

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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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 2021/56/OCS-NFSDU](#) available on the Codex webpage/Circular Letters: <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

SUMMARY AND RECOMMENDATIONS

Background

At the 41st session of CCNFSDU the Committee agreed:

- i. to continue its work on NRVs-R for persons aged 6 to 36 months following the work programme as spelt out in the revised project document (REP20/NFSDU Appendix VII)
- ii. to inform CCEXEC79 of the revised timeline for completion of work
- iii. to establish an eWG chaired by Ireland and co-chaired by Costa Rica and the United States of America working in English and Spanish to develop General Principles to guide the establishment of NRVs-R for persons aged 6 to 36 months.

The Terms of Reference (ToR) for the work of this eWG were:

To develop general principles to guide the establishment of NRVs-R for persons aged 6 to 36 months that describe:

- A. the most appropriate approach to derive NRVs-R, based on an analysis of Dietary Intake Reference Values (DIRVs) from FAO/WHO and the 6 RASBs;
- B. the purpose(s) of these NRVs-R for labelling and, if appropriate, for composition for Guidelines on Formulated Complementary Foods for Older Infants and Young Children

The EWG should take into account discussions at CCNFSDU41.

Conduct of the eWG

The eWG was established in January 2020 and had 45 members (38 Codex Members, 1 Codex Member Organisation and 6 Codex Observers). A list of participants can be found in Appendix III.

The Chair and Co-Chairs developed one Consultation Paper to explore ToR B – developing all other aspects of the General Principles for NRVs-R for persons aged 6–36 months. Responses to this Consultation Paper exploring ToR B were as follows:

23 eWG members responded

- 21 Codex Members
- 1 Codex Member Organisation
- 1 Codex Observer

Request for scientific advice

At the 41st session, while no direct request was made to FAO or WHO, the Committee noted that there would be a need for scientific advice (REP20/NFSDU, para 151) focusing on how the Dietary Intake Reference Values (DIRVs) for each of the 24 nutrients¹ were derived by the FAO/WHO and 6 Recognized Authoritative Scientific Bodies (RASBs)² (therefore providing the background information needed for ToR A). This advice would also evaluate and rank these DIRVs based on quality of evidence to help inform the work of the Committee in establishing the NRVs for persons aged 6 – 36 months.

Since CCFSDU did not directly make a request, and in order to expedite the work, the eWG Chair, Co-Chairs, Codex Secretariat, and WHO and FAO collaborated to address the need for scientific advice and developed the Request for Advice. FAO commissioned Janine Lewis (former Delegate of Australia) to undertake this external work which was described under the following ToRs:

To produce a report on the appropriate approaches to derive NRVs-R based on an analysis of the approaches used to derive Dietary Intake Reference Values (DIRVs) from FAO/WHO and 6 RASBs. This work will comprise:

- 1) Tabulate the DIRVs for up to 25* designated nutrients for older infants and young children sourced from WHO/FAO and 6 RASB publications.
- 2) For each nutrient, identify the DIRV whose adult DIRV was selected as the basis of the general population NRV-R.
- 3) Examine and document the derivation of each DIRV in the tabulation in 1) and classify according to major differences in approach. Name and define these approaches.
- 4) Evaluate and rank these approaches according to their strengths and weaknesses.
- 5) Perform other tasks as required and related to the above points.

*CCNFSDU41 agreed to establish for persons aged 6 – 36 months NRVs-R for protein and 23 vitamins and minerals - 24 nutrients in total. When assigning this external work, the eWG Chairs included sodium given its importance in diets for this age group and included questions on this in the Consultation Paper described below.

This scientific advice became available to the eWG Chairs in July 2021. While there was not sufficient time for a consultation on the findings of this report, the findings have been considered by the eWG Chairs to develop General Principles for discussion at CCFSDU42 (see Appendix II). The full scientific advice report can be found [here](#).

This paper presents the discussions in the EWG and conclusions and recommendations of the chairs. The complete summary of discussions and additional questions for consideration are presented in Appendix I.

CONCLUSIONS AND RECOMMENDATIONS

Consistent with the TORs, the EWG has successfully had some discussions on the General Principles and as the report on the scientific advice for appropriate approaches to derive NRVs-R only became available in July 2021, there was no time for a consultation in 2021. To progress work, the EWG chairs have drafted a separate annex of General Principles based on this advice for consideration by CCFSDU42.

