

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
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Organization

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Agenda Item 6

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GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVs-R FOR PERSONS AGED 6 – 36 MONTHS

Comments in reply to CL 2021/56/OCS-NFSDU

Comments of Australia, Brazil, Canada, China, Colombia, Costa Rica, Cuba, Egypt, European Union, Guatemala, Indonesia, Iran, Malaysia, Panama, New Zealand, Paraguay, Peru, Philippines, Republic of Korea, Rwanda, Thailand, United Kingdom, Uganda, Uruguay, USA and HKI, ICGMA, International Special Dietary Food Industries

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/56/OCS-NFSDU issued in September 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

GENERAL COMMENTS	MEMBER / OBSERVER
<p>Considering the recommendations presented on document CX/NFSDU 21/42/7, Brazil would like to provide the following comments:</p> <p>Recommendation 1 - Brazil supports the approaches proposed in recommendation 1 that are based in the FAO Draft Report Review of derivation methods for dietary intake reference values for older infants and Young children.</p> <p>Recommendation 2 - Brazil suggests including the General Principles for NRVs-R for persons aged 6 to 36 months as a separate Annex in CXG 2 -1985 since consistency between the texts of the Annexes is maintained and specificities for different age groups are preserved.</p> <p>Recommendation 3 - Brazil agrees with recommendation 3. Issues related to the declaration on nutrition labelling should be referred to the CCFL. It is up to the CCFNSDU to de-fine the principles and reference values for nutrients.</p> <p>Brazil understands that the specific ranges of 6 – 12 and 12 – 36 months should be in-cluded in the nutritional table, as the nutrient requirements are very different between these ranges. If the product is indicated for infants and children aged 6 to 36 months, the most appropriate value can be selected or a combination of values from both ranges can be discussed. The criteria for choosing the most appropriate NRV or derivation of a single NRV should be further discussed after consulting the CCFL.</p> <p>Recommendation 4 - Brazil considers premature defining that NRVs for labelling purposes should also apply to the composition criteria of these products. We suggest waiting for the definition of values to evaluate the impact. In addition, we request clarification on the rationale for excluding the protein from the recommendation.</p> <p>Brazil also agrees with item 3 of the recommendation. The NRVs for this age group must be used for labelling purposes in the Codex standards of products specially formulated for infants and children from 6 to 36 months of age: (i) processed cereal-based foods for in-fants and young children; (ii) canned baby foods; (iii) complementary foods for older in-fants and young children; (iv) drink/product for young children with added nutrients or drink for young children.</p> <p>The use of these NRVs in food labelling of products not specially formulated for this age group can mislead consumers and make them understand that the product is specially formulated for infants and children aged 6 to 36 months, a practice that should be avoided.</p>	<p>Brazil</p>
<p>After careful consideration of the EWG's summary of discussion and recommendations (Appendix 1 of CX/NFSDU 21/42/7), Canada agrees with the Proposed draft principles for establishing nutrient reference values for persons aged 6 – 36 months, with the exception of the editorial change included under the specific comments section below.</p>	<p>Canada</p>
<p>In providing comments to the Committee we remain cognisant of the purpose of these values - to provide caregivers labelling information to enable them to determine the relative contribution of individual products to overall healthful dietary intakes of nutrients and to compare the nutrient content between products.</p> <p>We support the derivation of NRVs-R that will provide Codex with a set of NRVs-R that are the most up-to-date, scientifically sound, and globally relevant. However, we do note the paucity of physiological evidence specific to this age group. As such a pragmatic approach should be taken to ensure that we can progress this work. For example, where there is no physiological evidence for this age group available, the Committee should prioritise consistency with the RASBs selected for the NRV-R for the general population. We also note that we should be seeking to prioritise the selection of WHO/FAO as the principle source of these values, as stated in the general principles.</p> <p>Regarding the establishment of an NRVs for sodium, we consider that this should be in the view that it is a nutrient to limit in the diets of older infants and young children rather than a target to meet. It is important that the Committee consider what the purpose of this value represents</p>	<p>New Zealand</p>

and how it will assist caregivers in their decision making and how it relates to other information on the pack (i.e. all other NRVs are for 'requirement'). Products targeted to this age range tend to be highly regulated and in most cases will either have a maximum composition limit for sodium or requirement that limits the use of sodium chloride as an ingredient.

Recommendation 1

New Zealand appreciates the efforts that have been taken to progress this work for the Committee and the drafting of the accompanying FAO scientific report. It is clear that there remains a significant amount of work in determining the NRVs-R for this age group. It will be of interest to the Committee the timeframe for the WHO review of nutrient requirements for this age group. This is of particular importance as WHO/FAO are to be considered the primary sources of NRVs-R in the draft general principles.

In general, we support the ranking of the methods but question whether these will need to be included in the Annex or as part of the working documents for the eWG. The same scientific methods were also a factor in considering the appropriate dietary intake reference value (DIRV) for the general population but they were not reflected in the general principles.

Furthermore, the ranking approach may not distinguish between RASBs for each nutrient as generally the presence of physiological evidence for the target group will be considered by all RASBs that have derived DIRVs and there is very limited evidence for this age group. For many nutrients the values will have been extrapolated down from older age groups, in this scenario a pragmatic step may be to seek consistency with the decision made for the NRV-R for the general population for which a decision has already been made as to the most appropriate evidence base and RASB.

As with the general population, priority should still be given to those DIRVs where a systematic review has been used to establish a value.

The Committee should also be mindful that an NRV-R developed for Codex must reflect a globally appropriate value.

Recommendation 2

The decision as to how the Annex is structured should be upon completion of the drafting. At CCNFSDU41 it was agreed that once the NRV-Rs were established then their presentation within the Guidelines would be considered. New Zealand continues to support this approach.

New Zealand notes that the text drafted by the Chairs is very similar to the General Principles for the general population and supports its inclusion in the same Annex. The derivation of all NRVs should remain together as any amendments to the general principles for the general population would likely be relevant to this age group.

At this stage, the main points of difference between the two sets of general principles are in the selection and basis of NRVs for the two population groups. As such it would be pragmatic to integrate the Principles into Annex I of The Guidelines on Nutrition Labelling (CXG 2 – 1985) with a separate section focussed on this population group.

Recommendation 3

New Zealand considers that it is premature to refer this question to CCFL at this time as there are questions around the nutritional suitability of different NRVs being applicable to foods that CCNFSDU must first consider. Referring this to CCFL at this point in time would result in significant delays in the work due to the delay in the next meeting of CCFL and may be unlikely to provide the answers that the Chairs seek to address.

CCNFSDU41 agreed that the decision on whether or not to combine the two sets of NRVs would be made depending on the actual values in these two sets. In the meantime, separate sets of NRVs-R would be prepared. New Zealand continues to support this approach.

