



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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NRVs-R FOR PERSONS AGED 6 – 36 MONTHS:

DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES (NRVs-R) FOR PERSONS AGED 6 TO 36 MONTHS

(Prepared by the EWG chaired by Ireland and co-chaired by 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 2024/51-NFSDU available on the Codex webpage/Circular Letters:

<https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

Background

- At the 43rd session of CCNFSDU the Committee agreed to forward the proposed draft General Principles for establishing Nutrient Reference Values (NRVs-R) for persons aged 6 to 36 months to CAC46 for adoption at Step 5. CAC46 adopted the General Principles at Step 5 and advanced it to Step 6.
- CCNFSDU43 further agreed to re-establish the EWG open to all Members and Observers, chaired by Ireland, and co-chaired by Costa Rica and the USA, working in English and Spanish to complete work under the terms of reference outlined below.
- The Terms of Reference (ToR) for the work of this 2023-24 EWG (REP2/NFSDU) were:
 - Revise the draft Stepwise Process taking into account the revisions to the draft General Principles and to develop an approach to propose NRVs-R for the combined age range of 6 to 36 months.
 - Apply the revised draft Stepwise Process to propose NRVs-R for persons aged 6 – 12 months, 12-36 months and 6 – 36 months, for the following nutrients:
 - Vitamins A, D, C, K and E, thiamine, riboflavin, niacin, vitamins B6 and b12, folate, pantothenic acid and biotin;
 - Calcium, magnesium, iron, zinc, iodine, copper, selenium, manganese, phosphorus and potassium.
- The part of the work to meet TORs above are presented in CX/NFSDU 24/44/4 Part B.

Additional work undertaken by the EWG

- Recent communication with the Codex Secretariat, Chair of CCNFSDU, WHO and FAO provided more data relative to areas in the draft General Principles that remain in square brackets.
- This allowed for further progression of the draft General Principles as the remaining outstanding area, NRVs-R for 6-36 months, is included under ToR B.
- Therefore, this Agenda Paper includes a revised General Principles for the establishment of NRVs-R for persons aged 6 – 36 months (Appendix I).
- Two areas in the draft General Principles remained in square brackets []:

Definition of Adequate Intake

- At CCNFSDU43, the Representative of WHO noted that to aid users of the forthcoming FAO/WHO guidance on calcium, vitamin D, and zinc intake values and facilitate the work of the EWG and CCNFSDU on the General Principles for establishing NRVs-R for persons aged 6 to 36 months, the FAO/WHO expert group

that is updating the nutrient intake values for infants and young children will be tasked with reviewing and updating the definition for adequate intake (along with other relevant terms) as needed.

The combined NRV-R value for persons aged 6–36 months

10. Given the many foods on the market covering the entire age range of 6-36 months, it was agreed to consider approaches for establishing NRVs-R for this entire age group.

11. CCFSDU43 agreed to insert the following text on the combined NRVs-R values for persons aged 6-36 months in square brackets for further consideration under section **3.2 Appropriate Basis for Establishing NRVs-R**:

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

OR

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

OR

The combined NRV-R value for persons aged 6-36 months should be determined by calculating the mean value of the two age groups 6-12 months and 12-36 months.]The update from work of the EWG is presented in Appendix II to this paper.

12. An update of the work and the conclusions of the EWG are presented in Appendix II.

Recommendations

13. The Committee is **invited** to:

- a. Consider the revised General Principles in Appendix I taking into account the following recommendations of the EWG Chair and co-Chairs:
 - i. agree with the definition of Adequate Intake currently in square brackets [] (see *Section 2 (DEFINITIONS AS USED IN THESE PRINCIPLES)* presented in **Appendix I**).
 - ii. consider Option 3 whereby the combined NRV-R value for persons aged 6-36 months is determined by selecting the mean value of the proposed NRVs-R for older infants and young children.
 - iii. Note that clarification on how these combined NRVs-R for persons aged 6–36 months should be used will be outlined in relevant text that relates to where the three sets of NRVs-R are presented in CXG 2-1985.

DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR PERSONS AGED 6 TO 36 MONTHS

(For comment at Step 6)

1. PREAMBLE

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

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

2. DEFINITIONS AS USED IN THESE PRINCIPLES

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

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

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

Upper Level of Intake (UL)¹ is the maximum level of habitual intake from all sources of a nutrient judged to be unlikely to lead to adverse health effects in persons aged 6 to 36 months.

Other than FAO and/or WHO (FAO/WHO), a Recognized Authoritative Scientific Body (RASB) refers to an organization supported by a competent national and/or regional authority(ies) that provides independent, transparent*, scientific and authoritative advice on daily intake reference values through primary evaluation** of the scientific evidence upon request and for which such advice is recognized through its use in the development of policies in one or more countries.

*In providing transparent scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value.

**Primary evaluation involves a review and interpretation of the scientific evidence to develop daily intake reference values, rather than the adoption of advice from another RASB.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R

3.1 Selection of suitable data sources to establish NRVs-R

Relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science should be taken into consideration as primary sources in establishing NRVs-R.

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

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

3.2 Appropriate Basis for Establishing NRVs-R

Ideally, the NRVs-R should be based on Individual Nutrient Level 98 (INL98). In certain cases, where there is an absence of, or an older, established FAO/WHO DIRV for a nutrient, it may be more appropriate to consider the use of other daily intake reference values or ranges that have been more recently established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.

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

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

~~OR~~

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

~~OR~~

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

3.3 Consideration of Upper Levels of Intake

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

Update of discussion in the EWG¹

Update from work of EWG

1. Definition of Adequate Intake

During the second Consultation held by the EWG, FAO/WHO made the following definition of **Adequate Intake** available for use by the EWG and, ultimately, by the Committee:

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

Therefore, this definition is presented in square brackets [] in section 2. **DEFINITIONS AS USED IN THESE PRINCIPLES** ().

2. The combined NRV-R value for persons aged 6–36 months

To examine the outcomes of the three options (**HIGHEST**, **LOWEST** and **MEAN** - see below) to identify the most appropriate choice for the establishment of a combined NRV-R value for persons aged 6–36 months, all three have been applied to each nutrient on a case-by-case basis.

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

OR

LOWEST (Option 2): The combined NRV-R value for persons aged 6-36 months should be determined by calculating the lower value of the two age groups 6-12 months and 12-36 months.

OR

MEAN (Option 3): The combined NRV-R value for persons aged 6-36 months should be determined by selecting the mean value of the proposed NRVs-R for older infants and young children.

All three options were applied to seven nutrients in a pilot test presented in Consultation Paper 1 (CP1) where the EWG Chair and Co-Chairs proposed Option 1 (HIGHEST) as the most appropriate.

On the basis of the pilot application of all three options to seven nutrients presented in CP1, the EWG Chair and Co-Chairs proposed that option 1 (the highest value) to be the most appropriate option given the benefits of covering the requirements of all in the age group without risk of exposure to excessive intake levels as the value must not exceed the UL for older infants and/or young children, where available.

There was a mixed response to this, where feedback to CP1 provided the different rationale for choosing each of the three options tested (see *quantitative analysis of the pilot test application of each of the three options on seven nutrients in CX/NFSU 24/44/4, Part B*):

HIGHEST (Option 1): Those in favour maintained this would ensure the requirements of all persons aged 6–36 months are met without exposing anyone to an excessive intake.

This was the rationale that led the EWG Chair and Co-Chairs to consider this option to be the most appropriate given the benefits of how this will cover the requirements of all in the age group without risk of exposure to excessive intake levels.

Option 2 (lowest value): Those in favour maintained that the consumption of products targeting an age range will mostly be at the lower end of that age range.