Recommendations

The Committee is invited to consider:

- a) The proposed draft principles for establishing nutrient reference values for persons aged 6 to 36 months (Appendix II) taking into account the discussion and recommendations 1 – 5 in Appendix I;
- b) Whether the principles should be integrated into Annex I of *The Guidelines on Nutrition Labelling* (CXG 2 – 1985) or remain as a separate text (recommendation 2 in Appendix I);

¹Vitamin A, Vitamin D, Vitamin C, Vitamin K, Vitamin E, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenate, Biotin, Calcium, Magnesium, Iron, Zinc, Iodine, Copper, Selenium, Manganese, Phosphorus, Potassium, Protein

²The 6 Recognized Authoritative Scientific Bodies (RASBs) are as follows: European Food Safety Authority (EFSA); United States Institute of Medicine (IOM); Australian National Health and Medical Research Council & New Zealand Ministry of Health (NHMRC/MOH); Japanese National Institute of Health and Nutrition (NIHN); International Zinc Nutrition Consultative Group (IZINCG); Nordic Council of Ministers (Nordic countries).

- c) Whether sodium should be included in the list of nutrients for the establishment of labelling NRVs and the type of NRV for sodium and potassium (i.e. NRV-R or NRV-NCD; recommendation 5 in Appendix I).

APPENDIX I

(Summary of discussion and recommendations of EWG / chairs of the EWG)

INTRODUCTION

At the 41st session of CCNFSDU, five recommendations (of a total of 7) were discussed and considered for the development of NRVs-R for persons aged 6 to 36 months. The subject of these recommendations and what was agreed (REP20/NFSDU) is described below:

Recommendation 1 REP20/NFSDU, para. 143

The Committee agreed that NRVs-R would be developed for persons from 6 months to not more than 12 months and persons more than 12 months to 36 months (from 1 day after the 1st birthday to the day of 3rd birthday).

Recommendations 2 and 4 REP20/NFSDU, para 146

The Committee agreed that the general principles for the establishment of NRVs-R for the identified age groups would be established in the Guidelines on Nutrition Labelling and that once the NRVs-R were established consideration should be given to how they were presented in the Guidelines on Nutrition Labelling in order to clarify to which foods these would apply to.

Recommendations 5 and 6 REP20/NFSDU, paras 147 - 148

The Committee agreed that potassium be added to the list for which NRVs would be established. The Committee also agreed to include protein in the list of nutrients to be considered for deriving NRVs-R but giving it low priority.

The Committee also noted that there would be a need for scientific advice which would focus on how the requirements for each of the 24 nutrients were derived by FAO/WHO and 6 RASBs and evaluate and rank these nutrient requirements based on quality of evidence to help inform the work of the Committee.³

The Committee previously agreed (REP19/NFSDU) that two sets of NRVs-R (one for older infants and one for young children) would be prepared. However, the importance of having a single set of NRVs-R (6 – 36 months) in case the product was intended for both the age groups in order to avoid confusing consumers (by having two sets of values on a label) was noted. It was agreed that the decision on whether or not to combine the two sets of NRVs-R would be made depending on the actual values in these two sets. In the meantime, separate sets of NRVs-R for older infants and for young children would be prepared.

The Committee also agreed to continue the work to develop NRVs-R for the four Codex texts identified and to exclude the *Guidelines for Vitamin and Mineral Food Supplements* (CXG 55-2015) (para. 120, REP19/NFSDU).

TERMS OF REFERENCE

The Terms of Reference (ToR) agreed for this 2020 eWG work were as follows:

To develop general principles to guide the establishment of NRVs-R for persons aged 6 to 36 months that describe:

- A. the most appropriate approach to derive NRVs-R, based on an analysis of Dietary Intake Reference Values (DIRVs) from FAO/WHO and the 6 RASBs;
- B. the purpose(s) of these NRVs-R for labelling and, if appropriate, for composition for Guidelines on Formulated Complementary Foods for Older Infants and Young Children

The EWG should take into account discussions at CCNFSDU41.

PARTICIPATION AND METHODOLOGY

In January 2020, Codex Members and Codex Observers were invited to participate in the eWG for 2020 through the Codex Platform. The eWG is made up of 38 Codex Members (CMs), 1 Codex Member Organisation (CMO) and 6 Codex Observers (COs) (the list of participants is in Appendix III). The following abbreviations have been used throughout the paper:

CM(s) = Codex Member(s)

CMO = Codex Member Organisation

CO(s) = Codex Observer(s)

³REP20/NFSDU, para. 151

One consultation was carried out. This Consultation Paper addressed ToR B and was held between May and July 2020. There were 23 responses to the Consultation Paper (21 CMs, 1 CMO and 1 CO).