Recommendation 4

<p>New Zealand does not support amending the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991) until the work to establish the General Principles and list of NRVs-R for you older infants and young children has been completed.</p> <p>The list in CXG 8-1991 is a duplication of the WHO/FAO INL98 values for young children. The Committee has not yet decided what values will be selected for NRVs-R, whether these are to be a single set for both age groups or two sets. Any amendment to these Guidelines in the context of composition should be considered as separate work as the ToR for the eWG and General Principles indicate that these NRVs-R are for labelling purposes.</p>	
<p>The Philippines expresses its support to the proposed Draft General Principles for the Establishment of NRVs for Persons Aged 6-36 months since these are aligned with Section 3 of Annex: General Principles for Establishing NRVs for the General Population. It may be relevant for regional or national competent authority to consider such principles in establishing their own reference values for labeling purposes.</p> <p>We are expressing our support to approaches in deriving the daily intake reference values (DIRVs) for persons aged 6-36 months per the recommendations of the EWG Chairs specifically following the ranking below from WHO/FAO and 6 Recognized Authoritative Scientific Bodies based on independent systematic review of the science and the quality of current scientific evidence:</p> <p>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:</p> <ol style="list-style-type: none"> 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 <p>These daily intake reference values should reflect intake recommendations for older infants and young children.</p> <p>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:</p> <ol style="list-style-type: none"> 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 <p>We also are in favor to refer the application of different sets of NRVs for persons aged 6 to 36 months to the Codex Committee on Food Labeling particularly on the criteria for selection on the most appropriated set of NRVs for a food and the position in the text of CXG-2 1985 of such criteria.</p> <p>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).</p> <p>We are of the opinion that a common set of NRV for older infants and young children be established specifically for labeling and reference criteria for vitamin and mineral composition to avoid confusion. The latter purpose may address micronutrient inadequacies. However, it will be prudent to wait until the actual NRVs-R are derived prior to establishment of NRVs applicable to both age groups.</p>	Philippines
<p>We would like to provide our comments to the summary of discussion and recommendations of EWG / chairs of the EWG (Appendix I) as follows:</p> <p>Recommendation 1: Thailand concurs with the Chairs' recommendation on the three-category ranking to be used in the General Principles.</p>	Thailand

<p>Recommendation 3: Thailand supports the Chairs' recommendation to inquire CCFL wherein the main text of CXG2-1985 should the criteria to be placed (Question #2). On the other hand, we view that it is still premature to bring the issue on the criteria for choosing the most appropriate set of NRVs (Question #1) to CCFL's for consideration, noting this issue is the technical matter. We therefore prefer Question#1 to be considered by the CCNFSDU.</p> <p>Recommendation 4: Thailand agrees with the Chairs' recommendation for NRVs-R established for labelling should apply as reference criteria for vitamin and mineral composition, but not protein in the CXG 8-1991.</p>	
<p>Whether the principles should be integrated into Annex I of <i>The Guidelines on Nutrition Labelling (CXG 2 – 1985)</i> or remain as a separate text (Recommendation 2 in Appendix I of CX/NFSDU 21/42/7)</p>	
<p>Australia recognises providing as separate text (as in Appendix II of CX/NFSDU 21/42/7) could provide clarity and a clear distinction between the principles for establishing NRVs for the general population and those for individuals aged 6-36 months. However, at this stage we consider it is too early to decide on the location of the text. For example as there is some duplication with the existing Annex for establishing NRV for the general population, clarity may still be achieved by combining elements common to both the general population and the younger age group (e.g. Preamble and definitions) and then creating two parts specific to establishing NRVs for the general population (Part 1) and for the 6-36 month age group (Part 2). We also note that CCFL46 has progressed the proposed draft Guidelines for Front of Pack Nutrition Labelling (FOPNL) to CAC44 also as an Annex to the Guidelines on Nutrition Labelling (CXG2-1985) for adoption at Step 5/8. In which case it may be preferable to combine the principles for both the general population and 6-36 months age group in one Annex to the Guidelines on Nutrition Labelling.</p>	<p>Australia</p>
<p>Canada agrees with Recommendation 2 of Appendix 1 of CX/NFSDU 21/42/7, that the principles for establishing NRVs for persons aged 6 – 36 months should remain as a separate annex (i.e. Annex II of Guidelines on Nutrition Labelling CXG 2 - 1985) and not integrated in the current Annex of the CXG 2 – 1985. This approach will prevent confusion and highlight details specific to persons aged 6 – 36 months.</p>	<p>Canada</p>
<p>China recommends the principles should not be integrated into Annex I but rather be included as Annex 2 in CXG 2-1985.</p>	<p>China</p>
<p>Yes. The NRVs-R for older infants and young children should be established and listed in the Codex Guidelines on Nutrition Labelling (CXG 2-1985). The principles for establishing nutrient reference values for children aged 6 to 36 months should be established as a separate annex (Annex II) to the Guidelines on Nutrition Labelling (CXG 2 - 1985); thus giving relevance to this age group and clearly differentiating it from children older than 36 months.</p>	<p>Colombia</p>
<p>Costa Rica considers that the NRVs-R for older infants and young children should be established and listed in the Codex Guidelines on Nutrition Labelling (CXG 2-1985). The principles for establishing nutrient reference values for children aged 6 to 36 months should be established as a separate annex (Annex II) to the Guidelines on Nutrition Labelling (CXG 2 - 1985).</p>	<p>Costa Rica</p>
<p>Regarding point (a) on whether the principles should be included in Annex I of the Guidelines on Nutrition Labelling (CXG 2-1985) or should continue to be presented as independent text (recommendation 2 of Annex I), in our opinion the principles should be included in Annex I.</p>	<p>Cuba</p>
<p>Egypt supports that the principles should be remain as a separate text in The Guidelines on Nutrition Labelling (CXG 2 – 1985)</p>	<p>Egypt</p>
<p>The EU considers that the agreed Codex text should not be modified but remain as it is. Therefore, the EU considers that a separate Annex should be created.</p>	<p>European Union</p>
<p>We consider that the NRVs-R for older infants and young children should be established and listed in the Codex Guidelines on Nutrition Labelling (CXG 2-1985). The principles for establishing nutrient reference values for children aged 6 to 36 months should be established as a separate annex (Annex II) to the Guidelines on Nutrition Labelling (CXG 2 - 1985).</p>	<p>Guatemala</p>

