailed how this is not relevant for this age group. The EWG Chair and Co-Chairs understood that the request relates to concerns about establishing NRVs-R for the combined age group, which was addressed in CRD 08 under the General Principles. It was decided to omit "population-weighted values" in the Preamble because the NRVs-R for the combined age group was addressed in discussions under section 3 of the draft General Principles. The PWG generally agreed that the reference to "population-weighted values" can be further discussed at the Committee.

**Recommendation 1**

The PWG recommends that the Committee adopt the Preamble text as outlined in the Appendix.

*Definitions*

There was widespread agreement on the Definitions. The PWG agreed to adopt the original wording of the definition for RASB from Annex Part A in CAC/GL 2-1985.

**Recommendation 2**

The PWG recommends that the Committee adopt the original wording of the definition for RASB from Annex Part A in CAC/GL 2-1985.

The PWG discussed the definition for Adequate Intake (AI). The PWG proposed the WHO definition and agreed it would present the new definition to the Committee in [ ]. WHO advised that while the definition uses the term 'average intake' this can be amended to 'adequate intake' for the purposes of the NRV-R work.

**Recommendation 3a**

The PWG recommends that the Committee consider adoption of the WHO definition for Adequate Intake as follows:

"Adequate intake (AI) is a recommended intake based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate (2007)\*"

\**Guidelines on food fortification with micronutrients* (2007)

[https://apps.who.int/iris/bitstream/handle/10665/43412/9241594012\\_eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/43412/9241594012_eng.pdf)

**Recommendation 3b**

If this definition for AI is adopted, the footnote on growth and development can be removed.

**Recommendation 3c**

The PWG recommends that the AI definition is moved to come before the UL definition.

*General Principles for the establishment of NRVs-R*

## 3.1 Selection of suitable data sources to establish NRVs-R

**Recommendation 4**

The PWG recommends that the Committee adopt the text of 3.1, as outlined in the Appendix.

## 3.2 Appropriate Basis for Establishing NRVs-R

Based on feedback, the CRD 08 presented revised text under 3.2 to align it more closely with the 2021 FAO report (utilizing the term derivation which was considered more appropriate). These changes enabled more retention of the original text in the Annex of CAC/GL 2- 1985.

The PWG discussed these changes at length and agreed that the FAO/WHO DIRVs are the primary source in establishing NRVs-R. It was also agreed that this is clearly outlined under the text in 3.1. Therefore, the text under 3.2 was revised to outline the particular cases where it may be more appropriate to consider the use of other DIRVs more recently established by RASBs. The PWG generally agreed that the derivation of these values should be reviewed on a case-by-case basis.

The PWG further revised the second paragraph under 3.2 to detail how the derivation of values from RASBs shall take account of the rigour of scientific methods, underlying data quality, strength of evidence used to establish these values and the most recent review of the science. The PWG suggested omitting the 2021 FAO report to ensure the General Principles do not become outdated, and noted this also allows for flexibility to consider the factors proposed in addition to the rigour of the derivation method.

The PWG considered whether first sentence on INL98 should be retained, given the interchangeable use of AI and INL98 across RASBs; some members raised concerns that reference to INL98 is important to clarify

that this is the DIRV that should be used for NRVs-R. Further discussion is needed on the inconsistent use of the terms AI and INL98 by different RASBs.

**Recommendation 5**

The PWG recommends that the Committee consider the proposed text in 3.2, as outlined in the Appendix, and whether there is a need to include reference to INL98.

In the discussions under 3.2, the issue of how the NRVs-R for the separate age groups will be combined for the 6-36 month age group was raised. The Chair described the proposal of the EWG Chair and Co-Chairs on approaches for the establishment of NRVs-R for the combined age group. The Chair explained that 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.

**Recommendation 6**

The PWG recommends that the approach for establishing the NRVs-R for the 6-36 month age group be developed and piloted in the revised Stepwise Process by the next EWG.

### 3.3 Consideration of Upper Levels of Intake

**Recommendation 7**

The PWG recommends that the Committee adopt the text of 3.3, as outlined in the Appendix.

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

The PWG agreed to revise the proposed stepwise process given the amendments to the General Principles. Edits proposed were to retain Step 4a and clarify that the medians of DIRVs are being compared.

The PWG discussed how the stepwise process could be documented, for example, in the general principles. Chair noted that general principles are overarching and need to be flexible for future use and suggested a possible option might be to document the stepwise process in a separate report, as was done for the NRVs for the general population.

The PWG discussed whether the stepwise process should include a step 5 to address global applicability. The PWG noted that (1) regional and local factors are addressed in para 2 of the Preamble; (2) physiological requirements vary little globally; (3) footnotes could be used as has been done for specific nutrients for the general population to address existing geographic and environmental factors; (4) the FAO/WHO DIRVs are indicated as a primary source because they address global applicability. For these reasons, the PWG agreed not to include a step addressing global applicability.

In addition, the stepwise process will need to incorporate the approach for combining the separate NRVs-R for older infants and young children to provide NRVs-R for the 6-36 month age group.

**Recommendation 8**

The PWG recommends that the stepwise process be revised by the next EWG taking account of these discussions.

**APPENDIX****PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES 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~~ may be used in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6–36 months to help consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products.

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

**2. DEFINITIONS**

**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)**<sup>1</sup> 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)**<sup>2</sup> 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<sup>3,4</sup>. [Adequate intake (AI) is a recommended intake based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate (2007)<sup>5</sup>]~~

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

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

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

~~<sup>3</sup>Growth and development is considered as a part of the broader term sustain health in persons 6-36 months of age.~~

~~<sup>4</sup>King JC, Vorster HH, Tome DG (2007). Nutrient intake values (NRVs): 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).~~

~~<sup>5</sup>Guidelines on food fortification with micronutrients (2007)~~

~~[https://apps.who.int/iris/bitstream/handle/10665/43412/9241594012\\_eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/43412/9241594012_eng.pdf) ]~~

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). In certain cases, where there is an absence of, or an older, established FAO/WHO DIRV 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.~~

~~Nevertheless, the derivation of these values from recognized authoritative scientific bodies, shall take ~~can take~~ into account, without indicating a hierarchy of the following elements: the rigor of scientific methods (2021 FAO report), the underlying data quality, the strength of evidence used to establish these values and the most recent independent review of the science.~~

### 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.

#### PROPOSED PILOT STEPWISE APPROACH ON THE PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES (NRVS-R) FOR PERSONS AGED 6 – 36 MONTHS

**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 with the intention to determine a globally applicable NRV-R.

**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.

**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.

[Step 5: There are public health issues and confounding variables unique to several of the minerals and vitamins that impact their global assessment and monitoring and adjustment factors should be considered when establishing the NRVs.]

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

~~<sup>†</sup>The median of the FAO/WHO and RASBs DIRVs is the same as the FAO/WHO DIRV (when rounded up).~~

**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)**

<b>Nutrient</b>	<b>Older Infants</b>	<b>Young Children</b>	<b>General Population*</b>
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