Scientific advice

In order to have the General Principles ready for discussion at Step 4 at CCNFSDU42, the scientific advice was progressed so that the work under ToR A would be completed and reported in the Agenda Paper for CCNFSDU42.

In March 2020, the eWG Chair, Co-Chairs, Codex Secretariat, WHO and FAO collaborated on the request for scientific advice from external experts. WHO shared their data and scoping review of nutrient requirements from their on-going work updating the recommended nutrient intakes for infants and young children aged 0–36 months from their 2004 publication on vitamin and mineral requirements in human nutrition. The Chair and Co-Chairs gratefully acknowledged this input from WHO as it was very relevant and useful for progressing the work of this eWG.

A list of external experts with the relevant background to undertake this work on providing scientific advice was established and ranked in order of those with the most suitable background knowledge and experience. The most highly regarded expert on the list compiled, Janine Lewis (former Delegate of Australia), agreed to undertake this external work described under the following ToRs:

To produce a report on the appropriate approaches to derive NRVs-R based on an analysis of the approaches used to derive Dietary Intake Reference Values (DIRVs) from FAO/WHO and 6 RASBs. This work will comprise:

- 1) Tabulate the DIRVs for up to 25* designated nutrients for older infants and young children sourced from WHO/FAO and 6 RASB publications.
- 2) For each nutrient, identify the DIRV whose adult DIRV was selected as the basis of the general population NRV-R.
- 3) Examine and document the derivation of each DIRV in the tabulation in 1) and classify according to major differences in approach. Name and define these approaches.
- 4) Evaluate and rank these approaches according to their strengths and weaknesses.
- 5) Perform other tasks as required and related to the above points.

*CCNFSDU41 agreed to establish for persons aged 6 to 36 months NRVs-R for protein and 23 vitamins and minerals - 24 nutrients in total. When assigning this external work, the eWG Chairs included sodium given its importance in diets for this age group and included questions on this in the Consultation Paper described below.

This scientific advice became available to the eWG Chairs in July 2021. While there was not sufficient time for a consultation on the findings of this report, the findings have been considered by the eWG Chairs and General Principles have been drafted for discussion at CCNFSDU42 (see Appendix II). The full scientific advice report can be found [here](#).

CONSULTATION FEEDBACK WITH DISCUSSION AND CONCLUSIONS

The Chairs received responses to the Consultation Paper from 23 eWG members (21 CMs, 1 CMO and 1 CO).

1. Establishing General Principles

i. Selection of suitable data sources to establish NRVs-R

Using the General Principles for the general population from the *Guidelines on Nutrition Labelling* (CXG 2-1985), General Principles for persons aged 6 to 36 months were drafted. The eWG members were asked to consider the following two draft General Principles which are already in place for the General Population:

Draft General Principle⁴ – ‘Relevant and recent daily nutrient intake values provided by FAO/WHO that are based on a review of the science should be taken into consideration as one of the primary sources in establishing NRVs-R.’

Draft General Principle⁴ – ‘Relevant and recent daily intake reference values (DIRV) that reflect independent review of the science, from recognized authoritative scientific bodies (RASBs) other than FAO/WHO could also be taken into consideration. Higher priority should be given to values in which the evidence has been evaluated through a systematic review.’

⁴Draft General Principles modified from those outlined in CXG 2-1985 Annex section 3.1.

The feedback from the 2020 eWG was unanimous with all CMs (100%; n21), one CMO (100%) and one CO (100%) agreeing with the draft General Principles outlined above.

The eWG were also asked for feedback on the following draft General Principle:

***Draft General Principle**⁴ – ‘The daily intake reference values (DIRVs) should reflect intake recommendations of older infants from 6 months to not more than 12 months, of young children from 12 months to 36 months and of both older infants and young children combined - from 6 months to 36 months.’*

While the majority of CMs (67%; n14) and one CO (100%) were in favour there was a significant minority that disagreed.

One CMO (100%) disagreed stating that different scientific bodies have DIRVs for slightly different age group definitions and there is significant concern that this General Principle may de facto eliminate daily intake reference values that are recent and scientifically based, because the age definition on which they were set may slightly differ.