Indonesia is of the view that the principles for the establishment of NRVs for persons aged 6 - 36 months should be integrated to Guidelines on Nutrition Labelling (CXG 2 – 1985) as additional annex (as separate text from Annex I of Guidelines on Nutrition Labelling).	Indonesia
According to the issues that you have provided in CX/NFSDU 21/42/7, the “Principles for establishing nutrient reference values for persons aged 6 to 36 months” would be better to remain as a separate Annex (i.e. Annex 2), after annex 1 “General Principles for establishing nutrient reference values for the general population” in CXG 2-1985.	Iran
Malaysia is of the view that the principles for establishing NRVs-R for persons aged 6 to 36 months should not be integrated into Annex 1 but rather be included as separate Annex (i.e Annex 2) in Guidelines on Nutrition Labelling (CXG 2-1985). A separate Annex to the guidelines will avoid confusion with the general principles for the general population for persons older than 36 months.	Malaysia
The decision as to how the Annex is structured should be upon completion of the drafting. At CCFSDU41 it was agreed that once the NRV-Rs were established then their presentation within the Guidelines would be considered. New Zealand continues to support this approach. At this stage, the main points of difference between the two sets of general principles are in the selection and basis of NRVs for the two population groups. As such it would be pragmatic to integrate the Principles into Annex I of The Guidelines on Nutrition Labelling (CXG 2 – 1985) with a separate section focussed on this population group.	New Zealand
Because the Guidelines on Nutrition Labelling show in NRVs-N and NRVs-NCD for population older than 36 months, it could be included as Annex I to facilitate its use as part of the nutrition information for use in the presentation of the % nutrient reference value.	Panama
It is our view that the principles should continue to be presented as independent text, as recommended by the EWG.	Paraguay
Peru considers that the principles should be included in Annex I of the Guidelines on Nutrition Labelling (CXG 2-1985).	Peru
The Philippines is of the opinion that it would be appropriate if the principles should be integrated into Annex 1 of the Guidelines on Nutrition Labeling (CXG 2-1985). However, the location where to put these principles will be best determined by the Committee as this work progresses.	Philippines
Rwanda supports that the principles should remain as a separate text. This is because older infants and young children have different nutritional needs therefore guidelines/NRVs should be different	Rwanda
Thailand suggests that the developing text on General Principles for NRVs-R for persons aged 6 to 36 months should be kept as a separate text at this stage. Once finalized, CCFSDU may subsequently reconsider whether the final draft text is more appropriate to be integrated into Annex 1 or remain as a separate Annex.	Thailand
Uganda proposes to incorporate the principles as an annex in the Guideline on Nutrition Labelling (CXG 2- 1985). Justification: This will ease reference for the users through increased use-ability and accessibility of the principles to the standard users.	Uganda
The UK’s preference for the General Principles for NRVs-R for persons aged 6 to 36 months would be for the NRVs to remain as a separate text (Annex). This will prevent confusion with the General Principles for the general population as having a separate Annex will highlight details specific to persons aged 6 to 36 months. The UK suggest this could remain on review subject to the NRV’s being established and any potential overlap with the General Principles for the general population.	United Kingdom

We consider that the principles should continue to be presented as independent text, including a description of the use that should be made of these NRVs to avoid incorrect uses. We do not agree with their inclusion in Annex I of the Guidelines on Nutrition Labelling (CXG 2-1985) as this applies to all foods intended for children over 4 years of age and could lead to misuse of these NRVs.	Uruguay
The United States position is that the General Principles for NRVs-R for persons 6-36 months be maintained as independent text and not incorporated into Annex I.	USA
Helen Keller International supports maintaining the General Principles for NRVs-R as a separate annex.	HKI
ICGMA could support either approach. However, it may make sense to wait until the General Principles for NRVs for persons aged 6 to 36 months are further developed before making this decision.	ICGMA
ISDI recommends the principles relating to the establishment of NRVs-R for persons aged 6-36 months should not be integrated into Annex 1 but rather be included as Annex 2 in CXG 2-1985.	International Special Dietary Food Industries
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 of CX/NFSDU 21/42/7).	
Australia supports sodium being included in the list of nutrients for the establishment of labelling NRVs as sodium intakes are important for these young age groups. We also agree that the type of NRV is relevant to both sodium and potassium. In this case we support establishing NRV-Rs as the basis for labelling NRVs for sodium and potassium as it is more appropriate to use a measure of adequacy rather than a measure of chronic disease risk for these very young age groups.	Australia
Brazil is in favour of defining NRV for sodium for both age groups. Regarding the type of NRV, in line with the approach adopted for the general population, we understand that an NRV-NCD should be established for sodium and potassium, that is, a value based on outcomes related to chronic non-communicable diseases.	Brazil
As stated in the previous consultation, Canada agrees that sodium should be included in the list of nutrients for the establishment of NRVs for labelling purposes. As for the adult population, Canada recommends that the committee considers establishing NRV-NCD for both sodium and potassium.	Canada
1. Inclusion of sodium China considers that NRVs for sodium for both older infants and young children should be established. Such reference values are important for all parts of the population and in particular for this specific and sensitive target population. 2. The type of NRV for sodium and potassium China considers that for both Sodium and Potassium NRVs –R are appropriate as it is essential to ensure sufficient intake of the nutrient for the target groups. And it may be lack of solid scientific evidence for development of Sodium and Potassium NRVs –NCD for older infants and young children.	China
1. Inclusion of sodium Agreed. We consider that NRVs for sodium should be established, both for older infants and for young children. 2. The type of NRV (NRV-R or NRV-NCD) for sodium and potassium:	Colombia

<p>We believe that, for both sodium and potassium, NRVs-R should be established as a priority. We believe that NRVs-R are appropriate, as it remains essential to ensure sufficient intake of these nutrients.</p> <p>Potassium: we believe that NRVs-R for potassium should be established for older infants and young children. Most diets for older infants and young children do not meet the dietary recommendations for potassium intake (FITS 2016 Study).</p> <p>Sodium: we consider that for older infants an NRV-R for sodium should be established. For young children, an NRV-R for sodium should also be established. However, an NRV-NCD for young children could also be considered according to nutritional needs in the country.</p> <p>It should be noted that in Colombia the importance of the reference values for sodium and potassium are included in Colombian regulations: Resolution 3803 of 2016 and Resolution 810 of 2021, Law 2120 of 2021.</p> <p>With respect to question 3, a clarification is requested since it is not specified why reference is made to foods for special dietary uses, if it is a revision of a standard for follow-up formula.</p> <p>Likewise, it only applies to a few product categories and should be focused on age groups.</p> <p>The authorities should define how the NRVs are applied at the local level.</p>	
<p>1. Inclusion of sodium: Costa Rica considers that NRVs for sodium should be established, both for older infants and for young children.</p> <p>2. The type of NRV (NRV-R or NRV-NCD) for sodium and potassium: Costa Rica supports the establishment of NRVs-NCD for both sodium and potassium, in line with the types of NRVs applicable to the general population that are already included in the Guidelines on Nutrition Labelling CAC/GL 2-1985 for both. For sodium, an intake level that should not be exceeded, and for potassium, an intake level that should be reached. This would further be supported by Principle 3.2.2 of Annex II Selection of Nutrients and Appropriate Basis for NRVs-NCD, which states that “in some cases, it may be more appropriate to establish NRVs based on assessment criteria relating to the NCDs, instead of basing them on the values needed to avoid risk factors for chronic diseases that may appear at an early age and be associated with long-term health problems.”</p> <p>3. Restrict the use of NRV-N for labelling purposes in texts on foods for special dietary uses other than the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991): Costa Rica supports the recommendation, given that other standards for infants and young children already include nutritional composition requirements, so it would not make sense for them to use NRVs as reference criteria for the optional addition of vitamins and minerals. In this regard, we suggest deleting the following from the preamble of the PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR PERSONS AGED 6 TO 36 MONTHS, Annex II point 3: “3) These values may also be useful for setting nutrient levels in Codex standards or guidelines.” This could be contradictory.</p>	Costa Rica
<p>Regarding point (b) on whether sodium should be included in the list of nutrients for which NRVs should be established for labelling purposes, and the type of NRV for sodium and potassium (i.e. NRV-N or NRV-NCD: recommendation 5 in Annex I of CX/NFSDU 21/42/7). Given the importance of sodium and potassium, since both excesses and deficiencies thereof can cause health disorders, they should be included in the list of nutrients for labelling purposes.</p>	Cuba
<p>Egypt supports that sodium should be included in the list of nutrients for the establishment of labelling NRVs and the type of NRV for sodium and potassium in both NRV-R and NRV-NCD.</p>	Egypt