The EWG Chair and Co-Chairs were concerned that application of this option will result in a lower than optimal value for those at the older end of the combined age range.

Option 3 (mean value):

Those in favour pointed out that this option was consistent with the establishment of NRVs-R for the general population, because the general population NRVs-R are based on the widest applicable age range which is determined by calculating the mean value (see 3.2.1 of Annex 1 in CAC/GL 2-1985).

The EWG Chair and Co-Chairs noted, however, that the age range for the general population is several decades wide, while the age range for persons aged 6–36 months is only 30 months.

¹ The list of participants to the EWG are presented in CX/NFSU 24/44/4, Part B

In the second consultation all three options were applied to ALL nutrients under consideration and presented in Consultation Paper 2 (CP2). In CP2, the EWG Chair and Co-Chairs continued to propose Option 1 (HIGHEST) as the most appropriate.

In CP2, the EWG Chair and Co-Chairs outlined the different merits described in feedback to CP1 for each of the three options. Due to the mixed response to CP1, they continued to apply all three options on a case-by-case-basis to all nutrients requiring an NRV-R. This was undertaken to fully explore and inform EWG members how each option performs for all nutrients under consideration.

In CP2, the EWG Chair and Co-Chairs continued to recommend Option 1 (highest value without exceeding the UL for either age group).

Agreement with selection of Option 1 (HIGHEST)

A sizable proportion of feedback in CP2 agreed with the views of the EWG Chair and Co-Chairs expressed in CP2 that Option 1 (HIGHEST) is the most appropriate for establishing a combined NRV-R value for persons aged 6-36 months.

Reasons, where given, included:

1. There is a need to choose Option 1 because Options 2 and 3 will not establish the most appropriate NRVs-R value for persons aged 6-36 months.
2. NRVs-R are ideally based on INL98, estimated to meet the nutrient requirements of 98 percent of the apparently healthy persons ages 6-36 months. However, Option 2 or 3 would result in NRVs-R that do not meet that criterion for those at the older end of the 6 – 36 month age range.

This was cited as being of particular concern for nutrients where NRVs-R are established based on physiological evidence and Options 2 and 3 would result in some within the combined age range not meeting their requirements.

3. One CM in favour of selecting Option 1 (HIGHEST) expressed some concern that care needed to be taken in selecting the highest value if this resulted in a much higher NRVs- R for the group with the lowest requirements (usually Older Infants). This concern related to not having ULs available for all nutrients.

Disagreement with selection of Option 1 (HIGHEST)

Two areas of disagreement against choosing Option 1 (HIGHEST) included:

Firstly, the CMO supported Option 2 (LOWEST) as the most appropriate on the basis that the majority of those consuming products targeting the combined age group are at the younger end of the age range and not at the older end.

Secondly, concern was expressed for jurisdictions where labelling is provided per fixed quantities, e.g. per 100 g or ml, and not per portion on the basis that this could lead young children to consume higher amounts of the food and bigger portion sizes (due to higher energy requirements).

Unable to provide an answer on which Option to select

Two CMs and one CO stressed the need for the Committee to provide clarification on how these values should be used. One CM and one CO called for guidance as to *when* and *how* a combined NRVs-R for persons aged 6-36 months should be utilised over the 6-12 month or 12-36 month age group.

Clarification on the following questions was sought:

1. Will these NRV-s R be presented as up to national or regional authorities to determine whether to have two NRVs-R for the two age groups, or a single combined value 6-36 months?
2. Alternatively, will all three be considered to be appropriate to be chosen by the manufacturer?
3. Will there be guidance as to how to select the appropriate value?

These questions raise the concern that always selecting the highest value (Option 1), as proposed by the EWG Chair and Co-Chairs, may be inappropriate if the food is intended for older infants as the requirements specified will be higher than necessary.

Confusion about the question

Finally, there was some **confusion** noted in the feedback from one CO who was in favour of choosing Option 1 but mistakenly thought all three Options were to be permitted.