This concern was raised by others who pointed out that RASBs vary how they delineate between young children and the general population. While the age range for the NRVs-R for labelling in Codex texts spans 23 months, several RASBs use age ranges that span 12, 24, and 36 months. Clarifying that DIRVs by RASBs may still be pertinent for the derivation of NRVs-R for labelling even if the specific age ranges considered do not fully match those required for NRVs-R would be helpful.

Four CMs (19%) also disagreed with including the age ranges in the *Draft General Principle* above, suggesting this should instead be captured in a definitions section, as is done in the Guidelines on Nutrition Labelling. It was also stated that combining older infants and young children is inappropriate and would cause confusion as DIRVs for older infants and young children are based on different types of endpoints (dietary intake versus experimental data) and are generally established by RASBs as separate population groups.

A solution to some of these issues through re-wording this *Draft General Principle* was suggested by eWG members. Therefore, the Chairs propose this draft General Principle be worded as follows: *The daily intake reference values (DIRVs) should reflect intake recommendations for older infants and young children*⁵

ii. Approaches to derive DIRVs from WHO/FAO and 6 RASBs

Appropriate Basis for Establishing NRVs

In drafting the Annex for General Principles for Establishing NRVs-R for Persons Aged 6 to 36 months, the Chairs noted the Annex to be incomplete without addressing principles for NRVs-NCD as well. In anticipation of the need to set future NRVs, the Chairs have drafted principles for consideration that are generally aligned with CXG-2 Annex: General Principles for Establishing NRVs for the General Population section 3. Sections 3.1 – 3.4 have been modified to reflect the evidence base for nutrient needs of persons aged 6 to 36 months.

Selection and Priority of Derivation Methods for Establishing NRVs-R

The scientific advice report “*Review of derivation methods for dietary intake reference values for older infants and young children*”⁵ was commissioned to provide advice on the details of DIRVs for protein and 24 micronutrients for older infants and young children in the publications of six RASBs and the WHO/FAO.

The methods used in the RASB publications to derive the DIRVs for older infants and young children were assessed for similarities and differences in approach and overall scientific rigour. The report grouped the methods used in these publications into 3 categories and 10 subcategories (Table 1).

⁵Report available at [here](#).

Table 1.

| | Category description | Subcategory number and description |
|----------|--|--|
| 1 | Using physiological evidence from the target group | 1a The factorial summation of the various components involved in physiological growth, maintenance and loss e.g. for protein, iron and zinc. |
| | | 1b The estimation of nutrient intake based on maintenance of a healthy plasma or urinary biomarker, or absence of deficiency disease in the target group e.g. for vitamin D, iodine. |
| 2 | Extrapolation up or down from DIRVs or other measures of other population age groups | 2c Allometric scaling up from young infant DIRV |
| | | 2d Allometric scaling down from adult DIRV |
| | | 2e Isometric/linear scaling up from young infant DIRV |
| | | 2f Isometric scaling down from adult DIRV |
| | | 2g Linear scaling down from adult DIRV |
| | | 2h Linear scaling from unit measures |
| 3 | Estimates of nutrient intake of the target group, or interpolation | 3i Estimates of nutrient intake from diets of healthy older infants and young children |
| | | 3j Interpolation between DIRVs of younger and older age groups |

The report provides a series of tables, one for each nutrient, outlining the DIRV, the nomenclature (INL₅₀, INL₉₈, AI), the age range and the derivation method used. The RASB publications used to establish general population NRV-Rs are also identified in these tables.

The report concludes that there is strong coherence in the derivation methods used across the RASBs for some nutrients, with various levels of variability for others. This variation is due to several factors; primarily the selected method, the choice of reference DIRV, body weights and human milk volumes.

The report recommends that the NRVs-R for older infants and young children be based on the rigour of the derivation method. The derivation methods in order of decreasing scientific rigour are outlined in Table 2. This three category ranking is proposed as suitable for use in the General Principles as the categories are sufficiently diverse not to overlap.