<p>The EU considers that the scope of the work has been discussed and agreed: to establish General principles for the establishment and use of NRVs-R for persons aged 6–36 months. Nutrients for which NRVs-R should be established were agreed. Sodium was not among the nutrients and should thus not be included in the list or nutrients. Furthermore, it was agreed to establish NRVs-R and not NRVs-NCD for persons aged 6–36 months.</p>	<p>European Union</p>
<p>We consider NRVs-R for sodium and potassium to be adequate, as it is essential to ensure sufficient intake of these nutrients.</p>	<p>Guatemala</p>
<p>Indonesia supports to include sodium in the list of nutrients for the establishment of labelling NRVs. In addition, Indonesia also supports the establishment of general NRV-R for sodium and potassium.</p>	<p>Indonesia</p>
<p>Iran agrees that sodium to be included in the list of nutrients. Because Nutrient Reference Values – Non-communicable Disease (NRVs-NCD) refer to NRVs that are based on levels of nutrients associated with the reduction in the risk of diet-related non-communicable diseases not including nutrient deficiency diseases or disorder,so it is better that sodium to be included as an NRV-NCD.</p>	<p>Iran</p>
<p>1. Inclusion of sodium</p> <p>Malaysia supports the inclusion of sodium in NRV-R for both older infants and young children. Such reference values are important for all part of the population and in particular for this specific and sensitive target population. Sodium is a nutrient that should not be consumed in excess due to possible long-term consequences.</p> <p>2. The type of NRV (NRV-NCD or an NRV-R) for sodium and potassium</p> <p>Malaysia is of the view that sodium and potassium NRV-R are appropriate as it is essential to ensure sufficient intake of these nutrients. However, if sodium and potassium need to be put as NRV-NCD, it is beyond the mandate of TOR as mentioned in CX/NFSDU 21/42/7.</p>	<p>Malaysia</p>
<p>New Zealand does not consider that the establishment of NRV-NCDs are within the scope of this work as they are outside of the Terms of Reference that were agreed. The Committee should take the time to consider whether it would be appropriate to develop NRV-NCDs for this age range and what the purpose of these would be. The current Codex Guidelines and Standards for this age group do not permit nutrient content claims and there are compositional limits already in place for sodium to manage the risk of excessive sodium in the majority of these products.</p> <p>A separate process was undertaken to develop NRV-R and NRV-NCD for the general population.</p> <p>New Zealand considers that further work would be required to determine if sodium and potassium are suitable to be included in the list of established NRVs for labelling purposes for this age group. If an NRV were to be established for sodium this should be an NRV-NCD, consistent with the general population. Although sodium is an essential nutrient, advice is generally to limit its addition to foods targeted to older infants and young children. However, it is unclear from the Agenda paper if there is a sufficient evidence basis to establish an NRV-NCD for this age group.</p> <p>It could be useful to seek clarification from CCFL as to whether there should be consideration of any differences in how NRVs should be presented for those nutrients to limit and those to promote. For example, sodium in comparison to the proposed essential vitamins and minerals.</p>	<p>New Zealand</p>
<p>Sodium should be included in the list of nutrients for which NRVs are established, because in population older than 36 months both sodium and potassium were established as NRVs-NCD, but it must be ensured that they are based on acknowledged and convincing scientific evidence or GRADE level of evidence, in addition to their public health significance.</p>	<p>Panama</p>
<p>Likewise, it is our opinion that sodium should be included in the list of nutrients in the document and NRV-N should be used as NRV.</p>	<p>Paraguay</p>

Peru considers that sodium should be included in the list of nutrients for which NRVs should be established for labelling purposes.	Peru
The Philippines is also supportive of the establishment of NRV for sodium considering its importance in the diets of older infants and young children. We are also expressing our support that the NRVs for older infants and young children be established for labeling purposes only. We hope that establishment of NRVs would not pave the way to open discussion on the permission to approve claims for older infants and young children which runs counter to the prohibition on health and nutrition claims based on Codex Guidelines on Health and Nutrition Claims (CAC/GL 23-1997).	Philippines
Rwanda supports the inclusion of Sodium and Rwanda proposes Sodium to fall under NRV-NCD and Potassium to fall under NRV-R. This is because Sodium has a negative impact on health by triggering Non-Communicable Diseases. Limits should be guided by NRV-NCD; and Potassium is a required nutrient for normal health functioning therefore content requirement should be guided by NRV-R.	Rwanda
Thailand concurs with the inclusion of sodium. We prefer the type of NRVs-R for sodium and potassium as it is more relevant to the target group of aged 6-36 months. We take note that the NRVs-R is limited to labelling purposes in FSDU texts (i.e., CXS 74-1981 and CXS 73-1981) other than CXG 8-1991, without further comments.	Thailand
Uganda suggests need to include Nutrient Reference Values as for non communicable diseases (NRV-NCD) for sodium and potassium as reflected in the CXG 2, consideration for general population. Uganda however, calls for provision of more scientific and relevance data from the Codex expert committee for nutrition for further support and guidance on our proposal in relation to the targeted population (6-36 months of age), this being a vulnerable group. Extrapolations of data or obtaining the Dietary Intake Reference Values (DIRs) should consider the sensitivity of the targeted age group.	Uganda
The UK's preference would be, given its importance in diets for this age group, to include sodium in the list of nutrients for the establishment of labelling NRVs. The UK consider it more appropriate to use NRV-R for sodium and potassium rather NRV-NCD for this age group.	United Kingdom
Yes, we consider that sodium should be included in the list of nutrients for which NRVs should be established for labelling purposes. Regarding the type of NRV for sodium and potassium, we consider that given that the epidemiological situation of the countries may be different, the possibility of opting for one or the other (NRV-N or NRV-NCD) should be left as established so far in the preliminary draft.	Uruguay
The United States supports evaluating the evidence for and setting NRVs for sodium and potassium for older infants and young children when appropriate. The United States notes that agreement on the general principles for the establishment for NRVs for older infants and young children should be established before decisions on the type of NRV for sodium and potassium are made. 1) The United States supports setting a NRV for sodium because of its public health importance. Increased sodium intake can increase risk of NCD. In addition, sodium and potassium are essential and inter-related nutrients that play an important role in the maintenance of cellular membrane potential. These nutrients appear to mediate blood pressure, which has a relationship with cardiovascular disease [1]. As the Committee will be establishing an NRV for potassium for older infants and young children and the evidence reviewed overlaps with the evidence for sodium, the United States also supports setting a NRV for sodium. 2) Should the proposed general principles be finalized, the United States would support establishing an NRV-NCD for sodium and NRV-R for potassium based on review of systematic reviews conducted by WHO/FAO and RASBs. The WHO/FAO[2] and RASBs have reported a high strength of evidence for the relationship between sodium and reduced blood pressure. In addition, the 2019 National Academies of Sciences, Engineering, and Medicine (NASEM) report, "Dietary Reference Intakes for Sodium and Potassium"[3] reported moderate to high strength of evidence for a causal relationship and intake-response relationship between sodium and CVD, hypertension and elevated blood pressure. However, the 2019 NASEM report found a lower strength of evidence for the NCD relationship between potassium and reduced blood	USA