Summary of issues identified

The EWG Chair and Co-Chairs are grateful to the FAO/WHO for providing the definition of Adequate Intake,

which has been added to the first square bracket [] (see Section 2 (DEFINITIONS AS USED IN THESE PRINCIPLES))

The other remaining square brackets [] in the draft General Principles concern the establishment of **the combined NRV-R for persons aged 6–36 months**. The following summarises the issues to be agreed on:

Option 1 is supported by a sizable proportion of CMs as the most appropriate way to establish combined NRVs-R for persons aged 6-36 months. This involves selecting the *higher* value of the proposed NRVs-R for older infants and young children if it does not exceed the UL for older infants and/or young children, where available.

Nonetheless, there were concerns that always selecting the highest value (Option 1) may be inappropriate if the food for the combined age range (6-36 months) is targeted more at the younger age group (6-12 months Older Infants) as the requirements specified will be higher than necessary. Added concerns expressed include unknown potential risk for this vulnerable age group due to excessive intake of nutrients where no UL has been set.

Selecting Option 2 (LOWEST) is supported as a way of addressing this where the combined NRV-R value for persons aged 6-36 months would be determined by calculating the lower value of the two age groups 6-12 months and 12-36 months.

Nonetheless, concerns around selecting the lowest value (Option 2) centred on how this will not reflect the INL98 of the older age group (Young Children) and will, therefore, not align with the draft General Principles under 3.2 where 'Ideally, the NRVs-R should be based on Individual Nutrient Level 98 (INL98)'.

Selecting Option 3 (MEAN) represents a compromise where agreement may be achieved

MEAN (Option 3): The combined NRV-R value for persons aged 6-36 months should be determined by selecting the mean value of the proposed NRVs-R for older infants and young children.

Conclusions and recommendations

Conclusions

The Committee is invited to consider the work of this EWG on the draft General Principles for the establishment of NRVs-R for persons aged 6 – 36 months presented in Appendix I.

Regarding the square brackets [] on definition of Adequate Intake in the draft General Principles, the EWG Chair and Co-Chairs conclude that:

- The FAO/WHO definition of Adequate Intake is the most appropriate definition and the [] can be removed.

Regarding the remaining square brackets [] in the draft General Principles, the EWG Chair and Co-Chairs conclude from the varied feedback in CP1 and CP2 that:

- None of the three Options can establish NRVs-R that align with the INL98 of all persons aged 6-36 months;
- Choosing Option 1 over Option 2 (or *vice versa*) result in a 'seesaw situation' where risks associated with higher or lower NRVs-R are exchanged between those persons at the younger or older ends of the age range 6 – 36 months;
- Choosing the Option 3 – the mean value of the proposed NRVs-R for older infants and young children as the combined NRV-R value for persons aged 6-36 months addresses concerns about this vulnerable age group getting 'too much' or too little' and so represents the most appropriate option.
- Clarification on how these combined NRV-R value for persons aged 6–36 months should be used will be addressed as part of the next steps of this project, where text in relevant Codex documents is amended to clarify use of the NRVs-R for persons aged 6-36 months.

This will address a similar question for the NRVs-R established separately for each age group (Older Infants 6 – 12months) or Young Children 12 – 36 months).

Recommendations

The EWG Chair and Co-Chairs recommend:

- i. the Committee agree with the definition of Adequate Intake currently in square brackets [] (see Section 2 (DEFINITIONS AS USED IN THESE PRINCIPLES) *presented in Appendix I*).
- ii. Option 3 whereby the combined NRV-R value for persons aged 6-36 months is determined by selecting the mean value of the proposed NRVs-R for older infants and young children.

Clarification on how these combined NRVs-R for persons aged 6–36 months should be used will be outlined in relevant text that relates to where the three sets of NRVs-R are presented in CXG 2-1985.