Table 2.

| | Derivation method | Method description |
|----------|--|--|
| 1 | Using physiological evidence from the target group | The 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. |
| 2 | Extrapolation up or down from DIRVs of other age groups | Allometric, isometric and linear scaling methods using reference DIRVs from adults or young infants. |
| 3 | Estimates of nutrient intake of the target group; or interpolation | Estimates of nutrient intake from diets of healthy older infants and young children; or interpolation between DIRVs of younger and older age groups. |

Selection and Priority of Derivation Methods for Establishing NRV-NCDs

In some cases, it may be more appropriate to set NRVs based on NCD endpoints, rather than requirements to address chronic disease risk factors that may be established early in life and are associated with long term health.

Thus, the Chairs have drafted principles for consideration, that are aligned with CXG2 Annex: General Principles for Establishing NRVs for the General Population section 3.2.2, except where modified to reflect the evidence base for nutrient needs of persons aged 6 to 36 months.

The Chairs agree with the report's recommendation of using DIRVs derived with the most scientific rigour thus recommend using the three category ranking proposed by the report as a General Principle.

RECOMMENDATION 1 – Approaches to derive DIRVs from WHO/FAO and 6 RASBs

The Chairs recommend that a three category ranking is used in the General Principles and that NRVs should be based on DIRVs derived using the most rigorous scientific methods. These methods, ranked in order of overall scientific rigor, are as follows:

1. Using physiological evidence for the target age group
2. Extrapolating up or down from DIRVs of other age groups
3. Estimates of nutrient intake of the target group; or interpolation

To fulfil ToR A and develop General Principles to guide the establishment of NRVs-R for persons aged 6 to 36 months, the Chairs and Co-chairs considered options for where these draft General Principles should be located in the *Guidelines on Nutrition Labelling* (CXG 2-1985):

- A. Draft a separate Annex (i.e. draft Annex 2) to the Guidelines on Nutrition Labelling (CAC/GL 2-1985) outlining the General Principles for establishing NRVs-R for persons aged 6 to 36 months.
- B. Adapting Annex 1 of the Guidelines on Nutrition Labelling (CXG 2-1985) to accommodate for persons aged 6 to 36 months, assuming there will be overlap between the principles for persons aged 6 to 36 months and the general population identified as individuals older than 36 months.

As outlined in Option A, drafting a separate Annex (i.e. draft Annex 2) to the Guidelines on Nutrition Labelling (CXG 2-1985) for discussion purposes will prevent confusion with the General Principles for the general population and highlight details specific to persons aged 6 to 36 months. However, the merits of delaying a final decision on whether a separate Annex is needed enables the Committee to determine how much Annex 1 and 2 overlap and decide on the best location for this information. For the purpose of this paper and consideration by CCNFSDU, the general principles have been developed as a separate text pending a decision on whether to retain it as a separate text or to integrate it into Annex 1 of CXG 2 – 1985.

RECOMMENDATION 2 – Establishing General Principles as a separate Annex

A separate Annex has been drafted by the eWG Chairs for consideration by the Committee (see Appendix II). The Chairs recommend that the Committee considers this draft text on General Principles for NRVs-R for persons aged 6 to 36 months and that it also considers whether the information contained should be integrated into Annex 1 or remain as a separate text.

2. The application of different sets of NRVs-R for persons aged 6 to 36 months

The Committee has agreed (REP19/NFSDU para 116) to establish up to three sets of NRVs-R for persons aged 6 to 36 months (older infants only; young children only; possibly older infants and young children combined). The Committee had previously noted the view that it is important to have a single set of NRVs-R on a label to avoid confusing consumers (REP19/NFSDU). Taking account of Table 3 below, the eWG were asked to consider:

- 1) only one set of NRVs-R on a label
- 2) how the NRVs-R are applied to foods to achieve this.

Table 3.

| Foods specifically labelled for older infants | Foods specifically labelled for young children | Foods specifically labelled for both older infants and young children |
|--|---|--|
| NRVs-R for older infants | NRVs-R for young children | NRVs-R for older infants and young children combined |

The feedback from the 2020 eWG is summarised below:

The majority of CMs (62%; *n*13) agreed that only one set of NRVs-R (as described in the table) should appear on a label. The reasons given were that having only one set of NRVs-R on a label would help avoid confusion of consumers. However, there were further issues raised in this feedback that need to be considered in making this decision. These are summarised in the following:

- a General Principle needs to be developed to outline the need for a combined set of NRVs-R for persons aged 6 to 36 months for use on foods labelled for both older infants and young children
- criteria on which set of NRVs-R should be applied to foods also needs to be clarified in the General Principles

Some countries believed the decision on having only one set of NRVs-R on a label needs to be delayed until the NRVs-R are derived. A minority (4 CMs) was in favour of delaying a decision on having only one set of NRVs-R on a label until the NRVs-R have been established, which would allow any combined set of NRVs-R to take account of the differences in NRVs-R for older infants compared with young children.