<p>pressure and CVD outcomes compared to prior FAO/WHO and RASB reports. Considering evidence from recent systematic reviews from FAO/WHO and RASBs to determine the basis for an NRV would be consistent with the proposed general principles.</p> <p>[1] National Academies of Sciences, Engineering, and Medicine. 2019. Dietary Reference Intakes for sodium and potassium. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/25353</p> <p>[2] WHO. Guideline: Sodium intake for adults and children. Geneva, World Health Organization (WHO), 2012.</p> <p>[3] National Academies of Sciences, Engineering, and Medicine. 2019. Dietary Reference Intakes for sodium and potassium. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/25353</p>	
<p>1. Helen Keller International supports the inclusion of sodium in the NRVs to be set for older infants and young children. Sodium is a nutrient of public health concern, including for this young age group. Elevated salt/sodium intake early in life has been shown to correlate with high blood pressure in childhood and can increase the risk of NCDs later in life. Taste preferences are established during early infancy and childhood, so exposure to heightened levels of sodium/salt has the potential to establish longer-term unhealthy dietary patterns. Given these concerns, Helen Keller would support the development of an NRV-NCD for sodium.</p> <p>2. Helen Keller International will follow the discussion on items 2. related to the type of NRV for sodium and potassium.</p> <p>3. Helen Keller International supports that the NRVs-R 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).</p>	HKI
<p>ICGMA supports including sodium in the list of nutrients for the establishment of labeling NRVs because of its public health importance.</p> <p>ICGMA supports the development of an NRV-NCD for sodium and an NRV-R for potassium.</p>	ICGMA
<p>1. Inclusion of sodium ISDI considers that NRVs for sodium for both older infants and young children should be established. Such reference values are important for all parts of the population and in particular for this specific and sensitive target population.</p> <p>2. The type of NRV (NRV-NCD or an NRV-R) for sodium and potassium ISDI questions if the discussions on NRVs NCDs are part of the TOR of the eWG and in the mandate and scope of original work as agreed by the Codex Alimentarius Commission. ISDI believes that for both Sodium and Potassium NRVs-R are appropriate as it is essential to ensure sufficient intake of these nutrients.</p> <p>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). ISDI does not support the approach proposed by the eWG chairs, as it would overly restrict the usefulness of the NRVs-R once established and national authorities should be allowed to use these NRVs-R where relevant.</p>	International Special Dietary Food Industries
SPECIFIC COMMENTS ON THE PROPOSED DRAFT PRINCIPLES FOR ESTABLISHING NRVs FOR PERSONS AGED 6 TO 36 MONTHS	
Agree with proposal draft	Iraq
The proposed NRVs for persons aged 6 to 36 months should be presented at the end of this preliminary draft.	Panama
Thailand has no further comment to the proposed draft, as currently presented in appendix II. We understand that some of the texts may need to be revised once the issues under recommendations 1-5 be decided by CCNFSDU	Thailand
1. PREAMBLE	

<p>We note the scope of the Guidelines for Nutrition Labelling (CXG 2-1985) apply to the nutrition labelling of all foods i.e not just pre-packaged foods as indicated in the Preamble.</p> <p>At this stage use of NRVs-R has been recommended to guide vitamin and mineral composition only in the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991). Including the third point in the Preamble implies broader application.</p>	Australia
<p>The EU notes that the agreed, original text in the Annex of the Guidelines in Nutrition Labelling CAC/GL 2-19 should be retained where there is no need to accommodate the changed population group, persons aged 6 to 36 months. The EU proposes therefore a number of modifications:</p> <p>“These Principles apply to the establishment of Codex Nutrient Reference Values (NRVs) for persons aged 6 to 36 months. These values may be used for helping caregivers of persons aged 6 to 36 months:</p> <ol style="list-style-type: none"> 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>The EU is of the view that the following paragraph needs to be retained in the proposed draft General Principles, modified to accommodate the age group 6 to 36 months:</p> <p>“For example, governments may establish reference values 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 food label reference values for specific segments of the age group 6 to 36 months.”</p>	European Union
<p>We support the recommendation of the EWG Chairs using the classification with three categories in the general principles.</p>	Guatemala
<p>These Principles apply to the establishment of Codex Nutrient Reference Values (NRVs) for persons aged 6 to 36 months. These values are [may be] used for nutrient declaration in labelling according to Codex Guidelines CXG 2-1985 for pre-packaged foods.</p> <p>Amended to be consistent with the general principles for the general population, no need to deviate.</p> <p>This labelling information may be helpful to caregivers of these individuals to:</p> <ol style="list-style-type: none"> 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. <p>This is a new addition that is not relevant for the derivation of NRVs nor are they relevant to the statement that this labelling information would be helpful to caregivers</p> <p>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. [In addition, governments may establish reference values for food labeling that take into account country or region specific factors that affect nutrient absorption, utilization, or requirements.]</p> <p>Amended to be consistent with general principles for general population, no need to deviate, particularly as the NRV-R may have multiple values for some nutrients (e.g. iron) or footnotes for countries to consider their own unique environmental factors (e.g. vitamin D)</p>	New Zealand
<p>No new comments. Agree with current draft.</p>	Republic of Korea

<p>The United States supports the proposed text in the Preamble and Definitions sections.</p> <p>In Section 1, the United States supports the text:</p> <p>“... 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.”</p> <p>as it was taken from the CXG 2-1985 and modified to apply to ages 6-36 months.</p> <p>Also, in Section 1, the United States believes that sub-paragraph 3 should be a separate statement because it does not relate to caregivers; rather, it pertains to Codex. This would appear as follows:</p> <p>2) compare the nutrient content between products.</p> <p>These values may also be useful ...</p> <p>Finally, the United States supports Recommendation 4 regarding the application of NRVs-R 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).</p> <p>The United States views revision of approach for adding vitamins and minerals in Guideline CXG 8-1991 to be out of scope of the terms of reference for this working group. However, the guideline references WHO 2004 INL98 values in the Annex to provide for populations where dietary intake data is lacking. The United States views it appropriate to update the Annex with proposed NRVs-R as they will reflect daily intake reference values or ranges that have been recently established by recognized authoritative scientific bodies. In this case, using the NRVs established for labelling to guide possible addition of vitamins and minerals would provide reference values based on the most recent science until the Committee decides to revisit the approach to setting levels for the addition of vitamins and minerals to formulated complementary foods.</p>	<p>USA</p>
<p>Helen Keller International supports this text.</p>	<p>HKI</p>
<p>ICGMA supports the establishment, and the development of principles to guide that establishment, of NRVs for persons aged 6-36 months, using the most rigorous scientific methods. The eventual NRVs will be very useful in the development, composition and labeling of safe and suitable products intended for normal, healthy persons aged 6 – 36 months.</p> <p>ICGMA supports Recommendation 4 regarding the application of NRVs-R 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).</p>	<p>ICGMA</p>
<p>ISDI is of the view that CCNFSDU should lead this discussion as products targeting this population are foods for special dietary uses (FSDU) per Codex definition. Therefore, CCNFSDU would be the most appropriate Committee for this discussion, while CCFL could be consulted without delaying the progress of the work (noting that CCFL47 takes place in 2023, the text would then not be addressed until CCNFSDU44 in November 2023).</p> <p>ISDI believes it is essential to establish science based NRVs separately for older infants and younger children. This would then consider their specific needs in the context of their different growth velocities.</p> <p>ISDI also considers that the target population of a product should drive which set of NRVs is on the label:</p> <ul style="list-style-type: none"> • For products targeting OI, the OI set of NRVs; • For products targeting YC, the YC set of NRVs; • For products targeting both OI and YC (e.g. canned baby foods), there should be the flexibility of labelling with the most relevant set(s) of NRVs. 	<p>International Special Dietary Food Industries</p>

<p>ISDI notes that there is a possibility for a third set of NRVs for the 6-36 months' age group (in particular for the same values in both sets of NRVs, these could be declared as one) but this will not be decided upon until the sets of NRVs for OI and YC are scientifically established and finalised.</p> <p>ISDI also considers that these specific labelling considerations should be left to each appropriate Standard covering specific infant and young children categories. The principles currently established by Codex for labelling and nutrition labelling may be sufficient and competent authorities can ensure that products are labelled properly in line with the requirements and principles established by Codex.</p>	
2. DEFINITIONS	
<p>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 – 3.4⁴³ have been modified to reflect the evidence base for nutrient needs of persons aged 6 to 36 months.</p> <p>Canada is proposing edits to Section 3, as it appears that the relevant section is 3.3. (editorial)</p>	Canada
<p>In the section of definitions, the EU considers that the terms “older infant” and “young child” have been already defined at Codex level in different texts and should not be repeated. Furthermore, the EU proposes the following modifications:</p> <p>Adequate Intake (AI) is “A dietary recommendation used when there is not enough data to calculate an average requirement. An adequate intake is the average nutrient level consumed daily by a typical healthy population that is assumed to be adequate for the population's needs.”</p> <p>The proposed draft text under section 3. (“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.”) needs to be discussed once section 3.1 to 4.4 have been agreed.</p>	European Union
<p>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:</p> <p>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).</p> <p>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).</p> <p>These should be consistent with other Codex definitions for older infants and young children. Amendments have been made to align with the draft Codex Standard for Follow-up Formula as the most recently reviewed relevant Codex standard for this age group.</p> <p>b) Adequate Intake (AI) is [the observed or experimentally derived intake by a defined population group that appears to sustain health.] “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 can not be determined”. This concept can also be referred to as Net Requirement, Estimated Values or Suggested Daily Intake.</p> <p>This needs to be aligned with the new definitions used. The NRV-R do not refer to RDAs only INL98 values. ‘The observed or experimentally derived intake by a defined population group that appears to sustain health (UNU/FAO/WHO/UNICEF (2007)).’</p> <p>This is the definition used in the Codex NRV publication: http://www.fao.org/3/ca6969en/CA6969EN.pdf</p>	New Zealand
<p>Helen Keller International supports this text.</p>	HKI
3.1 Selection of suitable data sources to establish NRVs	

<p>The EU notes that the agreed, original text in the Annex of the Guidelines in Nutrition Labelling CAC/GL 2-19 should be retained where there is no need to accommodate for the changed population group, persons aged 6 to 36 months. The EU proposes therefore a number of modifications. The EU is particularly worried that the proposed changes to the original text abolishes an agreed principle without clarifying or highlighting this change and the motivation leading to this change in an accompanying and explanatory text in order to enable an informed discussion: that the values provided by FAO/WHO are the primary source. Furthermore, the text defines FAO/WHO as one of the RASBs, while the EU understands that in the original text, FAO/WHO are considered as the primary sources of values, and only in case no recent values are available from FAO/WHO, data from RASBs could also be considered. The proposed new text places values provided by RASBs on an equal footing with values provided by FAO/WHO, to which the EU disagrees. The EU proposed therefore the following modification to retain the agreed, original principle:</p> <p>“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.</p> <p>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.</p> <p>The daily intake reference values should reflect intake recommendations for persons aged 6 to 36 months.“</p>	European Union
<p>We consider that the NRVs-R for older infants and young children should be established and listed in the Codex Guidelines on Nutrition Labelling (CXG 2-1985). The principles for establishing nutrient reference values for children aged 6 to 36 months should be established as a separate annex (Annex II) to the Guidelines on Nutrition Labelling (CXG 2 - 1985).</p>	Guatemala
<p>Malaysia supports the recommendation of the eWG chairs regarding the approach to derive DIRVs from WHO/FAO and 6 RASBs.</p>	Malaysia
<p>As we have discussed during 2020 electronic working group and concluded in CX/NFSDU 21/42/7, page 5~6, Republic of Korea supports draft General Principles suggested.</p>	Republic of Korea
<p>The United States supports the proposed text in Section 3.1. The text aligns with the Guidelines on Nutrition Labelling (CXG 2-1985) and has been modified to apply to ages 6-36 months.</p>	USA
<p>Helen Keller International supports this text.</p>	HKI
<p>ISDI supports the recommendation of the eWG chairs regarding the approach to derive DIRVs from WHO/FAO and 6 RASBs.</p>	International Special Dietary Food Industries
3.2 Appropriate Basis for Establishing NRVs	
<p>In relation to 3.2.1.2 Australia does supports having one set of NRVs-R on a label to avoid confusion. However as it is yet to be decided how to achieve one set of NRVs-R at this stage, and until there is agreement to refer to CCFL, Australia is of the view it is too early to include this provision.</p>	Australia
<p>The EU notes that the Draft Report Review of derivation methods for dietary intake reference values for older infants and young children, a dense 44 pages report, on which the proposed principles are based has been published only recently. The EU considers that the outcome of the report and the inclusion in the proposed Draft General Principles for Establishing Nutrient Reference Values for Persons aged 6 to 36 Months deserves more detailed discussions in an eWG. The EU considers that such changes in approach deserve a more detailed discussion and time for Codex Members and Codex Member Organizations to prepare for such discussions.</p>	European Union