One CMO (100%) answered both yes and no, supporting that only one set of NRVs-R should appear on a label but not as outlined in the table. This was based on concerns that such product differentiation would lead to product proliferation that is marketing driven and less science-based. It was also stated that the options in the tables may prevent caregivers from being able to compare products.

Minority feedback was in favour of:

- providing a dual column labelling option to assure consistency across product labelling and to allow manufacturers flexibility on how to present nutrition information for these age groups
- involving CCFL in decisions on the application of labelling NRVs-R for two population groups on a single label.

In summary, this feedback indicates:

1. there is a majority in favour of one set of NRVs-R on a label to avoid confusion.
2. there is uncertainty until the NRVs-R are established around how to achieve only one set of NRVs-R on a label because:
 - a. The Committee previously agreed (REP20/NFSDU, para 116) that two sets of NRVs-R (one for older infants and one for young children) would be prepared and the decision on whether or not to combine the two sets of NRVs-R would be made depending on the actual values in these two sets.
 - b. What criteria will be used to apply the different sets of NRVs-R to foods

This concerns the application of NRVs and is more appropriate for the main text of CXG 2–1985 rather than the Annex on General Principles for the establishment of NRVs. This is a labelling issue requiring the input of CCFL.

RECOMMENDATION 3 – The application of different sets of NRVs for persons aged 6 to 36 months

The Chairs recommend that the application of different sets of NRVs for persons aged 6 to 36 months on a label needs to be referred to CCFL for their input as follows:

Having only one set of NRVs on a label is preferable to avoid confusion. This raises the following questions where the input of CCFL is required:

1. what criteria should be used to choose the most appropriate set of NRVs for a food
2. where in the main text of CXG 2-1985 should such criteria be placed

3. Purpose of NRVs-R for persons aged 6 to 36 months

Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991)

In these guidelines, two different sets of INL₉₈ values are referred to; one set of INL₉₈ values for nutritional labelling for the general population as outlined in the *Guidelines on Nutrition Labelling (CXG 2-1985)* and a second set in the Table in the Annex of this Guideline to guide the vitamin and mineral composition of the Formulated Complementary Food.

The INL₉₈ values listed for guiding composition are only to be used when dietary intake data for the target population is not available that would allow the assessment of the prevalence of either inadequate or excessive nutrient intakes (paras 6.6.1.2 and 6.6.1.3). In this case, these Guidelines suggest that the total quantity of each of the vitamins and/or minerals contained in a daily ration of the Formulated Complementary Food is at least 50% of INL₉₈.

Feedback from previous eWG consultations (CX/NFSDU 18/41/8) indicated some support for using the newly established NRVs-R for both labelling and composition in this Codex text because there was no scientific reason for having different nutrient reference values to guide labelling and composition. This feedback also

indicated that having different nutrient reference values for labelling and composition in the same Codex text may create confusion. In order to establish General Principles for the use of the NRVs-R, the 2020 eWG members were asked to consider if the newly established NRVs-R for labelling should also apply as reference criteria for vitamin and mineral composition in this Guideline. The feedback on this is summarised below.

The majority of CMs (86%; *n*18) and one CO (100%) suggest that the newly established NRVs-R for labelling also apply as reference criteria for vitamin and mineral composition in this Guideline. The rationale provided included:

- no logical reason for having two different sets of NRVs-R for labelling and composition,
- having two different sets could potentially cause confusion
- using NRVs-R as reference criteria for composition could address micronutrient inadequacies.

A minority (one CM and one CMO) were not in favour stating that labelling and compositional criteria involve different issues that need to be reviewed. Review of compositional issues was seen as a separate exercise that is outside the mandate of this eWG.

Some concerns were also raised that updating the current INL₉₈ values in the Annex of this Guideline, would require review and possible amendment to the percentage of the INL₉₈ as stated in the Annex; '*The suggested total quantity of each of these vitamins and/or minerals contained in a daily ration of the Formulated Complementary Food is at least 50% of INL₉₈*'. However, it should be noted that in section 6.3 of this Codex text, criteria for determining the protein composition is outlined but no information is provided on the criteria of providing at least 50% of the INL₉₈ for vitamins and minerals listed in the Table in the Annex. This indicates that 50% may be an arbitrary criterion and that providing more up-to-date INL₉₈ levels for the vitamins and minerals listed represents an improvement. The Chairs are also of the view that applying the newly established NRVs-R for labelling as reference criteria for vitamin and mineral composition in this Guideline could also address the omission of potassium and sodium from the Table in the Annex.