<p>The EU is not convinced that there is a need to include a ranking method, as proposed, in the General Principles. However, aligned with the agreed, original text in the Annex of the Guidelines in Nutrition Labelling CAC/GL 2-19, in case there are no and recent daily nutrient intake reference values provided by FAO/WHO, values that have been recently established by recognized authoritative scientific bodies could be reviewed on a case-by-case basis. The EU considers that including aspects of scientific rigor into the General Principles as well could be helpful, as well as quality of the underlying evidence and overall strength of the evidence, but is not convinced that the proposed table is the most helpful tool, while also noting that the time available to scrutinise the approach was too limited to come to a final judgement.</p> <p>The EU considers that a combined set of NRVs-R for both older infants and young children combined needs to be established and the relevant text in the General Principles should be adapted accordingly throughout the text.</p>	
<p>The CCNFSDU should take the lead in this debate, since products intended for this population are foods for special dietary uses (FSDU) according to the Codex definition. Therefore, the CCNFSDU would be the most appropriate committee for this discussion. In parallel, the CCFL can be consulted without delaying the progress of the work.</p> <p>It is essential to establish separate science-based NRVs for older infants and younger children. This would then consider their specific needs in the context of their different growth rates.</p> <p>In addition, the target population of a product should determine the set of NRVs on the label:</p> <ul style="list-style-type: none"> - For products aimed at Old Infants, the Old Infant NRV set; - For products aimed at Young Children, the Young Children NRV set; - For products aimed at both OI and YC (e.g. canned baby food), there should be flexibility to label with the most relevant sets of NRVs. <p>These specific labelling considerations should be left for each appropriate Standard covering specific categories of infants and young children. The principles currently established by Codex for labelling and nutrition labelling may be sufficient and the competent authorities can ensure that products are adequately labelled in accordance with the requirements and principles established by Codex.</p>	Guatemala
<p>Malaysia is of the view that all the vitamins and minerals above should be discussed at parallel without ranking when establishing NRVs-R for older infants and young children. This is because some countries are using NRV-R for general population to make nutrition claim on the product. Therefore, with the new list of NRV-R for older infants and young children it can facilitate the country to use the appropriate NRV-R for specific age group. Establishing NRVs-R for young children may be based in the first instance on literature review and assessment of the quality of the scientific data available for each of the nutrients.</p>	Malaysia
<p>The methods used to derive DIRVs</p> <p>See response to Recommendation 1. We are unsure that this level of detail is required for the general principles. A similar range of methods were also considered for the general principles.</p> <p>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.</p> <p>This is a decision that should be made by the Committee rather than a general principle.</p> <p>Note CCNFSDU41 agreed that the decision on whether or not to combine the two sets of NRVs would be made depending on the actual values in these two sets. In the meantime, separate sets of NRVs-R would be prepared.</p>	New Zealand

<p>The committee need to clarify the definition of DIRV in the text. On document CX/NFSDU 21/42/7, ToR for the 2020 eWG, it is stated that Dietary Intake Reference Values are DIRVs. However, On the proposed draft general principles for 6~36month, section 3.1 and thereafter, DIRV is used as Daily intake reference value. Are we talking the same value?</p> <p>This is confusing because;</p> <ol style="list-style-type: none"> 1. the definition of 'Daily' intake reference value is as followed : it is provided by FAO/WHO or other RASBs may be expressed in different ways (e.g. as a single value or a range), and are applicable to the general populations or to a segment of the population (e.g. recommendation for a specified age range(reference: Codex nutrient reference values by Janine Lewis, FAO/WHO, 2019) vs. 2. the definition of 'Dietary' intake reference value or 'dietary reference value' is : the collective term that may indicate all the nutrient reference values, includes average requirement, population reference intake, adequate intake and reference intake range for macronutrient. (reference: efsa.europa.eu, Dietary reference values) 	Republic of Korea
<p>With regards to Section 3.2.1, the United States supports using a three-category ranking to differentiate scientific rigor of methods. The text reflects the recommended approach in the FAO request for scientific advice “Review of derivation methods for dietary intake reference values for older infants and young children” and addresses the existing evidence for persons ages 6-36 months. A ranking system based on the rigor of the evidence available is useful to guide the Committee and/or authorities in establishing an NRV-R.</p> <p>The United States notes a combined set of NRVs may be needed for use in labeling. The United States supports Recommendation 3 to request that CCFL determine the criteria for the application of different sets of NRVs-R for labelling purposes, and location of the criteria in the Guidelines on Nutrition Labelling (CXG 2-1985). However, the United States views the referral to CCFL as independent from the completion of the CCNFSDU work on establishing general principles for older infants and young children. The United States recommends that CCNFSDU establish the method(s) for combining the two sets of NRVs as part of the general principles in Para. 3.2.1.2.</p> <p>Finally, the United States supports Recommendation 1 which uses a three-category ranking to differentiate scientific rigor of derivation methods, as proposed in the text recommended by the chairs. The text reflects the recommended approach in the FAO response to CCNFSDU’s request for scientific advice “Review of derivation methods for dietary intake reference values for older infants and young children” and addresses the existing evidence for persons ages 6–36 months. A ranking system based on the rigor of the evidence available is useful to guide the Committee and/or Authorities in establishing an NRV-R.</p>	USA
<p>Helen Keller International supports the use of a three category ranking system as proposed. This hierarchy reflects the degree of scientific rigour and evidence for derivation of NRVs and will therefore be a useful tool for the Committee.</p> <p>Helen Keller notes that use of one set of NRVs on labels would be beneficial to avoid confusion among caregivers and recommends that the methods to combine separate sets of NRVs for older infants versus young children be established in the general principles.</p> <p>Helen Keller International acknowledges the confusion that may arise from multiple sets of NRVs present on labels. The use of one set of NRVs on a label in accordance with the recommended age of use of the product would reduce this confusion. Helen Keller International in theory supports the development of the following sets of NRVs: 1) for older infants; 2) for young children; 3) for older infants and young children combined, noting that the last set would only be applicable to products that are recommended for an age group overlapping older infants and young children. However, Helen Keller International also recommends that there be detailed discussion on how to practically combine two different NRVs for these age groups for the 3rd set, and that these methods for combining should be noted in the General Principles. Because NRVs may differ for different age groups (i.e. iron) careful consideration needs to be given for selection of a value that optimizes health and safety of older infants and young children.</p>	HKI