In summary, there is majority support that the NRVs-R established for labelling should also apply as reference criteria for vitamin and mineral composition (but not for protein which is not listed in the Table in the Annex). As there is no scientific reason for having different values to guide labelling and composition, it is logical to have just one set of NRVs-R for both labelling and composition in this Guideline. Having just one set will also prevent any potential confusion.

RECOMMENDATION 4 – Purpose of NRVs-R for persons aged 6 to 36 months

The Chairs recommend that the NRVs-R established for labelling should also apply as reference criteria for vitamin and mineral composition, but not protein, in the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991).

AREAS RELEVANT TO LABELLING NRVS-R FOR OLDER INFANTS AND YOUNG CHILDREN THAT ARE OUTSIDE CURRENT TORS

The following two issues came up during the consultation process.

1. Inclusion of sodium and whether this should be an NRV-NCD

The Committee agreed to establish NRVs-R for protein and 23 vitamins and minerals (24 nutrients in total; REP20, para 147). Given the importance of sodium in diets for this age group, further consideration should be given to:

- (a) including sodium in the list of nutrients for the establishment of labelling NRVs, and
- (b) the type of NRV for sodium (i.e. NRV-R or NRV-NCD).

The type of NRV (i.e. NRV-R or NRV-NCD) is also likely to be relevant for potassium, as it was agreed at CCNFSDU41 (REP20/NFSDU) that potassium would be added to the list of nutrients, however no decision was made on the type of value.

2. NRVs-R should be limited to labelling purposes in FSDU texts other than the Guidelines on Formulated Complementary Foods for older infants and young children

Feedback from previous eWG consultations indicated that the NRVs-R to be established should be limited in purpose to labelling rather than as reference criteria for optional addition of vitamins and minerals to products covered by the other FSDU Codex texts targeting this age group (Processed Cereal-Based Foods (CXS 74-1981), Canned Baby Foods (CXS 73-1981) and the Standard for Follow-Up Formula under revision (CXS 156-1987)).

RECOMMENDATION 5 – Issues relevant to General Principles but outside current TORs

The Chairs recommend that the Committee consider issues relevant to the General Principles but that are outside the current ToRs:

1. Inclusion of sodium
2. the type of NRV (NRV-NCD or an NRV-R) for sodium and potassium
3. NRVs-R should be limited to labelling purposes in FSDU texts other than the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991).

APPENDIX II**PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR PERSONS AGED 6 TO 36 MONTHS****(for comments at Step 3 through [CL2021/56/OCS-NFSDU](#))****1. PREAMBLE**

These Principles apply to the establishment of Codex Nutrient Reference Values (NRVs) for persons aged 6 to 36 months. These values are used for nutrient declaration in labelling according to Codex Guidelines CXG 2-1985 for pre-packaged foods. This labelling information may be helpful to caregivers of these individuals to:

- 1) estimate the relative contribution of individual products to overall healthful dietary intake of nutrients, and
- 2) compare the nutrient content between products.
- 3) These values may also be useful for setting nutrient levels for Codex Standards/Guidelines.

Governments are encouraged to use the NRVs, 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 reference values for labelling purposes.

2. DEFINITIONS

In addition to relevant definitions under section 2 Definitions in the Annex: General Principles for Establishing NRVs for the General Population of these Guidelines, the following definitions are relevant to the setting of NRVs for persons aged 6 to 36 months:

- a) The term **older infant** means a person from the age of 6 months and not more than 12 months of age (up to the first birthday).

The term **young child** means a person from the age of more than 12 months (starting 1 day after the first birthday) up to the age of three years (36 months, ending at the 3rd birthday).

- b) **Adequate Intake (AI)** is *“The Adequate Intake is the recommended average daily intake level 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—used when an RDA cannot be determined”*. This concept can also be referred to as Net Requirement, Estimated Values or Suggested Daily Intake.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs

These principles are aligned with section 3 Annex: General Principles for Establishing NRVs for the General Population of these Guidelines, except that sections 3.1 – 3.4 have been modified to reflect the evidence base for nutrient needs of persons aged 6 to 36 months.

3.1 Selection of suitable data sources to establish NRVs

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

Relevant and recent daily intake reference values (DIRVs) that reflect independent review of the science, from recognized authoritative scientific bodies (RASBs) other than FAO/WHO 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 (DIRVs) should reflect intake recommendations for older infants and/or young children.’

3.2 Appropriate Basis for Establishing NRVs**3.2.1 Selection and Priority of Derivation Methods for Establishing NRVs-R**

The NRVs-R should be based on DIRVs derived using the most rigorous scientific methods also considering data quality and strength of evidence. The methods used to derive DIRVs, ranked in order of overall scientific rigor, are:

| Rank | Derivation Method | Description |
|------|--|---|
| 1 | Using physiological evidence for the target age group | The factorial summation of the nutrient requirements to support physiological growth or to maintain adequate stores. Includes nutrient requirements to maintain healthy plasma or urinary biomarkers, or to prevent deficiency disease. |
| 2 | Extrapolating up or down from DIRVs of other age groups | Allometric, isometric and linear scaling methods based on DIRVs of infants, children or adults to estimate Adequate Intake (AI). |
| 3 | Estimates of nutrient intake of the target group; or interpolation | Based on AI and interpolation of DIRVs from DIRVs of older infants or DIRVs of younger children set from intake data. |

3.2.1.1 The NRVs-R should be based on evidence derived using Rank 1, 2, or 3 methods, preferably in that order. The scientific rigor and derivation of these values should be reviewed on a case-by-case basis and should consider the derivation method, quality of the underlying evidence, overall strength of the evidence and the upper levels of intake.

3.2.1.2 A combined set of NRVs-R for both older infants and young children combined may be required for use in labeling of products intended for both older infants and young children.

3.2.2 Selection and Priority of Derivation Methods for Establishing NRVs-NCD

In some cases, it may be more appropriate to set NRVs based on NCD endpoints, rather than requirements to address chronic disease risk factors that may be established early in life and are associated with long term health.

The following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD:

- Relevant convincing⁶/ generally accepted⁷ scientific evidence or the comparable level of evidence under the GRADE classification⁸ for the relationship between a nutrient and non-communicable disease risk, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g. adults).
- Public health importance of the nutrient-non-communicable disease risk relationship(s) among Codex member countries.

Relevant and peer-reviewed scientific evidence for quantitative reference values for daily intake should be available in order to determine an NRV-NCD that is applicable to persons 6 to 36 months. When such evidence is not available, extrapolation from NRV-NCDs from the general population could also be considered.

Daily intake reference values from FAO/WHO or recognized authoritative scientific bodies that may be considered for NRVs-NCD include values expressed in absolute amounts or as a percentage of energy intake.

For practical application in nutrition labelling, a single NRV-NCD for older infants and/or young children should be established for each nutrient that meets the principles and criteria in this Annex.

An NRV-NCD for older infants and/or young children should be determined from the daily intake reference value for these target age groups, or if given by sex, the mean of males and females.

Where a daily intake reference value is based on a percentage energy intake, the NRV-NCD should be expressed in grams or milligrams based on an appropriate reference energy intake [xxxx kilojoules/ xxxx kilocalories]⁹ for older infants and/or young children.

⁶At the time these guiding principles were drafted, the definition and criteria for “convincing evidence” from the following FAO/WHO report were used: Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 916. WHO, 2003.

⁷For these General Principles the terms convincing/generally accepted evidence are considered synonymous.

⁸WHO’s Guidelines Review Committee. WHO Handbook for guideline development. Geneva, World Health Organization (WHO), 2014 (http://www.who.int/kms/handbook_2nd_ed.pdf)

⁹Numbers to be obtained from WHO/FAO scientific advice.

3.3 Consideration of Upper Levels of Intake

The establishment of NRVs for persons aged 6 to 36 months should also take into account daily intake reference values for upper levels of intake (UL) established by FAO/WHO or other RASBs where applicable.

APPENDIX III**LIST OF PARTICIPANTS**

| NUMBER | MEMBER NAME/ OBSERVER NAME | PARTICIPANT NAME |
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| 1 | Argentina | Andrea Moser |
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| 43 | IFT | Rosetta Newsome |
| 44 | ISDI | Jean-Christophe Kremer |
| 45 | SNE | Aurelie Perrichet |