<p>With regards to Section 3.2.1, ICGMA supports the use as a General Principle the three-category ranking system that differentiates scientific rigor of methods, the approach consistent with the FAO response to CCNFSDU's request for scientific advice.</p> <p>ICGMA suggests the Committee consider seeking scientific advice from JEMNU to develop the NRVs by applying the three-category ranking system to the available evidence.</p> <p>ICGMA supports Recommendation 3 in CX/NFSDU 21/42/7 to request input from CCFL on what criteria should be used to choose the most appropriate set of NRVs for a food, and where in the main text of CXG 2-1985 should such criteria be placed.</p> <p>ICGMA believes that CCNFSDU should continue its work on developing NRVs while it waits for input from CCFL.</p>	ICGMA
3.2.2 Selection and Priority of Derivation Methods for Establishing NRVs-NCD	
<p>As per our comment in response to Q2 above Australia supports establishing NRV-Rs as the basis for labelling NRVs for sodium and potassium as it is more appropriate to use a measure of adequacy rather than a measure of chronic disease risk for these very young age groups.</p>	Australia
<p>The EU considers that the scope of the work has been discussed and agreed: to establish General principles for the establishment and use of NRVs-R for persons aged 6–36 months. Nutrients for which NRVs-R should be established were agreed. It was agreed to establish NRVs-R and not NRVs-NCD for persons aged 6–36 months. Therefore, the EU considers section 3.2.2 to be obsolete and does not provide detailed comments.</p>	European Union
<p>We support the approach proposed by the EWG Chairs for vitamins and minerals, as described in the recommendation. However, a clarification is requested regarding the exclusion of proteins.</p>	Guatemala
<p>- Para 3 of section 3.2.2:</p> <p>Indonesia proposes to delete the sentence "When such evidence is not available, extrapolation from NRV-NCDs from the general population could also be considered." in the end of this para. So the paragraph changes to:</p> <p>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.</p> <p>Rationale: NRV-NCD for persons age 6 to 36 months should not be extrapolated from NRVNCDs for general population because children are not miniature adults and have different physiology compared to adults.</p> <p>- Para 4 of section 3.2.2:</p> <p>Indonesia proposes to add sentences in the beginning of this para. So the paragraph changes to:</p> <p>The establishment of NRVs-NCD for persons 6 to 36 months should consider daily intake reference values from FAO/WHO as primary sources. Daily intake values from recognized authoritative scientific bodies may also be considered for NRVs-NCD. Daily intake reference values from FAO/WHO or recognized authoritative scientific bodies include values expressed in absolute amounts or as a percentage of energy intake.</p> <p>Rationale: to emphasize and be consistent with general principle stated at section 3.1 that daily nutrient intake values provided by FAO/WHO should be considered as primary resources.</p>	Indonesia
<p>Malaysia is of the view that establishing NRV-NCD is beyond the mandate of TOR as mentioned in CX/NFSDU 21/42/7.</p>	Malaysia

<p>We have not provided comment on this text. We do not think that the establishment of NRVs-NCD are within the scope of this work. The Committee must first determine whether NRVs-NCD are appropriate/needed for labelling purposes in this age group</p>	New Zealand
<p>Agree with current draft</p>	Republic of Korea
<p>The United States supports the proposed text in Section 3.2.2 and welcomes discussion of daily intake reference values (DIRVs) suitable for persons aged 6-36 months. When evidence for DIRVs in this age group is not available, extrapolation from NRV-NCDs from the general population could also be considered. The United States notes that providing a global reference caloric intake for this age group will be necessary for future determination of NRV-NCDs based on a percentage energy intake for persons aged 6-36 months. The United States notes that FAO/WHO has determined mean caloric intakes for these age groups (FAO/WHO/UNU Human Energy Requirements, Rome, October 2001).</p>	USA
<p>ISDI supports the approach proposed by the eWG chairs for vitamins and minerals as outlined in recommendation 4. ISDI also seeks clarification regarding the exclusion of protein.</p>	International Special Dietary Food Industries
<p>3.3 Consideration of Upper Levels of Intake</p>	
<p>3.3 Consideration of <u>Daily Intake Reference Values for Upper Levels of Intake</u></p> <p>With regard to the draft section 3.3, the EU notes that the agreed, original text agreed in the Annex of the Guidelines in Nutrition Labelling CAC/GL 2-19 should be retained where there is no need to accommodate for the changed population group, persons aged 6 to 36 months and proposes the following text changes:</p> <p>"3.3 Consideration of Daily Intake Reference Values for Upper Levels</p> <p>The establishment of NRVs for persons aged 6 to 36 months should also take into account daily intake reference values for upper levels established by FAO/WHO or recognized authoritative scientific bodies where applicable (e.g. Upper Level of Intake, Acceptable Macronutrient Distribution Range)."</p> <p>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 recognized authoritative scientific bodies where applicable applicable (e.g. Upper Level of Intake, Acceptable Macronutrient Distribution Range).</p>	European Union
<p>1. Inclusion of sodium</p> <p>We believe that NRVs for sodium should be established, both for older infants and for young children. These reference values are important for all segments of the population and, in particular, for this specific and sensitive target population.</p> <p>2. The type of NRV (NRV-NCD or NRV-R) for sodium and potassium</p> <p>We consider NRVs-R for sodium and potassium to be adequate, as it is essential to ensure sufficient intake of these nutrients.</p> <p>3. NRVs-R should be limited for labelling purposes in FSDU texts other than the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991).</p> <p>Likewise, we do not support the approach proposed by the EWG Chairs, as it would unduly restrict the usefulness of NRVs-R once they are established and national authorities should be able to use these NRVs-R where appropriate.</p>	Guatemala
<p>Indonesia proposes to add the phrase "as primary sources" in this para. So the paragraph changes to:</p>	Indonesia

<p>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 as primary sources or other RASBs where applicable.</p> <p>Rationale: to emphasize and be consistent with general principle stated at section 3.1 that daily nutrient intake values provided by FAO/WHO should be considered as primary resources.</p>	
<p>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 recognised authoritative scientific bodies RASBs where applicable.</p> <p>The text should be consistent with the general population, no need to deviate. This current GP for the general population could be amended to cover both population groups if all general principles were to be included in the same annex.</p>	New Zealand
<p>Finally, the United States also supports Section 3.3.</p>	USA
<p>Helen Keller International supports this text.</p>	HKI